Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background document

to the Opinion on the Annex XV dossier proposing restrictions on 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus") [covering any of its individual anti- and syn-isomers or any combination thereof]

ECHA/RAC/RES-O-0000007082-81-01/F

ECHA/SEAC/RES-O-0000007126-77-01/F

IUPAC NAMES	EC NUMBER	CAS NUMBER
1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.$1^{6,9}$.$0^{2,13}$.$0^{5,10}$]octadeca-7,15-diene	236-948-9	13560-89-9
(1S,2S,5S,6S,9R,10R,13R,14R)-1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.$1^{6,9}$.$0^{2,13}$.$0^{5,10}$]octadeca-7,15-diene		135821-74-8
(1S,2S,5R,6R,9S,10S,13R,14R)-1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.$1^{6,9}$.$0^{2,13}$.$0^{5,10}$]octadeca-7,15-diene		135821-03-3

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LIST OF ACRONYMS AND ABBREVIATIONS

ACEA	European Automobile Manufacturers' Association
ASR	Auto Shredder Residue
BCF	Bioconcentration Factor
C	Coatings
B&CW	Building and construction waste
CAGR	Compound Annual Growth Rate
CAS no	Chemical Abstract Service registry number
CfE	Call for Evidence
Cl	Chlorine
CLEPA	European Association of Automotive Suppliers
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
CoRAP	Community Rolling Action Plan
CSR	Chemical Safety Report
DecaBDE	Decabromodiphenyl ether
DP	Dechlorane Plus
EA	Environment Agency
EAV	Equivalent Annual Value
EBP	Ethane-1,2-bis (pentabromophenyl)
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
EEE	Electrical and Electronic Equipment
EiF	Entry into Force
ELVs	End-of-life Vehicles
EP	Extreme Pressure
EPA	Environmental Protection Agency

ERC	Environmental Release Categories
ESD	Emission Scenario Documents
EU	European Union
EUSES	European Union System for the Evaluation of Substances
FEICA	Association of the European Adhesive and Sealant Industry
FR	Flame retardant
JAPIA	Japan Auto Parts Industries Association
KEMI	The Swedish Chemicals Agency
LCCP	Long Chain Chlorinated Paraffins
LoQ	Limit of Quantification
MCCP	Medium Chain Chlorinated Paraffins
MSC	Member State Committee
NACE	European Classification of Economic Activities
NEA	Norwegian Environment Agency
OECD	Organisation for Economic Co-operation and Development
OxyChem	Occidental Chemical Corporation
P	Plastics
PBT	Persistent Bioaccumulative and Toxic
PCB	Printed circuit board
PECs	Predicted Environmental Concentrations
POP	Persistent Organic Pollutants
POPRC	Persistent Organic Pollutants Review Committee
PROC	Process Categories
PST	Post Shredder Treatment
RAC	Risk Assessment Committee
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMO	Risk Management Option
RO	Restriction Option
SDA	Small domestic appliances

SEAC	Committee for Socio-Economic Analysis
SEv	Substance Evaluation
SME	Small and Medium Enterprises
SPERCs	Specific Environmental Release Categories
STC	Supplemental Type Certificate
STP	Sewage Treatment Plant
SVHC	Substance of Very High Concern
TCP	Tricresyl Phosphate
UNEP	United Nations Environment Programme
vB	very Bioaccumulative
vPvB	very Persistent and very Bioaccumulative
WEEE	Wastes from electrical and electronic equipment
WVTA	Whole Vehicle Type Approval
WWTP	Wastewater Treatment Plant

About this report

The preparation of this restriction proposal on Dechlorane Plus [covering any of its individual anti- and syn-isomers or any combination thereof] was initiated on the basis of Article 69(4) of the REACH Regulation.

The proposal has been prepared by using version two 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 Norwegian Environment Agency (hereafter referred to as the Dossier Submitter) would like to thank the many stakeholders that made contributions to the Call for Evidence (CfE) and the stakeholder consultation, which was performed and summarised by our consultants Economics for the Environment Consultancy (eftec), as well as contribution submitted in the public consultation.

This report has been reviewed for confidential information. Any such information has been included in a separate Annex (Confidential Annex H) that will be made available for ECHA's committees (restricted access) during the Opinion development.

RAC and SEAC box

RAC and SEAC noted several inconsistencies between different sections and between the Background Document and its annexes. These inconsistencies concern the conditions of the restriction proposal concerning derogations of spare parts.

The justification for this consideration is explained in the RAC and SEAC opinion.

Summary

Dechlorane Plus (DP)[1] is a man-made substance mainly used as a flame retardant. It was identified by ECHA as a Substance of Very High Concern (SVHC) in 2018 because of its very persistent and very bioaccumulating properties. REACH registration data indicates that the volume of DP placed on the EU market is in the range of 10 – 100 tonnes/year (downgraded from 100 – 1 000 tonnes/year by the REACH registrant in October 2020[2]). However, based on information from the stakeholder consultation carried out from April to June 2020, DP is estimated to currently be used in volumes of between 90 and 230 tonnes/year in the EU, with a central estimate of 160 tonnes/year. Motor vehicles are thought to be the main user of DP, with an estimated consumption ranging from 81 to 161 tonnes in 2020.

DP is imported to EU in articles. There is no manufacture of DP within EU. According to information from the previously active REACH registration, DP is used as a flame retardant in adhesives/sealants and polymers. Furthermore, our survey indicates that DP is used as an extreme pressure additive in greases. In these applications DP is used in motor vehicles, aerospace and defence applications, marine, garden and forestry machinery, electrical and electronic equipment, including consumer electronics and medical devices. Another confirmed minor use is in fireworks.

Even though there are no natural sources to DP, it is detected in humans, wildlife and environmental samples all around the world, including the Arctic and Antarctic. The main releases of DP to the environment are attributable to the waste stages. We can be exposed to DP through drinking water, food and air. The unborn child may receive DP via the umbilical cord and via breast milk after it is born.

The Persistent Organic Pollutants Review Committee (POPRC) assessed the intrinsic properties of DP at their sixteenth meeting in January 2021 and then decided to defer its decision on the draft risk profile for DP to its seventeenth meeting. However, POPRC-16 noted that the information on persistence, bioaccumulation and the potential for long-range environmental transport was conclusive but the Committee was unable to agree that the information on adverse effects was sufficient to reach a conclusion on the risk profile for DP (POPRC, 2021a). The present proposal is coordinated with activities on DP under the Stockholm Convention. An EU restriction will be an important step to reduce the risks from DP within the EU internal market. It will also assist the global regulation in the POPs Convention by analysing the impact in the EU of an equivalent global regulation.

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[1] The substance 1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo- [12.2.1.1^{6,9}.0^{2,13}.0^{5,10}] octadeca-7,15-diene has two isomers, named anti- and syn-. This dossier covers the individual anti- and syn- isomers (monoconstituent substances) and all possible combinations of the syn- and anti- isomers. "Dechlorane Plus" (often abbreviated as DP) is the registered trade name used throughout this Annex XV report and the Annexes for convenience.

[2] The REACH registrant ceased their activities related to DP in May 2021. From the available information under REACH it is not clear whether manufacture of DP outside the EU is still taking place. Imports of DP in articles into the EU may therefore continue to take place.

DP is neither safe nor sustainable by design. It is necessary to minimise potential adverse effects from DP on human health and the environment. If no regulations are put on DP, the environmental levels - and the levels in humans and biota - will increase and become a contamination problem for future generations. Since DP persists in the environment for a very long time and accumulates in humans and wildlife, effects of current emissions may be observed or only become apparent in future generations. Avoiding effects may then be difficult due to the irreversibility of the exposure.

The demonstrated very persistent and very bioaccumulating properties of DP calls for urgent action to reduce the potential risk from continued emissions. Based on the available information on alternatives, costs and benefits for society as a whole, the Dossier Submitter considers it most appropriate to propose a ban on the use of DP with time limited derogations for the aerospace and defence sector and medical imaging devices and radiotherapy devices/installations. This includes a review clause to assess if limited use areas will need further derogations after the end of the proposed derogation periods. In addition to this the Dossier Submitter proposes derogations for use in spare parts for the following use areas; aerospace and defence sector, medical imaging devices and radiotherapy devices/installations, motor vehicles and marine, garden and forestry machinery applications. This provides a significant reduction in DP emissions and hereby reduces potential adverse effects on human health and the environment.

RAC and SEAC box *RAC and SEAC proposed changes to the conditions of the restriction for derogations of spare parts.* *The details of these changes are reported in the RAC and SEAC opinion, together with the justification for these changes.*

Based on analysis of the effectiveness, practicality and monitorability of the Risk Management Options, the following restriction option is proposed:

Proposed restriction:

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
XX. 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [$12.2.1.1^{6,9}.0^{2,13}.0^{5,10}$] octadeca-7,15-diene ("Dechlorane Plus"™) [covering any of its individual anti- and syn-isomers or any combination thereof] CAS No 13560-89-9; 135821-74-8; 135821-03-3	1. Shall not be manufactured, or placed on the market as a substance on its own from [18 months after entry into force]. 2. Shall not, from [18 months after entry into force], be used in the manufacture of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article,

EC No 236-948-9; -; -	in a concentration equal to or above 0.1% by weight. 3. Paragraph 2 shall not apply to: • articles placed on the market for the first time before [18 months after date of entry into force] 4. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of: • aerospace and defence applications* before [date of entry into force + 5 years]. • spare parts for aerospace and defence applications manufactured before [date of entry into force + 5 years]. 5. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of: • medical imaging applications manufactured before [date of entry into force + 7 years] • Radiotherapy devices/installations manufactured before [date of entry into force + 10 years] • spare parts for medical imaging applications manufactured before [date of entry into force + 7 years] • spare parts for radiotherapy applications manufactured before [date of entry into force + 10 years] 6. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of spare parts for: • motor vehicles** placed on the market for the first time before [18 months after date of entry into force]

	• marine, garden and forestry machinery applications placed on the market for the first time before [18 months after date of entry into force] 7. The Commission shall review the exemptions in paragraph 4, 5 and 6 and, if appropriate, modify them accordingly.

*Aerospace and defence applications: All applications of DP within aerospace and defence.

**Motor vehicles: Includes all applications of DP within land-based vehicles. Examples are cars, motorcycles, agriculture vehicles and industrial trucks.

Identified hazard and risk

The ECHA Member State Committee identified DP as a Substance of Very High Concern due to its very persistent and very bioaccumulating properties in 2018. According to REACH Annex I para 6.5, the risk to the environment cannot be adequately controlled for PBT/vPvB substances. No safe concentration, thus no threshold, can be determined for PBT/vPvB substances. DP is transported over long distances and has frequently been detected in the Arctic. Due to these properties, DP may cause severe and irreversible adverse effects on the environment and on human health if the releases are not minimised.

DP is not manufactured in the EU but is widely used in the EU at around 90-230 tonnes per year. Baseline estimates shows that, in the absence of a restriction, average future use of DP may lie in the range 109 – 278 tonnes per year between 2023 and 2042. The average baseline emissions between 2023 and 2042 are estimated to be between 9.1 and 28.8 tonnes per year. Around 76%-80% of the releases of DP to the environment comes from waste dismantling and recycling and approximately 82% of the total releases of DP goes to air.

Justification that action is required on a Union-wide basis

DP is used as a flame retardant and/or extreme pressure additive in motor vehicles, aircrafts, electrical and electronic equipment. These products are traded between all EU countries. A national restriction would hinder an even playing field within EU and is not expected to function in practice. Furthermore, since DP is a long-range transported, very persistent and very bioaccumulating substance, a national restriction is not expected to efficiently reduce the environmental levels of the substance in one country. An EU-wide restriction is therefore deemed to be the most appropriate measure to reduce the risks that DP represents to human health and the environment. Risk management measures on a Union-wide basis may also be a first step towards a global regulation of DP.

An EU restriction will assist the global regulation in the POPs Convention by analysing the impact in the EU of an equivalent global regulation and be in line with the Commission's common understanding paper on REACH and POPs (EC, 2014) that states "*it would be good practice for the Member States or the Commission to initiate a restriction procedure under REACH following a nomination for listing of a substance under the POP Convention.*" Furthermore, the Commission foresees that even if the result of the assessment under the

POP Convention is that the substance does not fulfil the criteria for a POP, the substance can still pose an unacceptable risk in the Union due to other properties (EC, 2014). DP is a very persistent and very bioaccumulating substance. Hence there are no safe levels of DP in the environment and the emissions should be reduced as much as possible.

Effectiveness

According to REACH Annex I para 6.5, the risk to the environment cannot be adequately controlled for PBT/vPvB substances. There is no safe concentration for these substances, thus a threshold cannot be determined for PBT/vPvB substances (RAC/SEAC, 2015). For such substances a REACH restriction would be based upon minimising the emissions of the substances to humans and the environment.

After entry into force + 18 months, DP cannot be placed on the EU market if a derogation has not been granted. The proposed restriction will therefore remove new emissions from the most important use areas and related exposures of DP both to humans and the environment in the EU. Reduced emissions are used as a proxy for risk reduction.

An alternative to the restriction would be to list the substance in Annex XIV to REACH. However, since DP is also imported in articles and mainly emitted to the EU environment during the waste stage, the effects of such a measure would be marginal. A REACH restriction is deemed to be the most effective risk reducing measure for DP. The proposed regulation will effectively restrict the import of substances, mixtures and articles containing DP. The proposed restriction is expected to reduce around 89% of the emissions of DP to the EU environment over 20 years.

Alternatives to Dechlorane Plus

Based on information from literature, it was concluded that there are three potentially suitable alternatives for DP when used as a flame retardant – aluminium hydroxide, ammonium polyphosphate and EBP. Two alternatives were also found to be potentially suitable for DP when used as an extreme pressure additive – long chain chlorinated paraffins (LCCPs) and tricresyl phosphate (TCP).

The limited number of stakeholders that provided information on availability of alternatives, in the Call for Evidence (CfE) or the stakeholder consultation, indicated that there were no suitable alternatives presently available. Submissions from the public consultation indicated that inorganic flame retardants are available and to some extent already in use in wire harnesses and tape in the EU. However, none of the stakeholders provided the specific technical criteria that could not be fulfilled by other flame retardants or lubricants. In the absence of such information, it is not possible to reach a robust conclusion on the availability of suitable alternatives for all applications.

Costs of the proposed restriction

The cost of the proposed restriction is potentially high. The proposed restriction is similar to RO2 with a few added derogations. The cost of RO2 is estimated at <€180 million per year. However, this includes highly uncertain estimates of potentially lost profits which are by far the largest cost component.

Proportionality

In line with SEAC's recommendation in (ECHA, 2014), proportionality of the restriction options are assessed through a cost-effectiveness analysis.

The central estimate for the cost-effectiveness of the proposed restriction is <€10 000 kg per DP emissions reduced. This falls within the "grey zone" of benchmarks set out in IVM (2015), which means that the restriction can be deemed either proportionate or disproportionate.

Due to the many similarities of DP and decaBDE, e.g., in terms of uses and sectors involved, the previous restriction on decaBDE may serve as a useful comparator[3]. The cost per kg reduced emissions of decaBDE was estimated as to 484 €/kg (508 €/kg when uplifted to 2020). In contrast to cost estimates for DP, the total costs estimated for the decaBDE restriction only include the material cost of using a different chemical (i.e., R&D, investments, profit losses, job losses etc., were not included). When looking at the costs of chemicals alone, a restriction on DP would result in cost savings . Although there is greater uncertainty about the availability of alternatives to DP, the cost-effectiveness of restricting DP could be in the same order of magnitude as that of decaBDE if all cost elements were considered for both substances.

Practicability

The practicability of this proposal could not be extensively assessed due to limited stakeholder information on alternatives and time needed for substitution. However, our literature study identifies alternatives for the different use areas of DP.

The proposed restriction is deemed to be enforceable. Enforcement activities should cover the manufacture, import of DP as such, in mixtures and in articles, and the use of DP in production of articles in the EU. For articles placed on the market (i.e. except for derogated articles), enforcement authorities could check documentation from the supply chain confirming that the articles do not contain DP. In addition, it is envisaged that they will verify if the articles contain DP by testing. Currently, 0.1% w/w is the limit that triggers the notification requirement under article 7(2)27 of REACH and the information requirement under article 33 of REACH.

The typical Limit of Quantification (LOQ) for DP is significantly lower than the proposed 0.1% w/w concentration limit in the restriction entry. This implies that the available analytical methods can measure concentrations lower than the restriction entry limit. In conclusion, the available techniques are sensitive enough to produce reliable analytical results for all relevant matrices to enable compliance monitoring and enforcement.

Uncertainties and sensitivities

The most important drivers for the uncertainties connected to the assessments in the current proposal are associated with the sparse information on:

- Use volumes, both site-specific (local) and EU-wide;

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[3] To note that the REACH restriction of DecaBDE is removed from Annex XVII of REACH and is listed to Annex I of the POPs Regulation.

- Fractions on DP released to air, water, and soil; and
- Existence of technical and economically feasible alternatives to DP.

The uncertainties in relation to the use volumes are accounted for by the large tonnage band chosen for this analysis. Other uncertainties can only be reduced if more information is received by stakeholders .

For the input variables and assumptions that could be tested analytically, it was shown that variations in these were unlikely to change the overall conclusions.

Report

1. The problem identified

1.1. Manufacture and use

This section draws on Annex A which provides further details on the manufacture, import, export and use of Dechlorane Plus (DP)[4].

1.1.1. **Manufacture**

Volume data on the manufacture, import and use of DP was gathered from REACH registration data, existing literature, a Call for Evidence (CfE) as well as a targeted stakeholder consultation and the public consultation. Information in literature is sparse, with only a few underlying sources frequently being quoted in most studies, articles and regulatory documents. Some of the data quoted/used in newer reports is old and is unlikely to be representative/accurate of the situation in 2020. Information gathered from stakeholders was therefore deemed more reliable and reflective of the current situation and was used as the primary source of information on manufacture, import and use for the exposure assessment and the socio-economic assessment.

The DP market in the EU is deemed mature and relatively stable (ECHA, 2017b, ECHA, 2019b). In the preparation phase of this restriction proposal, there was one active registration of DP: a company based in the Netherlands called *ADAMA Agriculture BV (Adama)*. They first registered as a supplier in 2017, and updated their registration dossier in 2018, 2019 and 2020, before notifying a "ceased manufacture" to ECHA on 31 May 2021 (ECHA, 2020b). *ADAMA* – the 'only representative' for the Chinese company *Jiangsu Anpon Electrochemical Company Ltd*, which they recently acquired – was previously the only supplier of DP in the EU (ADAMA, 2019).

The Dossier Submitter has assumed that the total volume of DP placed on the market in the EU is manufactured in China and imported into the EU. *Velsicol*, a global company manufacturing and distributing specialty and commodity chemicals, was the sole EU importer according to information from stakeholders in 2020. The UK Environment Agency (EA) reported that DP was imported into the EU as the substance itself with one active REACH Registrant supplying quantities of 10 - 100 tonnes/year (EA, 2018). It was noted by the UK EA that "a small number of non-EU companies also offer DP for sale, so there could be a handful of other EU importers of <100 tonnes/year". Publicly available 2020 REACH registration data accessed in April 2020 when the CfE and stakeholder consultation for the present proposal were launched indicated that the volume placed on the EU market is in the range of 100 – 1 000 tonnes/year. A more precise import volume estimate of 300 tonnes/year

[4] The academic literature usually refers to this substance by a registered trade name "Dechlorane Plus" (often abbreviated as DP, but sometimes DDC-CO), and this is the name used throughout this Annex XV report and the Annexes for convenience.

is reported in comments received during the public consultation on ECHA's draft 9th recommendation to include DP in Annex XIV of the REACH regulation (ECHA, 2019a).

The Dossier Submitter notes that there are only two REACH registrations for DP and both of them are part of a joint dossier. From the submitted information it is clear that imports of bulk DP have taken place since at least 2010 at 100 - 1000 tonnes/year. One registrant ceased their activities relating to DP in December 2017 and the other (ADAMA) downgraded the tonnage band to 10 – 100 tonnes/year in October 2020 , before ceasing their activities in May 2021 (ECHA, 2020a).

From the available information under REACH it is not clear whether manufacture of DP outside the EU is still taking place. Imports of DP in articles into the EU may therefore continue to take place. This is supported by the comments and derogation requests received from stakeholders in the public consultation.

DP is not registered for use as an intermediate in the EU (ECHA, 2017b). The substance is used by industrial sites and professional users (widely spread across the EU) and is also contained in articles used by end-users (EC, 2019, ECHA, 2019b, ECHA, 2020a).

The stakeholder consultations, carried out in preparation for this restriction proposal, confirmed that DP is not manufactured in the EU. In line with the import volume reported in comments received in response to ECHA’s draft 9th recommendation, Dutch authorities reported in an open commenting round to the Stockholm Convention on POPs that the highest volume imported to the EU was 300-400 tonnes/year, with imports of less than 100 tonnes in 2019 (POPRC, 2021b). Information provided by downstream user sector groups suggests imports between 200 and 260 tonnes/year.

Based on both confidential and non-confidential data provided by stakeholders, between 90 and 230 tonnes/year of DP are estimated to be imported into the EU. This volume estimate is used to derive emissions and assess the impacts of a potential restriction.

1.1.2. **Use**

New information was received from stakeholders in the public consultation. All non-confidential comments including responses from the Dossier Submitter, RAC and SEAC are available on the ECHA website[5].

A key change is that the use categories have been further refined, after receiving more detailed information on applications of DP. The refined use categories are as follows:

- **Aerospace and defence applications:** All applications of DP within aerospace and defence.
- **Motor vehicles:** Includes all applications of DP within land-based vehicles. Examples are cars, motorcycles, agriculture vehicles and industrial trucks.

[5] https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e184a168c4

- **Other applications:** All other applications. Confirmed uses includes electronics, marine applications, medical devices and various machinery (e.g. used in gardening, forestry and other industry). This category also includes imported articles.

Limited quantitative information was received, so it has not been possible to carry out a complete update of the analysis.

Between 70%-90% of the DP is used in motor vehicles, corresponding to 81- 161 tonnes per year. Communication with stakeholders also indicate that DP is used in electronics, aerospace and defence applications, medical devices, marine applications and in various machinery (gardening, forestry and other industrial). According to ECHA (2020a), it may also be used in fabrics, textiles and apparels, and plastic articles, but this has not been confirmed by consulted stakeholders. Explosives in fireworks is a further, yet minor, use of DP (ECHA, 2020a. In the public consultation on the Draft 9th recommendation for inclusion of substance in Annex XIV of REACH, the use of DP for the development of fireworks was confirmed by one stakeholder, who reported usage of less than 100 kg/year (ECHA, 2019a). During the stakeholder consultation conducted in support of the development of this restriction dossier, one stakeholder reported that DP in explosive is being phased out in the EU, with an expected annual decline in use of DP of more than 10%.

Volume data has only been provided for motor vehicles and aerospace and defence applications.

A significant share (between 8% and 28%) of the total volume has therefore been grouped under "other uses". Table 1 shows the estimated use volumes (updated based on information from the stakeholder consultation), which are used as the basis for the exposure assessment and the socio-economic assessment.

Table 1. Volumes of Dechlorane Plus used in the EU (by sector)

Sectors	**Low-volume scenario**		**High-volume scenario**	
	Share of total	**EU volume (t/y)**	**Share of total**	**EU volume (t/y)**
Automotive	90%	81	70%	161
Aviation	2%	2	2%	5
Other, including computer, electronics and imported articles etc.	8%	7	28%	64
All	**100%**	**90**	**100%**	**230**

Note to Table 1: The low- and high-volume scenarios are based on differing information from various sources, which is why market shares as well as tonnages used by different sectors vary between the two scenarios. See Annex A for more details.

Applications of DP include its use in formulations, e.g. adhesives, sealants and greases, and the production of plastic products. Submissions from the six-month public consultation (#3527; #3536) indicate that DP might have another technical function than flame retardancy, such as improving the Critical Comparative Tracking Index of the materials. It is however unclear whether this is a separate or additional function of DP.

Table 2 provides a break-down of use volumes per application. Based on information provided by several stakeholders, it has been estimated that wire and printed circuit board (PCB) housings and other plastic and rubber parts together account for over 90% of DP used.

Table 2. Volumes of Dechlorane Plus used in the EU (by use application)

Uses		**Share of total**	**Low-volume scenario (t/y)**	**High-volume scenario (t/y)**
Polymers	Wire and PCB housing, other plastics and rubber parts	93%	84	214
Adhesives etc.	Tape, adhesives, sealants	5%	5	12
Greases	Lubricant	2	2	5
All		**100%**	**90**	**230**

Note:

- A more detailed breakdown of volume per application is presented in Table H3 in the Confidential Annex H, Section H.1. Manufacture and use.
- Sums may not add up due to rounding.

Concentrations of DP in polymeric systems, e.g. electrical and electronic systems and wires, where it is present, i.e. where the detected concentration lies above 0%, vary widely from 8% in polybutylene terephthalate (PBT) to 40% in silicon rubber (Canada, 2019, ECHA, 2020a, OxyChem, 2007, UNEP, 2019). As of 2013, OxyChem names the use of DP in, firstly, nylon incorporated in electrical connectors, and, secondly, polyolefins applied in commercial wires and cables as the two primary applications of DP with respect to polymers. Wire coatings and housing as well as plastics and rubber parts, e.g. connectors, have been reported to contain DP in a concentration of between 13% and 20% by stakeholders. The reported concentration of DP in greases is slightly higher at 20% - 25%, while tapes and adhesives are reported to contain DP in a concentration of between 5 % and 30%. Explosives are reported to contain DP at a concentration of 0.1%. For finished articles, a concentration of 20% is reported in literature. Whether this refers to the mass or weight share of DP is unclear (EC, 2019).

1.1.3. **Recycling**

A REACH restriction on use by default also applies to recycled material. As a result, a consideration of how to treat recycled material in the proposed restriction, while balancing the risks associated with continued use and the benefits of recycling, is necessary (ECHA, 2020b). In view of this, Annex A.2.5 looks at the importance assigned to recycling in the EU, the current extent of recycling of articles potentially containing DP and available techniques for identifying and removing DP-containing materials from the recycling stream. If not exempt, a restriction of DP under REACH would prevent DP from recycled materials to re-enter the market. At the same time, it might however also render the achievement of recycling targets more difficult and increase the use of primary materials, which stands in sharp contrast to various EU policy objectives.

A recent publication from the European Environment Agency (EEA) report that the largest end-use plastic markets account for almost 70% of all plastic used in the EU and are (1) packaging; (2) building and construction; and (3) the automotive industry (EEA, 2021). According to the European Strategy for Plastics in a Circular Economy, the most important plastic waste streams in the EU is by far plastic packaging (59%) followed by the category others (14%) and electrical and electronic equipment (EEE) (9%), agriculture (5%), automotive (5%), construction and demolition (4%) and non-packaging household waste (4%) (EC, 2018). DP-containing plastics are present in the automotive industry and waste electrical and electronic equipment (WEEE) (as well as other smaller groupings), but it is not expected to be a significant share of the total plastic used in the EU.

Plastics, which is an important use of DP, are identified as a key priority under the European Commission's *Circular Economy Action Plan* (EC, 2020). Specific recycling targets are also set by both Directive 2012/19/EU, covering waste electrical and electronic equipment (WEEE), and Directive 2000/53/EC on end-of-life vehicles (ELVs), which are sectors in which plastics containing DP are commonly used.

A consideration of how to treat recycled material containing DP under the restriction is therefore crucial. A restriction of DP under REACH would, depending on the limit values set by this restriction, prevent all or a certain percentage of recycled materials containing DP to re-enter the market. It might also temporarily (until the supply chain is free from DP due to the proposed restriction) render the achievement of recycling targets more difficult and increase the use of primary materials in the EU. On the other hand, if recycled materials containing DP are not adequately regulated it might however also have a negative impact on the EU ambitions for a move towards toxic-free material cycles and for establishing a circular economy. The EU Chemicals Strategy for Sustainability specifies that:

"To move towards toxic-free material cycles and clean recycling and ensure that "Recycled in the EU" becomes a benchmark worldwide, it is necessary to ensure that substances of concern in products and recycled materials are minimised. As a principle, the same limit value for hazardous substances should apply for virgin and recycled material. However, there may be exceptional circumstances where a derogation to this principle may be necessary. This would be under the condition that the use of the recycled material is limited to clearly defined applications where there is no negative impact on consumer health and the environment, and where the use of recycled material compared to virgin material is justified on the basis of a case by case analysis."

Based on the confirmed uses of DP in the EU, the waste streams that will most likely be affected by a restriction of DP under REACH are ELVs and WEEE.

With respect to **ELVs**, Directive 2000/53/EC sets a recycling rate of 85% and a recovery rate of 95% of the vehicle weight, meaning that a maximum of 5% of ELVs should end up in landfill. However, as stated in the *Circular Economy Action Plan* (EC, 2020); *"the Commission* *will also propose to revise the rules on end-of-life vehicles with a view to promoting more circular business models"*. Thus, the current recycling requirements for ELV recycling rates could be altered in the future. In an impact assessment evaluation for the announced proposal for a revision of Directive 2000/53/EC on end-of-life vehicles the provisional conclusions are that the ELV Directive has largely delivered on its initial objectives (notably elimination of hazardous substances from cars, attainment of the recovery and recycling targets, increase in collection points for end-of-life vehicles). An important problem identified was however the large number of "missing vehicles", which are not reported, and represent about 35% of estimated ELVs each year, so approximately 4 million vehicles per year.[6]

Quota achievements must be proven under the Whole Vehicle Type Approval (WVTA) process (ACEA, 2015). In the EU, around 15 million new passenger cars were registered in 2019 (ACEA, 2020). The average EU recycling rate (by vehicle weight) for ELVs is 87.9%, while 93.7% are recovered (Eurostat, 2020a). Recovery thereby includes both recycling of material and its use for energy recovery. The European Automobile Manufacturers' Association (ACEA, 2020) shows that ~ 5.3 million cars were registered as ELVs in the EU in 2017, and 88% of the weight of these vehicle was recycled. ACEA informed in the stakeholder consultation that European cars contains between 2 g and 35 g DP per vehicle, whilst JAPIA submitted information in the public consultation (#3527) indicating that the volume per vehicles manufactured in Japan would be in the range 20 - 60 g DP. However, the Dossier Submitter notes that according to the "state of the art vehicle recycling" presented in (ACEA, 2015), as much as 75% of the vehicle weight constitutes metals and only up to 15% would be relevant materials for plastic recycling. It is therefore highly unlikely that all DP-containing parts will be recycled, which means that the actual DP volumes potentially being recycled from ELV is probably much lower.

With respect to electrical and electronic equipment, the amount of arising waste – commonly referred to as **WEEE**, i.e. waste electrical and electronic equipment, is consistently increasing between 3 and 4% globally every year (Baldé et al., 2017). In the EU, 3.7 million tonnes of WEEE were collected in 2017, of which 39.4% were recycled (Eurostat, 2020a, Eurostat, 2020b). Plastics constitute 20 % of WEEE. Based on the general recycling rate of 39.4%, around 300 000 tonnes of WEEE plastic are thus estimated to have been recycled. The recycling rate has likely increased because of an increased collection target – from 45% in 2016 to 65 % in 2019 – being stipulated in Directive 2012/19/EU (Eurostat, 2020b). The share of recycled WEEE plastics containing DP in the EU/EEA is unknown, as is the amount of DP that is recovered and re-entering the market. In Switzerland, between 30% and 45% of flame retardants contained in WEEE have been found to be recovered (BAFU, 2017).

A restriction on DP would thus likely have implications on the handling of these waste streams. If the use of recycled material containing DP was restricted, common sorting processes of plastics, e.g. by polymer type and colour, would need to be supplemented by a process, in which DP-containing materials are identified and removed.

[6] End-of-life vehicles – revision of EU rules: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12633-Revision-of-EU-legislation-on-end-of-life-vehicles

Recycling processes for ELVs and WEEE consist of four general stages, i.e. (i) pre-treatment and dismantling, (ii) shredding, (iii) post-shredding treatment and (iv) recycling and recovery (Plastics Market Watch, 2016). Shredding is reported to be widely used during ELV treatment and increasingly used in relation to WEEE recycling (Krinke et al., 2006, Maisel et al., 2020, Plastics Market Watch, 2016). According to (ECHA, 2012), 210 installations in the EU carry out such shredding operations. With respect to plastics, mechanical recycling, which accounts for 99% of recycled quantities, currently constitutes the main form of recycling in Europe (Plastics Europe, 2021).

According to ACEA (2015), DP can be removed either during the dismantling stage where DP-containing plastics (e.g. wire harnesses) are separated from the parts not containing DP, or after the shredding of the vehicle where the auto shredder residue (ASR) goes through post-shredder treatment (PST). PST thereby involves a variety of separation technologies, from float-sink tanks to laser and infra-red systems. A more detailed description of commonly applied sorting and separation steps for WEEE and ELV waste could be found in a recent study on substances of concern in post-consumer plastics performed by Ramboll Deutschland on behalf of the Dossier Submitter (Norwegian Environment Agency, 2021).

Despite the existence of various possible techniques for removing DP during the recycling process, general use of those by all actors is not guaranteed. Technical and economic barriers to effectively detecting and removing DP from waste streams during recycling are reported by several stakeholders. The technical and economic feasibility of technologies for removing DP would, however, not be the only factors hindering the recycling of plastics. With respect to ELVs, the low effectiveness of collection and pre-sorting, the missing market for recyclates and the complex multi-material design are further factors hindering recycling (EC, 2018, EuRIC, 2020). Similarly, the recycling of WEEE is not only complicated by the presence of regulated hazardous substances but also the highly complex plastic mixtures that can contain more than 15 different polymer types (Maisel et al., 2020).

While EC (2018) reports that recyclers might have to rely on manual dismantling to remove hazardous substances, like DP, advanced technologies for recycling polymer fractions are deemed to be the most suitable treatment option by some industry stakeholders. The feasibility of such advanced technologies with respect to DP is reported to depend on the allowed concentration limit (ACEA, 2015). It is, however, not known how widely adopted these advanced technologies are within the EU.

A project was commissioned by the Norwegian Environment Agency in order to obtain more knowledge on DP and other substances of concern in post-consumer waste destined for recycling and related secondary raw materials (Norwegian Environment Agency, 2021).

In general, the project did not indicate any mismanagement of waste streams containing increased levels of the investigated substances. None of the waste fractions intended for recycling contained elevated levels of contaminants (e.g. compared to concentration limits established for POPs), whereas increased substance concentrations were found in rejects of one company, indicating the efficiency of their separation process. The results from the targeted analysis showed that only low levels of DP (below 20 mg/kg) in a few samples were detected by GC/MS in fridges, small domestic appliances (SDA) and ELV.

It should be noted that the results of the project have a limited representativity as only 8 recycling facilities in Norway, Sweden, Germany, the Netherlands and Italy were investigated. As regards to the waste flows considered in the project, i.e. plastic fractions from ELVs, WEEE and building and construction waste (B&CW), state of the art recycling technologies enable an efficient removal of halogen-containing plastics from other fractions to a certain degree (Norwegian Environment Agency, 2021).
A comment received from the plastic recycling industry in Europe in the public consultation (#3398) aligns with the information in the Background Document that the proposed restriction will not have an impact on the recycling industry and thereby confirms the conclusion by the Dossier Submitter that a derogation for this sector is not needed (see section 2.1.1).

1.2. Hazard, exposure/emissions and risk

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

The information in this section is based on the identity, physical and chemical properties of Dechlorane Plus™ as presented in the SVHC support document for DP (ECHA, 2017d).

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

The substance 1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo-[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene has two isomers, named anti- (see Figure 2 and Table 4 for structural formula and details) and syn- (see Figure 3 and Table 5 for structural formula and details). This dossier covers the individual anti- and syn- isomers (monoconstituent substances) and all possible combinations of the syn- and anti- isomers (Figure 1 and Table 3). The proposed restriction also covers the individual isomers, therefore any substance containing one of the isomers at concentration levels >=0.1% is covered by the restrictions. (In other words or as an example: also restricted under the proposal is a substance, where one of the isomers is in concentration of below 10 % (and above 0.1%) and the other isomer is 0 % and substance where one of the isomers is in concentration of 20 % and the other isomer 0 %).

This dossier does not constitute a comprehensive record of all relevant numerical identifiers available. Please note that a substance identified by a numerical identifier other than those specified in this dossier may still be covered by this restriction. Similarly, a substance for which no numerical identifier is available may also be covered by this restriction.

Table 3. Substance identity of 1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo- [12.2.1.^{16,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene, Dechlorane Plus (Figure 3)

EC number:	236-948-9
EC name:	1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloro-pentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene
CAS number (in the EC inventory):	13560-89-9
CAS number: **Deleted CAS numbers:**	13560-89-9 -
CAS name:	1,4:7,10-Dimethanodibenzo[*a*,*e*]cyclooctene, 1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6,6a,7,10,10a,11,12,12a-dodecahydro-
IUPAC name:	1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene
Index number in Annex VI of the CLP Regulation	Not applicable
Molecular formula:	$C_{18}H_{12}Cl_{12}$
Molecular weight range:	653.73 g/mole
Synonyms:	Bis(hexachlorocyclopentadieno)cyclooctane; 1,2,3,4,7,8,9,10,13,13,14,14-Dodecachloro-1,4,4a,5,6,6a,7,10,10a,11,12,12a-dodechydro-1,4:7,10-dimethanodibenzo[a,e]cyclooctene; Dodecachlorododecahydrodimethanodibenzocyclooctene; Dechlorane Plus 25 (Dech Plus); Dechlorane Plus 35 (Dech Plus-2); DP-515; Dechlorane 605; DP; DDC-CO

Note: The academic literature usually refers to this substance by a registered trade name "Dechlorane Plus" (often abbreviated as DP, but sometimes DDC-CO), and this is the name used throughout this Annex XV report and the Annexes for convenience.

Table 4. Substance identity of (1S,2S,5S,6S,9R,10R,13R,14R)-1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene, anti- (or exo) Dechlorane Plus (Figure 5)

EC number:	-
EC name:	-
CAS number: **Deleted CAS numbers:**	135821-74-8 -
CAS name:	1,4:7,10-Dimethanodibenzo[*a*,*e*]cyclooctene, 1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6, 6a,7,10,10a,11,12,12a-dodecahydro-, (1*R*,4*S*,4a*S*,6a*S*,7*S*,10*R*,10a*R*,12a*R*)-*rel*-
IUPAC name:	(1S,2S,5S,6S,9R,10R,13R,14R)-1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene
Index number in Annex VI of the CLP Regulation	Not applicable
Molecular formula:	$C_{18}H_{12}Cl_{12}$
Molecular weight range:	653.73 g/mole
Synonyms:	anti-DP, anti-Dechlorane plus, anti-Dodecachloropentacyclooctadecadiene

Table 5. Substance identity of (1S,2S,5R,6R,9S,10S,13R,14R)-1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene, syn- (or endo) Dechlorane Plus (Figure 6)

EC number:	-
EC name:	-
CAS number: **Deleted CAS numbers:**	135821-03-3 -
CAS name:	1,4:7,10-Dimethanodibenzo[a,e]cyclooctene, 1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6,6a,7,10,10a,11,12,12a-dodecahydro-, (1*R*,4*S*,4a*S*,6a*R*,7*R*,10*S*,10a*S*,12a*R*)-*rel*-
IUPAC name:	(1S,2S,5R,6R,9S,10S,13R,14R)-1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene
Index number in Annex VI of the CLP Regulation	Not applicable
Molecular formula:	$C_{18}H_{12}Cl_{12}$
Molecular weight range:	653.73 g/mole
Synonyms:	syn-DP, syn-Dechlorane plus, syn-Dodecachloropentacyclooctadecadiene

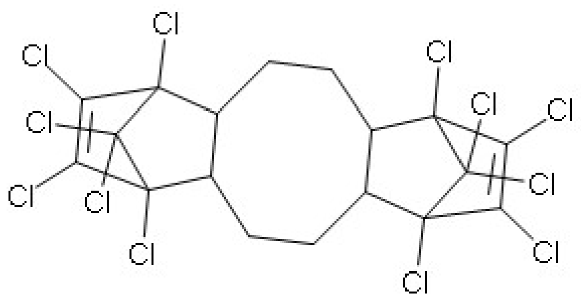

Figure 1. Structural formula

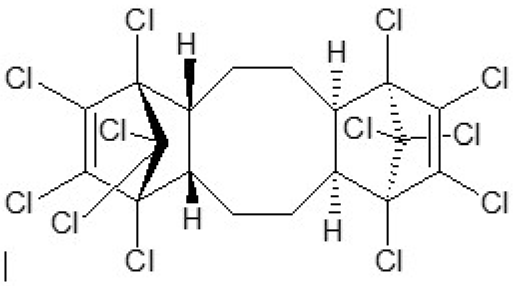

Figure 2. anti- (or exo) Dechlorane Plus

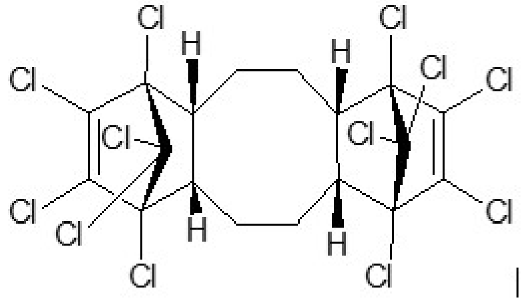

Figure 3. syn- (or endo) Dechlorane Plus

1.2.1.2. Composition of the substance(s)

Name: Dechlorane Plus™

Substance type: not applicable (group entry)

The information in this section is for the substance containing both the anti- and the syn-isomers as main constituents.

Table 6. Constituents other than impurities/additives

Constituents	**Typical concentration**	**Concentration range (w/w)**	**Reference**
anti- (or exo-)Dechlorane Plus (CAS no. 135821-74-8)	-	60-80%	Ben et al. (2013)
syn- (or endo-)Dechlorane Plus (CAS no. 135821-03-3)	-	20-40%	Ben et al. (2013)

The substance is described as mono-constituent by the Registrant. However, two geometric isomers are present in the commercial substance (e.g. (Chou et al., 1979, OxyChem, 2013). This means that it is multi-constituent. The structures of the two isomers are provided in Figure 4.

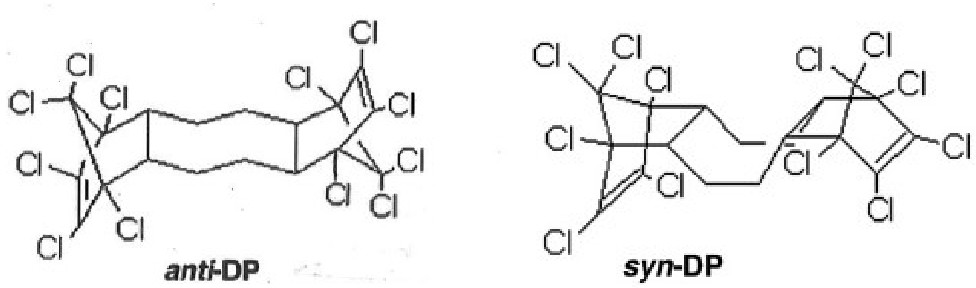

Figure 4. Geometric isomers of Dechlorane Plus (reprinted from Muñoz-Arnanz et al. (2010)). Copyright 2010: International Symposium on Halogenated Persistent Organic Pollutants)

Ben et al. (2013) reported that the anti- isomer fractional abundance (f_{anti}) value (defined as [anti- isomer]/([anti- isomer] + [syn- isomer])) is not constant in Chinese commercial products, and varies from 0.60 to 0.80. The f_{anti} value of OxyChem commercial products has also been reported by several authors to be in the range 0.64 to 0.80 (e.g. see references in (Wang et al., 2010)).

The substance is made by a Diels-Alder reaction between 1,5-cyclooctadiene and hexachlorocyclopentadiene in a molar ratio of 2:1. Cyclooctadiene can also exist as 1,4- and 1,3- isomers, and both these, 4-vinylcyclohexene and 1,2-divinylcyclobutane might be present as impurities in, or formed via thermal rearrangement of, the starting materials (Sverko et al., 2010). Consequently, they can produce Diels-Alder reaction products with the same molecular weight as Dechlorane Plus. Sverko et al. (2010) analysed a technical Dechlorane Plus product and detected four minor chromatographic peaks that are potentially related to these other substances.

Compounds with a smaller number of chlorine atoms may also be impurities in the commercial substance. For example, (Li et al., 2013) found a mono-dechlorinated substance (DP-1Cl) in the commercial substance produced by Jiangsu Anpon Co. Ltd., China; in contrast, (Peng et al., 2014) could not detect DP 1Cl in samples from the same source (although this might reflect differences in detection limits).

1.2.1.3. Physicochemical properties

An overview of DP's physiochemical properties is given in Table 7. Unless otherwise stated, the data are taken from the REACH registration on the ECHA public dissemination website (ECHA, 2020a). There is no information available for the individual syn- and anti- isomers. Therefore, it is not possible to conclude whether there are physicochemical differences between these or not.

Table 7. Overview of physicochemical properties

Property	**Value [Unit]**	**Reference/source of information/remarks**
Physical state at 20°C and 101.3 kPa	The substance is a free flowing solid	
Melting/freezing point	Decomposition from 340 – 382 °C (no melting observed)	
Boiling point	*Data waived on the basis of a melting point > 300 °C*	
Vapour pressure	*Data waived on the basis of a melting point > 300 °C*	A vapour pressure of approximately 9.4E-08 Pa at 25 °C is predicted using MPBPVP v1.43 (U.S. EPA, 2012, modified Grain method, recommended for solids). This is highly uncertain (approximately ±1 log unit) as it is close to the lower limit of the range of the model, where there is some scatter in the training set. However, the molecular weight of the substance is within the range of the model's training set. Also, structural analogues are part of the MPBPVP training and test sets. A measured vapour pressure of approximately 0.008 hPa (0.8 Pa) at 200 °C was reported by Occidental Chemical Company (2003). An extrapolated vapour pressure of 4.6E-04 Pa at 25 °C can be estimated from this result using EUSES v2.1.2, and this is preferred for assessment purposes. There is some uncertainty due to the extrapolation from very high temperature, and the unknown reliability of the underlying result. The substance has a very low vapour pressure at environmentally relevant temperatures.
Surface tension	*Data waived on the basis of low water solubility (<1 mg/L).*	
Dissociation constant	*Data waived on the basis of low solubility in water.*	The substance does not contain any acidic or basic functional groups.

Property	Value [Unit]	Reference/source of information/remarks
Water solubility	< 1.67 ng/L at 20 °C (below the limit of quantitation)	Reliability 1: OECD Test Guideline 105 (column elution method) and GLP (ECHA website, 2017)). Dechlorane Plus (>99% purity) was coated onto the column using dichloromethane. HPLC grade reagent water was pumped through the column at two different flow rates, and analysed using gas chromatography with micro electron capture detection (GC-ECD). There is some uncertainty in the precise value for water solubility. However, all available measurements and predictions[7] are in agreement that the substance is very poorly water soluble.

[7] Chou *et al*. (1979) reported mean water solubilities of 207 and 572 ng/L for the two isomers at 22±2.5°C using radiolabelled substance in equilibration with water by slow stirring for six weeks. This is considered unreliable by the Registrant. No reason is provided, but the report concluded that samples in the solubility experiment may have contained particulates, and so estimated a solubility of 44.1±2 ng/L at 22 °C (total for both isomers).

Water solubilities estimated based on a log K_{OW} range of 7 to 9 using WSKOWWIN v.1.42 (U.S. EPA, 2012) are 7.5E-05 – 1.5E-06 mg/L [75 – 1.5 ng/L]. The substance is outside the estimation domain of the model because both molecular weight and log K_{OW} are outside the ranges of these parameters in the training and test sets for the method. A water solubility of 6.5E-07 mg/L [0.65 ng/L] can be estimated using the WaterNT v1.01 fragment method (U.S. EPA, 2012), which does not use log K_{OW} as an input. The molecular weight is outside the range of this parameter in the training set, but not the test set. The number of aliphatic attached chlorines exceeds the maximum occurrences of this fragment in a single compound in the training set (8 in Dechlorane Plus, maximum 6 in the training set). Therefore, the substance is not considered to be within the estimation domain of the model.

U.S. EPA (2011) reported another measured value of 2.49E-04 mg/L [240 ng/L] at 25 °C (Scharf, 1978). In EPI Suite (U.S. EPA, 2012), a measured water solubility of 4.4E-08 mg/L at 25 °C is reported citing a HPV Robust Summary as the source; this result is discounted given the discrepancy between the value quoted and the original source (4.4E-05 mg/L, Chou *et al*., 1979).

Property	Value [Unit]	Reference/source of information/remarks
Partition coefficient n-octanol/water (log value)	*Waived by Registrant due to low water solubility.*	Chou *et al*. (1979) reported a log K_{OW} of 9.3 (also reported by the U.S. EPA, 2012). This is a calculated value; its validity has not been assessed. A log K_{OW} of 11.3 is predicted using KOWWIN (U.S. EPA, 2012). This result was also reported in the U.S. EPA (2001) review. The predicted result is considered to be within the validity range of the model because the molecular weight of the substance is within the range for this parameter for both the training and test sets. The number of aliphatic chlorines exceeds the maximum occurrences of this fragment in a single compound in the training set (8 in Dechlorane Plus, maximum 6 in the training set). The value is above the log K_{OW} values used in the training and tests sets and above the normal experimental range, but is indicative of the expected lipophilic character of the substance. It would be unusual to expect to quantify values above approximately 9 experimentally. The log of the ratio of n-octanol and water solubilities is >8.4, using a solubility of < 2 ng/L at 20 °C for water (ECHA website, 2017) and 470 mg/L at 25 °C for n-octanol (see below). Additional estimation methods give similar values. For example, the ACD/Percepta platform gives the following results: LogP Classic: 9.51±0.67; LogP GALAS: 9.16 (Reliability: Borderline; RI = 0.41. Chlordene and different chlordane isomers are in the training set). Whilst there is clearly uncertainty in the value of log K_{OW}, the value is assumed to be ≥9.
Partition coefficient air/water (log value) **[log K_{AW}]**	*No data were provided by the Registrant.*	The following log K_{AW} values at 25 °C are estimated based on the Henry's Law constant: -3.2 (from measured water solubility and estimated vapour pressure) 0.44 (from measured water solubility and vapour pressure) -2.8 (from EPIWIN predicted water solubility using log K_{OW} of 9 and vapour pressure) -3.5 (from HENRYWIN v.3.20, predicted from structure using Bond Method). See discussion of Henry's Law Constant (Section 3.2.2 of Appendix 1 in the SVHC Support document for DP) for further details (ECHA, 2017c).
Partition coefficient n-octanol/air (log value) [log K_{OA}]	*No data were provided by the Registrant.*	A log K_{OA} of 14.8 is estimated using KOAWIN (U.S. EPA 2012). This is a simple ratio of the octanol-water (log K_{OW} 11.3) and air-water (log K_{AW} -3.5) partition coefficients calculated within EPI Suite. There is uncertainty in this value resulting from uncertainty in the estimated K_{OW} and K_{AW} (see above). Using a log K_{OW} of 9, a log K_{OA} of 12.5 is estimated with a log K_{AW} of -3.5, or 8.6 with a log K_{AW} = 0.44.

Property	Value [Unit]	Reference/source of information/remarks
Henry's Law Constant	*No data were provided by the Registrant.*	The following values were obtained using a range of estimation methods (including a structural fragment based QSAR method) in light of the uncertainty in vapour pressure and solubility measurements and predictions: 1.4 Pa.m^3/mol at 25 °C (from measured water solubility and estimated vapour pressure) 6800 Pa.m^3/mol at 25 °C (from measured water solubility and extrapolated vapour pressure) 41 Pa.m^3/mol at 25 °C (from EPIWIN predicted water solubility using log K_{OW} of 9 and vapour pressure) 0.75 Pa.m^3/mol at 25 °C (from HENRYWIN v.3.20, predicted from structure using Bond Method). The Bond method training set comprises much smaller molecules than Dechlorane Plus, which are generally much more soluble and of higher vapour pressure than the substance, although the predicted Henry's Law constant is mid-range for the method. It is therefore difficult to estimate the uncertainty of the predicted values. See also Section 3.2.2 of Appendix 1 in the SVHC Support document for DP for further discussion (ECHA, 2017c).
Solubility in organic solvent[8]	n-Octanol solubility: 470 mg/L (to the nearest 10 mg/L) at 25 °C	Reliability 1: non-guideline study conducted in a GLP facility but not formally to GLP (reference not provided, but it appears to have been conducted in the UK in 2013) Approximately 2 g sample was weighed into a 125 mL conical flask and 20 mL n-octanol was added. A magnetic stirrer was placed on a thermostatic water bath overnight followed by slow stirring. Stirring was stopped and test solutions containing insoluble test substance were allowed to settle for 30 minutes before filtration under gravity. Clear colourless filtrates were obtained and test solution was analysed using GC-ECD without further dilution. The solubility in octanol is used as part of the assessment of octanol-water partitioning and also bioaccumulation. Although the test solution was filtered, it is not known whether the reported result represents truly dissolved substance.

[8] Occidental Chemical Company (2004) refers to a study from 1978 that mentions a solubility in n-octanol of 264 - 346 (average 305) ppb (µg/L) at 25 °C. No further details are available, but the result was obtained "after partitioning" (presumably with water, as the data entry is for the water solubility end point) so this is probably not a true solubility value.

Product literature (OxyChem, 2007) provides further values (all in units of g/100 g solvent at 25 °C) as follows: benzene 2.0, xylene 1.0, styrene 1.8, trichloroethylene 1.4, methyl ethyl ketone 0.7, n-butyl acetate 0.7, hexane 0.1, methyl alcohol [methanol] 0.1. The analytical information provided in the REACH registration dossier mentions that the substance is "insoluble" in methanol, but "soluble" in tetrachloroethane, dichloromethane and tetrahydrofuran.

1.2.2. **Justification for grouping**

As described in Section 1.2.1.2 and B.1.2. in the Annexes, two geometric isomers are present in the commercial substance (e.g. Chou *et al*., 1979, Oxychem, 2013), and hence DP is defined as a multi-constituent. DP is produced by the Diels−Alder condensation of hexachlorocyclopentadiene and 1,5-cyclooctadiene in a 2:1 molar ratio (Sverko et al., 2011). Formation of geometric isomers occurs naturally during synthesis of DP and as a result of the thermodynamically and sterically most favorable reaction. It is also demonstrated that the reaction stereoselectivity can be affected by solvent nature and reaction temperature (Pavelyev et al., 2016).

There is no information available for the individual syn- and anti- isomers. Therefore, it is not possible to conclude whether there are physicochemical differences between these or not. The two isomers are not expected to have significant differences in physiochemical properties, and it is generally accepted to consider geometric isomers as similar substances.

The justification for grouping is underpinned on the basis of the similarity of the two isomeric forms.

1.2.3. **Classification and labelling**

No harmonised classification is reported for Dechlorane Plus (CAS 13560-89-9) in Annex VI of Regulation (EC) No. 1272/2008 (CLP Regulation).

There are no proposals for new or amended harmonised classification of Dechlorane Plus (CAS 13560-89-9) on the Registry of Intention.

The Registrant has not proposed classification for any hazard.

The European Chemical Agency (ECHA) online Classification & Labelling (C&L) Inventory database, which was checked on 8 March 2021, reports a joint submission (consisting of 151 notifiers) indicating no classification according to the CLP criteria. In addition, 99 notifiers have classified the substance as Acute Toxicity Category 4, H332 Harmful if inhaled.

1.2.4. **Hazard assessment**

DP is very persistent and very bioaccumulating and therefore a toxicity assessment is not relevant for this dossier.

The Dossier Submitter notes that the potential adverse effects/toxicity of DP are currently discussed under the Stockholm Convention. Information on the environmental hazardous properties can be found in the draft POPs risk profile for DP (POPRC, 2021b)[9].

[9] Note that the draft POPs risk profile for DP still is in preparation. Information from the risk profile that is referred in the Background document is taken from the revised version of the risk profile from 11 May 2021 (POPRC16 Follow-up (pops.int)).

It is also noted that more information on human health effects of DP is expected to become available in accordance with ECHAs compliance check decision on DP[10].

1.2.5. **Release and exposure assessment**

The release and exposure assessment of DP comprises both estimated and monitoring data for the environment and humans (see Annex B.9.3. and B.9.4. for detailed information). Estimated environmental releases are described in section 1.2.5.3., while environmental monitoring data and human biomonitoring and exposure data are described in section 1.2.5.4 and section 1.2.5.5, respectively.

Exposure of DP occurs from releases to air and water from both point sources (e.g. industrial sites, dismantling plants, etc.) and via diffuse emissions from e.g. service life of articles. Subsequent distribution processes, such as adsorption to sludge or volatilisation to air during wastewater treatment plants, and atmospheric deposition of the airborne dust to soil from dismantling, result in exposure of air, water, sediment, soil and organisms. There are currently no active REACH Registrations of DP in the EU after the previous active registrant, ADAMA Agriculture BV, notified a "ceased manufacture" to ECHA on 31 May 2021(see section 1.1.1). As discussed in sections 1.2.5.4 and 1.2.5.5, monitoring information shows that DP is found in remote areas (e.g. the Arctic). It is also found in house dust, WWTP sludge and other matrices (ComRef, 2019, ECHA, 2017c), indicating use of the substance in articles with potential for releases.

The exposure assessment is given in two parts for each relevant lifecycle stage. Firstly, the initial releases to air, wastewater and industrial soil[11] have been estimated using generic exposure methods. This is carried out at the local (site), regional (highly industrialised area) and continental (approximates to the whole EU) scale.

The overall release estimates for DP for the EU are summarised in Annex B.9.3.11 and also below, see Table 10. The estimates show that emissions to air far exceed other routes, comprising around 78 - 82% of the total DP released to the environment. The updated use volume estimates per sector do not affect the total release estimates for DP (see Box 2 in Annexes).

The second part of the exposure assessment considers the distribution of the initial releases to wastewater in sewage treatment plants, direct releases to air and the resulting predicted environmental concentrations (PECs). The estimated PECs for different evironmental compartments can be found in Annex B.9.3.

The properties of DP (see Annex B.4.2. for details) mean that a large fraction of the emissions of the substance entering into a sewage treatment plant (STP) will adsorb onto sewage sludge

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[10] https://echa.europa.eu/documents/10162/c13636b7-c6ee-569a-dd8d-75d299e0d8a8

[11] Direct releases to soil at an industrial site. ECHA Guidance R.16 indicates that such industrial soil is not itself a protection target, but the releases are taken into account at the regional scale.

and this may subsequently be applied to agricultural land as a fertiliser and smaller fractions are distributed to air and water, as shown in Table 8.

Table 8. Estimated distribution of DP after entering a sewage treatment plant (STP)

Distribution	Share of total
Percentage to air	0.092%
Percentage to water	7.27%
Percentage to sludge	92.63%
Percentage degraded	0%
Total	**100**

1.2.5.1. General discussion on releases and exposure

Acknowledging the very persistent and bioaccumulating nature of DP (see Annex B.4.1), emissions will lead to increasing exposure of DP to humans and the environment over time. Measures to reduce the ongoing emissions of DP are therefore necessary.

There is limited information on releases to the environment that is publicly available. The ECHA Substance Infocard (accessed in March 2021) summarises potential sources of emissions:

- **Manufacture** - No public information is available on the routes of release to the environment.
- **Formulation or re-packing** - Releases to the environment can occur from formulation in materials and formulation of mixtures.
- **Uses at industrial sites** - Releases to the environment can occur from the production/formulation of adhesives and sealants, polymers and semiconductors and in the production of articles from these products.
- **Widespread uses by professional workers** - No public information is available on the products in which the substances might be used or on the routes of release of the substance to the environment.
- **Consumer uses** - No public information is available on the products in which the substances might be used or on the routes of release of the substance to the environment.
- **Article service life** - Releases to the environment are likely to occur from long-life materials with low release rate such as metal, wooden, and plastic construction and building materials, flooring, furniture, toys, curtains, footwear, leather products, paper and cardboard products and electronics. Releases could occur during both indoor and outdoor use of such articles.

More detail on the precise Environmental Release Categories (ERCs) – which describe the processes from which releases to environment could occur – and the Process Categories (PROCs) – which describe the processes from which occupational exposure could occur can be found in Annex B.9. Exposure Assessment.

All the exposure estimates are associated with uncertainties, further discussed in Annex F.

1.2.5.2. Manufacture and uses of DP

The stakeholder consultation confirmed that there is currently only one manufacturer of DP globally, ADAMA Agriculture BV, and the manufacturing facilities are located in China. There is no information on the releases to the environment from this plant. Stakeholders also provided information indicating that the volumes used in the EU are around 90 -230 tonnes per year. It was found that DP is currently used in the following applications in the EU: (i) use in sealants and adhesives; (ii) use in polymers; and (iii) use in greases. It is important to note that there may be different uses of DP within some of these main areas of use, see Annex A.2. for more details.

For the emissions assessment, nine specific uses were analysed and the remaining, releases, were collated in the tenth use category: 'other'. The uses were as follows:

1. Formulation of sealants and adhesives
2. Industrial use of sealants and adhesives
3. Industrial use in polymers
4. Formulation of greases
5. Indoor use of articles containing DP over their service life
6. Outdoor use of articles containing DP over their service life
7. Dismantling and recycling of waste/articles containing DP
8. Disposal of waste/articles containing DP by incineration
9. Disposal of waste/articles containing DP by landfill
10. Other sources

The draft POPs risk profile for DP states that the substance and its isomers are not known to be unintentionally produced and there are no natural sources of DP (POPRC, 2021b).

1.2.5.3. Estimated releases from the use of Dechlorane Plus

The default release factors for the ERC from ECHA Guidance R.16 (ECHA, 2016a), summarised in Table 9, provides worst case estimates for the percentage of the substance used in each application that could be released from the process to air, water (before sewage treatment) and soil.

Table 9. Default release factors for relevant ERCs from ECHA Guidance R.16 (ECHA, 2016)

ERC	ERC description	Default release factor to air	Default release factor to water	Default release factor to soil
ERC 2	Formulation into mixture	2.5%	2%	0.01%
ERC 3	Formulation into solid matrix	30%	0.2%	0.1%
ERC 5	Use at industrial site leading to inclusion into/onto article	50%	50%	1%
ERC 10a	Widespread use of articles with low release (outdoor)	0.05%	3.2%	3.2%
ERC 11a	Widespread use of articles with low release (indoor)	0.05%	0.05%	Not applicable
ERC 12c	Use of articles at industrial sites with low release	0.05%	0.05%	Not applicable

Environmental exposure is estimated in line with the ECHA (2016) guidance, in conjunction with generic information on the release factors to the environment developed by the Association of the European Adhesive and Sealant Industry (FEICA). These are documented in FEICA SPERC 2.1a.v3 (for formulation of solvent-borne products), FEICA SPERC 2.2b (for formulation of water-borne products) (FEICA, 2017a, FEICA, 2017b) and OECD Emission Scenario Documents. See Annex B.9. Exposure Assessment for the actual release factors used in the different use scenarios.

Exposure assessments have also been carried out in the EU registrant's CSR for all life cycle stages including the waste stage, see Confidential Annex H, Section H.2.1 for more information. However, these exposure assessments have not been directly taken into account due to assumptions in the CSR which does not seem to be well documented.

Summary of overall releases and environmental exposure

The tonnage information used below was provided during the stakeholder consultation carried out in preparation for this dossier and information submitted to the global regulatory process for DP under the Stockholm Convention (POPRC, 2021b). The results from the exposure assessment are summarised in Table 10, where the lower and upper bound for the emissions estimates reflects uncertainty in the amount of DP being used in the EU (see Table 1). The 'Total' DP refers to the sum of estimated releases to the air, water, agricultural soil and industrial soil. These include any direct releases and also take account of the redistribution in the STP for emissions to wastewater. The table shows that emissions to air by far exceed the estimates of the other routes, comprising 78% - 82% of total DP released.

Table 10. Estimated total EU releases for DP

Environmental compartment	Estimated EU emissions in 2020 (kg/year)		
	Low	**High**	**Share of total**
Air	5 857	19 479	78% - 82%
Water	413	1 081	4.5% - 5.5%
Agricultural soil	1 185	3 102	13% - 16%
Industrial soil	72	184	0.8% - 1.0%
All / Total	**7 527**	**23 845**	**100%**

Note: Sums may not add up due to rounding.

Table 11 shows the emission sources of DP. The exposure assessment shows that the largest source of emission of DP to the environment in the EU is dismantling and recycling, which is responsible for 76% - 80% of the total emission. The second largest source is landfill at 10.5% - 8.5%. This means that 86% - 89% of the releases of DP to the environment are attributable to the waste stages. A number of environmental monitoring studies points at e-waste recycling sites and landfills as sources of release of DP to the environment, see section 1.2.5.4 and Annex B.9 for details.

Table 11. Emission sources of DP

Scenario	Share of total – Low emission scenario	Share of total – High emission scenario
Manufacture of substance	0%	0%
Formulation of sealants/ adhesives	0.02%	0.3%
Industrial use of sealants/ adhesives	1.1%	1.0%
Polymer raw materials handling, compounding and conversion	7.3%	5.9%
Formulation of greases	0.1%	0.1%
Widespread use of articles over their service life - indoor use	1.1%	0.8%
Widespread use of articles over their service life - outdoor use	3.8%	3.1%
Waste dismantling and recycling	76.0%	80.2%
Waste incineration	0.1%	0.1%
Landfill	10.5%	8.5%

1.2.5.4. Environmental monitoring data and long-range transport

DP is detected in wildlife and environmental samples in all global regions, including the Arctic and Antarctic. This part is a summary of the information in Annex B.9.4.2.

There are no natural sources of DP; elevated levels of DP are associated with human activity. It is ubiquitously present in the environment, including the Arctic and Antarctic, and it is detected in humans, wildlife and environmental samples such as dust, sludge and wastewater treatment plants (WWTPs) (POPRC, 2021b).

European monitoring studies show that the two isomers of DP are widely dispersed in the European environment. However, the concentrations are generally lower than those measured in the vicinity of DP manufacturers and e-waste recycling cites in the USA and China. A number of recent studies have confirmed e-waste recycling sites as a source of release of DP to the environment (Ge et al., 2020, Iqbal et al., 2017). The highest environmental levels of DP are measured in environmental samples, wildlife and humans living near point sources such as e-waste recycling sites and production plant (POPRC, 2021b).

Furthermore, DP has been detected in environmental samples near landfills in Europe, Asia and North America (Hafeez et al., 2016, Ma et al., 2022., Morin et al., 2017, Wang, 2016). These environmental samples include soil, leachates, air and biota, such as foraging birds (Chen et al., 2013, Kerric et al., 2021, Ma et al., 2022, Morin et al. 2017, Sorais et al., 2020, Tongue et al., 2019). Some studies show that greater levels of DP are detected in birds with terrestrial diets foraging in or near landfills, than those breeding in more rural areas or with predominantly aquatic or marine diets (Chen et al., 2012, Su et al., 2016, Tongue et al., 2019).

Although there is no production of DP in Norway, the Norwegian Environment Agency (2019) reported DP levels in sediments from the Oslo fjord in the same range as sediments tested from Lake Ontario – close to a DP manufacturing plant (Sverko et al., 2011). Several recent studies have shown DP and its analogues in terrestrial and marine biota, including birds, reindeer, seals, cetaceans and polar bears (Abdel Malak et al., 2018, de Wit et al., 2020, Heimstad et al., 2020, Heimstad et al., 2019, UNEP, 2019). Environmental monitoring results show that temporal trends for DP are equivocal.

It is predicted that DP has a high adsorption potential, suggesting that sediment and soil are more likely to contain DP than water. Thus, it is expected to find the substance in sewage sludge rather than in the water phase at wastewater treatment plants. Several publications have recorded concentrations of DP in sewage sludge, with the highest recorded level being 75.1 ng/g dry weight (Barón et al., 2012, De la Torre et al., 2011, Norwegian Environment Agency, 2018, Norwegian Environment Agency, 2019).

Moreover, DP is not volatile due to its low water solubility and vapour pressure, although these physical properties result in DP readily being adsorbed by particles in air. Available monitoring data confirms this assumption and shows that DP is found predominantly in the particulate phase both in air and water (see Annex B.9.). Long-range transport of DP is thus likely mediated by sorption to particles in the atmosphere and in seawater (CEMC, 2004) and lead dispersion of DP throughout multiple remote environments. Furthermore, birds have been identified as biovectors for the transport and deposition of POPs to ecosystems in remote regions through deposition of guano, feather loss and decaying carcasses and may represent an additional transport pathway for DP to remote regions (POPRC, 2021b).

In summary, DP is released to the environment from human activities. It is detected in wildlife and environmental samples in all global regions including the Arctic and Antarctic, thus confirming long-range transport. DP is also measured in environmental samples near production sites and urban areas.

1.2.5.5. Biomonitoring and human exposure

This section is a summary of the information retrieved in the published, peer-reviewed literature as described in Annex B.9.4.1.

Human exposure to DP and its *syn*- and *anti*-isomers (*syn*-DP and *anti*-DP) can occur through worker exposure, consumer exposure and indirect exposure of humans via the environment. There is not enough data available to conclude on whether stereoselective accumulation of DP isomers (*syn* and *anti*) occur in human samples. In this section the mean/median concentrations of *anti*-DP are reported as the commercial DP contain 75% of the *anti*-isomer. Data on both isomers can be found in Annex B.9.4.1. (Tables 61-64).

The exposure to DP can arise from multiple sources such as dust in workplaces, indoor house dust, food, beverages, and outdoor air and water. Further, the foetus is exposed due to transfer of DP through the placenta, and breast-fed children are exposed through the intake of breast milk. It should be noted that most of the literature is based on non-European sources. At present there is too little knowledge to conclude on the relationships between DP concentrations in blood and gender or age of participants.

Occupational exposure

The published studies in workers occupationally exposed to DP are from China. Several studies show elevated levels of *syn*-DP and *anti*-DP in occupationally exposed workers employed in the DP manufacturing plants and in e-waste dismantling facilities. In the studies *syn*-DP and *anti*-DP was measured in serum and/or hair from the workers. Mean level of anti-DP in serum from workers in DP manufacturing plants was 207-471 ng *anti*-DP/g serum lipids (Zhang et al., 2013). The median level in serum from workers in e-waste dismantling facilities was 103.6-120 ng *anti*-DP/g serum lipids (Chen et al., 2015, Yan et al., 2012). In hair the median was 158 ng *anti*-DP/g hair from workers in DP manufacturing plant and 8.52-30.2 ng *anti* -DP/g hair from workers in e-waste dismantling facilities (Chen et al., 2015, Qiao et al., 2019, Zhang et al., 2013). One study show that indoor dust could be one of the major pathways for DP exposure in workplaces (Zheng et al., 2010).

Consumer exposure

Most of the published studies in consumers come from China. The rest come from Europe, Canada, and South Korea. DP are found in house dust, indoor air and on hand wipes, demonstrating that consumer exposure is likely to occur, but the relative importance of each exposure pathway is not yet clear. DP are assumed to leach from consumer products such as electronic equipment and to occur in outdoor and indoor air and house dust as pollution.

Indirect exposure of humans via the environment

DP are found in both food and beverages, outdoor air and water, demonstrating that indirect exposure of humans via the environment is likely to occur. Studies from China show that individuals living in close vicinity to DP manufacturing plant or e-waste handling facilities have higher internal levels of DP. There is limited knowledge on the relative importance of each exposure pathway, but there are indications that food intake and dust ingestion are important exposure pathways, when taking into account both consumer exposure and indirect exposure of humans via the environment.

Combined human exposure assessment

Exposure to DP has been demonstrated worldwide, despite the fact that no manufacture of DP occurs in most countries. Furthermore, elevated concentrations of DP are observed in non-occupationally exposed individuals, in particular when residing in areas where DP are manufactured or where e-waste is handled.

Levels of DP in blood, adipose tissue, hair, cord blood and breast milk

Available studies indicate a relatively similar exposure to DP during the last two decades. DP have been detected in blood (serum or plasma) from workers and from non-occupational exposed adults and children worldwide. The levels detected are in general lower in Europe and Canada compared to China and South Korea, but DP were in most studies detected in more than 75% of the samples. In Europe, DP levels in blood serum from adults have been reported from studies in France, Germany, Sweden and Norway. In these EU/EEA countries the median level of *anti*-DP in serum has been reported to be in the range from below the limit of detection (LOD) in Sweden and Norway (Cequier et al., 2015, Sahlström et al., 2014, Tay et al., 2019) up to 1.23 ng/g serum lipids in Germany (Fromme et al., 2015). In China the levels found are significantly higher, especially in towns with e-waste dismantling facilities or in individuals living close (approximately 3 km) to a manufacturing plant, where the mean *anti*-DP concentration in serum was reported to be up to 207 ng/g serum lipids (Zhang et al., 2013). DP have been detected in adipose tissue, and both the tissue lipid content and type of organ have an influence on the DP tissue distribution. DP has been measured in human hair and the data clearly demonstrate human exposure to DP. Measurements of *anti*-DP in hair are only available from China where the mean level ranged from 0.220 ng/g dry weight in students in Minzu (Chen et al., 2019) up to 53.3 ng/g dry weight for individuals not working in a manufacturing plant but living approximately 3 km from a manufacturing plant (Zhang et al., 2013). Children are exposed to DP in utero through transplacental transfer. Both *syn*-DP and *anti*-DP have been observed in cord blood samples, demonstrating prenatal exposure to DP. DP are partially retained in the placenta and partially transferred to the foetus. Further, strong correlations between DP concentrations in maternal serum, placenta, and cord serum demonstrate that children of women with high exposure to DP will experience high prenatal exposure to DP. A single study of DP in maternal sera, placenta and cord blood indicate exposure *in utero*. The median of *anti*-DP in maternal sera, placenta tissue and cord blood sera was 6.16, 2.75 and 1.89 ng/g lipid weight, respectively, in a group of mother−infant pairs in an e-waste recycling area in China, while it was 2.83, 0.90 and 1.40 ng/g lipid weight in a group who had lived in the area for a shorter time and not in villages where e-waste recycling activities were undertaken (Ben et al., 2014). The DP concentrations in the maternal serum, placenta, and cord serum strongly correlated, indicating that DP could transfer between the tissues.

Newborns and toddlers are exposed to DP through breast milk. The data on breast milk support data on blood, and clearly demonstrate postnatal exposure to DP through breastfeeding. Furthermore, similarly as for blood, elevated concentrations of DP in breast milk are observed in non-occupationally exposed individuals, in particular when residing in areas where DP are manufactured or where e-waste is handled. More information is needed on the ratio between breast milk and blood concentrations in order to be able to extrapolate data on blood to breast milk and vice versa. Information of the level of *anti*-DP in breastmilk is only available from a single study in Europe (mothers from Norway, the Netherlands and Slovakia) where the mean concentration ranged from 0.055 to 0.155 ng/g breast milk lipids (median below LOQ) (Čechová et al., 2017). In China levels in breastmilk is reported to be up to 3.32 ng/g breast milk lipids (median) / 27.4 ng/g breast milk lipids (mean) in the single available study of Chinese mothers living in villages heavily involved in e-waste recycling but who did not participate in the e-waste recycling operations (Ben et al., 2013).

Estimated data on the indirect exposure of DP to humans via the environment can be found in Annex B.9.3.

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 DP, to the environment or to humans cannot be adequately addressed in a quantitative way. The overall aim for vPvB substances is to minimise the exposures and emissions to humans and the environment (REACH Annex I, section 6.5).

1.3. Justification for an EU wide restriction measure

DP is identified as an SVHC based on its very persistent and very bioaccumulative (vPvB) properties according to Article 57(e) of Regulation (EC) No 1907/2006 (REACH).

The substance is chemically 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. DP is also widely dispersed in both the aquatic and terrestrial food chains, including top predators. It is frequently detected in remote regions which shows that the compound is transported over long distances from point sources and production facilities.

Humans are also exposed to DP and the substance has been detected in human blood in studies from Europe, Canada and Asia. Furthermore, it has been shown that DP is transferred to the foetus during pregnancy via blood, and after delivery via breast feeding.

There is no EU manufacture of DP, but it is imported in articles to the EU (see section 1.1.1). According to the registrant information, DP is used as a flame retardant in adhesives/sealants and polymers. Furthermore, DP is used as an extreme pressure additive in greases. The substance is used in a wide range of products, such as computers, electronic and optical products, vehicle textiles, automobiles, aerospace and defence engines, as well as in fireworks (see Annex A). There is a potential for release of DP to the environment during processing and use, as well as from waste disposal and recycling activities (see Annex B.9). Products imported in one Member State may be transported to and used in other Member States.

Since DP persists in the environment for a very long time and accumulates 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 restriction of DP will thus be the avoidance of these potential transgenerational impacts on the environment and human health in the future, through reductions in emissions and exposure to these substances.

Another aspect worth considering is the political goal to phase out the use of vPvB substances, see for example the recent Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (European Commission, COM (2020) 667 final). Furthermore, Recital 70 of the REACH Regulation 1907/2006 states that exposure of the environment and humans from SVHC's should be reduced as much as possible.

Norway proposed to list DP as a POP under the Stockholm Convention in May 2019 (UNEP, 2019). If the substance is listed, EU will include the listing into Regulation (EU) 2019/1021 (the POPs regulation). The Persistent Organic Pollutants Review Committee (POPRC) assessed the intrinsic properties of DP at their sixteenth meeting in January 2021 and then decided to defer its decision on the draft risk profile for DP to its seventeenth meeting. However, POPRC-16 noted that the information on persistence, bioaccumulation and the potential for long-range environmental transport was conclusive but the Committee was unable to agree that the information on adverse effects was sufficient to reach a conclusion on the risk profile for DP (POPRC, 2021a). If the risk profile is approved by POPRC, the next step towards a global regulation is preparation of a risk management evaluation that includes an analysis of possible control measures for DP.

An EU restriction will be an important step to reduce the risks from DP within the EU internal market. It is desirable to go ahead with a restriction under REACH in order to benefit from an earlier implementation of a restriction of a substance presenting an unacceptable risk in the Union before it is superseded by a listing in the POP Convention (EC, 2014). It will also assist the global regulation by the POPs Convention by analysing the impact in the EU of an equivalent global regulation. If the result of the assessment under the POP Convention is that DP does not fulfil the criteria for a POP, DP still poses an unacceptable risk in the Union due to its vPvB-properties. Hence, it is good practice to initiate the restriction procedure under REACH following the nomination for listing of DP under the POP Convention. Where, following the listing in Annex XVII to REACH, DP is also listed under the Convention, the REACH restriction should - in principle - be removed from REACH Annex XVII (EC, 2014).

National regulatory actions are not considered adequate to manage the risks of DP. 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 action undertaken by individual Member States.

Furthermore, since a considerable share of articles containing DP may be imported from outside the EU, the inclusion of DP on the list of substances subject to authorisation (REACH Annex XIV) would create an uneven playing field.

A short description of different Union-wide legislative options that may have the potential to influence emissions of DP to the environment is presented in Annex E.1.3. An EU-wide restriction will prevent and reduce the releases of the substance and is 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 Risk Management Option (RMO) or intervention being implemented to reduce the environmental risks from manufacture, import and use of DP.

In this analysis, the consideration of DP for inclusion in the Stockholm Convention on POPs is excluded from the baseline scenario, i.e. there is no regulation of DP in the EU or globally under the baseline scenario. If one instead assumed that the global restriction would move forward without the REACH restriction, the baseline use and emissions derived in this dossier would not be applicable. Since the REACH restriction and the listing under the Stockholm Convention will be interlinked (EC, 2014), their separate effects have not been further investigated in this analysis.

1.4.1. **Use**

As mentioned in Section 1.1, DP is estimated to currently be used in volumes of between 90 and 230 tonnes/year in the EU, with a central estimate of 160 tonnes/year. Motor vehicles are thought to be the main use of DP, with consumption ranging from 81 to 161 tonnes in 2020.

A 20-year period starting in 2023 – the earliest possible Entry into Force (EiF) date of a potential restriction – was chosen for the analysis. The use volumes between 2023 and 2030 were estimated using the predicted annual growth rate (CAGR[12]) in the motor vehicle market of 2.2% (PwC, 2017) up until 2030, under the assumption that this sector – as the biggest user – would be the main driver behind demand for DP. Existing predictions for annual growth rate in the motor vehicle industry ends in 2030. It is considered unrealistic to prolong this growth rate for the rest of the period. In the absence of information on market development after 2030, a growth rate equal to the projected population growth in the EU of -0.05% was used (Eurostat, 2020c). The effect of using different growth rates has been assessed in chapter F.3 Sensitivity analysis in the annexes.

Figure 5 shows the expected development in DP volumes used in the EU between 2020 and 2042, estimated based on the abovementioned growth rates. The central estimate is shown in green, whilst blue and orange represent the low and high estimate, respectively.

[12] CAGR is a derived constant growth rate over a certain time period, excluding year-to-year variations.

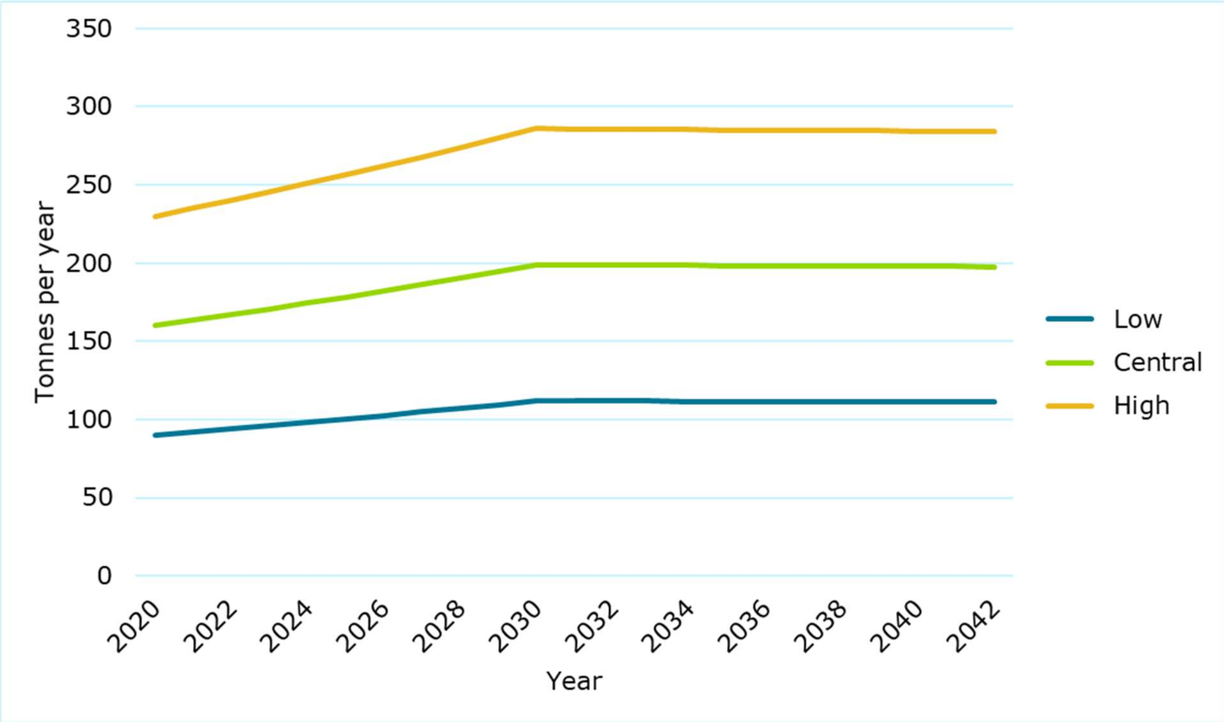

Figure 5. Expected development in the use of DP between 2020 and 2042 within the EU

Over 20 years, this equates to a total estimated use volume of DP of between 2 200 tonnes and 5 600 tonnes and a central use estimate of around 3 900 tonnes. The corresponding average annual use of DP was estimated at around **190 tonnes per year (central estimate).** Table 12 shows the breakdown of projected use volumes per sector (central estimate only), assuming that the consumption split (% of total use) between the sectors will remain the same over the analytical period.

Table 12. Total and average baseline use volumes (central estimate) between 2023-2042

Sector/use	Total use volumes (t)	Average use volumes (t/y)	Share of total
Automotive	2 925	146	76%
Aviation	86	4	2%
Other including imported articles	8 57	43	22%
All uses	**3 867**	**193**	**100%**

Note: Sums may not add up due to rounding.

As a result of the exit of the UK from the EU, EU use volumes for this period are likely overestimated, but it was not possible to exclude the UK from the available data used to derive the baseline volumes.

1.4.2. **Emissions**

It is difficult to estimate total annual emissions from both new and old emission sources. A restriction will only affect future use of DP. It will not reduce emissions from products already in use or, for instance, emissions from waste already deposited in landfills. Total emissions are not usually estimated in restriction proposals, and this has not been done in this restriction proposal either. In the restriction proposal the focus has been to try to estimate future emissions from new use that will be directly affected by the restriction. As a result of that, Figure 6 does not show total emissions from all existing sources but emissions from sources that will be affected by the restriction.

Based on the exposure modelling set out in Section 1.2.5, current emissions were estimated to lie between 7.5 and 23.8 tonnes in 2020. The emission projections for the EU were developed considering the changes in demand for DP over time set out above. The corresponding projected emissions of DP between 2020 and 2042 are shown in Figure 6. The central estimate is shown in green, whilst blue and orange represent the low and high estimate, respectively.

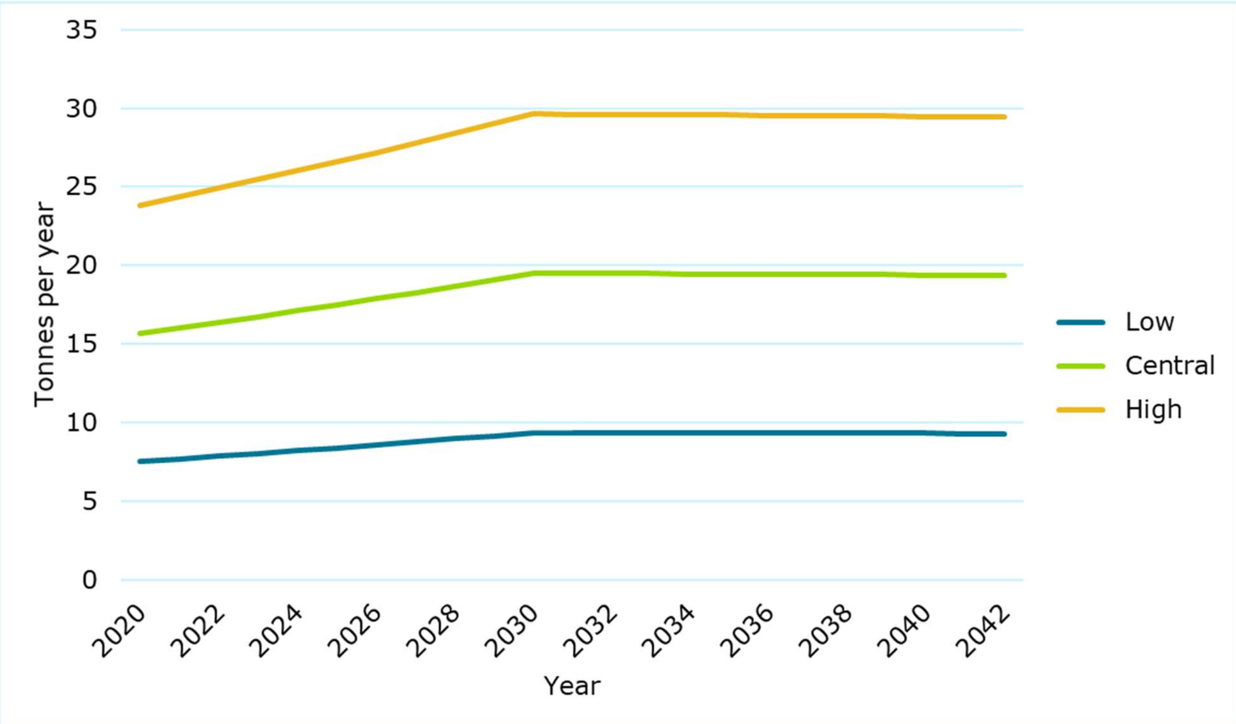

Figure 6. Expected emissions of DP between 2020 and 2042

It should be noted that emissions of DP were derived using a static exposure model, i.e. the model implicitly assumes that emissions occur simultaneously with use. This means that emissions from articles (e.g. used in vehicles, aircrafts and electronics) manufactured prior to 2020 are not included in the estimates, and future emissions from service life, recycling and disposal of articles manufactured in 2020 are allocated to 2020. As an example; the exclusion of emissions resulting from historic uses will lead to an underestimation of emissions in 2020, whilst the inclusion of future emissions from service life and disposal results in an overestimation. It is therefore not possible to conclude whether the derived, current emissions are over- or underestimated. This is, however, not expected to have a large impact on the total baseline emissions between 2023 - 2042, as it is assumed that, in general, DP will continue to be used by the same sectors over the analytical period. A small to moderate overestimation is likely due to the market growth predicted for the early phase of the analytical period.

The use of DP is estimated to result in total emissions of between 182 and 576 tonnes in the EU between 2023 and 2042, with a central estimate of 379 tonnes. This equates to average annual emissions of between 9 and 29 tonnes per year, or **19 tonnes per year under the central estimate**.

Table 13 shows the total emission and average emission (central estimates) breakdown per sector, assuming that the split between the sectors will be the same as in the baseline and remain constant over the analytical period.

Table 13. Total and average baseline emission volumes (central estimate) between 2023-2042

Sector/use	Total emission (tonnes)	Average emission (tonnes/year)	Share of total
Automotive	287	14.3	76%
Aviation	8	0.4	2%
Other including imported articles	84	4.2	22%
All uses	**379**	**19.0**	**100%**

Note: Sums may not add up due to rounding.

2. Impact assessment

2.1. Risk management options

2.1.1. Selection of proposed restriction

Various regulatory risk management options have been assessed to identify the options that are most appropriate to DP. Discarded restriction options as well as other union-wide measures are set out in Annex E.1.2 and Annex E.1.3 respectively, whilst the restriction options included in the socio-economic assessment are set out below. Rejected requests for derogations are summarised in section 2.1.2 and 2.1.3 below.

All considered restriction options (ROs) restrict the manufacture, use and placing on the market of DP in concentrations >0.1% by the end of a transition period of 18 months (i.e. 18 months after Entry into Force). Whilst the strictest restriction option (RO1) does not include any derogations, RO2 and RO3 include derogations of varying scope and length for uses in motor vehicles and aerospace and defence applications. Derogations for spare parts allow for the continued production of such parts for the entire remaining lifetime of relevant aircrafts or vehicles already containing DP.

Under **RO1**, there are no derogations granted, which would mean that all uses of DP must cease by the end of the transition period (EiF + 18 months). This is the only restriction option that will effectively mitigate all new sources of emissions of DP in the EU.

It was deemed appropriate to include a restriction option without derogations that will be effective as soon as possible to ensure minimising potential adverse effects on human health and the environment. This is in line with REACH recital 70 which states that "*… substance for which it is not possible to establish a safe level of exposure, measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with a view to minimising the likelihood of adverse effects.*"

RO2 allows for continued use of DP in the aerospace and defence sector for a limited time period (EiF + 5 years). In addition to this it includes derogations for use in spare parts in the aerospace and defence sector and for motor vehicles. This restriction option follows a similar (but not identical) approach adopted for the REACH restriction on decaBDE.

The aerospace and defence sector is subject to strict regulations, where some parts need rigorous testing and compliance demonstrations in order to be certified for use. New materials or design changes can only be introduced on the aircraft if testing and compliance demonstrations has been approved. The approval will result in the issuance of a Supplemental Type Certificate (STC), change approval or repair approval (ECHA, 2015). This implies that transitioning to alternatives can be more time consuming for the aerospace and defence sector than for some other industries. In the decaBDE REACH restriction, a derogation for use in the aerospace and defence sector was granted for 10 years. Under RO2, a shorter time period (5-year) period is proposed, as information from stakeholders indicated that one or more actors have already started the substitution process. Still, it is not expected that all companies will be able to complete the transition to alternatives within this period, which will induce additional costs.

The main benefits of allowing use in spare parts is that it would avoid premature replacements due to lack of parts. Premature replacements will induce costs to society both in terms of additional resource use to manufacture for instance new vehicles and aircrafts, but also environmental costs like increased energy use and wastes.

This restriction option is considered highly effective, as most of the primary sources of DP in the environment are removed. Emissions from use in aircrafts is limited to a short time-period, and the emissions from spare parts will naturally decline over time as vehicles and aircrafts are replaced with newer models which would not contain DP.

RO3 is the restriction option with the lowest emission reduction capacity. RO3 is still expected to reduce the majority of the emissions of DP, as the proposed derogations are time limited. A 10-year derogation for the use in the aerospace and defence sector and a 5-year derogation for the use in motor vehicles are included in this option, in addition to the use in spare parts.

The motor vehicle industry has in the Call for Evidence and the stakeholder consultation indicated that they will need five years to transition to an alternative, so it is expected that almost all actors will be able to substitute by the end of the transition period for use in motor vehicles (EiF + 5 years). Similarly, it is expected that a 10-year transition period will be sufficient for the aerospace and defence sector to identify and implement alternatives to DP.

These 3 restriction options show the difference in effects on emission and costs. RO1 has the largest effect on emissions and the largest costs. RO3 has the smallest effect on emissions but at the same time smaller cost. All 3 restriction options have been fully calculated. As a result of this it is possible for the committees to consider which RO to choose.

RAC and SEAC box

RAC and SEAC proposed changes to conditions of the restriction proposal presented in Table 14.

The details of these changes are reported in the RAC and SEAC opinion, together with the justification for these changes.

The restriction options are further discussed in Annex E.1. A summary of the considered restriction options is provided in Table 14.

Table 14. Restriction options

	RO1	RO2	RO3
A restriction on the manufacture, use and placing on the market in the EU of Dechlorane Plus (DP) in concentrations > 0.1%, from EiF[13] + 18 months.			
(I) Derogation for aircrafts produced before:	None	EIF + 5 years	EIF + 10 years
(II) Derogation for motor vehicles produced before:	None	None	EIF + 5 years
(III) Derogation for spare parts for existing aircrafts/vehicles during their lifetime	None	<u>Aircrafts:</u> For aircrafts covered by the derogation in RO2 (I) <u>Motor vehicles:</u> For vehicles produced before EIF + 18 months	<u>Aircrafts:</u> For aircrafts covered by the derogation in RO3 (I) <u>Motor vehicles:</u> For vehicles covered by the derogation in RO3 (II)

Note that the provision in RO2 allows continued production of spare parts for the remaining lifetime of any motor vehicle manufactured before EiF + 18 months or aircraft manufactured before EiF + 5 years.

Note that the provision in RO3 allows continued production of spare parts for the remaining lifetime of any motor vehicle manufactured before EiF + 5 years and for any aircraft manufactured before EiF + 10 years.

The analysis in Annex E.8 shows that the inherent uncertainties in the analysis prevent a robust conclusion on proportionality of each restriction scenario. The uncertainties are primarily driven by the lack of details on the technical function(s) of DP, i.e. why DP is needed, potential alternatives and their feasibility as well as the cost of and time required for transitioning to alternatives. As a result of this it was stated, prior to the public consultation, that it is important that more information is submitted to warrant derogations.

The information received in the public consultation and information from existing restrictions points out that a restriction on the use in the aerospace and defence industry (#3353, #3355, #3531) and for medical imaging devices and radiotherapy devices/installations (#3352, #3537) without transition periods will result in significant costs. The same will be the result if derogations for use in spare parts are not granted. Based on the information obtained from the public consultation, the Dossier Submitter has proposed some derogations from the restriction in the Background Document.

As a result of this none of the current ROs are fully in line with the final restriction proposal from the Dossier Submitter. The final proposal is close to RO2. The main difference is that the new proposal also contains: 1) a derogation that allows for continued use of DP in medical imaging devices and radiotherapy devices/installations for limited time periods (EiF + 7 and 10 years respectively, 2) a review clause for these use areas to assess if further derogations will be needed after the end of the proposed derogation periods, 3) derogations for use in

[13] Entry into Force

spare parts in the following use areas; medical imaging devices and radiotherapy devices/installations and marine and garden/forestry engines. These are minor use areas and should, as a result of this, not affect the calculations in the analysis to a significant degree.

A general derogation for the use of DP in motor vehicles has not been proposed. The assessment of alternatives identified several potential alternatives to DP that might be technically feasible. Submissions from the public consultation have shown that the use of DP in vehicles differ between vehicles manufactured in the EU and Japan (#3332, #3527). ACEA informed in the stakeholder consultation that European cars contains between 2 g and 35 g DP per vehicle. Contrary to this information, the Japan Auto Parts Industries Association (JAPIA) submitted information in the public consultation (#3527) indicating that Japanese cars have a higher content of DP per vehicle, i.e. between 20 g – 60 g DP. The Dossier Submitter understands that this difference is primarily due to alternatives (inorganic flame retardants) being readily available and, to some extent, already in use in wire harnesses and tape in the EU.

Not allowing a general derogation for the use of DP in motor vehicles will ensure a high level of emission reductions as this is the main use area representing a significant source of emissions of DP to the environment. It follows therefore that a restriction similar to **RO2 with a few minor adjustments is chosen as the proposed restriction.**

More detailed information on the considered risk management options is provided in Annex E.1.

2.1.2. **Rejected derogation for recycling**

No specific information regarding issues related to recycling of articles containing DP was received during the development phase of the restriction proposal. The Dossier Submitted therefore presumed that recycling activities would not be negatively affected by the proposed restriction. This was confirmed by Plastics Recyclers Europe in the public consultation, where it is stated that a concentration limit of 0.1% will not affect the recycling industry (#3398).

Based on these considerations, derogations for recycled materials containing DP have not been included in the proposed restriction.

2.1.3. **Other rejected derogations**

DP is a very persistent and very bioaccumulative substance (vPvB) and its emissions should therefore be minimised. As explained in Section 2.1.1, the main arguments for the proposed restriction are therefore to minimise emissions, whilst avoiding premature replacements due to lack of spare parts. Several requests for derogations from the proposal for a general restriction on DP in the Annex XV report were submitted by stakeholders during the public consultation. The following requests for derogations were not considered to be in alignment with the abovementioned arguments and have therefore been rejected (further explanations to why they were rejected are provided below):

Motor vehicles, trucks, machines and agricultural equipment:

- 5-7 years transition time for all parts (except PDAP resin) for motor vehicles, industrial trucks and agricultural machinery.
- Permanent derogation for PDAP resin in motor vehicles, industrial trucks and agricultural machinery.
- 5 years transition period for "Type Approved, and vehicles declared in conformity with Machinery Directive".
- 5 years transition time for "engines / powertrains in the marine industry".
- 7 years transition time for garden and outdoor power equipment

Electrical and electronic equipment:

- 3 years transition time for "complicated articles such as electric and electronic equipment".
- ~7-10 years to substitute DP in 'EEE for social infrastructure'.
- Permanent derogation to spare parts for the repair and the reuse of the articles (or electric or electronic equipment) already placed on the EU market before 3 years from entry into force of the regulation.
- 5-year transition period for all EEE articles;9 years transition time for thermoset plastic mixtures and articles intending to meet VDE Group 1 CTI requirement coupled with UL Class B and/or UL Class F.
- 20 years transition time for spare parts for thermoset plastic mixtures and articles intending to meet VDE Group 1 CTI requirement coupled with UL Class B and/or UL Class F

Motor vehicles, trucks, machines and agricultural equipment

It was explained above that a general exemption for uses in motor vehicles is not justified. However, some stakeholders also requested a time-unlimited derogation for a specific material in motor vehicles, namely "PDAP resin". It was stated that this material is used to maintain the integrity of electric components in electric vehicles and therefore is important for the continued electrification of the carpark. It is, however, unclear if this is the only application of PDAP resin. Furthermore, no volume information on this use was provided. It is also noted that the use of DP in PDAP resin has only been reported by Japanese vehicle and machinery manufacturers, whilst it has not been put forward as a use by the equivalent EU-based manufacturers. Without further information on the uses of PDAP resin, corresponding DP volumes and alternatives (e.g. alternatives may exist in the EU) a derogation for this material is not considered justified.

Electrical and electronic equipment:

No information on the volume of DP used in electrical and electronic equipment has been provided, but its frequent mentions in various literature indicate that this use may represent a significant source of emissions of DP to the environment. A number of environmental monitoring studies points at e-waste recycling sites and landfills as sources of release of DP to the environment, see sections 1.2.5.3, 1.2.5.4 and Annex B.9 for details. Considering the broad range of products, and thereby technical requirements, within the electronics industry, it is not unlikely that there will be alternatives at least for some applications. Without further information on the uses, corresponding DP use volumes and potential alternatives to DP in electrical and electronic equipment, a derogation for this use is not considered justified.

Similarly, the specific request for a 20-year derogation for thermoset plastic mixtures and articles is not supported. Indicative estimates of volume DP used for articles intending to meet "*VDE Group 1 CTI requirement coupled with UL Class B requirement and/or UL Class F requirement and/or medical devices*" should be provided alongside more detailed information on the product longevity of these devices, the costs related to substitution of DP and information on alternatives to DP within these use areas.

A general derogation for spare parts for this sector was also rejected, as many electronic devices and electrical equipment has a short lifespan. A derogation for spare parts for specific, long-lived devices could be warranted, however, no information to base such a derogation on has been submitted.

2.2. Alternatives

This chapter identifies and analyses potential alternatives to DP in terms of hazards, technical feasibility, economic feasibility and availability. Section 2.2.1. sets out the functions and applications of DP that were confirmed in the stakeholder consultation, only the uses that are still used are assessed for alternatives.

2.2.1. **Use and Function of Dechlorane Plus**

A review of the literature and input from the consultation indicates that there are two main functions that DP serves: (i) as an additive flame retardant; and (ii) as an extreme pressure (EP) additive in greases.

In applications where DP is used as a flame retardant, the substances functions as an additive i.e., it is not chemically bound to the material (see Annex A.2.2. for more information). DP is most commonly added to a polymer matrix during the manufacturing process. The overall function of DP is to slow the ignition and spread of fire in the materials to which it is applied. In other applications, DP functions as an EP additive in greases and is primarily used for industrial gear lubricants. The EP additive is temperature-activated (decomposes at high temperature) and reacts with metal ‘asperities’ - tiny irregularities on the metal surface - to form a sacrificial film, thought to be iron chlorinate. In the information gathered from the CfE, the motor vehicle industry indicated an essential use for DP in greases.

There is limited information in the literature on alternatives to DP and no alternatives to DP when used as a flame retardant or an extreme pressure agent were identified through the stakeholder consultation. The conclusions from the analysis of the alternatives are therefore uncertain (see Annex F.2.: Uncertainty).

2.2.2. **Approach for selecting alternatives to Dechlorane Plus**

Potential alternatives to DP 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 alternatives.

The three general steps taken to screen the literature for potential alternative substances to DP were as follows:

- **Step 1**: An initial list of possible alternatives based on a review of existing literature was produced, see Annex E.2.2.2. for more information.
- **Step 2**: The suitability of these alternatives was assessed - again based on a review of existing literature.
- **Step 3**: Hazard criteria of the initial list of alternatives was used to screen out substances that are persistent, bioaccumulative and toxic (PBT) or carcinogenic, mutagenic or toxic for reproduction (CMR) to avoid an instance of regrettable substitution in the selection of alternatives to DP as far as feasible.

Additionally, one last substance, chlorendic anhydride, was added to the shortlist, identified through Velsicol's website (Velsicol, 2020). Velsicol is the sole importer of DP in the EU according to information from stakeholders.

As specific information in the literature relating to alternatives for DP was lacking, the initial list of potential alternatives was taken from a literature review on alternatives to decabromodiphenyl ether (DecaBDE) (ECHA, 2015, RPA, 2014). DecaBDE is a chemical with similar physico-chemical properties to DP, it is used as a flame retardant additive and is marketed as an alternative to DP (POPRC, 2021b). The literature review on alternatives to decaBDE was judged to be the most complete conducted and few new sources of publicly available information have been published on either decaBDE or DP since. Any new literature used in this report was obtained from various manufacturers manuals and/or publicly available databases and pertains to alternatives to DP as a high-pressure lubricant/grease.

2.2.2.1. Initial screening criteria

For a substance to be considered in the initial screening as having a minimum level of technical feasibility, the following criteria based on the approach taken in the decaBDE restriction were applied (ECHA, 2015, RPA, 2014)

1) Substance appears to be suitable for both manufactured article types (Plastics (P) and Coatings (C));

2) Substance appears in at least five literature sources as a potential alternative for use in polymers;

3) Substance appears as potentially suitable for use in coatings, and in the absence of detailed information this includes adhesives and sealants; and

4) If the substance only appears in the literature for one of the two manufactured article types (P or C) but appears in more than **several distinct literature** sources for uses in polymers, it was considered.

Alternatives to DP as an extreme pressure additive in greases were assessed separately. See Annexes section E.2.2.4. Discussion of alternatives to DP as an extreme pressure additive for more details.

2.2.2.2. Initial list of potential alternatives to DP

A list of almost 200 substances from the REACH restriction dossier on decaBDE (ECHA, 2015, RPA, 2014) was used as a starting point for identifying potential alternatives to DP (Step 1). A shortlist of 20 substances (Step 2) were retained after applying the screening criteria described in Section 2.2.2.1 Initial screening criteria. These 20 alternatives to decaBDE have the highest occurrence in the literature (i.e. referred to as suitable alternatives) and as such, represent the most frequently cited of each manufactured article type and are available for use. The complete list of the 20 substances can be found in Table 74 in Section E.2.2.2. in the Annexes. It should be noted that for any one application, the most technically feasible option may not appear in the literature at a high occurrence rate and therefore, it is possible that a suitable alternative was not identified. Conversely, alternatives appearing in this list may be incompatible with some/many DP applications, but this will only be resolved with input from stakeholders.

There are other options that may allow affected actors to move away from DP, without switching to a chemical alternative. Non-chemical alternative techniques are defined as techniques that may be both technical solutions and or changes in product design or construction. Due to a lack of information gathered during the literature review and stakeholder consultation, no alternative techniques were analysed for DP’s use as an EP additive. For alternatives to DP in its function as a flame retardant, intumescent systems, nanocomposites, expandable graphite, smoke suppressants, polymer blends and use of inherently flame-retardant materials were some of the techniques assessed (see E.2.2.5. for details). However, without the precise technical function that the flame retarded materials were providing in specific sectors, it was not possible to fully assess or conclude that non-chemical alternatives could be feasible replacements for DP.

2.2.3. **Assessment of shortlisted alternatives**

Alternative substances can be used in the substitution process at three different levels of the product: (i) the flame retardant additive, (ii) the base material, or (iii) the end-product itself. An alternative can therefore replace either:

(i) the flame retardant additive without changing the base polymer;
(ii) the base polymer with flame retardants and other additives with another material, plastic or non-plastic, and other additives; or
(iii) the product can be replaced by a different product, or the function can be fulfilled by the use of a totally different solution (Danish EPA, 1999, Defra, 2010)

Seven potential alternatives were chosen after the screening described:

Alternatives to DP as a flame retardant:

(i) chlorendic anhydride;

(ii) ammonium polyphosphate;

(iii) aluminium hydroxide;

(iv) ethane-1,2-bis(pentabromophenyl) (EBP);

Alternatives to DP as an extreme pressure additive:

(v) long chain chlorinated paraffins (LCCPs);

(vi) tricresyl phosphate (TCP); and,

(vii) diallyl chlorendate.

The seven alternatives were further assessed in terms of availability, technical and economic feasibility as well as hazards to the environment and human health.

2.2.3.1. Availability of alternatives

REACH registration tonnages for each of the seven alternatives were compared to that of DP in order to indicate how readily available the substances were. Diallyl chlorendate did not have an annual tonnage on the ECHA website for manufacture and/or import and was the only substance judged to be insufficiently available. A submission from the public consultation (#3527) indicates that inorganic flame retardants are readily available and, to some extent, already in use in wire harnesses and tape in the EU.

2.2.3.2. Human Health and Environment Risks related to alternatives

Since DP has been identified as a vPvB substance, quantitative risk characterisation is not appropriate nor meaningful. Instead, a comparison of hazard properties has been used as an indicator of potential regretful substitutions. Short-listed alternatives were assessed qualitatively based on a comparison of available information on the hazard profile. Refer to Annex E.2.3. for more details.

Ammonium polyphosphate and aluminium hydroxide are of low concern to the environment and for human health. Chlorendic anhydride is of slight concern due to the harmonised classification of Skin Irrit. 2, Eye Irrit. 2 and STOT SE 3 hazards; further PBT concerns are outlined in Annex E.2.3.1.3.

Although EBP's hazard profile is unclear and still under investigation due to suspected PBT/vPvB concern, it has a high aggregated tonnage and wide dispersive use, hence, it may be a regrettable substitute. LCCPs, do not meet the PBT/vPvB criteria, but can be regarded as persistent in the environment. Additionally, in some cases, LCCPs may contain significant amounts of medium-chained chloroparaffins (MCCP) which meet the PBT/vPvB criteria. Hence LCCP would be a regrettable substitute to DP. TCP has no harmonised classification but notified classifications as Repr. 2, which could mean that TCP is a regrettable substitute. Moreover, there is currently a substance evaluation being carried out on Isopropylated Triaryl Phosphate, which is a similar substance to TCP, based on endocrine disruptor and suspected PBT/vPvB concerns (ECHA, 2020c). Diallyl chlorendate is also not considered a suitable alternative even though there is no experimental data available. The substance is predicted as 'likely' to meet criteria for category 1A or 1B carcinogenicity, mutagenicity, or reproductive toxicity.

2.2.3.3. Technical and Economic feasibility of alternatives

The assessment of economic feasibility is limited to changes in recurring costs based on changes in loading (% of substance required to deliver required affect) and price. Due to a lack of available information, it was not possible to factor any other cost parameters. Refer to Annex E.2.3. for more details.

Ammonium polyphosphate, aluminium hydroxide, LCCPs and EBP are all technically and economically feasible alternatives to DP. EBP notably requires similar loading percentages to DP but with a considerably lower price, while aluminium hydroxide is also considerably cheaper than DP, it has a loading factor approximately 3 times that of DP.

Conversely, chlorendic anhydride– which is technically feasible for some of the uses of DP – is not considered economically feasible. Although TCP and diallyl chlorendate are also technically feasible alternatives, their economic feasibility is unknown and so cannot be positively compared to the other alternatives.

2.2.3.4. Conclusions on the shortlisted alternatives

The assessment of alternatives indicates that there are three potentially suitable alternatives for DP when used as a flame retardant – ammonium polyphosphate, aluminium hydroxide and EBP. It is noted that EBP might be a regrettable substitute due to the substance being a suspected PBT/vPvB and having a high aggregated tonnage and wide dispersive use. Two alternatives were also found to be potentially suitable for DP when used as extreme pressure additives – LCCPs and TCP. It is noted that both alternatives could be regrettable substitutes due to their inherent properties.

There is some uncertainty as to whether these alternatives would be suitable for all applications within the uses set out. Generally, if alternatives that are equally effective and/ or cheaper than DP are available, there is already an economic incentive for companies to switch to these alternatives regardless of whether a restriction is implemented or not. The fact that this has not been observed, may indicate that there are some further technical criteria not fulfilled that cannot be found by looking at the substance properties alone. According to several comments received in the public consultation substitution is complex and time consuming. It can take several years to go through the complete process of evaluation and testing related to introducing an alternative substance. The lack of information about alternatives can be a result of the fact that the process of substitution is ongoing and the final outcome still unsure. Alternatively, or in addition, there could also be other costs (e.g. R&D and investments) not reflected in the cost of chemicals (price x loading) that might outweigh costs savings from purchase of chemical compounds. A third possibility is that some stakeholders have identified feasible alternatives but have not yet completed the substitution process.

The limited number of stakeholders that provided information on availability of alternatives, in the CfE, the stakeholder and public consultation, indicated that there were few suitable alternatives presently available. Only some of the stakeholders provided the specific technical criteria that could be fulfilled by other flame retardants or lubricants. A submission from the public consultation (# 3527) indicates that inorganic flame retardants are readily available and, to some extent, already in use in wire harnesses and tape in the EU. In the absence of more detailed information, it is not possible to reach a robust conclusion on the availability of suitable alternatives for all applications.

Since only the affected actors have the specific information required to fully assess the alternatives to DP, it is considered their responsibility to provide the necessary data to enable the public to carry out a fair assessment. Since few specific technical criteria has been provided, it is assumed that the assessment of alternatives for the functions of DP as a flame retardant and lubricant and its conclusions are valid.

If affected actors do not agree with the conclusions, it is strongly recommended that they provide more information in consultation of the draft SEAC opinion allowing ECHA to revise this analysis and its conclusions.

Table 15 summarises the conclusions from the assessment of alternatives carried out for the confirmed uses of DP. Color-coding has been used to indicate the level of suitability per category (i) Availability, (ii) Hazards, (iii) Technical feasibility, and (iv) Economic feasibility , as well as for the overall suitability. The colours should be interpreted as follows:

Table 15. Summary of assessment of alternatives relative to DP (net changes from the current situation)

Substance	**Availability**	**Hazards**	**Technical feasibility**	**Economic feasibility**	**Overall suitability**
		Alternatives to DP as a flame retardant			
Chlorendic anhydride	Potentially similar	Potentially similar	Potentially similar	Potentially worse	**Potentially worse**
Ammonium polyphosphate	Potentially similar	Clearly better	Potentially similar	Potentially better	**Clearly better**
Aluminium hydroxide	Potentially similar	Clearly better	Potentially similar	Clearly better	**Clearly better**
EBP	Potentially similar	Potentially similar	Potentially similar	Clearly better	**Potentially better**
		Alternatives to DP as an extreme pressure additive			
LCCPs	Potentially similar	Potentially similar	Potentially similar	Unknown	**Potentially similar**
TCP	Potentially similar	Potentially similar	Potentially similar	Unknown	**Potentially similar**
Diallyl chlorendate	Potentially worse	Potentially similar	Potentially similar	Unknown	**Potentially worse**

- **Chlorendic anhydride** is technically feasible for some of the uses of DP (i.e. as coating and epoxy resin applications) but is not considered economically feasible. There is also a concern due to the identified hazards for human health and the environment. Overall, chlorendic anhydride is considered a poor substitute for DP.

- **Ammonium polyphosphate** is a both technically and economically feasible alternative to DP. Based on the available evidence, the substance is of low concern to the environment and for human health. Overall, it is concluded that ammonium polyphosphate is a suitable alternative to DP for flame retardant applications.
- **Aluminium hydroxide** is an economically and technically feasible alternative to DP. Based on the available evidence, the substance is of low concern to the environment and for human health. Overall, it is concluded that aluminium hydroxide is a suitable alternative to DP for flame retardant applications.
- **EBP** is considered a technically feasible alternative, requiring similar loading as DP and with a considerably lower price. It therefore seems to be the most obvious replacement for DP. However, its hazard profile is unclear and still under investigation due to suspected PBT/vPvB concern, high aggregated tonnage and wide dispersive use, hence, it may be a regrettable substitute.
- **LCCPs** are technically feasible alternatives for DP in the function as extreme pressure additives for lubricants and greases. The substance group is also likely economically feasible and available, and thus is a potential alternative for DP for the function as an extreme pressure additive for lubricants and greases. The substance is not a PBT, but it is persistent in the environment. An additional concern is that, in some cases, LCCPs may contain significant amounts of MCCPs which are identified as PBT/vPvBs. In such cases, LCCPs would be a regrettable substitute to DP.
- **TCP** is a technically feasible alternative for DP in the function as a lubricant, but its economic feasibility is unknown. Availability is seemingly not a problem. It does, however, have notified classifications as Repr. 2, which could mean that it is a regrettable substitute.
- **Diallyl chlorendate** is potentially a technically feasible alternative to DP in lubricants/greases. However, due to the lack of information on economic factors and availability, it is not considered a suitable alternative in the short term.

2.3. Restriction scenario(s)

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

Based on limited information from the stakeholder consultation on the most likely responses of companies using DP, the following four behavioural options are deemed to be most plausible:

- Switch to an alternative, resulting in transfer of market shares between EU actors (to the benefit of companies switching first);
- Temporarily ceasing parts of the production until an alternative is found;
- Relocation of production activities to non-EU countries (if the company has non-EU customers); and
- Permanently ceasing parts of or all of the production.

The responses are expected to vary between the three restriction scenarios and it is not expected that each downstream user sector will respond in the same way. It is also important to highlight that the assumed responses set out below reflect the share of DP used that falls within each response category, not the share of actors. An illustrative example is set out below:

Actor A and Actor B produce goods containing DP that account for 50% of the market each. Actor A is able to find an alternative in time, whilst actor B is not. When use of DP ceases, Actor A is able to increase its productions and as a result increases its overall market share to 80%, while Actor B is still looking for an alternative. The total response of the market will then be that 80% of the market switch to alternatives, i.e. distributional effects are not quantified as costs or benefits as they cancel each other out.

Behavioural responses expected to be taken by affected actors within the motor vehicle industry, the aerospace and defence sector and other users are shown in Table 16. Limited information was received by stakeholders on the most likely responses of companies using DP. As a result of this the expected behavioural responses are based on expert judgement. The basis for the expert judgement is further elaborated in Annex E.3.

Table 16. Behavioural responses

Behavioural responses	**Share of DP volume**		
	RO1	**RO2**	**RO3**
Automotive industry			
Switch to an alternative, including transfer of market shares between EU actors	50%	50%	95%
Temporarily ceasing parts of production, until an alternative is found	40%	45%	5%
Relocation (requires non-EU customers) and permanently reduced production	10%	5%	0%
Aviation industry			
Switch to an alternative, including transfer of market shares between EU actors	20%	70%	95%
Temporarily ceasing parts of production, until an alternative is found	70%	30%	5%
Relocation (requires non-EU customers) and permanently reduced production	10%	0%	0%
Other uses, including imported articles			
Switch to an alternative, including transfer of market shares between EU actors	100%	100%	100%
Temporarily ceasing parts of production, until an alternative is found	0%	0%	0%
Relocation (requires non-EU customers) and permanently reduced production	0%	0%	0%

Note: Relocation and full closure are grouped, as the impacts to EU society will be the same.

For the purpose of the socio-economic analysis, it is assumed that most actors will not start the substitution process until EiF (in 2023). However, considering that the substance was identified as an SVHC in 2018, recommended for Annex XIV in 2019 (ECHA, 2019c), proposed to be listed as a POP under the Stockholm convention in 2019, and given the recent announcement of the initiation of the restriction process, this may have triggered and accelerated R&D efforts to find an alternative to DP. However, information from stakeholders submitted in the public consultation does not give a clear picture of whether they have started a substitution process or not.

Given the generally high R&D spending in the **motor vehicle industry** – enabling rapid technological changes – and the expected accelerating effect of past regulatory considerations in relation to DP on R&D activities, it is assumed that 50% of the market may be able to substitute before 2025, i.e. by the end of the 18-month transition period. This includes both transition of market shares from companies that started the transition period late and companies that started the process earlier (early movers). By 2028, it is expected that 95% of the market is able to implement alternatives, whilst niche applications (5%) are assumed to need an additional two years, until 2030.

The **aerospace and defence sector** is subject to strict regulations, where some parts need rigorous testing and compliance demonstrations in order to be certified for use. New materials or design changes can only be introduced to the aircraft if testing and compliance demonstrations have been approved. The approval will result in the issuance of a Supplemental Type Certificate (STC), change approval or repair approval (ECHA, 2015). This implies that transitioning to alternatives can be more time consuming for the aerospace and defence sector than for other industries. A small share of actors is, however, assumed to be able to substitute DP by 2025 based on one consulted stakeholder who reported an ongoing substitution process which is expected to be completed within five years. It is therefore assumed that 20% of DP used in the aerospace and defence sector can be substituted with alternatives by 2025. By mid-2028, i.e. after a transition period of 5 years, substitution is expected to be feasible for most actors (70%), and 95% of the market is assumed to be able to use alternatives by 2033. It is expected that substitution will not be possible for some niche applications (5%) until 2035.

No information received in the public consultation indicated that the behavioural responses used for the motor vehicles and aerospace and defence applications are incorrect. The behavioural options set out in Table 16 are therefore expected to be reasonable assumptions for these two use areas. For aerospace and defence applications as well as for motor vehicles, the proposed restriction is identical to that of RO2. The corresponding behavioural responses are therefore expected to be the same as for RO2 (for more details see Annex E.3).

Some actors using DP for electronics, medical devices, marine applications and motorised machinery indicated in the public consultation that they would not be able to substitute by EiF + 18 months. However, because no information on volumes used was provided for these applications, it has not been possible to refine the assumed behavioural responses for the "Other application" category. The assumptions set out in Table 16 will therefore be incorrect for some applications. The potential implications of this are assessed were relevant in subsequent sections.

2.4. Economic impacts

2.4.1. Economic impacts

SEAC box

SEAC acknowledges the challenges of the Dossier Submitter in the assessment of costs. SEAC agrees with the DS assumptions to estimate costs.

The details of the SEAC evaluation are in the SEAC opinion.

A restriction can induce several types of impacts, e.g. substitution costs for industry actors, enforcement costs for public authorities and environmental costs from changes in the amount of greenhouse gases emitted. With respect to a proposed restriction on DP, only (i) substitution costs, and (ii) lost profits could be (partly) quantified based on available information. Enforcement costs have been assessed qualitatively. All costs have been estimated on the basis of a 4% discount rate and an analytical period of 20 years (covering 2023 to 2042). Prices are expressed in 2020 prices. Further details on cost estimates and the methodology underlying their estimation are available in Annex E.4.

Alternatives incorporated in the assessment of impacts have been selected based on the conclusions of the assessment of alternatives, as no information on specific alternatives was provided in the stakeholder consultation nor in the subsequent public consultation

In relation to the use of DP as a flame retardant, the most suitable alternatives are thought to be (i) aluminium hydroxide; (ii) ammonium polyphosphate; and (iii) ethane-1,2-bis pentabromophenyl (EBP) due to considerations regarding hazard, and economic feasibility/availability, respectively. However, EBP’s hazard profile is under investigation due to suspected PBT/vPvB concerns and therefore could be a regrettable substitution (ECHA, 2015, ECHA, 2016b). Information on the price and loading of DP in comparison to these alternatives is provided in Table 17.

Table 17. Available information on the most likely alternatives to DP as a flame retardant

Flame retardant	Market share of DP substituted	Price €/tonne	Loading	Price x loading compared to DP
Dechlorane Plus	-	6 000 - 10 000	17 %	100 %
Aluminium hydroxide	40%	964	65%	40% - 60%
Ammonium polyphosphate	30%	2 675	31%	50% - 80%
Ethane-1,2-bis (pentabromophenyl) (EBP)	30%	5 782	17%	60% - 100%

Note:

- When *Price x Loading vs. DP* is < 100% it is cheaper to use the alternative than using DP, and conversely more expensive if >100%.

- The accurate price for DP was claimed confidential by ADAMA. See Table H10 in Annex H:Confidential information for more precise estimates.

The total costs (per unit of finished material produced) of using DP (or one of its alternatives) is determined by multiplying the price of the substance by the necessary concentration (loading) needed to fulfil the function as a flame retardant. As shown in Table 17, the cost associated with using any of the three alternatives seems to be lower than for DP. As a result, it is assumed that the majority, i.e. 40 %, will choose to replace DP by aluminium hydroxide. While it could be argued that all affected actors would choose the cheapest alternative, it is unlikely that one alternative is technically suitable for all uses.

In order to calculate the change in the cost of chemicals induced by a potential restriction, it is necessary to estimate how much DP will continue to be used and how much is substituted under each restriction scenario. These volume estimates were derived using the behavioural responses set out in Table 16 and the associated timeline for when substitution will happen, as well as information on loading presented in Table 17. Table 18 presents the resulting volumes of DP substituted under each scenario and the corresponding increase in the use of the alternatives.

Note that the reason why the tonnage substituted under RO1 is lower than under RO2 is that RO1 lead to a higher share of relocations, permanent and temporary closures. In the case of relocation or closures, no (immediate) substitution will take place, hence the total volume DP substituted will be reduced. The avoided emissions are higher for RO1 than for RO2 (as shown in Table 20), although the total volumes substituted is slightly lower.

Table 18. DP use substituted (not ceased) and increased use of alternative substances compared to the baseline, in tonnes per year

Substance	RO1	RO2	RO3
Dechlorane Plus	-161	-164	-150
Aluminium hydroxide	253	258	235
Ammonium polyphosphate	90	92	84
Ethane-1,2-bis (pentabromophenyl) (EBP)	50	51	46

Note:

- Negative number indicate a reduction in use compared to the baseline.
- The sum of the volumes of alternatives to DP used will be higher than DP reduction due to the higher loading required to achieve required flame retardancy

The changes in use volumes combined with the difference in the prices of the chemicals translate to cost savings on chemicals, where the cost savings are expected to be €15 million or less for all three scenarios. Due to the price of DP being confidential more accurate estimates cannot be provided in the public sections of the Background document.

Changes in costs for chemicals for the use of DP as lubricant (accounting for 2% of total use volumes of DP) have not been quantified due to a lack of information on necessary concentrations (loading) of identified possible alternatives, i.e. long chain chlorinated paraffins (LCCPs) and tricresylphosphate (TCP). Due to the limited use of DP as an extreme pressure additive in greases/lubricants (2% of total use), this omission of costs is not deemed to be problematic for evaluating the net total costs of different restriction options.

The public consultation confirmed that the restriction will induce one-off costs associated with R&D and testing for motor vehicles. JAPIA (#3527) reported that within the Japanese automotive parts industry, one-off costs could be between €0.7 million to €21 million per company. It is unknown to what extent these costs would be passed on to EU customers.

No information on costs was received by stakeholders within the motor vehicle industry in the EU. Considering that there seems to be available alternatives for the majority of applications of DP within this industry (#3527), the costs will likely be lower for EU-based companies.

No quantitative information was provided on costs of substitution for other uses of DP in the public consultation, but one-off costs are expected to be incurred at least for some applications.

Based on information received in the public consultation it is considered likely that the costs of substitution will outweigh potential cost savings resulting from lower prices of alternative. However, the lack of available information hinders the quantification of potential costs. To avoid bias, the cost savings have been excluded when assessing proportionality of the proposed restriction.

Estimated profit losses focus on the impact of a restriction on the sales of wires and printed circuit boards, and other plastic and rubber parts (accounting for 93% of DP uses according to information provided by stakeholders). Based on Eurostat data (PRODCOM) on turn-over for such products produced for use in the automobile and aerospace and defence sectors and information on gross profit margins from Eurostat (Structural Business Statistics) lost profits of between 6 and 303 million per year (EAV)[14] have been estimated. As shown in Table 19, the profits potentially lost (i.e., at risk) under RO1 and RO2 are substantially higher than those under RO3. This can be explained by the extended transition period for the use of DP in the manufacture of motor vehicles granted under RO3. Under all scenarios, motor vehicles is by far the largest contributor to costs in terms of lost profits.

Profits losses are deemed to be temporary and only occur until the substitution to an alternative has been successfully completed. Due to high uncertainty with respect to profits at risk, knock-on effects, i.e. impacts on profits in other parts of the supply-chain, have not been estimated. The estimated lost profits represent the net societal impact and not distributional effects, i.e. transfer of profits from one company to another, which are accounted for by the behavioural responses. See Annex E.3. and Annex E.4. for more details.

Table 19. Profit at risk, EAV in € million per year

Sector	**RO1**	**RO2**	**RO3**
Automotive	262	167	5
Aviation	41	9	2
Other, including imported articles	0	0	0
Total profits at risk	**303**	**175**	**6**

[14] Equivalent annual values (EAV) represent the equivalent series of equal cash flows over a selected time period (in this case 20-years) with a specified discount rate (in this case 4%).

Note:
- The category *"Other, including imported articles"* represents all uses for which immediate substitution is assumed possible.
- Sums may not add up due to rounding.

Since the profit lost is directly linked to the expected time it takes to transition to alternatives as well as the share of the sales affected, there is a high degree of uncertainty associated with these estimates. Further details on caveats and uncertainties can be found in Annex E.4 and Annex F, respectively.

Box 1 sets out the changes induced by the new information received in the public consultation.

Box 1. Potential profits lost from production halts
New information provided in the public consultation (#3527) indicated that wire harnesses and tape may have alternatives available on the EU market. Wire harnesses, tape and adhesives were reported by ACEA in the stakeholder consultation to comprise 90% of the total volume DP used in the automotive industry. It should, however, be noted that production halts may occur even though alternatives exist for the majority of the volumes DP used, e.g. if DP is used in a critical part of a product. Still, it is considered likely that the potential profits lost for the motor vehicle industry may have been significantly overestimated in the original analysis.

The estimates in **Error! Reference source not found.** for the aerospace and defence sector are considered representative, as no new information that would affect the calculation of profits lost was put forward in the public consultation.

For other applications, which include electronics, marine applications, medical devices and various machinery (e.g. used in gardening, forestry and other industry), potential losses will vary between the uses. For example, no production halts and thereby no associated loss will be associated with medical devices, since the proposed restriction includes a derogation for these. The electronics sector, on the other hand, may experience production halts if alternatives cannot be found by the end of the transition period. Since no information that can be used to estimate profits lost due to production halts has been provided by any of the stakeholders in the "Other applications" category, no estimates could be derived for this use category. It is, however, not unlikely that production halts and associated profit losses will occur for some selected applications within this category.

As explained, there are factors indicating lower profits and some that indicates higher profits than was originally estimated. However, since between 83%-95% of the potential profits lost in the original analysis were associated with the motor vehicle industry, the net loss will likely be lower than that presented in **Error! Reference source not found.**. Due to the strong similarities with RO2, the potential profits will likely be significantly lower than €175 million per year.

Note that the caveats set out E.4.3.2. still applies to the confidence surrounding the use of profits lost as the main indicator for costs for the proposed restriction.

Enforcement costs incurred by public authorities are expected to be limited (and deemed not to be significant in comparison to other costs associated with the proposed restriction), in part as it is deemed possible/feasible to carry out such enforcement activities in parallel with enforcement of existing restrictions (e.g. decaBDE) affecting similar products.

2.5. Human health and environmental impacts

This section draws on Annex E.5 which provides further details on: (i) the benefits of a restriction on DP to the environment and human health, (ii) why emission reductions are used as a proxy for estimating potential environmental benefits and (iii) the methodology used for estimating changes in emissions as a result of the restriction.

In 2018 DP was identified as a substance meeting the criteria of Article 57 (e) as a substance which is very persistent and very bioaccumulative (vPvB), both in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC)1907/2006 (REACH) (ECHA, 2017a), (see Annex B.4.1 for more detail). DP is chemically stable in various environmental compartments with minimal or no abiotic degradation and is very bioaccumulative, which means that environmental stock may increase over time (see Annex B.4.3 for more detail). The substance is widely dispersed in both aquatic and terrestrial food chains, and in top predators, including humans. DP is transferred to the developing fetus during pregnancy via blood, and after delivery via breast feeding. (see Annex B.4.4 and B.9.4 for more details).

The ECHA Guidance for PBT/vPvB assessment (Chapter R.11) (ECHA, 2017e) states: "Experience with PBT/vPvB substances has shown that they can give rise to specific concerns that may arise due to their potential to accumulate in parts of the environment and

- that the effects of such accumulation are unpredictable in the long-term;
- such accumulation is in practice difficult to reverse as cessation of emission will not necessarily result in a reduction in substance concentration."

The toxicity of DP has not yet been thoroughly investigated, in particular with respect to effects upon long-term exposure (ECHA, 2017c). The Dossier Submitter notes that potential adverse effects/toxicity of DP are currently discussed under the Stockholm Convention (UNEP/POPS/POPRC.16/9, Annex I, Decision POPRC-16/1) (POPRC, 2021a). Information on these adverse effects can be found in the draft POPs risk profile for DP (POPRC, 2021b).

The estimated half-lives of DP in soil have been predicted to be 10 years (Zhang et al., 2016), thus for practical purposes the exposure due to continued emissions may be considered irreversible. The very high persistence of the substance will thus lead to an increasing environmental stock and exposure over time if emissions of DP continue. The effects of current emissions may therefore be observed or only become apparent in future generations. Avoiding effects may then be difficult due to the irreversibility of exposure. The main benefits to society from a restriction of DP will thus be the avoidance of these potential transgenerational impacts on the environment and human health in the future, through reductions in emissions and exposure to these substances.

Quantification of impacts is not currently possible for PBTs or vPvB substances, which makes quantification of benefits challenging. However, the potential benefits will be linked to the environmental stock and therefore also to reductions 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 recommended by SEAC (ECHA, 2014), a cost-effectiveness analysis approach was taken, using emission reductions as a proxy for benefits. The advantage of this approach is that the total emission reduction associated with the implementation of a restriction is independent of the timing of the reductions, as long as they fall within the analytical period. As explained in Section 1.4.2., using a static exposure model means that the modelled emissions of DP occurs in the same year as the modelled use of DP. Similarly, the modelled emission reductions will occur simultaneously with the cessation of use. This means that most of the modelled emission reductions will fall within the analytical period, and the total emission reductions are expected to be close to the actual, expected reductions in emission of DP under each restriction scenario.

Determining factors of emission reductions resulting from a restriction on DP are (i) the scope of the restriction, (ii) the length of granted transition periods, and (iii) granted derogations. Estimated emissions under the baseline scenario, set out in detail in Section 1.4.2., and the three assessed restriction options are illustrated in Figure 7, whereby the dark blue line at the top illustrates the baseline scenario, the blue line illustrates emissions under RO1, the green line illustrates RO2 and the orange line illustrates emission under RO3. Estimated emission reductions are set out in Table 20.

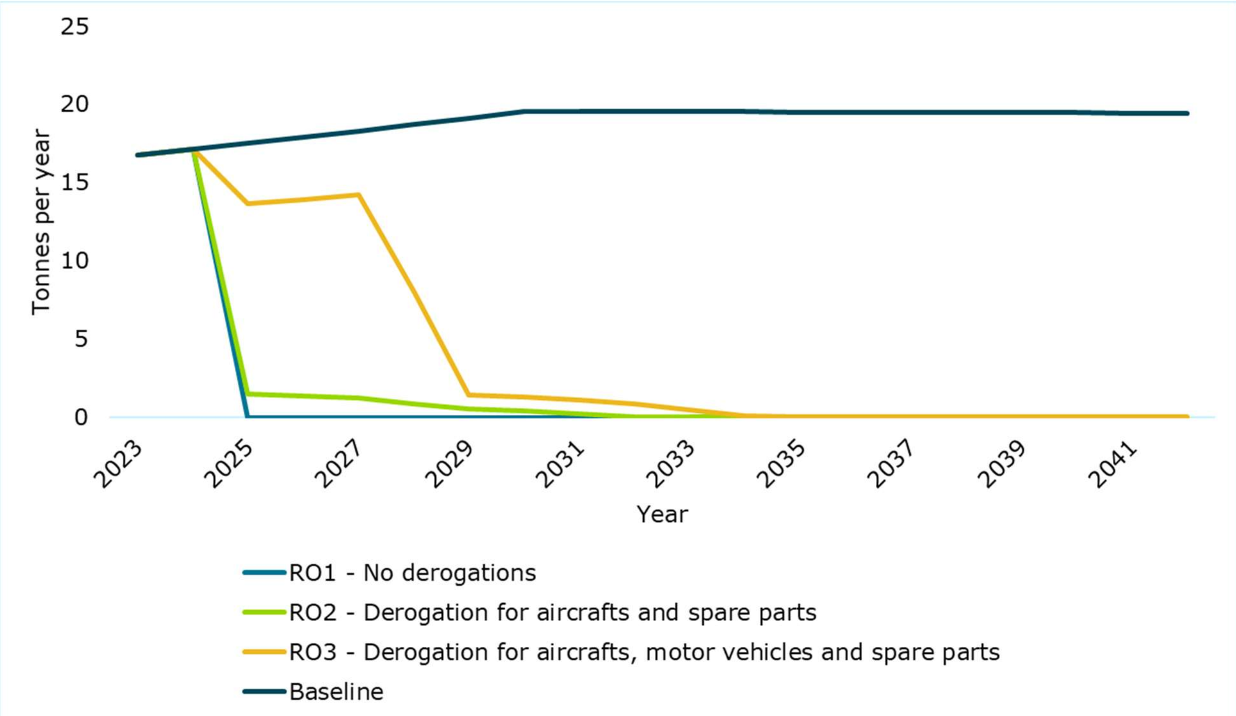

Figure 7. Continued emission of DP under each restriction scenario and the baseline

As shown in Table 20 and Figure 7, all restriction options are fairly effective and result in high emission reduction capacity, ranging from 76% to 91% based on central reduction estimates. Please note that emissions from previously used products containing DP is not included in the baseline and reduction estimates. Figure 7 does only include emissions that will be impacted by the restriction. See also section 1.4.2 Emissions.

Table 20. Emission reduction under each restriction scenario, tonnes per year

Sector/use	Baseline emissions (t/y)	Annual reduction (t/y)		
		RO1	RO2	RO3
Automotive	6.9 - 21.8	6.3 - 19.8	6.2 - 19.5	5 - 15.9
Aviation	0.2 - 0.6	0.2 - 0.6	0.1 - 0.4	0.1 - 0.3
Other including imported articles	2 - 6.4	1.8 - 5.8	1.8 - 5.8	1.8 - 5.8
All uses	**9.1 - 28.8**	**8.3 - 26.2**	**8.1 - 25.8**	**6.9 - 22**
Scenario emission reduction capacity		**91%**	**89%**	**76%**

Note:

- Sums may not add up due to rounding.
- The broad ranges in emissions and emission reductions are a result of the broad use volumes reported by stakeholders. See Table 1 for more details on use volumes.

The emission reductions associated with the proposed restriction will be similar, but not identical to RO2. This is due to the proposed additional derogations for medical imaging and radiography devices and spare parts for the following use areas: medical imaging devices and radiotherapy devices/installations and marine, garden and forestry machinery applications.

Even though accurate estimates cannot be provided, some observations can be made. The difference in emission reductions between RO1 and RO2 for motor vehicles, is 0.1 – 0.3 tonnes per year. This difference is solely due to the derogation for spare parts. Considering that motor vehicles is by far the largest use area, the corresponding use in spare parts is significantly lower than that of motor vehicles. The additional time-limited derogations for spare parts are therefore not expected to notably change the emission reduction capacity compared to RO2 (the difference is likely << 0.1 tonnes/year).

RAC and SEAC box

RAC and SEAC proposed changes to conditions of the restriction related to the derogation of spare parts for motor vehicles.

The details of these changes are reported in the RAC and SEAC opinion, together with the justification for these changes.

Multiple stakeholders within the electric and electronic equipment industry provided comments in the public consultation, and this use of DP was also mentioned in literature sources. Furthermore, information from the public consultation indicated that machinery used for gardening, forestry, construction, and other industrial applications could be a significant use. Combined, these applications are therefore expected to comprise the majority of the DP volume within the "other applications" category. Considering this and the fact that the number of medical imaging and radiography devices will be very small in comparison to electronic devices and machinery, it is reasonable to assume that the time-limited derogation for these specific medical devices will not significantly increase the emissions as compared to RO2.

Overall, it is therefore concluded that the emission reduction capacity of RO2 is reasonably representative for the proposed restriction, i.e. a reduction of around 89% of the total emissions of DP between 2023 and 2042.

2.6. Other impacts, practicability and monitorability[1]

2.6.1. **Other impacts**

This section draws on Annex E.6 which provides further details on the methodology used for assessing social impacts, wider economic impacts and distributional impacts, as well as Annex E.7 evaluating the practicality and monitorability of the proposed restriction options.

Social impacts affect workers, consumers and/or the general public. According to the SEAC guidance (i.e. ECHA, 2008), social impacts incorporate all impacts of a regulatory option that are not covered by the assessment of economic, health and environmental impacts, e.g. changes in employment, working conditions and social security.

Impacts on EU employment are closely linked to what extent there might be any potential production halts, or any permanent reduction in production and relocation of production outside the EU under each restriction scenario. A similar approach as used to estimate profit losses was therefore deployed in order to calculate societal costs from potential EU jobs lost. The number of jobs at risk shown in Table 21 has been estimated based on high-level NACE code employment data from Eurostat - apportioned to affected sectors based on turnover ratios. The relevant share of jobs at risk is assumed to be proportional to the share of profits at risk.

The jobs lost will not be equally distributed across the analytical period but will be concentrated in the period before the majority of the market has switched to alternatives. It has therefore been assumed that the total number of jobs lost are equally distributed between 2025 and 2030. In line with the SEAC guidance (i.e. ECHA, 2008), job losses are considered to be temporary as human resources are assumed to be redistributed. The societal value of lost jobs has been estimated on the basis of an average EU annual gross salary of ~ € 25

000[15], assuming – in line with the SEAC guidance – that the societal value of a lost job is around 2.7 times as high as the annual pre-displacement wage (ECHA, 2016c).

[15] The average gross salary was estimated based on an average EU gross earning of €13.7 per h when uplifted to 2020 (Eurostat, 2018a) 40.3 hours work weeks (Eurostat, 2018b) and 33 holidays per year (European Data Portal, 2016).

Table 21. Average annual number of jobs at risk and their net present value (€ million per year), 2023-2042

Sector	RO1		RO2		RO3	
	Annual number of jobs at risk	Societal value (€ million/ year)	Annual number of jobs at risk	Societal value (€ million/ year)	Annual number of jobs at risk	Societal value (€ million/ year)
Automotive	368	18.6	234	12	7	0.3
Aviation	78	3.9	16	0.8	3	0.2
Other, including imported articles	0	0	0	0	0	0
Total	**446**	**23**	**251**	**13**	**10**	**0.5**

Note:

- Average annual jobs are calculated by dividing the total number of jobs lost by 20 years.
- The actual jobs lost are assumed to happen over the first 5 years 2025 – 2030. This is accounted for when the net present value is calculated.
- Sums may not add up due to rounding. Decimals are only included for values < 1

Box 2 sets out the changes induced by the new information received in the public consultation.

Box 2. Impacts on employment
Impacts on EU employment are closely linked to what extent there might be any potential production halts, or any permanent reduction in production and relocation of production outside the EU under each restriction scenario. The same considerations made for the estimates of potential lost profits from production halts therefore applies (see

LIST OF ACRONYMS AND ABBREVIATIONS

No significant **wider economic impacts** are expected in relation to a restriction on DP. As EU and non-EU suppliers of products to the EU market are equally affected by the restriction no impact on competition is expected for the EU market. Impacts on competition on the global market depend on whether DP will be listed as a Persistent Organic Pollutant (POP) under the Stockholm Convention, which is expected to likely prevent major impacts on competition. No impacts on the recycling industry are expected, as it is deemed that the sector is able to comply with the proposed concentration limit of 0.1% (see Section 2.1.2 for more details).

With respect to **distributional impacts**, the main sectors adversely affected by a restriction on DP are the motor vehicle and aerospace and defence industries. Both sectors are large, with a strong foothold in the EU, and are, as industries, deemed resilient enough to withstand small to moderate changes in the market. Actors expected to be disproportionately affected, especially under RO1 and RO2, are SMEs supplying simple parts or materials that are part of the automotive industry supply chain. These SMEs might not have the financial means for required investments nor to withstand periods of production halts. A restriction might therefore lead to market consolidation to the benefit of larger companies. If the structure in the aerospace and defence sector resembles that of the automobile sector, similar impacts on SMEs can be expected in this sector. The redistribution of market shares from late adopters (companies starting the substitution process late) to early movers is deemed to be the most significant positive distributional impact of all assessed restriction options. The distributional impacts are expected to be more significant the shorter transition periods are and the lower the number of time limited derogations adopted.

2.6.2. **Practicality and monitorability**

Practicability cannot be fully judged due to the inherent uncertainties regarding identification of proper alternatives and techniques to replace use of DP. Generally, it can be concluded that in some cases a longer transition period will increase the practicability, as it increases the probability for industry actors being able to transition to alternatives before the end of the transition period in the most cost-effective manner. As such R03 is deemed to be the most practical restriction option for industry followed by RO2 and then RO1.

The proposed restriction is deemed to be enforceable. Enforcement actions, likely consisting of (i) documentation checks from the supply chain for mixtures and articles imported to as well as produced in the EU and (ii) testing to determine the concentration of DP, are deemed feasible and facilitated by the proposed 0.1% w/w concentration limit coinciding with the concentration limit triggering notification and information requirements under REACH. While no international standard methods for the determination of DP and its isomers exist as of now, reference standards for the determination and quantification are available and precise determination and quantification of DP and its isomers have been reported in almost all environmental matrixes (Cheng et al., 2019, Ganci et al., 2019, Reche et al., 2019), including samples of human serum (Ren et al., 2011), and in consumer products, building materials and waste (Vojta et al., 2017).

The typical Limit of Quantification (LOQ) is significantly lower than the concentration limit proposed in the restriction entry, meaning that the available analytical methods can measure concentrations lower than the restriction entry limit, see Section E.7.2 in the Annexes for details. In conclusion, the available techniques are sensitive enough to produce reliable analytical results for all relevant matrices to enable compliance monitoring and enforcement.

2.7. Proportionality (including comparison of options)

SEAC box

SEAC reached different conclusions than the Dossier Submitter regarding the proportionality of the restriction proposal. To enhance the analysis SEAC undertook a restriction options analysis, cost abatement curve, and compared DP to other restrictions. This aided the consideration of the key uncertainties and information gaps related to the proposed restriction.

The details of the SEAC evaluation are reported in the SEAC opinion, together with the justification for its conclusion on proportionality.

This section draws on Annex E.8 which provides further details on the methodology and results of the proportionality assessment.

As mentioned in Section 2.5., the quantification of adverse impacts of PBT and vPvB substances is not yet possible. This prohibits the use of a traditional cost-benefit analysis for assessing the proportionality of the proposed restriction on DP. In line with SEAC's recommendation ECHA (2014), the cost-effectiveness of the assessed restriction options is compared to a benchmark on the level of costs that are deemed worthwhile for reducing emissions.

Total costs associated with each restriction option are set out in Table 22. Costs for RO1, i.e. a total ban, and RO2, granting derogations for the aerospace and defence sector and spare parts used in aircrafts and vehicles, are much higher than for the least stringent restriction option RO3. Lost profits account, by far, for the largest share of the costs under all three scenarios.

Table 22. Summary of costs associated with the restriction options, 2023 – 2042, € million per year

Type of cost	RO1	RO2	RO3
Cost of substitution, including one-off and recurring costs	> 0	> 0	> 0
Lost profits	< 303	< 175	< 6
Value of jobs at risk	< 23	< 13	< 0.5
All uses	**<320**	**<180**	**<10**

As explained above, it is expected that the costs of substitution are underestimated, whilst lost profits and jobs at risk are expected to be overestimated in the original analysis. The latter two are expected to dominate, hence the net costs of the restriction scenarios are lower. The costs associated with proposed restriction are expected to be close to that of RO2. It is therefore concluded that the costs of the proposed restriction are likely to be less than €180 million per year.

As shown in Table 20, RO1 has the biggest emission reduction capacity and leads, by proxy, to higher environmental benefits. In light of the cost information in Table 22, the main trade-off for society is between the potential environmental benefits associated with reducing emission of DP and the costs associated with potential profit and job losses.

The **cost-effectiveness** of the originally assessed restriction options for DP, detailed in Table 23, ranges from a central estimate of ~ €500 per kg (for RO3) to a central estimate of ~€20 000 per kg for (RO1). More precise estimates as well as cost-effectiveness per sector can be found in Tables H15 and H16 in Annex H: Confidential information.

Table 23. Cost-effectiveness ranges for the assessed restriction options, € per kg

Sector/use	Cost effectiveness €/kg DP		
	RO1	**RO2**	**RO3**

All uses	13 000 – 39 000	8 000 – 23 000	0 – 1 000
Scenario emission reduction capacity	91%	88%	75%

Note:

- Numbers have been rounded to the nearest € 100 to avoid a false impression of precision as well as to ensure confidentiality of some of the input factors used.

Box 3 sets out the changes induced by the new information received in the public consultation.

Box 3. Proportionality

The emission reduction potential of RO1-RO3 has not changed since the original analysis, which means that the cost-effectiveness will still change in proportion with the costs. It can therefore be inferred that the cost-effectiveness estimates of RO1 – RO3 are as follows:

- RO1: < € 20 000 per kg DP emission reduced
- RO2: < € 10 000 per kg DP emission reduced
- RO3: < € 500 per kg DP emission reduced

Since both the cost and emission reductions are expected to be close to that of RO2, it is concluded that the cost-effectiveness of the proposed restriction is likely to be less €10 000 per kg DP reduced.

If alternatives are available for the majority of the volume used and the applications for which alternatives are currently unavailable does not prohibit production of critical parts, then the costs may be significantly lower than €10 000 per kg DP emissions reduced. However, the information available at the present time does not allow a firm conclusion on the exact order of magnitude.

To determine whether the estimated costs are likely to be acceptable for the regulators and the EU society, SEAC recommends using benchmark (range) to compare the cost against. There are currently no agreed benchmarks for PBT and vPvB substances, but a comparator may, for example, be based on previous studies and estimated costs of regulations implemented in the past. IVM (2015) and ECHA (2014) present a comprehensive list of cost-effectiveness estimates for different types of risk reduction measures for a large variety of substances. The overall conclusion drawn in the paper is that the costs below € 1 000 per kg (2015 prices) is generally deemed acceptable whilst costs above €50 000 per kg (2015 prices) is considered disproportionate (2015 prices). It is also stated that there is a "*'grey zone' (with margins [in] the order of magnitude somewhere between EUR 1 000 and EUR 50 000 per kg PBT substituted*" in which cost may be deemed either proportionate or disproportionate. The cost-effectiveness for RO1 and RO2 fall within this "grey zone", whilst RO3 is below the "low cost" benchmark, as shown in Table 23

A past regulation that can serve as a useful comparator is the restriction on decaBDE due to the many similarities of DP and decaBDE, e.g. in terms of uses and sectors involved. The cost per kg reduced emissions of decaBDE was estimated to be 484 €/kg (508 €/kg when uplifted to 2020). In contrast to cost estimates for DP, the cost estimate for decaBDE included only the cost of chemicals, i.e. R&D, investments, profit losses and job losses were not included. When looking at the costs of chemicals alone, a restriction on DP would result in cost savings (as shown in Table 22).

While there is greater uncertainty about the availability of alternatives to DP, the cost-effectiveness of restricting DP could be in the same order of magnitude as that of decaDBE, if all cost elements were considered for both substances. Since the costs of the decaBDE restriction were deemed acceptable by the European Commission, this might be a supporting argument for the acceptability of the costs associated with a restriction on DP.

The Dossier Submitter has received limited information about use of DP, alternatives and on the time and costs associated with the substitution to alternatives from the majority of the stakeholders. As a result of this it is difficult to draw a robust conclusion on proportionality of the three assessed restriction options. Only a limited amount of new information was provided by industry in the public consultation to justify the impacts on their company/sector. This could indicate that the costs are manageable for the main part of the industry.

3. Assumptions, uncertainties and sensitivities

All key variables and input parameters used for the exposure assessment and the socio-economic analysis are set out in Annex F.1: Input parameters and assumptions.

No changes have been made to this section in the Background document after the public consultation. The uncertainties are broadly the same, albeit slightly reduced due to additional information received on uses and use volumes for some applications. The sensitivity analysis has not been updated, but since only minor changes have been made to the analysis, it is believed that the overall conclusion "*uncertainties induced by single input factors are not likely to change the overall conclusions*" is still valid.

3.1. Uncertainty

A number of uncertainties are described in Section F.2. in the annexes. The most important drivers for these uncertainties are associated with the sparse information on:

- Use volumes, both site-specific (local) and EU-wide;
- Fractions on DP released to air, water and soil; and
- Existence of technical and economically feasible alternatives to DP.

Uncertainties in relation to the use volumes are accounted for in the large tonnage band chosen for the analysis. For the fractions on DP released to different environmental compartments, a combination of relevant release factors from OECD Emission Scenario Documents (ESD), industry Specific Environmental Release Categories (SPERCs) and default release factors from ECHA Guidance R16 were used. The feasibility of the identified alternatives could not be investigated in detail, due to lack of information from stakeholders on key functionality and uses. A set of assumptions (shown in Section 2.3.) was made to account for the possibility that alternatives would not necessarily be available for all uses, but these are intrinsically uncertain. This uncertainty could be reduced if more information is received by stakeholders.

3.2. Sensitivity analysis

Input variables that were considered highly uncertain and / or potentially impactful on the final conclusions were, as far as practically feasible, tested in a quantitative sensitivity analysis. The use volumes were identified as a key uncertainty, but these have not been tested in the sensitivity analysis as the uncertainty is already reflected in the broad tonnage band used throughout the analysis. The results from the sensitivity analysis are presented in Annex F.2: Sensitivity analysis, with more precise estimates provided in the confidential Annex H.6.

The sensitivity analysis showed that only a few of the tested parameters have a significant (here "significant" is defined as an absolute value higher than 10%) effect on the cost-effectiveness of the restriction options. The input factor with the highest impact on the cost-effectiveness estimates is the overall sales value associated with manufacture of plastics and wiring for the motor vehicle sector, where percentage variation in the sales value translate almost one for one in the cost-effectiveness estimates. The second largest driver is the corresponding profit margin for the motor vehicle sector. Considering the dominance of the motor vehicle sector in the market for DP, this is not surprising. These results also highlight the uncertainties introduced when using profits as the primary economic cost component. When only substitution costs are estimated, the primary cost drivers will be price and loading of alternatives as compared to the substance to be substituted, for which robust information is (typically) publicly available. Potential profit losses are associated with a higher degree of uncertainty as they will rely heavily on assumptions and modelling choices such as affected products, behavioural responses and inclusion or exclusion of knock-on effects.

Although large uncertainties are induced by the inclusion of profits lost in the cost estimates, the overall conclusions do not change throughout the sensitivity analysis where a change in profit loss of +- 50% was tested. The large interval for the use and emission volumes included in the core analysis encompasses most of the variation seen in the central value in the sensitivity analysis, i.e. most of the sensitivity values falls within the range estimated in the core analysis. Table 24 shows the key results from the sensitivity analysis as well as the low-high range from the core analysis.

Table 24. Summary of key results from the sensitivity analysis

Variation	**RO1**	**RO2**	**RO3**
	Central value ~ 20 000 €/kg	**Central value ~ 10 000 €/kg**	**Central value ~ 500 €/kg**
Total variation in central value (% change)	-42% - 34%	-47% - 38%	-40% - 20%
Total variation in central value (€/kg)	10 000 - 25 000	5 000 - 1 5000	0 - 1 000
Range from the core analysis (Low, High)	13 000 - 39 000	8 000 - 23 000	0 - 1 000

Note:

- Total variation in RO1 and RO2 variation is rounded to nearest 5000 €/kg DP, and RO3 to nearest 500 €/kg DP.
- See Table H17 in Annex H: Confidential information for the full sensitivity analysis, including more precise estimates.

As such, it is concluded that uncertainties induced by single input factors are not likely to change the overall conclusions.

4. Conclusion

DP (covering any of its individual anti- and syn-isomers or any combination thereof) is included in the REACH Candidate List as a Substance of Very High Concern (SVHC) based on its intrinsic properties as very persistent and very bioaccumulative (vPvB). DP is transported over long distances and has frequently been detected in the Arctic. According to REACH Annex I para 6.5, the risk to the environment cannot be adequately controlled for PBT/vPvB substances. There is no safe concentration for these substances, thus a threshold cannot be determined for PBT/vPvB substances. Since DP persists in the environment for a very long time and accumulates in humans and wildlife, effects of current emissions may be observed or only become apparent in future generations. Avoiding effects may then be difficult due to the irreversibility of the exposure. Recital 70 of the REACH Regulation 1907/2006 states that exposure of the environment and humans from SVHC's should be reduced as much as possible. For PBT/vPvB substances a REACH restriction would be based upon minimising the future emissions of the substances to humans and the environment.

DP is used as a flame retardant in adhesives/sealants and polymers. Furthermore, the consultations carried out for the preparation of this dossier indicated that DP is also used as an extreme pressure additive in greases and in electric insulation materials. Use of DP has been confirmed in motor vehicles, aerospace and defence applications, marine applications, electronics and electrical equipment and in various machinery (e.g. gardening, forestry and other industrial machines). Other confirmed, but minor, uses are explosives and fireworks.

There is no manufacture of DP within EU. DP has been imported to EU as a substance, in mixtures and in articles. Data from the previously active REACH registration indicates that the volume of DP placed on the EU market was in the range of 10 – 100 tonnes/year (downgraded from 100 – 1 000 tonnes/year) in October 2020. ECHA recently received a "ceased manufacture" notification from the REACH registrant on 31 May 2021. From the available information under REACH, it is not clear whether manufacture of DP outside the EU is still taking place. Imports of DP in articles into the EU may therefore continue to take place. However, based on information from the stakeholder consultation carried out from April to June 2020, DP is estimated to currently be used in volumes of between 90 and 230 tonnes/year in the EU, with a central estimate of 160 tonnes/year. Motor vehicles seems to be the main user of DP, with an estimated yearly consumption between 81 and 161 tonnes in 2020.

DP is chemically stable in various environmental compartments with minimal or no abiotic degradation and is very bioaccumulative, which means that environmental stock will increase over time if emissions are not controlled. DP is also widely dispersed in both the aquatic and terrestrial food chains, including top predators. It is frequently detected in remote regions which shows that the compound is transported over long distances from point sources and production facilities. DP has already been detected in human blood in studies from Europe, Canada and Asia. Furthermore, it has been shown that DP is transferred to the foetus during pregnancy via blood, and after delivery via breast feeding.

The current emissions of DP in the EU have been estimated to lie between 7.5 and 23.8 tonnes in 2020. The main releases of the substance to the environment are attributable to the waste stages, with dismantling and recycling being responsible for 76% - 80% of the total emissions.

A REACH restriction on use by default also applies to recycled material. No impacts on the recycling industry are estimated, as it is deemed likely that the sector is able to comply with the proposed concentration limit of 0.1%. Furthermore, if DP is listed under the Stockholm Convention, several obligations related to waste handling and material recycling would be imposed on the Parties, so an existing derogation under REACH would thus be problematic. Although, the outcome of the Stockholm Convention process is pending, harmonisation of the regulations should be considered when deciding on the scope of the REACH restriction. Information from the recycling industry received in the public consultation (#3398) confirms the conclusion by the Dossier Submitter that a derogation for this sector is not needed.

The Persistent Organic Pollutants Review Committee (POPRC) assessed the intrinsic properties of DP at their sixteenth meeting in January 2021and then decided to defer its decision on the draft risk profile for DP to its seventeenth meeting. However, the POPRC-16 noted that the information on persistence, bioaccumulation and the potential for long-range environmental transport was conclusive but the Committee was unable to agree that the information on adverse effects was sufficient to reach a conclusion on the risk profile for DP (POPRC, 2021a). The present proposal is coordinated with activities on DP under the Stockholm Convention. An EU restriction will be an important step to reduce the risks from DP within the EU internal market. It will also assist the global regulation in the POPs Convention by analysing the impact in the EU of an equivalent global regulation.

National regulatory actions will not adequately manage the risks of DP. Furthermore, since DP is also imported in articles and is mainly emitted to the environment during the waste stage, the risk reduction effect of an inclusion of DP in Annex XIV to REACH is deemed to be marginal. A REACH restriction is considered to be the most effective risk reducing measure for DP. The proposed regulation will effectively restrict the import of substances, mixtures and articles containing DP. The proposed restriction is expected to reduce around 89% of the emissions of DP to the EU environment over 20 years.

The public consultation indicated that alternatives may be available in the EU for a significant share of the total DP volume used, however, information on specific alternatives was not provided. The alternatives incorporated in the assessment of impacts have therefore been selected based on the conclusions of the assessment of alternatives.

Potential profit losses due to production halts is likely the largest (>95%) contributor to the overall costs. In light of the new information on alternatives, it is believed that the potential profit lost is significantly lower than originally estimated, implying that the total costs will also be lower. The proposed restriction (based on similarities with RO2) will likely induce cost significantly less than €180 million per year. It then follows that the central cost-effectiveness estimate may be significantly less than €10 000 per kg DP emission reduced. The favoured restriction proposes time-limited derogations for aerospace and defence application and medical imaging and radiography devices/installations. This is because the substitution process is more complex in these industries and more time is needed to avoid excessive costs.

The aerospace and defence sector is subject to strict regulations, where some parts need rigorous testing and compliance demonstrations in order to be certified for use. In the decaBDE REACH restriction, a derogation for use in civil and military aircrafts was granted for 10 years. In the proposed restriction, a shorter time period (5-year) is proposed, as early information from stakeholders indicated that one or more actors have already started the substitution process. Additional information was put forward by the industry in the public consultation, explaining that it may not be feasible to substitute within this timeframe for all applications. However, since the applications where the substitution of DP is more challenging were not specified (possibly not known at this stage), a longer derogation for these could not be assessed. The same justification is considered valid for medical imaging and radiography devices/installations. As a result of this, it is proposed that a review clause is included for these uses, allowing an assessment of the need for further derogations at the end of the time-limited derogation.

Information submitted in the public consultation also indicate that time-limited derogations will be needed to avoid excessive costs. The same applies for the proposed derogated uses in spare parts. By allowing these derogations premature replacement, that will induce costs to society in terms of lost profits and the need for additional resource use to manufacture new products and increased waste generation and associated emissions, can be avoided. A general derogation for spare parts for electric and electronic equipment was rejected. Many electronic devices and electrical equipment have a short lifespan. A derogation for spare parts for specific, long-lived devices such as medical imaging and radiography devices/installations is considered warranted. No information to base derogations for other specific uses of electric and electronic equipment has been submitted.

As stated above it is deemed important to implement a restriction option that will be effective as soon as possible to minimise potential adverse effects on human health and the environment. Considering that motor vehicles are by far the largest (70%-90%) user of DP and there seem to be alternatives for a significant share of the volumes used, a general derogation for this use is not considered to be sufficiently justified. As a result of this, RO2 with some minor adjustments (details on this are set out in Section E.1.1.7) is considered the most proportionate restriction option.

The proposed restriction bans all major uses of DP and thereby reduced close to 90% of the emissions, whilst allowing for derogations where excessive costs to society is foreseen.

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