EUROPEAN CHEMICALS AGENCY

ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): Terphenyl, hydrogenated

IUPAC NAME(S): Terphenyl, hydrogenated

EC NUMBER(S): 262-967-7

CAS NUMBER(S): 61788-32-7

CONTACT DETAILS OF THE DOSSIER SUBMITTER:

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on behalf of

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CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CSP	Concentrated Solar Power
CSR	Chemical Safety Report
C/E	Cost-effectiveness
C&L	Classification and Labelling
EAC	Equivalent Annual Cost
ECHA	European Chemicals Agency
EEA	European Economic Area
EiF	Entry into Force
EPA	Environmental Protection Agency
ERC	Environmental Release Category
EU	European Union
HTF	Heat Transfer Fluid
ISS	Istituto Superiore di Sanità - Italy
IU	Identified Uses
LR	Lead Registrant
NILU	Norwegian Institute for Air Research
NIVA	Norwegian Institute for Water Research
OC	Operational Condition
OECD	Organisation for Economic Co-operation and Development
OR	Only Representative (according to REACH Article 8)
ORC	Organic Rankine Cycle
PBT	Persistent, Bioaccumulative and Toxic
PC	Product Category
PEC	Predicted Environmental Concentration
PET	Polyethylene terephthalate

PHT	Partial Hydrogenated Terphenyl
PROC	Process Category
RAC	Risk Assessment Committee
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measures
RMO	Regulatory Management Option
RMOA	Regulatory Management Option Analysis
RO	Restriction Option
SCIP	Substances of Concern In articles as such or in complex objects (Products)
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis
SME	Small and Medium-sized Enterprises
SpERC	Specific Environmental Release Category
STP	Sewage Treatment Plant
SU	Sector of Use
SVHC	Substance of Very High Concern
UK	United Kingdom
USA	United States of America
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
vPvB	Very Persistent and very Bioaccumulative
WWTP	Wastewater Treatment Plant

About this Report

The preparation of this restriction dossier on Terphenyl, hydrogenated (in the following abbreviated as PHT from **P**artly **H**ydrogenated **T**erphenyl) was initiated on the basis of Article 69(4) of the Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[1]. The proposal has been prepared using the most recent version of the Annex XV restriction report format and consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of **Annexes** with more detailed information and analysis as well as details of the references used.

The Istituto Superiore di Sanità (ISS - on behalf of the Ministry of Health), hereafter referred to as the Dossier Submitter, would like to thank the many stakeholders that made contributions to the stakeholder consultations and provided information during interviews and meetings.

Summary

The substance was identified as potentially having Persistent, Bioaccumulative and Toxic (PBT) properties. Accordingly, in 2008 PHT was included in Commission Regulation 465/2008/EC[2] for further assessment as part of the Existing Substances programme. As a substance characterised as an Unknown or Variable composition, Complex reaction products or Biological materials (UVCB), Finland assessed PHT using a weight-of-evidence approach considering the properties of its constituents and published its evaluation report in 2017, concluding that PHT is very persistent and very bioaccumulative (vPvB). In November 2017 the inclusion of PHT as a Substance of Very High Concern (SVHC) was recommended and in 2018 it was duly added to the Candidate List.

PHT is not manufacturered in the European Union (EU) and the imported volume for 2020 is estimated with 7 500 tonnes. The main use with approximately 90% annual tonnage is as a high-temperature Heat Transfer Fluid (HTF). Other uses include applications as processing solvent and as plasticiser. Only two potentially viable alternatives exist for the HTF-use, which also have similar persistent and bioaccumulative properties. Both alternatives have been included in the Commission's Roadmap on Restriction[3] as part of a functional grouping approach for HTF use.

The Dossier Submitter concluded that although the HTF use is via closed loop manufacturing systems, environmental emissions are still possible. 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 and therefore a REACH Restriction was identified as the most relevant and proportionate Regulatory Management Option (RMO).

Moreover, for all non-HTF uses an unacceptable risk for the environment has been identified. When PHT is used as an **HTF**, it is constantly contained within a closed loop system with limited discharges. However, exposure to the environment cannot be disregarded as demonstrated under **Annex B.9.** (Exposure Assessment). During operation, special attention needs to be paid to the interfaces of the closed system to the atmosphere, such as closed draining, separation points (joints, mechanical seals, flanges, valves, etc.) and rotary transmission equipment (pumps, etc.). Potential emissions to the environment are prevented

[1] Regulation (EC) No. 1907/2006 (REACH Regulation). Consolidated version 01/03/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20220301&qid=1646849873367

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R0465

[3] Microsoft Word - Draft-Restrictions-Roadmap.docx (chemicalwatch.com)

by the implementation of stringent containment measures and control during the design stage of the closed system.

Other potential exposure and emission sources of PHT when used as HTF are related to transport, loading and refilling operations, replacement or topping-up of the HTF, industrial cleaning operations, and disposal of the HTF.

When PHT is used as a **plasticiser** it may be released into the environment during the various life cycle steps. The Lead Registrant (LR) has conducted a comparative risk assessment for the two main uses: HTF and plasticiser (Solutia, 2018). The calculation clearly showed that the plasticiser use is far more critical for risk management than the HTF use.

The estimated local and regional overall release associated with the use as a plasticiser is up to 10-times higher than the local and regional overall release associated with the use as an HTF, respectively. It was shown that the total environmental emissions based on the use of PHT as an HTF are significantly lower than the total releases from the plasticiser uses. The use of the substance as a plasticiser is more critical for risk management regarding the emissions to the environment than the use as an HTF within a closed system.

These results have been confirmed by the Environmental Monitoring program at HTF sites and migration modelling studies on plasticiser uses (see **Annex B.9.**: Exposure Assessment). Moreover, under the plasticiser use PHT will be incorporated into/onto an article. At the end of the service life, the article has to be disposed. During the disposal at a waste treatment plant PHT may be released into the environment as well. 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. As shown in **Annex A** (Manufacture and Uses), in total more than 12,000 articles containing PHT have been notified to the Substances of Concern In articles as such or in complex objects (Products) (SCIP) database. Most entries are related to the use as plasticiser in polymers. The dossier submitter assumes, that at the waste life-cycle stage of articles, the operational conditions and risk management measures are not sufficient and effective enough to control the risks of PHT.

The worst-case cumulative releases of PHT from 2025 to 2044 have been estimated with a total volume of 19 584 tonnes within the 20 years considered, which corresponds to an average annual release of 979 tonnes.

PHT has not been widely found in the environment so far. However, 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. A screening programme conducted in 2018 by the Norwegian Institute for Air Research (NILU) and the Norwegian Institute for Water Research (NIVA) (NILU, 2018), has focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT-properties, including PHT. The substance was found in the 100 ng/g range in marine sediments, and it was recommended that the chemical should consequently be studied in more detail.

PBT/vPvB substances give rise to specific concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are difficult to reverse even when releases cease. Therefore, the risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way, e.g. by derivation of risk characterisation ratios. Emissions and subsequent exposure, in the case of a PBT/vPvB substance, are therefore considered as a proxy for risk. Therefore, the Dossier Submitter concluded that the risk associated to the use of PHT is not adequately controlled and action is required on a Union-wide level and that the proposed restriction is the most appropriate measure.

In line with the Committee for Socio-Economic Analysis (SEAC) recommendation (ECHA, 2014), proportionality of the proposed restriction is assessed through a cost-effectiveness (C/E) analysis.

The proposed restriction is targeted to the exposure situations that are of most concern, e.g. the use of PHT as a plasticiser and during the life-cycle stage of articles. The proposed restriction is effective and reduces potential risks to an acceptable level within a reasonable period of time.

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

Furthermore, the proposed Restriction has a high C/E (€ 90/kg PHT emissions avoided) coupled with a high emission (risk) reduction capacity of 85%. The total costs have been estimated with approximately € 1.5 billion, assuming a 5-year transitional period for plasticiser use for the production of aircrafts and their spare parts.

Based on analysis of the effectiveness, practicality and monitorability of the assessed options, the below Restriction is proposed by the Dossier Submitter. The final legal wording will be ultimately decided by the European Commission after receiving the Risk Assessment Committee (RAC) and SEAC opinions.

Proposed Restriction:

Brief title: Restriction on the use of Terphenyl, hydrogenated and derogations.

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
Terphenyl, hydrogenated CAS No: 61788-32-7 EC No: 262-967-7	1. Shall not be placed on the market from [18 months after entry into force]: a) As a substance on its own. b) As a constituent of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w. c) In articles or any parts thereof containing Terphenyl, hydrogenated in concentrations equal or greater than 0.1% w/w. 2. By way of derogation, Paragraph 1 shall not apply for the use and placing on the market as a heat transfer fluid, provided that such sites implement strictly controlled closed systems with technical containment measures to prevent environmental emissions. 3. By way of derogation, Paragraph 1 shall not apply after entry into force +5 years, for the use and placing on the market in plasticiser applications for the production of aircrafts and their spare parts.

Report

1. The problem identified

PHT has been identified as a vPvB substance and was included in the Candidate List on 27 June 2018. This UVCB substance was assessed by evaluating the 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%), PHT is considered to fulfil vPvB criteria. Detailed information is provided in Section 8 to the CSR of the LR (Solutia, 2019) and the SVHC Support Document (ECHA, 2018a). Also, further information is available in **Annex B.1.2.** on Composition of the substance, **Annex B.4.1.** on Degradation, **Annex B.4.3.** on Bioaccumulation, and **Annex B.8.1.** on the assessment of PBT/vPvB properties.

In 2020/2021 the Dossier Submitter conducted a Regulatory Management Option Analysis (RMOA) which concluded that a restriction is the most appropriate regulatory instrument to address the substance (and potentially further substances used as HTF having a similar hazard profile in the future). The analysis clearly demonstrates that Restriction is the most proportionate regulatory management option. Conversely, Authorisation is considered to be a disproportionate, less practical and less effective provision, also on the base of the lack of suitable alternatives. On the 21 April 2021, the Dossier Submitter registered its intention to submit a Restriction Proposal on PHT.

When PHT is used as a plasticiser it may be released into the environment during the various life cycle steps. The exposure calculation clearly showed that the plasticiser use is far more critical for risk management than the HTF use. For all non-HTF uses an unacceptable risk for the environment has been identified. When PHT is used as an HTF, it is constantly contained within a closed loop system with limited discharges. However, exposure to the environment cannot be disregarded.

In total more than 12 000 articles containing PHT have been notified to the SCIP database. This is demonstrating that articles and their service life pose a risk to environmental releases too and need to be restricted as well. The current implemented risk management measures are not sufficiently effective to control the risks at the waste stage of articles.

1.1. Manufacture and Uses

This section draws on **Annex A** which provides further details on the manufacture, import and use of PHT.

According to the information from the REACH Registration on the ECHA public dissemination website (ECHA, 2021a), there are currently 6 active registrants of PHT. The amount of PHT manufactured and or imported into the EU is, according to registration data on the ECHA public dissemination website in the range of 10 000-100 000 tonnes per year. This is diverging from the volumes reported by industry and the information collected during stakeholder consultations. Based on information received from stakeholders, the global volume of PHT manufactured is approximately 32 000 tonnes per year, and the total volume imported in 2020 into the EU is assumed to be in the order of 7 500 tonnes per year. The EU volume of 7 500 tonnes per year includes as well estimates of imports in articles and formulations in the order of 100 tonnes per year. A significant number of articles (> 12 000 entries) are reported in the SCIP Database (ECHA, 2021b), and it is proven that mixtures containing PHT can be ordered via Internet, for example from the United States of America (USA) to the EU.

Moreover, the stakeholder information received indicates that some of the registrants are importing mixtures from non-EU countries into the EU and have therefore conducted a REACH registration. The trend in the EU and globally shows a significant increase of volume during the last years, the Danish Environmental Protection Agency (EPA) referenced in its report[4] a steady growth in the HTF market. This was confirmed by feedback during the public consultation.

Table 1 provides an overview of estimated EU volumes of PHT.

Table 1. Estimated volumes in the EU, based on stakeholder information.

	PHT Volume in EU (tonnes per year) - incl. in Articles imported		
	2020	2019	2018
Non-EU Manufacturers (via their ORs or EU affiliates)	7 000	5 100	4 200
EU Importers	500	400	200
Total Volume in EU (tonnes per year)	7 500	5 500	4 400

The main use of PHT (approximately 90% of the tonnage according to the stakeholder feedback) is as HTF. A HTF is a liquid or gas which is specifically manufactured for the transmission of heat. HTFs can be used by many sectors for any single- or multiple-station heat-using system. Thus, they are primarily used as an auxiliary fluid to transfer heat from a heat source to other areas of a process with heat demands. The 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 PHT do not require pressurizing at temperatures up to 350°C. 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.

The use described as "use in laboratory analysis", where small amounts of in-use HTF is analysed to determine its lifetime, is also related to the HTF uses in industrial set-ups.

The use of the substance as a **plasticiser** is the second relevant use, involving around 10% of the tonnage range. Plasticisers are additives that increase the plasticity or decrease the viscosity of a material. PHT is used as a plasticiser mainly for the production of coatings, sealants, and adhesives and in polymer applications. The final coatings, sealants/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). This application is addressed in the "additive in plastic application" scenarios as well as the corresponding "Plastic articles" service life scenario. Moreover, PHT is also used as plasticiser in coatings and inks.

[4] 40 - FINAL REPORT - Biphenyl LOUS - 2014 11 04 (windows.net).

The remaining registered uses (both industrial and professional) involve less than 1% of the amount of substance imported into the EU. Consumer uses and intermediate uses have not been registered.

Based on information received from stakeholders, **Table 2** was prepared showing the EU volumes used for the main applications of PHT in the EU. The HTF use accounts for approximately 6 700 tonnes per year, reflecting approximately 90% of the total EU volume used. The non-HTF uses represent approximately 10% of the total volume. Plasticiser uses in sealants, adhesives, castings, and coating make-up for more than 9% of the non-HTF uses, while < 1% remains to processing solvents, corrosion inhibitor oils and laboratory chemicals (e.g., analytical standards, immersion oils).

As shown in the below **Table 2**, the main use of PHT with approximately 90% annual tonnage is as a high-temperature non-pressurised HTF. When used as an HTF, PHT is a significant utility chemical for EU manufacturing of polyethylene terephthalate (PET) and other polymers, the conversion of biomass to energy, chemicals, and energy production in closed loop manufacturing systems.

Table 2. Split of volumes per use in the EU based on information provided by stakeholders.

EU Uses	**Volume (tonnes per year)**	**%**
HTF	**6 700**	**89.68**
Industrial Adhesives, Castings, Sealants	300	4.02
Aerospace Coatings	250	3.35
Aerospace Sealants	180	2.41
Processing Solvent/Aids	35	0.47
Corroson Inhibitor Oils	4	0.05
Analytical Standards	1	0.01
Microscope Immersion Oils	0.5	0.01
Total non-HTF	**771**	**10.32**

Table 3 outlines the use as HTF and it shows the estimated EU installed base in existing plants handling PHT for this use. This information is based on feedback from the stakeholder consultations and individual communications. The assumed EU-wide installed base is approximately 25 000 tonnes. In 2020 approximately 6 700 tonnes of PHT were sold on the EU market, from which around 5% were used for "top-up". The top-up or refill demand is driven by the degradation rate of the HTF and the separated low-boiling and high-boiling degradation products. It needs to be understood that the refill cannot be associated with loss of PHT into the environment. Approximately 35% of that volume (2 275 tonnes) was used for replacements of the whole PHT in existing plants, at the point when the HTF had to be completely exchanged and disposed of. The life cycle was reported with > 20 years. 60% (approximately 3 900 tonnes) account for filling new installed plants in the EU. The degradation rate of the system is determined by the sum of degraded fluid.

Table 3. Installed base in the EU and uses as HTF.

Use of HTF volumes on annual base		
	Tonnes	%
Installed Base in EU	25 000	-
Total volume sold in 2020	6 700	
Top-up existing plants	325	5
Replacement existing plants	2 275	35
Filling new plants	3 900	60

According to the data obtained from stakeholders, the total number of closed loop manufacturing systems using PHT as HTF in the EU is close to 1 300 systems, which are installed in 24 of the 27 EU Member States.

Around 40% of the plants have an installed capacity of < 10 tonnes, which is pointing to the use of systems in Small and Medium-sized Enterprises (SME) companies, approximately 50% are in the range of systems with > 10 to < 50 tonnes and less than 10% are > 50 tonnes.

Table 4 shows the distribution of the EU HTF use to the different application sectors. The total amount of installed volume is slightly higher compared to **Table 4** since the United Kingdom (UK) volumes are still included in this table. The highest percentage of HTF use is in the manufacturing of chemicals, specialty chemicals and petrochemicals. It should be noted that approximately 20% of PHT is already used in renewable energy processes. Concentrated Solar Power (CSP) is an innovative technology to transfer heat from the solar collectors to the power cycle. Organic Rankine Cycle (ORC) are considered to be a next generation technology as well for power generation from residual heat, for example for cost-effective power generation using waste or biomass heat from combustion or production processes. The waste heat evaporates an organic working fluid when temperatures are still relatively low and drives a generator in a closed thermal circuit. The heat used for ORC power generation can then be employed in further processes, for example for heating purposes. CSP and ORC are both innovative technologies for renewable energy generation. Other HTF uses include manufacturing of polymers, metals, oil and gas processing, process equipment heating, energy recovery, food processing and wood processing.

Table 4. Installed HTF Volume by application sector in 2017.

EU HTF Volume installed by Application Sector (2017) (incl. UK)		
Application	Installed volume (tonnes)	%
Chemicals, Specialties and Petrochemicals	11 900	48.08
Renewable Energy (e.g. ORC, CSP)	5 350	21.62
Polymers & Plastics (incl. PET)	5 000	20.20
Oil and Gas Processing	1 300	5.25
Process Equipment Heating (Food, Aluminium, Wood)	1 200	4.85
Total installed Volume	**24 750**	**100**

Table 5 provides an overview on the number of systems installed and installed volume per EU Member State. Italy, Germany, and France cover 70% of the volume and 75% of the systems.

Table 5. Installed HTF volume and number of sites in 2018 per EU Member State.

Member State	**No. of Systems**	**Volume (t)**	**Systems >50 t (%)**	**Systems >10<50 t (%)**	**Systems <10 t (%)**
Austria	40 - 50	730 - 750	**10**	**50**	**40**
Belgium	40 - 50	875 - 900			
Bulgaria	< 5	30 -40			
Croatia	< 5	100 - 120			
Czech Republic	5 - 10	100 - 120			
Denmark	5 - 10	130 - 140			
Estonia	5 - 10	40 - 50			
Finland	10 - 15	100 - 110			
France	175 - 200	2 200 - 2 300			
Germany	375 - 400	5 000 – 5 200			
Greece	25 - 30	600 - 620			
Ireland	5 - 10	15 - 20			
Italy	400 - 420	7 800 – 7 900			
Latvia	10 - 15	180 - 200			
Lithuania	< 5	330 - 350			
Luxembourg	5 - 10	40 - 50			
Netherlands	50 - 60	2 500 – 2 600			
Poland	15 - 20	900 - 950			
Portugal	5 - 10	50 - 70			
Romania	5 - 10	280 - 300			
Slovakia	< 5	120 - 140			
Slovenia	5 - 10	40 - 50			
Spain	35 - 40	750 - 780			
Sweden	5 - 10	130 - 150			
TOTAL	**1 300**	**25 000**			

Consumer uses have been designated by the registrants as uses advised against according to the ECHA public dissemination website (ECHA, 2021a). Consumer uses on coating/ink applications and as adhesives and sealants are advised against too.

1.2. Hazard, exposure/emissions and risk

1.2.1. Identity of the substance(s), and physical and chemical properties

This section draws on **Annex B** which provides further details on the identity, physical and chemical properties for PHT.

1.2.1.1. Name and other identifiers of the substance(s)

An overview of the name of the substance and other identifiers is given in **Table 6**. Unless otherwise stated, the data are taken from the REACH Registration on the ECHA public dissemination website (ECHA, 2021a), the SVHC Support Document (ECHA, 2018a) or the Chemical Safety Report (CSR) from the LR (Solutia, 2019).

Table 6. Substance identification information

Property	**Substance**
Regulatory process name	Terphenyl, hydrogenated Terphenyls, hydrogenated
IUPAC names	Hydrogenated Terphenyl Terphenyl, hydriert Terphenyl, hydrogenated
Other names (trade names and abbreviation)	Partially hydrogenated terphenyls PHT
EC number	262-967-7
EC name	Terphenyl, hydrogenated
CAS number	61788-32-7
CAS name	Terphenyl, hydrogenated
Molecular formula	C18Hn (n >18-36)
Molecular weight range	≥236 - ≤248

<u>Type of substance:</u>

UVCB.

<u>Description of the UVCB substance:</u>

PHT is produced by hydrogenation of a mixture of o-, m- and p-terphenyl and various quaterphenyls. The degree of hydrogenation is typically below 75%.

PHT is a complex substance containing isomers of terphenyl and quaterphenyls as well as their hydrogenated versions.

Methods of manufacture of the UVCB substance PHT:

This UVCB substance is manufactured by the batchwise, partial catalytic hydrogenation of the complete mixture of the ortho-, meta- and para- isomers of terphenyl, with a lesser amount of quaterphenyl isomers. There is no physical blending of any of the constituents to make this UVCB substance. Commercially available hydrogenated terphenyls are approximately 40% hydrogenated mixtures of ortho-, meta-, and para-terphenyls in various stages of hydrogenation, which are clear, yellow oils (Boogaard P.A., 2019)[5].

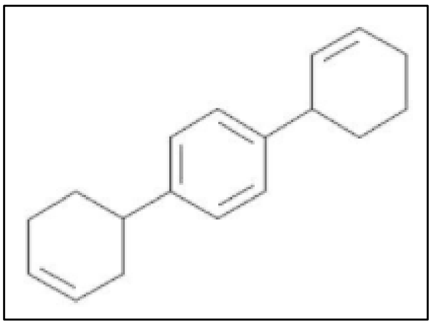
According to a patent (CN103804114A, 2014), PHT is manufactured within the production process of biphenyl (C12H10, CAS 92-52-4). Basically, terphenyls are manufactured merely as an accompanying product in the manufacture of biphenyl and vice-versa. Consequently, the economical manufacturing of both substances separately is not possible on commercial scale. The Danish EPA published in its report on Biphenyl (40 - FINAL REPORT, 2014)[6], that Monsanto (now Solutia) manufactures biphenyl via the dehydrocondensation of benzene and production is carried out in gas or electrically heated tubular reactors at 700 – 800 °C with residence and contact times of only a few seconds. The valuable accompanying substances produced are terphenyls, which come in the form of ortho-, meta-, para-, tri- and poly-terphenyl isomers. The yield is considered to be in the area of 50/50 between biphenyl and terphenyls (Thompson Q., 1992).

Origin:

Organic.

Structural formula:

Figure 1. Structural formula of PHT**.**



1.2.1.2. Composition of the substance(s)

The composition of the substance includes fully aromatic structures such as terphenyls, quaterphenyls, pentaphenyls and structures resulting from the hydrogenation of these constituents such as 1-cyclohex-2-en-1-yl-4-cyclohex-3-en-1-ylbenzene.

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[5] Boogaard P.J., Professor of Environmental Health and Human Biomonitoring, Wageningen University and Research Centre, and Toxicologist, Shell International BV, The Hague (until December 31, 2019). Hydrogenated terphenyl | Advisory report | The Health Council of the Netherlands

[6] 40 - FINAL REPORT - Biphenyl LOUS - 2014 11 04 (windows.net) https://prodstoragehoeringspo.blob.core.windows.net/9cbcbe23-83c1-4ff5-92bc-183a263dfe86/40%20-%20FINAL%20REPORT%20-%20Biphenyl%20LOUS%20-%202014%2011%2004.pdf

The composition of the substance (boundary) according to the SDS[7] is the following:

Table 7. Substance composition

Constituent	Reference name	Concentration range (w/w)	EC number	CAS number
1	Terphenyl, hydrogenated	74 - 87	262-967-7	61788-32-7
2	Terphenyl	3 - 8	247-477-3	26140-60-3
3	Quaterphenyls, Pentaphenyls and hexahydropentaphenyls, their isomers and other hydrocarbons	10 - 8	273-316-1	68956-74-1

1.2.1.3. Physicochemical properties

An overview of the physiochemical properties is given in**Table 8**. Unless otherwise stated, the data are taken from the REACH Registration on the ECHA public dissemination website (ECHA, 2021a), the SVHC Support Document (ECHA, 2018a) and the CSR of the LR (Solutia, 2019).

Table 8. Physicochemical properties

Property	Substance	Value	Reference
Physical state	Terphenyl, hydrogenated (CAS 61788-32-7)	Clear pale-yellow liquid	Newport plant specifications for Therminol 66, HB-40 (2008)
Melting point / Freezing point	Terphenyl, hydrogenated (CAS 61788-32-7)	below -24°C (pour point)	Unnamed study report
		below -28°C (pour point)	Secondary source
Boiling point	Terphenyl, hydrogenated (CAS 61788-32-7)	342°C (1 013 hPa)	Unnamed study report (2009)
		359°C (1 013 hPa)	Secondary source (2003)
Density	Terphenyl, hydrogenated (CAS 61788-32-7)	1 013 (20°C)	Company data (2009)
		1 008.4 kg/m^3 (20°C)	Secondary source (2003)
Vapour pressure	Terphenyl, hydrogenated (CAS 61788-32-7)	0.002 hPa (20°C)	Calculation using the Antoine equation
	4-Cyclohexyl-1,1'-biphenyl (CAS 3842-58-8)	2.24E-05 hPa	QSAR tool MPBPWIN v1.43
	1,3-diphenylcyclohexane (CAS 1667-08-9)	8.01E-05 hPa	QSAR tool MPBPWIN v1.43
	3-phenyldicyclohexyl (CAS 20273-26-1)	1.81E-04 hPa	QSAR tool MPBPWIN v1.43

[7] THERMINOL-66-SDS-EASTMAN.pdf (americasinternational.com)

	1,4-dicyclohexylbenzene (CAS 1087-02-1)	1.21E-04 hPa	QSAR tool MPBPWIN v1.43
	1,1':3',1''-Tercyclohexane (CAS 1706-50-9)	1.00E-03 hPa	QSAR tool MPBPWIN v1.43
Partition coefficient	Terphenyl, hydrogenated (CAS 61788-32-7)	6.5 (20°C)	Unnamed study report (2010)
	Terphenyl, hydrogenated (CAS 61788-32-7)	6.1 (20°C)	Secondary source, Monsanto international communication (1979)
Water solubility	Terphenyl, hydrogenated (CAS 61788-32-7)	0.061 mg/L (20°C)	Unnamed study report (1995)
	Terphenyl, hydrogenated (CAS 61788-32-7)	0.08 mg/L (20°C)	Unnamed study report (1995)
Flashpoint	Terphenyl, hydrogenated (CAS 61788-32-7)	170 °C (1013 hPa)	Secondary source (2003)
	Terphenyl, hydrogenated (CAS 61788-32-7)	171°C (atmospheric pressure not recorded)	Company data (1997)
	Terphenyl, hydrogenated (CAS 61788-32-7)	188°C (atmospheric pressure not recorded)	Company data (2003)
Auto flammability	Terphenyl, hydrogenated (CAS 61788-32-7)	374°C (1013 hPa)	Company data (1996)
	Terphenyl, hydrogenated (CAS 61788-32-7)	399°C (1013 hPa)	Secondary source (2003)
Viscosity	Terphenyl, hydrogenated (CAS 61788-32-7)	133 mm^2/s (static, 20°C)	Company data (2010)
	Terphenyl, hydrogenated (CAS 61788-32-7)	79.56 mm^2/s (25°C)	Unnamed study report (1994)

1.2.2. Justification for grouping

Not relevant for this substance.

1.2.3. Classification and labelling

No harmonised classification is reported for PHT in Annex VI of Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

There are no proposals for new or amended harmonised classification of PHT on the Registry of Intention.

The range of classifications that have been notified to the Classification and Labelling (C&L) Inventory (ECHA, 2021c), alone or combined, is the following:

- Not classified

- Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects)
- Aquatic Chronic 2 (H411: Toxic to aquatic life with long lasting effects)
- Aquatic Chronic 4 (H413: May cause long lasting harmful effects to aquatic life)
- Aquatic Acute 1 (H400: Very toxic to aquatic life)

The status of the notifications in the C&L Inventory (ECHA, 2021c) checked on 12th October 2021 is the following:

- Number of aggregated notifications: 8
- Total number of notifiers: 669

Detailed notifications are given in **Table 9**:

Table 9. C&L notifications

Aggregated Notification	Classification		Labelling		M-Factors	Additional Notified Information	Number of Notifiers	Joint Entries
	Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Pictograms and Signal Word Code(s)				
1	Aquatic Chronic 2	H411	H411	GHS09		State/Form	27	X
2	Aquatic Chronic 4	H413	H413			State/Form	596	
3	Aquatic Chronic 2	H411	H411	GHS09			18	
4	Not classified						15	
5	Aquatic Chronic 4	H413	H413		M(Chronic) = 0	State/Form	7	
6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	H410	GHS09 Wng		State/Form	3	
7	Aquatic Chronic 1	H410	H410	GHS09 Wng	M (Chronic) = 1		2	
8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	H400 H410	GHS09 GHS07 Wng			1	

The co-registrants of PHT provided the following self-classification in the registration dossier (ECHA, 2021a):

- Aquatic Chronic 2 (H411: Toxic to aquatic life with long lasting effects)

The labelling information provided by the registrants in the registration dossier is the following:

- Hazard statement/code: Toxic to aquatic life with long lasting effects/H411
- Pictogram code: GHS09 (environment)

- Signal word code: no signal word
- Precautionary statement / code: Avoid release to the environment / P273
- Precautionary statement / code: Collect spillage / P391

- Precautionary statement / code: Dispose of contents/container to ... …in accordance with local/regional/national /international regulations (to be specified). Manufacturer/ supplier or the competent authority to specify whether disposal requirements apply to contents, container, or both / P501

1.2.4. Hazard assessment

The environmental fate properties have been summarised previously (ECHA, 2018a) and were the key arguments leading to the identification of PHT as an SVHC due to its vPvB properties based on a weight of evidence approach of the available data.

This restriction report is based on the established PBT/vPvB properties of PHT. Therefore, the human health endpoints and a toxicity assessment are not relevant for this dossier.

1.2.5. Exposure assessment

1.2.5.1. Life cycle of PHT

Currently there are six active registrations for PHT in the EU (see also **Annex A** and **Annex B.9.2.** for further information).

According to registration information, PHT is not manufactured within the EU. It is mainly used as HTF within closed systems at industrial sites. Also related to the HTF uses is the industrial "use in laboratory analysis" where small amounts of in-use HTF is analysed to determine its lifetime. The use of this substance as a plasticiser is the second relevant use. Plasticisers are additives that increase the plasticity or decrease the viscosity of a material. PHT is used as a plasticiser mainly to produce sealants and adhesives. The final sealants/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). This application is addressed in the "additive in plastic application" scenarios as well as the corresponding "Plastic articles" service life scenario. Moreover, PHT is also used as plasticiser in coatings and inks. In addition, professional service life scenarios are also relevant for PHT since the substance is incorporated into or onto articles when used in adhesives and sealants as well as in coatings and inks.

Furthermore, PHT is also used as solvent or process medium by the industry and as laboratory chemical (e.g., as microscope immersion oils) by professionals.

In addition, a general scenario ("Formulation, transfer and repackaging of substances in preparations and mixtures") related to the formulation life cycle stage was indicated as relevant for PHT. Since specific formulation scenarios are also indicated ("Formulation of adhesives and sealants", "Formulation of coatings/inks" and "Formulation - use as additive in plastic applications") the general formulation will herein solely be used to cover formulation of laboratory chemicals used by professionals.

Currently, PHT is used in the following applications:

- Use in adhesives and sealants.
- Use in coatings and inks.
- Use as additive in plastic applications.
- Use as HTF.
- Use as solvent/process medium.
- Use as laboratory chemical.

1.2.5.2. Data collection

The substance is registered in the EU under the REACH Regulation and only limited information on the releases to the environment is available from the disseminated information on ECHA's webpage. In addition, specific information on the Identified Uses (IU) of the substance as well as its exposure patterns are obtained in a survey conducted in 2019 by the LR. Thereby, an advanced Exposure & Release Questionnaire was sent out to users as well as distributors. In this questionnaire, exposure related information on human health and the environment was requested. General information such as technical functions of the substance, total tonnages, relevant life-cycle steps, and their respective use descriptors (Environmental Release Categories (ERCs), Process Categories (PROCs), Sectors of Use (SUs), and Product Categories (PCs)) was obtained, as well as process specific data on the IU. This included the identification of specific contributing scenarios incl. their Operational Conditions (OCs) and applied Risk Management Measures (RMMs). The Exposure & Release Questionnaire is attached in Appendix 1.

In total, more than 50 companies were contacted. Overall, 17 companies from different industry sectors provided a completed questionnaire. Hence, this extensive feedback has been evaluated and used for the following exposure and risk assessment. If no specific information was available, worst-case release estimates for the relevant scenarios are used.

During the data collection phase of this proposal in summer 2021 via a Socio-Economic Analysis (SEA) Questionnaire to downstream users (see **Annex E**: Impact Assessment), the Dossier Submitter asked as well on assessment of relevant emissions. The responses (obtained only from HTF users) have been reported collectively as negligible.

Up until now only a few international measurements of PHT in the environment or other media have been reported. Moh et al. (2002) describe accidental contamination of food items with PHT, while Sturaro et al. (1995) detected PHT as contaminant in food cardboard packages made from recycled material containing carbonless copy paper.

A screening programme conducted in 2018 by NILU and NIVA (NILU, 2018), focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT-properties, including PHT.

Moreover, the SCIP database (ECHA, 2021b) was screened for PHT. At the date of access (2 March 2022) more than 12 000 articles containing PHT have been notified to this database. Most entries are related to use in polymers, rubber & elastomers (>60%), sealants (>25%), inks (> 5%), sensors (> 1%), paper (< 1%) and a few others. In summary it can be concluded that close to 85% of PHT use in articles is related to plasticiser uses. Therefore, there is also significant potential for release of PHT to the environment from waste disposal activities (see **Annex B.9.**: Exposure assessment). The information obtained through analysis of the SCIP database will be addressed in the exposure assessment (please refer to **Annex B.9.**).

Furthermore, migration modelling was conducted by FABES Forschungs-GmbH (FABES, 2021). Migration is a global term to describe a net mass transfer of a chemical substance from one material (e.g., plastic packaging) into another medium (e.g., food, water, air). Migration includes several macroscopic mass transfer mechanisms, such as:

- Mass diffusion in and through the different (polymer) materials as well as the liquid or gas phases separating the primary source from the target medium.
- Desorption/sorption at the interface between each crossed medium. When it involves fluid phases, migration may also cover an additional transport or mixing effect by advection.

The leaching/migration of PHT from a special epoxy topcoat, used in the aerospace & defence industry, into the surrounding air/atmosphere as well as the migration of PHT from a sample plate made of polysulfide sealant into the surrounding air/atmosphere was estimated by means of a theoretical modelling approach. For further information please refer to **Annex B.9.9.3** and **Annex B.9.13.3**, respectively.

In addition, exposure measurements at industrial sites using PHT as HTF were conducted. A monitoring program was designed and developed at a number of industrial sites that use PHT in order to obtain updated information on potential environmental emissions of PHT from industrial uses as HTF. Companies that participated in this program were requested to collect both air and soil samples, from locations at which releases of PHT could be regarded to be more likely. For further information please refer to **Annex B.9.3.3**.

1.2.5.3. Exposure assessment

1.1.5.3.1. Human health assessment

This restriction dossier is based on the established vPvB properties of PHT. Hence, the assessment of human health effects is therefore not conducted in this dossier.

1.1.5.3.2. Environmental assessment

For each exposure scenario an overview table with the input parameters is given in **Annex B.9.** Thereby the total volume is derived by summarising the imported volumes reported by the registrants or using the upper limit of the tonnage band of a registration.

Additionally, a table displaying the initial releases to air, water and soil based on the release rates is included in **Annex B.9** for each scenario. The releases are calculated using generic exposure methods.

Moreover, the distribution in the environment, e.g., the distribution of the releases in the sewage treatment plant is considered. The distribution within the sewage treatment plant is estimated using default percentages as calculated by SimpleTreat 3.0 (RIVM, 1994). Although the last stand-alone version of this assessment tool is 4.0, SimpleTreat 3.0 is used as it is implemented in CHESAR v3.7 (ECHA, 2022a). CHESAR v3.7 is the standard modelling tool to be used for exposure and risk assessments under REACH. In addition, the results of the two versions are identical. SimpleTreat 3.0 estimates the likely behaviour of a substance within the sewage treatment plant based on its properties. The herein assessed PHT is likely to adsorb onto sewage sludge which might subsequently be applied to agricultural soil as fertilizer.

The environmental exposure assessment is based on the default release factors in accordance with ECHA Guidance R.16 (ECHA, 2016). Using the default release factors has to be regarded as worst-case approach overestimating the actual emissions.

In case other information on the releases are available and applicable for PHT, e.g., Specific Environmental Release Categories (SpERCs) or Organisation for Economic Co-operation and Development (OECD) Emission Scenario Documents this information is used in preference to the default release factors as indicated in ECHA Guidance R.16 (ECHA, 2016). Additionally, specific information was made available through the Exposure & Release Questionnaire (2018) by the LR. The estimates are assumed to represent the reasonable worst-case emissions.

For further information on the used release factors please refer to the respective scenario in **Annex B.9**.

The main objective for the approach of the environmental exposure assessment was to present a realistic assessment. The default release factors represent a worst-case approach overestimating the actual emissions to the environment. Hence, the default release factors give an indication of the relative release potential from the various processes but do not take into account the physico-chemical properties of the substance or any risk management measure that is used during the process.

Using more specific information (if available) instead of the default release factors guarantees a more realistic exposure assessment which is based on actual emissions.

The properties of PHT that have been assumed in the exposure assessment were taken from ECHA's dissemination page.

1.2.5.4. Summary of environmental exposure assessment

The exposure assessment shows that the largest source of PHT emission to the environment in the EU is attributed to the use in adhesives/sealants. Regarding the high emission scenario, the "use of adhesives and sealants at industrial sites" contribute significantly to the overall emission (share of total: approximately 41%). Moreover, the use of coatings/inks at industrial sites as well as the use as HTF at industrial sites have a share of approximately 22 and 19%, respectively, of the total emissions.

Looking at the low emission scenario the "Service life of articles produced from use as plasticiser" has a share of approximately 67% of the total emissions followed by the industrial use of sealants and adhesives (approximately 14%).

Table 10. Emission sources of PHT.

Scenario	**Share of total (%)** **Low emission scenario**	**Share of total (%)** **High emission scenario**
Manufacture*	0	0
Formulation of coatings/inks	0.08	2.27
Direct use for industrial coatings/inks applications	6.66	21.59
Direct use for professional coatings/inks applications	2.77	1.18
Service life of articles produced from use of coatings and inks	0.77	0.04
Use as HTF at industrial sites	0	18.86
Laboratory analysis	4.08E-3	0.01
Use as HTF at professional sites	0.04	0.16
Formulation of adhesives and sealants	1.04	2.27
Use of adhesives and sealants at industrial sites	14.21	**40.63**
Use of adhesives and sealants by professionals	3.13	2.06
Service life of articles produced from use as plasticiser	**67.37**	3.24

Scenario	**Share of total (%) Low emission scenario**	**Share of total (%) High emission scenario**
Formulation, transfer and repackaging of substances in preparations and mixtures	3.58	0.17
Use as solvent/process medium	0.01	7.52
Use as laboratory chemical by professionals	0.33	0.02

*Please notice that there is no manufacture taking place within the EU/EEA.

Additionally, the share of total emissions is evaluated based on the market sector (please refer to the following table). Thereby the following market sectors are differentiated:

- Use in coatings/inks
- Use as HTF
- Use in adhesives/sealants
- Miscillaneous uses (i.e., general formulation, use as solvent and use as laboratory chemical by professionals)

The analysis showed that the adhesives/sealants have by far the largest share of the total emission. In the high emission scenario, the share is estimated to be approximately 48% whereas the share in the low emission scenario is even higher (approximately 86%).

Table 11. Emission sources of PHT based on market sector.

Scenario	**Share of total (%) Low emission scenario**	**Share of total (%) High emission scenario**
Coatings/inks	10.28	25.07
HTF	0.05	19.02
Adhesives/sealants	**85.76**	**48.21**
Miscellaneous (general formulation, use as solvent and use as lab chemical by professionals)	3.92	7.71

In **Table 12** the estimated emissions for each compartment (air, water, and soil) are displayed. These include the sum of estimated releases to the air, water, and soil. The redistribution in the Sewage Treatment Plant (STP) is not taken into account for emissions to wastewater.

Regarding the low emission scenario approximately the same amount is released to the water and soil compartment (approximately 42 and 37%, respectively) whereas the release to air is lower (approximately 22%).

For the high emission scenario approximately 40% is released to the air as well as the water compartment. Only approximately 21% is released to the soil.

In general, no major route of emission can be determined.

Table 12. Estimated total EU releases for PHT.

Environmental compartment	Estimated EU emissions based on data on volume for 2021		
	Low (kg per year)	High (kg per year)	Share of total (%)
Air	14 000	710 000	21.64 – 39.80
Water	26 900	706 000	41.58 – 39.57
Soil	23 800	368 000	36.79 – 20.63
All / Total	64 700	1 784 000	100

Emission to Wastewater Treatment Plant (WWTP) taking into account the redistribution of emission to wastewater in STP are displayed in the following table.

Taking into account the redistribution of the emission via wastewater the major route of exposure with a share of approximately 72% of the total emissions for the low emission scenario is clearly the soil compartment. The share of the total volume of the soil compartment is lower (approximately 54%) for the high emission scenario. The share of the air compartment on the total emissions is approximately 25 and 43% for the low and the high emission scenario, respectively. The share on the total emission of the water compartment is by far the lowest with only approximately 3% for both, the low and high emission scenario.

Table 13. Estimated total EU releases for PHT following redistribution in STP.

Environmental compartment	Estimated EU emissions based on data on volume for 2021		
	Low (kg per year)	High (kg per year)	Share of total (%)
Air	16 277	769 763	25.16 – 43.15
Water	2 032	53 331	3.14 – 2.99
Soil	46 391	960 899	71.70 – 53.86
All / Total	64 700	1 783 993	100

The estimated regional Predicted Environmental Concentrations (PECs) for PHT in the EU are summarised in the following table.

Table 14. Estimated regional PECs for PHT in the EU.

Environmental compartment	Lower estimate	Upper estimate	Unit
Fresh water	3.51E-6	6.12E-4	mg/L
Sediment (freshwater)	0.222	38.65	mg/kg dw
Marine water	4.41E-7	6.82E-5	mg/L
Sediment (marine water)	0.028	4.286	mg/kg dw
Air	1.01E-5	3.29E-4	mg/m³
Agricultural soil	6.73E-4	0.022	mg/kg dw
Man via environment - inhalation (systemic effects)*	1.01E-5	3.29E-4	mg/m³
Man via environment (oral)**	3.75E-4	0.057	mg/kg bw/d

*expressed as concentration in air
**expressed as exposure via food consumption

In general the high emission scenario represents a worst case assumption whereby e.g. the default release factors as indicated in ECHA Guidance R.16 (ECHA, 2016) are used. Hence, the high emission scenario has to be regarded as a very conservative approach overestimating the actual exposure. The low emission scenario takes into account information from e.g., SpERC and information obtained in a survey. Hence it is regarded a more realistic emission estimation. Also, the findings are proven by comparable results of the modelling conducted by FABES (FABES, 2021) as well as the monitoring data.

1.2.6. Risk characterisation

It is not relevant to perform quantitative risk assessments of vPvB substances, due to the uncertainties regarding long-term exposure and effects. Therefore, the risks of vPvB substances, such as PHT, to the environment or to humans cannot be adequately addressed in a quantitative way.

Due to the vPvB properties of PHT, emissions will lead to an increased exposure of humans and the environment since the substance will build up over time.

The overall aim for vPvB substances 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.

1.3. Justification for an EU wide restriction measure

PHT has been identified as an SVHC based on its vPvB properties according to Article 57(e) of the REACH Regulation. In addition, on 14 April 2021 ECHA has recommended the substance for the inclusion in Annex XIV to REACH (List of Substances subject to Authorisation).

This 10th ECHA Recommendation[8] is based on the inherent properties (vPvB), the volume and the wide dispersiveness of uses (industrial sites, professional workers and use in articles).

As outlined before, PHT is chemically very stable in various environmental compartments with minimal or no abiotic degradation and is very bioaccumulative, which means that environmental stock may increase over time upon continued releases. For vPvB substances a safe concentration level in the environment cannot be established with sufficient reliability and for this reason, vPvB substances are treated as non-threshold substances for the purpose of risk management under REACH. 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). Due to this fact, even small levels of environmental emissions of this kind of substances could be considered sufficient to demonstrate their risk.

When PHT is used as an **HTF**, it is constantly contained within a closed loop system with limited discharges. However, exposure to the environment cannot be disregarded as demonstrated under **Annex B.9.** (Exposure Assessment). During operation, special attention needs to be paid to the interfaces of the closed system to the atmosphere, such as closed draining, separation points (joints, mechanical seals, flanges, valves, etc.) and rotary transmission equipment (pumps, etc.). Potential emissions to the environment are prevented by the implementation of stringent containment measures and control during the design stage of the closed system. Other exposure and emission sources of PHT when used as HTF are related to transport, loading and refilling operations, replacement or topping-up of the HTF, industrial cleaning operations, and disposal of the HTF.

When PHT is used as a **plasticiser** it may be released into the environment during the various life cycle steps. The LR has conducted a comparative risk assessment for the two main uses, HTF and plasticiser (Solutia, 2018). The calculation clearly showed that the plasticiser use is far more critical for risk management than the HTF use.

The estimated local and regional overall release associated with the use as a plasticiser is up to 10-times higher than the local and regional overall release associated with the use as an HTF, respectively. It was shown that the total environmental emissions based on the use of PHT as an HTF are significantly lower than the total releases from the plasticiser uses. The use of the substance as a plasticiser is more critical for risk management regarding the emissions to the environment than the use as an HTF within a closed system. These results have been confirmed by the Environmental Monitoring program at HTF sites and migration modelling studies on plasticiser uses, conducted by the LR (see **Annex B.9.**: Exposure Assessment).

Moreover, for the plasticiser use PHT will be incorporated into or onto an article. At the end of the service life, the article has to be disposed. During the disposal at a waste treatment plant the PHT may be released into the environment as well. 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. As shown in **Annex A** (Manufacture and Uses), in total more than 12 000 articles containing PHT have been notified to this database. Most entries are related to use in polymers, rubber & elastomers (>60%), sealants (>25%), inks (> 5%), sensors (> 1%), paper (< 1%) and a few others. In summary it can be concluded that close to 85% of PHT use in articles is related to plasticiser uses. Therefore, there is also significant potential for release of PHT to the environment from waste disposal activities (see **Annex B.9.**: Exposure assessment). The Dossier Submitter assumes that at the waste life-cycle stage the uccrently implemented risk management measures are not sufficiently effective to control the risks.

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

PHT has not been widely found in the environment so far. However, 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. Only a few international measurements of PHT in the environment or other media have been reported. Moh et al. (2002) describe accidental contamination of food items with PHT, while Sturaro et al. (1995) detected PHT as contaminant in food cardboard packages made from recycled material containing carbonless copy paper.

A screening programme conducted in 2018 by NILU and NIVA (NILU, 2018), focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT-properties, including PHT. The substance was found in the 100 ng/g range in marine sediments, and it was recommended that the chemical should consequently be studied in more detail. Compared to surface water the detection frequency for hydrogenated terphenyls were found in all samples, still in low concentrations. In addition, PHT was measured in buildings. Analytical data shows in general a much lower concentration in non-residential buildings. However, there is one single case of extreme air concentration which might be due to leakage from technical installations in this building.

Since PHT persists in the environment for a very long time and it has the potential to accumulate in humans and wildlife, effects of current emissions may be observed or only become apparent in future generations. Avoiding effects will then be difficult due to the irreversibility of exposure. The main benefits to society from a partial restriction of PHT will be the avoidance of these potential transgenerational impacts on the environment and human health in the future, through proportionate reductions in emissions and exposure to this substance. It is therefore desirable to go ahead with a Restriction under REACH in order to benefit from an early implementation of emission reduction. Consequently, an EU Restriction will be an important step to reduce the emissions and risks from PHT within the EU internal market.

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

A description of the proposed Union-wide Restriction Option (RO) that has the potential to reduce emissions of PHT to the environment is presented in **Annex E.1.** (Risk Management Options). A corresponding EU-wide restriction will prevent and reduce the releases of the substance and is considered to be the most efficient and appropriate way to limit the risks (due to further releases into the environment) for human health and the environment on an EU level.

1.4. Baseline

This section draws on **Annex D** which provides further details on the baseline scenario in terms of current and future use and emission volumes and the methodology used to estimate them. The "baseline" is the scenario in the absence of any restriction or other RMO or intervention being implemented to reduce the environmental risks from manufacture, import and use of PHT.

The baseline is a projection of future PHT volumes used in the EU and the corresponding projected releases of PHT into the environment. The projections consider other external factors that could affect the market, such as implementation of new legislations/regulations or changes to existing ones that may affect the releases of PHT. The baseline scenario describes the "business as usual" situation. The baseline was developed based on the data gathered on manufacture, import and use of PHT within the EU as presented in **Annex A** (Manufacture and Uses) and the Exposure Assessment as outlined in **Annex B.9**.

The period from which the baseline is derived was chosen to be 2025 – 2044 as 2025 is considered the earliest, realistic Entry into Force (EiF) for a potential REACH restriction on PHT and 20 years is the analytical period commonly used for most restriction proposals. The tonnage and releases report in **Annex A** (Manufacture and Uses) and **Annex B.9.** (Exposure Assessment) are the starting point for the baseline in this analysis and the assumptions related to future trends of the use of PHT. The baseline scenario is compared to the proposed restriction scenario in the Impact Assessment (**Annex E**) in terms of both costs and benefits.

1.4.1. Volumes and Trends

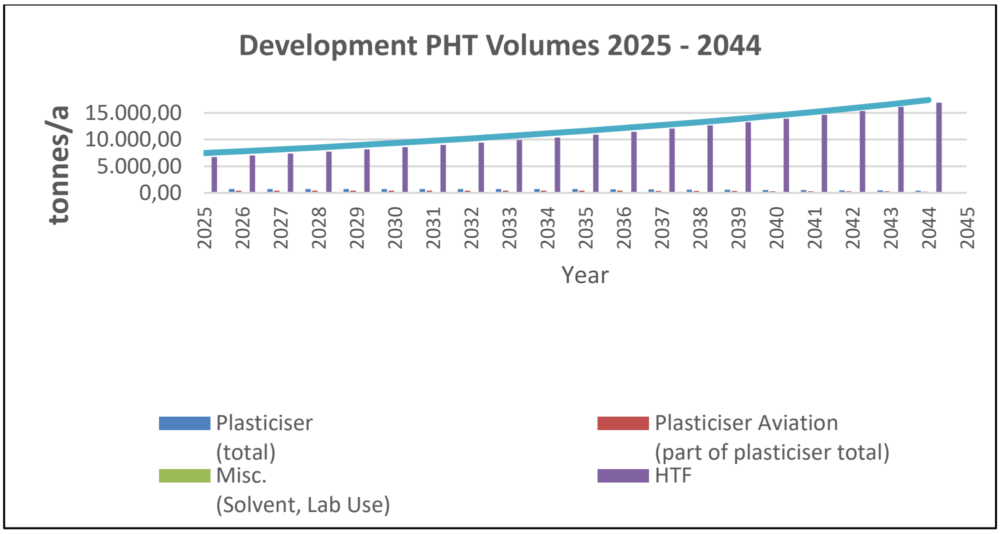
To be able to estimate the expected impact of the restriction proposal, it is important to know the current situation in terms of the use of PHT in the EU and to describe the expected trends that would occur without the introduction of any new regulatory measure.

From 2025 to 2044, it is expected that developments in the volume of PHT used as HTF in the EU will be dominated by the market trends. As shown before, PHT plays a significant role as HTF in alternative energy technology (ORC and solar) supporting the EU's Green Deal[9]. Moreover, chemical recycling of PET and other polymers is increasing following the EU's Circular Economy action plan[10]. The dossier submitter therefore assumes, that the growth trend as shown will continue in the next 20 years, but slightly levelled due to the SVHC listing. In addition and due to the feedback from the different questionnaires, the demand for PHT was higher than the available production capacity in the last 5 years, therefore new production plants have been installed in China and the Middle East.

This resulted in growth rates of up to 30% in the last 3 years globally as well as on EU level. It is reasonable to assume that this growth rate will flatten as more capacity has been installed globally and a continued volume increase of 5% annually for HTF use is assumed by the Dossier Submitter, resulting in a predicted volume for HTF use of approximately 16 931 tonnes per year by end of 2044.

Figure 2 below shows the estimated volume development in the EU between 2025 and 2044, based on the aforementioned growth rates.

Figure 2. Estimated trend of volume development of PHT in the EU from 2025 – 2044.



[9] Delivering the European Green Deal | European Commission (europa.eu)

[10] Circular economy action plan (europa.eu)

The plasticiser use is assumed to be stagnant from 2025 – 2035. Beyond 2035, the uncertainty in any projection increases and makes it difficult to identify the driving factors for the plasticiser use. The Dossier Submitter assumes, that due the SVHC listing the reformlation will kick in, resulting in a drop of the plasticiser use in the EU. It is expected that the decrease in volume as of 2036 will be 5% per annum. On the other hand, it is very likely that the production of articles including PHT as a plasticiser will be relocated outside the EU and that the volume of imported articles containing PHT into EU will increase. The high number of articles containing PHT notified to the SCIP Database shows evidence for that. Consequently, for the Baseline Scenario a stagnant plasticiser emission is assumed. The non-HTF and non-plasticiser use is assumed to be stagnant, too.

1.4.2. Current Releases of PHT and Baseline Emissions

The current emissions of PHT to the environment from various sources in 2021 were derived in **Annex B.9.** (Exposure Assessment). The environmental releases are based on the default release factors in accordance with ECHA Guidance R.16. In case other information on the releases was available to the Dossier Submitter and applicable for PHT, e.g., SpERCs or OECD Emission Scenario Documents, this information was used in preference to the default release factors as indicated in the ECHA Guidance R.16 (ECHA, 2016). Additionally, specific information was collected via the Exposure & Release Questionnaire (Appendix 1) by the LR, which was initiated to update the Exposure Assessment of the Registration Dossier.

The main objective for the approach of the environmental exposure assessment was to present a realistic assessment. The default release factors represent a worst-case approach, overestimating the actual emissions to the environment. Hence, the default release factors give an indication of the relative release potential from the various processes but do not take into account the physico-chemical properties of the substance or any risk management measure that is used during the process.

The share of the total emissions was evaluated based on the market sector and summarised in **Table 15**. The exposure assessment shows that in the "high emission scenario" the largest source of PHT emission to the environment in the EU is attributed to the use in adhesives/sealants. Regarding the high emission scenario, the "use of adhesives and sealants at industrial sites" contribute significantly to the overall emission (approximately 41%). The use of coatings/inks at industrial sites as well as the use as HTF at industrial sites have a share of approximately 25 and 19%, respectively, of the total emissions.

Looking at the low emission scenario the "Service life of articles produced from use as plasticiser" has a share of approximately 67% of the total emissions followed by the industrial use of sealants and adhesives (approximately 14%).

The following market sectors were considered:

- Use in coatings/inks
- Use as HTF
- Use in adhesives/sealants
- Miscellaneous uses (i.e., general formulation, use as solvent and use as laboratory chemical by professionals)

The analysis showed that the adhesives/sealants represent by far the largest share of the total emissions. In the high emission scenario, the share is estimated at approximately 48% whereas the share in the low emission scenario is even higher (approximately 86%).

Table 15. Sources of Emission of PHT by market sectors.

Scenario	Share of total (%) Low emission scenario	Share of total (%) High emission scenario
Adhesives and sealants	85.76	48.21
Coatings and inks	10.28	25.07
HTF	0.05	19.02
Miscellaneous (general formulation, use as solvent and use as lab chemical by professionals)	3.92	7.71

In **Table 16** the emissions for each compartment (air, water and soil) are displayed. These include the sum of estimated releases to air, water and soil. Regarding the low emission scenario approximately the same amount is released to water and soil (approximately 42 and 37%, respectively) whereas the release to air is lower (approximately 22%). For the high emission scenario, approximately 40% is released to air as well as to water. Only approximately 21% is released to soil. In general, no major route of emission can be determined. **Table 17** shows the estimated total release for PHT in EU by market sector in 2021. For the Baseline calculations, the below averaged release shares (average between low and high emission scenario) have been used. The high and low volume emission scenarios were averaged to an estimated PHT release of 925 tonnes in 2021.

Table 16. Estimated total release for PHT in EU in 2021.

Environmental compartment	Estimated EU emissions based on data on volume for 2021		
	Low (kg per year)	**High (kg per year)**	**Share of total (%)**
Air	14 000	710 000	21.64 – 39.80
Water	26 900	706 000	41.58 – 39.57
Soil	23 800	368 000	36.79 – 20.63
All / Total	**64 700**	**1 784 000**	**100**

Table 17. Estimated total release for PHT based on market sector in EU in 2021 based on average release shares and average total volume.

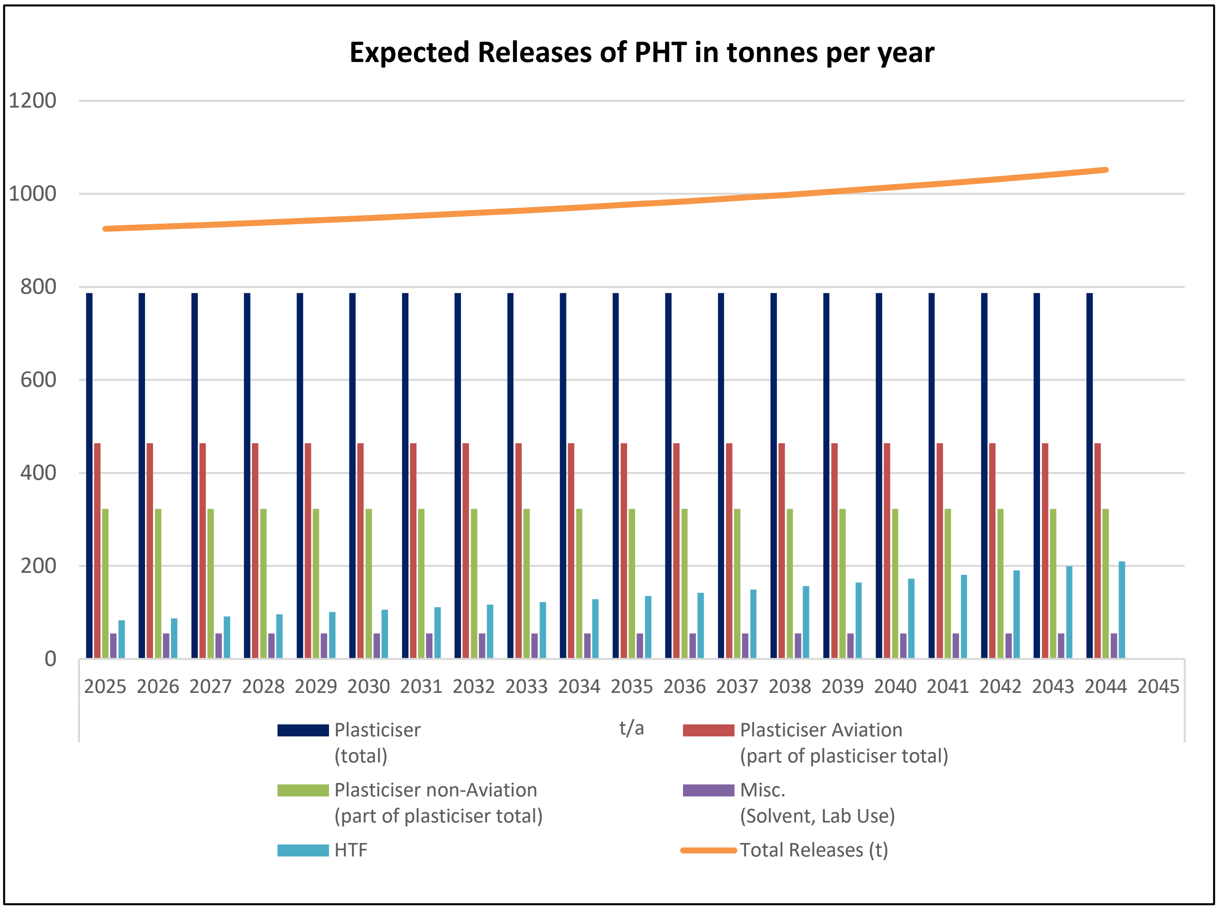
Market Sector of Use	Release Share average in %	Volume of total releases, average (tonnes per year)	Release, average (tonnes per year)
Plasticiser Adhesives and Sealants	67	**925**	620
Plasticiser Coatings and Inks	18		167
HTF	9		83
Miscellaneous	6		55

This means that the plasticiser applications, representing approximately 10% of the volumes used in the EU are responsible for 85% of the releases of the 2021 volumes. The

HTF use, representing 90% of the volume account for approximately 9% of the releases and the remaining non-HTF and non-plasticiser applications (< 1% of the volume used) sum up for 6% of the emissions. In addition, it needs to be considered that PHT will be entering the EU via articles containing PHT as a plasticiser and will be released during service life.

Figure 3 shows an estimation of expected PHT releases on an annual basis from 2025 – 2044.

Figure 3. Estimation of expected PHT releases on an annual basis from 2025 – 2044.



The worst-case cumulative releases of PHT from 2025 to 2044 have been estimated with a total volume of 19 584 tonnes, which corresponds to an average annual release of 979 tonnes. From 2025 to 2044 the annual releases increase from 925 to 1 052 tonnes, as illustrated in **Table 18.**

Table 18. Cumulated and averaged expected releases from 2025 – 2044 per use.

	Tonnes per year						
Expected releases	2025	2030	2035	2040	2044	Cumulated releases 20 years in tonnes	Average annual release in tonnes per year
Plasticiser (total)	787	787	787	787	787	15 740	787
Plasticiser Aviation	464	464	464	464	464	9 280	464
Plasticiser non-Aviation	323	323	323	323	323	6 460	323
Miscellaneous (Solvent, Lab. Use)	55	55	55	55	55	1 100	55
HTF	83	106	135	173	210	2 744	137
Total Releases (tonnes)	**925**	**948**	**977**	**1 015**	**1 052**	**19 584**	**979**

Since the emissions from plasticiser uses will be stagnating as outlined before, but the HTF volume will increase significantly over the next 20 years by a factor of 2.5, the HTF emissions will proportionately increase from 83 tonnes in 2025 to 210 tonnes in 2044, resulting in a doubling of emission share of HTF uses from 9% to approximately 20% of total PHT emissions. However, it should be noted that this is a very conservative and worst-case approach and most likely a significant overestimation. In particular since on-site exposure measurements (see Chapter B.9.3.3. Exposure measurements) only identified negligible releases.

Over the examined 20 years, the whole plasticiser releases account on average for approximately 80% of the emissions and the non-HTF uses in sum for 86%. Resulting in a 14% contribution of HTF uses to the total averaged releases.

2. Impact assessment

2.1. Introduction

The basis for the impact assessment were mainly the findings and results from stakeholder interactions and responses to questionnaires as well as comments submitted during public consultations (see **Annex E**: Impact Assessment, and **Annex G**: Stakeholder Consultation).

In summary, 135 responses were analysed for getting a better understanding of impacts for industry and society. Several individuals/companies responded to all or some of the requests. Removing duplicate responses leads to a total of 96 individual replies of which 89 are from individual companies and 7 from industry associations.

Furthermore, the Dossier Submitter had several telephone interviews with the LR and Member Registrants as well as individual users of the substance via its consultant.

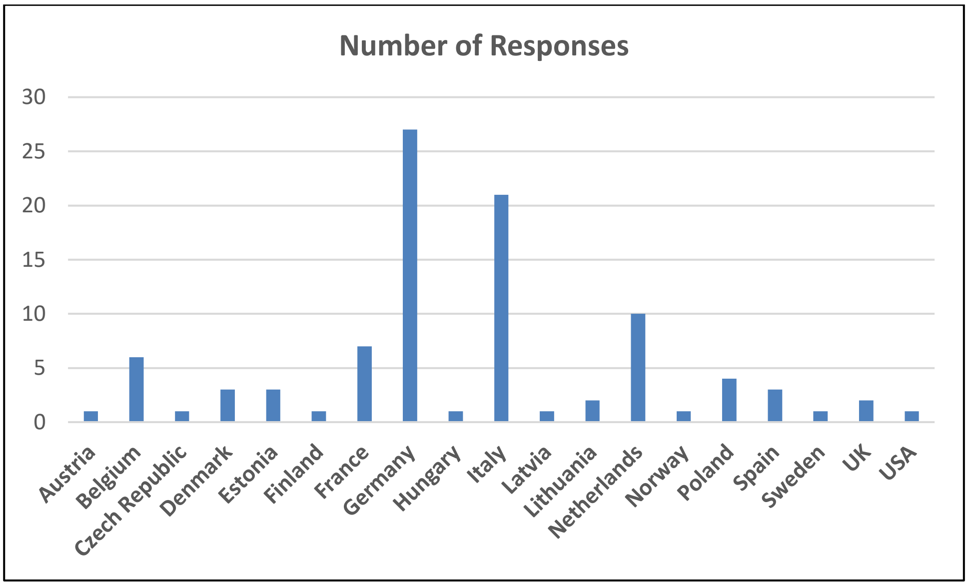
Table 19. Responses reviewed related to impacts on industry.

Type of Request/Response	Number of Responses
LR - SEA Questionnaire, 2018	24
Commission - Socio-Economic Impact Questionnaire, 2020	26
ECHA - Responses to 10th Recommendation, 2020	55
Dossier Submitter - SEA Questionnaire, 2021	30
Total	**135**
Individuals (removing duplicate responses)	96
Individual companies	89
Industry Associations	7

Analysing the number of responses per country it can be determined that unsurprisingly most of the responses came from EU countries, where PHT has the highest installed base.

Figure 4 does illustrate these numbers in a schematic diagram.

Figure 4. Schematic diagram to illustrate the number of responses per country



2.2. Analysis of alternatives

This section draws on **Annex E.2.** which provides further details on the analysis of the alternatives to PHT for its different uses. Detailed information can be consulted in this Annex.

The overall goal of this analysis is to support informed decisions regarding the advantages and disadvantages of different alternatives to PHT. These 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 identification process has been divided in three general steps:

- Screening of information sources
- Assessment on the technical suitability of the alternatives, considering the different uses of PHT.
- 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 PHT was defined. This list is shown in **Table 20**:

Table 20. List of potential alternatives to PHT

Alternative	Chemical name	CAS	EC
1	1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene	63231-51-6	400-370-7
2	Dibenzylbenzene, ar-methyl derivative	53585-53-8	258-649-2
3	Benzene, ethylenated, by-products from	68608-82-2	271-802-8
4	Reaction mass of diisopropyl-1,1'-biphenyl and tris(1-methylethyl)-1,1'-biphenyl	-	915-589-8
5	Reaction mass of m-terphenyl and o-terphenyl	-	904-797-4
6	Diphenyl ether	101-84-8	202-981-2
7	Biphenyl	92-52-4	202-163-5
8	Cyclohexylbenzene	827-52-1	212-572-0
9	Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues	84961-70-6	284-660-7
10	Benzyltoluene	27776-01-8	248-654-8
11	Ditolyl ether	28299-41-4	248-948-6
12	Mineral fluids	-	-

The second step of the identification process (technical suitability of the alternatives) ruled out alternatives 3, 4, 6, 7, 9, 10, and 11 because the values of their boiling points are not suitable for the conditions of use of PHT as HTF. Furthermore, considering the registered uses of PHT (ECHA, 2021a), alternatives 3, 10, and 11 have been discarded.

The summary of potential alternatives per use is detailed in **Table 21**:

Table 21. List of potential alternatives per use

Use	Alternatives
HTF	1, 2, 5
Plasticiser	2, 9
Solvent or process medium	6, 7, 8, 9
Additive in adhesive and sealants	9
Laboratory chemicals	4, 6, 7, 8, 9
Additive in coatings, paints, and inks	9

The last step of the identification process (assessment of the hazard profile) discarded alternatives 2 and 4 due to their classification as reprotoxic, and alternative 5 due to its PBT properties. The final list of alternatives to PHT and their potential uses is detailed in **Table 22**:

Table 22. Final list of potential alternatives to PHT

Alternative	EC	Potential uses
1	400-370-7	HTF
6	202-981-2	Solvent or process medium, laboratory chemical
7	202-163-5	Solvent or process medium, laboratory chemical
8	212-572-0	Solvent or process medium, laboratory chemical
9	284-660-7	Plasticiser, adhesive and sealants, paints and coatings, inks and toners, solvent or process medium, laboratory chemical

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 PHT has been done (see detailed information in **Annex E.2.3.**).

Due to the limited available information in the literature and lack of information provided by stakeholders for some of the uses, technical feasibility can only be assessed in terms of proven or confirmed uses of PHT. It may therefore be the case that some of the uses of PHT are not covered in this analysis of alternatives.

The analysis is specific for each potential alternative and use, and it comprises the following:

- Availability of alternative
- Human health risks related to alternative
- Environment risks related to alternative
- Technical and economic feasibility of alternative
- Other information on alternative

Since PHT has been identified as a vPvB substance, quantitative risk characterisation is not appropriate nor meaningful. Therefore, it is not feasible to carry out a risk comparison between PHT 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 the case of alternative 1, its PBT status is still under assessment but there are well-founded suspicions that this behaviour will be confirmed in the near future. Therefore, the substitution of PHT by this alternative when used as HTF in non-pressurised liquid phase systems could result in regrettable substitution.

The case of alternative 6 is similar to the above one, but in this case the main concern is the potential status as CMR substance, because it is currently under assessment. If it is confirmed in the future, the substitution of PHT by this alternative as solvent or process medium could lead to a regrettable substitution.

The result of the analysis of alternative 8 indicates that it cannot be considered an adequate substitute for PHT as a solvent or process medium due to technical reasons (high unsaturated degree), and because the registered volumes are not sufficient to fully replace PHT for this function.

Alternative 9 has been assessed as a potential alternative to PHT for the uses as plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent, or process medium, and laboratory chemical. However, as the PBT status of this substance is still under assessment, the substitution of PHT by this alternative could become a regrettable substitution if it is confirmed in the future.

Finally, only alternative 7 shows features that could be compatible for its use as solvent or process medium, mainly as a textile dyestuff carrier. However, the feasibility of the substitution in technical and economic terms could not be assessed due to the lack of information.

In summarising, an alternative to PHT that covers the IU 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.

It should be noted that, in general terms, the responses to the SEA questionnaires (appendix 4) on potential alternatives have been very scarce and poor. Since no specific technical and economic data related to the potential alternatives have been provided by the impacted actors, it is assumed that this assessment of alternatives for the functions of PHT and its conclusions are valid. If impacted actors do not agree with the conclusions, it is strongly recommended that they provide information during the public consultation allowing the Dossier Submitter to revise this analysis and its conclusions.

2.3. Risk Management Options

Various regulatory risk management options have been assessed to identify the options that are most appropriate to PHT. 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 the manufacture, use and placing on the market of PHT 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 23**.

Table 23. Restriction options

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

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

Therefore, RO1 is considered the most appropriate risk management option because it is effective and reduces potential risks to an acceptable level within a reasonable period of time.

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

2.3.1. Definition of the strictly controlled closed systems

RO1 and RO2 include a derogation that shall apply for the use and placing on the market of PHT for industrial sites as a HTF, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

The conditions and requirements that a HTF installation shall comply with to be considered as a strictly controlled closed system are defined below.

General regulatory conditions

The installation shall comply with all of the legislation in force, at the European, national, regional, and local levels, related to the design, construction, and operation of HTF systems, and to the protection of human health and the environment.

Specifically, the main European legislation that should be considered is the Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (Pressure Equipment Directive – PED).

PED is applicable to PHT because for most of the systems the maximum allowable temperature of the HTF installations (325-350°C) exceeds the flashpoint of the substance (170 °C), according to Point 1(a) of Article 13 to PED.

The installations shall be designed and constructed (new installations), adapted (existing installations), and operated according to technical requirements as outlined in the following guidelines, although any other guidelines or standards that ensure the same or higher level of safety than the ones listed below may be utilized:

- DIN 4754-1: Heat transfer installations working with organic HTFs - Part 1: Safety requirements, test.

  This standard applies to heat transfer appliances in which organic HTFs are being heated with atmospheric pressure to reach a temperature above or below their initial boiling point. The document applies to heating appliances only in so far as the pipes of the heater contain the HTFs. The document has the purpose of satisfying protection targets for the production and supply, in particular those specified in the PED.

- NFPA 87: Standard for Fluid Heaters.

  This standard provides safety guidance for fluid heaters and related equipment to minimize fire and explosion hazards that can endanger the fluid heater, the building, or personnel.

These guidelines and standards should be used as a basic requirement when designing, building, and operating new systems. In addition, existing systems must be assessed on a regular basis using the most up-to-date standards.

Technical protection measures (system and process safety)

Technical protection methods must be taken in order to guarantee the closed behaviour of the installation and to avoid improper emissions to the environment. Examples of this kind of measures are compiled in the following non-exhaustive list:

- Existence of general leakage collection systems
- Use of containment devices installed beneath flanges and pumps
- Use of retention systems in pumps and valves to ensure that any leakage of PHT through the seals is safely drained off and collected in a contained space
- PHT level monitoring

The interactions of the closed system with the atmosphere require special care, particularly draining points, sampling devices, joints, valves, and pumps. Containment devices should be installed beneath such system locations to avoid emissions to the environment.

Low-boiling fractions, formed as breakdown products of PHT at high temperatures, must be evacuated from the system. Different procedures (condensation, venting, etc.) can be used to complete this process, and the residuals are disposed of either internally or through an authorized external company.

Also, special containment measures should be taken for processes out of the usual OCs of the system, as shutdown and start-up of the process, or drain, fill, top-up, and disposal operations of degraded PHT.

General protection measures (structural and organisational)

Structural and organisational measures are essential for maintaining the safety of a closed HTF system, such as through proper maintenance and inspection. Examples of this kind of measures are compiled in the following non-exhaustive list:

- Performance of tests to prove the suitability of joints
- Periodical evaluation of the PHT quality (minimum once a year)
- Recurring inspections performed by competent technical bodies (internal or external)
- Control programs for potential leakages
- Training for operators and for maintenance and inspection teams

All operation, maintenance, and inspection operations, as well as all processes carried out outside of normal operating conditions, such as drain, fill, top-up, etc., should have written procedures and instructions in place. This documentation should be integrated into any management system implemented in the company (e.g., the Health, Safety, and Environment Management System - HSE).

2.4. Restriction scenario(s)

This section draws on **Annex E.3** which provides further details on the analysis of the restriction scenarios.

The restriction scenarios are defined by the anticipated behaviour of affected actors (current downstream users of PHT) in response to the ROs. These scenarios constitute the basis for assessing the socio-economic costs and benefits associated with the restriction.

The behavioural options deemed most plausible are:

- Switch to alternative substances, resulting in transfer of market shares between EU actors (to the benefit of companies switching first).
- Business reallocation outside the European Economic Area (EEA)[11], if the companies have customers outside the EU.
- Company would abandon business related to PHT globally.

The behavioural responses are based on information received from stakeholders through the SEA questionnaires (Appendice 4).

Considering the behavioural responses received in relation to the different industrial sectors that are using PHT as HTF in their production process, the proportion is the following:

Table 24. Responses from HTF users related to different industry sectors.

Industrial sector	Switch to alternative substances	Business reallocation outside EEA	Company would abandon business
Chemicals	66.7%	20.0%	13.3%
Fuels and petrochemicals	61.5%	15.4%	23.1%
Plastics	100.0%	0.0%	0.0%
Cement	0.0%	0.0%	100.0%

[11] The EEA includes EU countries and also Iceland, Liechtenstein, and Norway.

Steel	100.0%	0.0%	0.0%
Paints	50.0%	50.0%	0.0%
Total	**64.7%**	**17.6%**	**17.6%**

According to the information detailed in Annex E.3, the assumed behavioural responses for the use of PHT as plasticiser in the production of aircrafts are to switch to an alternative by 100%. Furthermore, this is the assumed behavioural response for the other uses of PHT.

2.5. Economic impacts

Economic impacts are concerned with 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), using a discount rate. 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.

Because of the expected increase in economic impacts from RO1 to RO3, the impact analysis will start with most severe option, which is RO3. The exact procedure and all details on costs and economic impacts considered are described and explained in **Annex E.5**.

The estimated total costs for RO3 are in the range of 13.3 billion €. 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** provides the summary of the costs.

Table 25. Total costs for RO3.

Type of Costs	Plasticiser Use Aviation	Non-Aviation Plasticiser and Other Uses	HTF Use
	in million €		
Substitution & Investment	3	2	10 032.62
Profit Losses	837.2	13.62	2 393.00
Enforcement costs	11	11	11
Subtotals	851.2	26.62	12 436.62
% of Total costs	6.39	0.20	93.41
Total Sum	**13 314.44**		

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, since these applications will be prohibited as of 2025. Most of the costs of the HTF use will be taken out, 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 have been significantly reduced to an amount of about **919 million €**. The cost contribution of HTF uses is now at about 4.5% and the majority of the costs is carried by the Aviation plasticiser use (>90%). The remaining uses carry about 3%. **Table 26** is summarizing the costs for RO2.

Table 26. Total costs for RO2.

Type of Costs	**Plasticiser Use Aviation**	**Non-Aviation Plasticiser and Other Uses**	**HTF Use**
	in million €		
Substitution & Investment	3	2	30
Profit Losses	837.2	13.62	0
Enforcement costs	11	11	11
Subtotals	851.2	26.62	41
% of Total costs	92.64	2.90	4.46
Total Sum	**918.82**		

Regarding RO1, the costs for the HTF use and the "Non-Aviation Plasticiser" and "Other Uses" remain the same as compared to RO2. Because the aviation plasticiser use will receive a derogation for 5 years (2025–2029), the loss in sales of PHT from PHT manufacturers and importers to formulators of sealants and adhesives will be reduced to 15 years. The profit loss by the importers and manufacturers of PHT in the aviation industry accounts for **12.9 million €** (430 tonnes per year x 8 000 € x 15 x 0.25). Same reduction due to a shortened restriction timeline applies for the profits at risk in the aviation industry.

As a profit loss 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 PHT as plasticiser in the aviation sector. PHT was included in the Candidate List in June 2018[12], thus providing more than 10 years of time for reformulation and re-certification (Supplemental Type Certificates).

Table 27 summarises the costs for RO1.

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

Table 27. Total costs for RO1.

Type of Costs	Plasticiser Use Aviation	Non-Aviation Plasticiser and Other Uses	HTF Use
	in million €		
Substitution & Investment	3	2	30
Profit Losses	615	13.62	0
Enforcement costs	11	11	11
Subtotals	629	26.62	41
% of Total costs	90.29	3.82	5.89
Total Sum	**696.62**		

Table 28 compares the costs for the different ROs to the Baseline Scenario. It is not surprising that RO3 shows the highest cost, since it is the most severe RO. The amount of RO3 is 19-times higher than RO1 and 14-times higher than RO2. Substitution and investment costs in RO3 account for >75%. In RO2 and RO1 there is a shift towards profit losses, with share of >90% for both ROs.

Table 28. Comparison of total costs for RO1 – RO3 relating to the Baseline.

Type of Costs	RO1	RO2	RO3
	in million €		
Substitution & Investment	35.00	35.00	10 037.62
Profit Losses	628.62	850.82	3 243.82
Enforcement costs	33.00	33.00	33.00
Total Costs (in million €)	**696.62**	**918.82**	**13 314.44**

2.6. Human health and environmental impacts

This section draws on **Annex E.5**. In 2018 PHT 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.

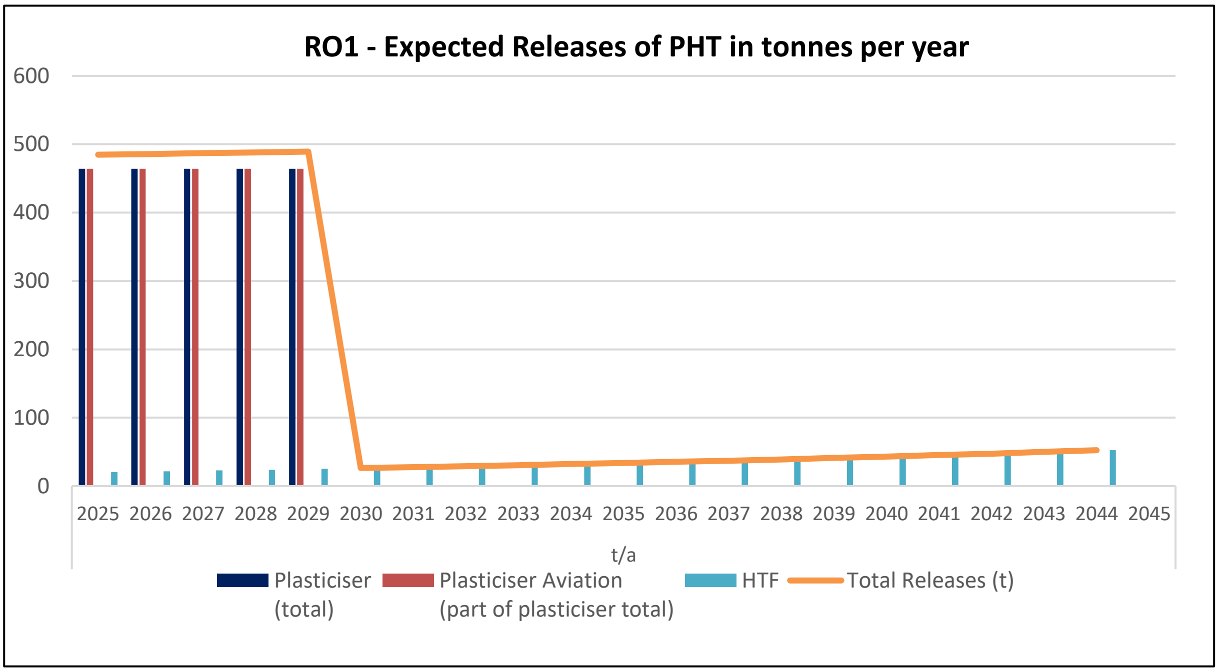
PHT is chemically stable in various environmental compartments with minimal or no abiotic degradation (see **Annex B.4.1**) and is very bioaccumulative, which means that the concentrations in the environment may increase over time (see **Annex B.4.3**). Quantification of risks is currently not possible 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).

As described in the baseline scenario of PHT in Annex D.3, the continued use of PHT was estimated as illustrated in

Figure 3. It should be noted that emissions prior to 2025 were not considered. Furthermore, the model assumes that emissions ceases when the use of PHT is baned for a certain use. A significant share of the emissions occurs at the end-of-life stage. Furthermore, if the use as HTF is banned, it has to be taken into account that due to required emptying and disposal of the currently installed base (approximately 25 000 tonnes in approximately 1 500 plants in the EU), there is a significant potential for additional releases that have not been taken into account in this analysis. Therefore, the reduction in emissions compared to the baseline will in reality be spread over the entire analysis period (2025-2044), which is not shown in the following figures.

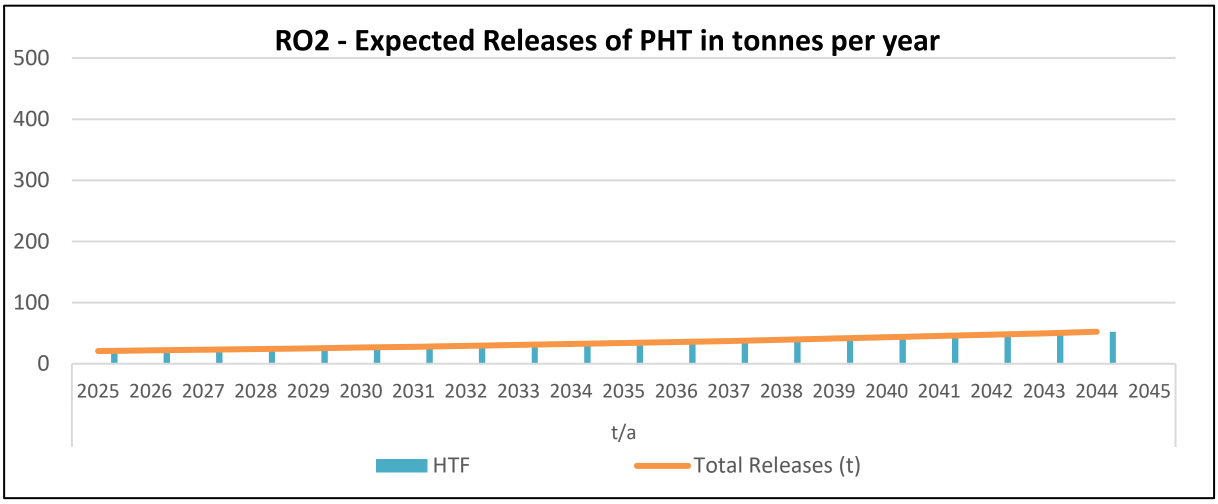
Figure 5 illustrates the trend of expected emissions for RO 1 where a derogation exists for plasticiser uses in the aviation industry (5 years after EiF) and a general derogation for HTF uses, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

Figure 5. Expected releases of PHT for RO1.



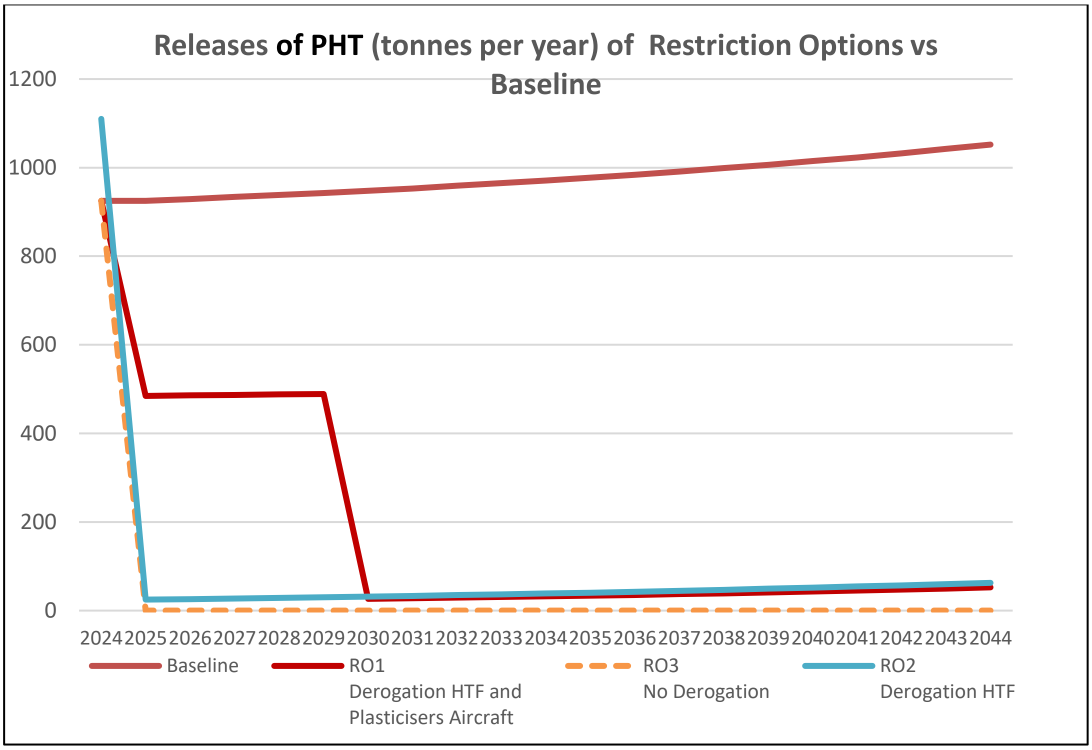
Since the HTF emissions are likely to be an overestimate as mentioned before, the introduction of controlled closed systems with engineered containment measures to minimise environmental emissions was considered with an emission reduction of 75% compared to the baseline scenario. **Figure 6** shows the expected releases for RO2, where the derogation exists only for the use of PHT as HTF. Consequently, emissions will only arise from the use of HTF.

Figure 6. Expected releases of PHT for RO2.



In case of RO3, where no derogations exist, all emissions will cease in 2025. **Figure 7** does exhibit the expected emissions of each ROs in comparison to the baseline scenario.

Figure 7. Expected emissions of each RO in comparison to the baseline scenario.



2.7. Other impacts, practicability and monitorability

2.7.1. Other Impacts

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 PHT, societal impacts may vary significantly. A complete restriction leading to a practical ban of all uses of PHT (RO3) would have a significant impact down the supply chain, particularly related to potential job losses in many industries that rely on PHT as an HTF. In contrast, RO1 would allow the continued use of PHT 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 PHT would be **2 074**. The Dossier Submitter assumes, that for the PHT use as plasticiser in the **aviation industry** due to its complex value chain, approximately **1 500 jobs could be lost** for a total PHT ban in this industry. Putting the lost revenues of the "**non-aviation plasticiser and other uses**" into perspective with the aviation plasticiser use, the percentage is approximately 1.6%. This would result in approximately **24 lost jobs**. For RO1 it is assume, that 50% of the formulators in the aviation plasticiser industry will be able to reformulate until the restrictions enter into force, so that the lost jobs will be reduced to half, which means 750 lost jobs would occur.

According to the SEA guidance (ECHA, 2008), the total societal value of a job loss is "around 2.7 times the annual pre-displacement wages". Since the number of jobs at risk in the various Member States is not known, the average annual gross salary in the EU is reported at € 24 700[13] 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**. 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.

13 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).

Table 29. Number of jobs at risk and their value in million €.

Sector	RO1		RO2		RO3	
	Lost Jobs	Societal Value million €	Lost Jobs	Societal Value million €	Lost Jobs	Societal Value million €
HTF	0	0	0	0	2 074	2 800
Plasticiser Aviation	750	760	1 500	2 025	1 500	2 025
Plasticiser non-Aviation and Other Uses	24	32.4	24	32.4	24	32.4
Total per RO	**774**	**792.4**	**1 524**	**2 057.4**	**3 598**	**4 857.4**

Related to **wider economic impacts** the proposed restriction (RO1) is not expected to affect competition between EU and non-EU actors placing products on the market in the EU significantly, due to the derogation for the use of PHT in HTF applications and the time-limited derogation for plasticiser uses in the aviation industry. It is expected that after 5 years of derogation, the aviation plasticiser industry will have successfully substituted PHT in this application. In contrast, implementation of RO3 would create distortion and unfair competition, since many products (e.g., PET) could be produced outside the EU using the more competitive heat transfer systems based on the use of PHT.

Moreover, in case of a complete PHT ban, some chemicals could not be produced in the EU anymore, which would play against the objective of a sustainable and self-sufficient EU chemical industry. In addition, PHT is used in certain key renewable energy technologies, therefore any ban would undermine the EU Green Deal activities related to clean energy production to address climate change. Due to the lack of information, those potential economic impacts have not been quantified.

The **distributional impacts** are not societal costs as such, as a negative impact on one actor can be counterbalanced by an equal but positive impact on another actor. However, distributional impacts may still be important, in particular, if "losing" actors are part of a vulnerable group. Information received in the stakeholder consultations indicates that the main sectors adversely affected by a restriction on PHT are the general manufacture of chemicals (including PET production), energy generation (via ORC systems), and the aviation industry. These cover large sectors with a strong presence in the EU, as well as SMEs. Under a full ban of PHT for all uses (RO3), the potential higher resilience of larger companies to adapt to changes compared to smaller businesses would not play a role; since it is not expected that feasible alternatives to PHT in its use as HTF (that would not lead to regrettable substitution in the future) will be available to downstream users in the short term, all industries (large or small) would be expected to be impacted in a similar way. Distribution of profits to industries that would transition early to different substances in the HTF sector does not play a role in the evaluation and therefore incentives for a proactive transitioning away from an SVHC cannot be considered.

2.7.2. Practicality and monitorability

Implementability is related to the degree in which the actors involved are capable to comply with the restriction proposal. On the assumption that no feasible alternatives for PHT are available for the use as HTF, without generating a situation of regrettable substitution, it is evident that RO3, leading to a full ban of PHT, would be complex to implement and manage for many users of PHT. Companies would be forced to change their production processes to either using other products that would likely result in similar regulatory action in the future, or a complete redesign of the heat transfer systems, which would lead to significant costs; relocation or closure of activity would be the other alternative options. In contrast, RO1 would allow continued use of PHT in the main application, provided that the relevant actors would adapt their installations to specific technical requirements. RO1 would also allow for sufficient time for the aviation industry to switch to alternative products in the use of PHT as a plasticiser in this sector. To be implementable within a reasonable timeframe, a restriction should be designed in such a way that a supervision mechanism exists and is practically implementable for enforcement authorities. The proposed restriction (RO1) is easily understandable for effected parties and therefore implementable and manageable. Furthermore, it is implementable as companies can test for concentration limits in concerned articles or make it a condition of sourcing contracts. In addition, the proposed restriction provides sufficient time to the impacted supply chains to transition.

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 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 PHT 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 PHT in this sector and implementation of inspections by the relevant Member States. The second action would be related to the import of PHT 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 PHT.

The SCIP Database could be useful to identify if new articles that do contain PHT have been notified after the restriction. In addition, it is expected that the verifications will be carried out via testing. A concentration of 0.1% w/w is the limit that is applicable to PHT in articles, as this is the limit that triggers notification requirement under article 7(2) of REACH, and the information requirement under REACH Article 33. The concentration limit of 0.1% w/w would therefore provide an option to establish enforceability criteria. Analytical methods for quantitative determination of PHT are available.[14]

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.

[14] 5021.new (cdc.gov)

2.8. Proportionality (including comparison of options)

As highlighted in **Annex E.5**, the risks and thereby the benefits of PBT and vPvB substances cannot be quantified, and in the case of vPvBs, 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 "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 PHT is higher for the more stringent ROs (RO2 and RO3) and the largest cost component by far is the potentially 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 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 produce without access to PHT as a HTF (e.g., PET). Based on the lack of feasible alternatives, it is difficult to evaluate substitution costs and R&D activities in detail.

Table 30 provides a comparison of environmental emissions versus expected costs, jobs at risk and the social impacts for the different ROs evaluated.

Table 30. Total economic impacts vs Emission values and Emission Reduction Capacity.

	Total Cost (in million €)	**Social Impacts** (in million €)	**Total Economic Impact** (in million €)	**Total Emissions** (tonnes)	**Emissions Reduction Capacity** (%)
Baseline				19 584	0
RO1	696.62	792.40	1 489.02	3 006	85
RO2	918.82	2 057.40	2 976.22	686	96.5
RO3	13 314.44	4 857.40	18 171.84	0	100

To determine whether the estimated costs of kg/PBT substance emissions reduced are likely acceptable for EU society, SEAC recommends using a benchmark to compare the cost against. There are currently no agreed benchmarks for PBT and vPvB substances, but a comparison could be drawn based on previous studies and estimated costs of regulations implemented in the past, e.g. Oosterhuis and Brouwer (IVM, 2015). The conclusion drawn in the paper is that costs below 1 000 € per kg reduced emission is generally deemed acceptable.

Table 31 shows the 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 31. Cost Effectiveness of all ROs.

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

The C/E falls within the benchmark zone for being acceptable.

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.

Table 32 compaares C/E values of other recent restrictions. RO1 is with a ratio of 90 €/kg at the lower level compared to other substances.

Table 32. C/E ratios of recent (including ongoing) REACH Restrictions.

REACH Restriction	**€/kg**
Lead Gunshot in Wetlands	9
PAHs in Clay Targets	130
Lead in PVC	308
D4/D5 in Wash-off Cosmetics	415
DecaBDE	464
Phenylmercury Compounds	649
PFOA Substances	734

3. Assumptions, uncertainties and sensitivities

All key variables, input parameters and assumptions used for the exposure assessment and the SEA are set out and described in detail in **Annex F.1**. Volumes and Uses (**Annex A**) as well as number of sites using PHT are considered to be accurate, since consistent data was provided from industry during the stakeholder consultations. Assumptions on Exposure Assessment (**Annex B.9.**) have been referenced in the respective tables.

Exposure values have been derived by applying defaults according to ECHA Guidance R.16 (ECHA, 2016). Concerning the Baseline scenario (**Annex D**), the Dossier Submitter assumes an average growth trend for the HTF use of 5% annually and a stagnant trend for the plasticiser applications from 2025-2035. Beyond 2035, the uncertainty in any projection increases and makes it difficult to identify the driving factors for the plasticiser use. It is expected that the decrease in volume as of 2036 will be 5% per annum. The Impact Assessment (**Annex E**) of this dossier is surrounded by various assumptions and uncertainties. The behavioural responses are based on comments made by industry via the stakeholder consultations. The same applies for the Economic Impacts as outlined in **Annexes E.4.** and **E.6**.

The lack of information on fractions released to air, water, and soil from the various processes during the lifecycle of PHT creates significant uncertainties in the exposure assessment. The PECs have been estimated using ECHA Guidance. The approach used is generic and uncertainties arise in modelled outputs from a number of sources. Moreover, it is to be noticed that the number of articles containing PHT imported into the EU and exported from the EU is not known. In addition, it is an uncertainty if a restriction of imported articles with PHT 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%. This is an uncertainty since it is not clear, how many articles with concentration levels <0.1% of PHT are being imported and if those imported articles would pose a risk of environmental exposure.

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. 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.

As highlighted in **Annex F.2.**, there are uncertainties associated with some of the input factors and consequently results of the analysis. However, since the use volumes have been identified as reliable and the exposure assessment was conducted according to ECHA Guidance, the dossier is considered to be robust. 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. **Table 33** 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 33. Sensitivity of key uncertainties.

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	↑	↑

4. Conclusion

To identify the most appropriate measure to address the risks of the PHT use, an analysis of risk management options (RMOA) was conducted, including regulatory measures under REACH, other existing EU legislation and other possible Union-wide RMOs, and it was concluded that a Restriction under REACH is the most appropriate risk management option.

A number of ROs were assessed on the basis of effectiveness, practicality, and proportionality. **The conclusion of the Dossier Submitter's assessment is to propose Restriction Option 1.**

The proposed restriction is targeted to the exposure situations that are of most concern, e.g., the use of PHT as a plasticiser and the service life of articles containing PHT. The proposed restriction is effective and reduces potential risks to an acceptable level within a reasonable period of time. It is assumed to impose low costs to reduce a potential risk and that the measures are proportionate to the risk. The restriction is practical because it is implementable, enforceable, and manageable, as the proposed restriction is easy to understand and communicate down the supply chain. Testing and sampling methods exist for enforcement activities.

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