

Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV restriction report 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

**Compiled version prepared by the ECHA Secretariat of RAC's opinion
(adopted 18 March 2022) and SEAC's opinion (adopted 08 June
2022)**

This document is a working document from the Committees for Risk Assessment and Socio-economic Analysis of the European Chemicals Agency (ECHA) intended for internal use only.

It has not been agreed and/or adopted by the Committee. In addition to Committee participants the document may only be disclosed to experts and advisors for the purpose of facilitating the work of the Committees.

Draft date: 08/06/2022

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

18/03/2022

RES-O-0000007082-81-01/F

08/06/2022

RES-O-0000007126-77-01/F

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

**on an Annex XV restriction report proposing restrictions of the manufacture,
placing on the market or use of a substance within the EU**

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s): 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]

EC No.: 236-948-9

CAS No.: 13560-89-9; 135821-74-8; 135821-03-3

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

Norway has submitted a proposal for a restriction together with the justification and background information. The dossier conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <https://echa.europa.eu/restrictions-under-consideration> on **16/06/2021**. Interested parties were invited to submit comments and contributions by **16/12/2021**.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Michael NEUMANN

Co-rapporteur, appointed by RAC: Manuel FACCHIN

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **18/03/2022**.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: João ALEXANDRE

Co-rapporteur, appointed by SEAC: Ida Svostrup PETERSEN

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **16/03/2022**.

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion was published at <https://echa.europa.eu/restrictions-under-consideration> on **17/03/2022**. Interested parties were invited to submit comments on the draft opinion by **16/05/2022**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **08/06/2022**.

The opinion takes into account the comments of interested parties provided in accordance with Article [s 69(6) and]⁵ 71(1) of the REACH Regulation.

The opinion of SEAC was adopted **by consensus**.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Contents

1. OPINION OF RAC AND SEAC	1
1.1. THE OPINION OF RAC	2
1.2. THE OPINION OF SEAC	5
2. SUMMARY OF PROPOSAL AND OPINION.....	6
2.1. Summary of proposal	6
2.2. Summary of opinion	7
2.2.1. RAC opinion summary.....	7
2.2.2. SEAC opinion summary	8
3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC	9
3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK	9
3.1.1. Description of and justification for targeting (scope)	9
3.1.2. Information on hazard(s)	10
3.1.3. Information on emissions and exposures	11
3.1.4. Characterisation of risk(s)	15
3.1.5. Uncertainties in the risk characterisation	16
3.1.6. Evidence whether the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk	16
3.1.7. Evidence if the existing regulatory risk management instruments are not sufficient	17
3.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS.....	18
3.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE	19
3.3.1. Scope including derogations	20
3.3.2. Effectiveness in reducing the identified risk.....	34
3.3.3. Socio-economic impact	38
3.3.3.1. Costs	39
3.3.3.2. Benefits.....	49
3.3.3.3. Other impacts	52
3.3.3.4. Overall proportionality.....	53
3.3.3.5. Uncertainties in the proportionality section	64

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

3.3.4. Practicality, incl. enforceability	65
3.3.4.1. Monitorability	68
3.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC	69
3.4.1. RAC	69
3.4.2. SEAC	71
REFERENCES	72

Tables

Table 1: Summary of emission sources of Dechlorane Plus with lower and upper estimates from the Background Document	13
Table 2: Estimated total EU releases for Dechlorane Plus in 2020 from the Annex B.9 to the Background Document	14
Table 3. Initial restriction options prior to the consultation.....	21
Table 4. Revised restriction options after the consultation.....	22
Table 5. Revised restriction options after the consultation proposed by SEAC	26
Table 6: Revised emission reduction estimates under each restriction scenario after the consultation on the Annex XV restriction report (see Box 8, Annex E.5.3. to the Background Document)	34
Table 7: Annual emission reduction of the different RO compared to the Baseline emissions	37
Table 8. Available information on the most likely alternatives to Dechlorane Plus as a flame retardant.....	40
Table 9. DP use substituted (not ceased) and increased use of alternatives compared to the baseline, tonnes per year	41
Table 10. The expected behavioural responses.....	42
Table 11. Structural Business Statistics and PRODCOM from Eurostat	44
Table 12. Profit at risk, EAV in € million per year	44
Table 13. Emission reduction under each restriction scenario, tonnes per year	50
Table 14. Assessment of job losses across industries	52
Table 15. Net present values of the estimated job losses (2023 – 2042).....	52
Table 16. Summary of costs associated with the restriction options, 2023-2042, Euro million per year	54
Table 17. Cost-effectiveness ranges for the assessed restriction options, € per kg	55
Table 18. Comparison of the cost-effectiveness of the proposed restriction and.....	59

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Table 19. Incremental marginal cost effectiveness analysis.....61

Table 20. Summary of the key results from sensitivity analysis72

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

1. OPINION OF RAC AND SEAC

The proposed wording of the restriction set out below aims to express the intention of the Dossier Submitter. Should a restriction be adopted then the final wording of the entry in Annex XVII of REACH will be decided by the European Commission.

It should be noted that the substance (with a similar scope) has also been submitted by the Dossier Submitter to the Stockholm Convention on Persistent Organic Pollutants (POPs). An EU restriction, if agreed, will be an important step to reduce the risks from Dechlorane Plus within the EU internal market and analysing the impact in the EU of an equivalent global regulation. Therefore, the Commission may need to take into account ongoing actions in the global forum in the decision making on the proposal.

The restriction proposed by the Dossier Submitter is:

Column 1	Column 2
<p>Designation of the substance, of the group of substances or of the mixture</p> <p>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]</p> <p>CAS No 13560-89-9; 135821-74-8; 135821-03-3</p> <p>EC No 236-948-9; -; -</p>	<p>Conditions of restriction</p> <p>1. Shall not be manufactured, or placed on the market as a substance on its own from [18 months after entry into force].</p> <p>2. Shall not, from [18 months after entry into force], be used in the manufacture of, or placed on the market in:</p> <ul style="list-style-type: none"> (a) another substance, as a constituent; (b) a mixture; (c) an article, <p>in a concentration equal to or above 0.1% by weight.</p> <p>3. Paragraph 2 shall not apply to:</p> <ul style="list-style-type: none"> • articles placed on the market for the first time before [18 months after date of entry into force] <p>4. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of:</p> <ul style="list-style-type: none"> • 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]. <p>5. Paragraphs 1 and 2 shall not apply to</p>

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

	<p>manufacture, use and placing on the market of:</p> <ul style="list-style-type: none">• 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] <p>6. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of spare parts for:</p> <ul style="list-style-type: none">• 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] <p>7. The Commission shall review the exemptions in paragraph 4, 5 and 6 and, if appropriate, modify them accordingly.</p>
--	--

*Aerospace and defence applications: All applications of Dechlorane Plus within aerospace and defence.

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

1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction 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 synisomers or any combination thereof** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

demonstrated in the justification supporting this opinion, provided that the conditions are modified, as proposed by RAC.

The restriction proposed by RAC:

Column 1	Column 2
<p>Designation of the substance, of the group of substances or of the mixture</p> <p>1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [12.2.1.1.1^{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]</p> <p>CAS No 13560-89-9; 135821-74-8; 135821-03-3*</p> <p>EC No 236-948-9; -; -</p>	<p>Conditions of restriction</p> <p>1. Shall not be manufactured, or placed on the market as a substance on its own from [18 months after entry into force].</p> <p>2. Shall not, from [18 months after entry into force], be used in the manufacture of, or placed on the market in:</p> <ul style="list-style-type: none"> (a) another substance, as a constituent; (b) a mixture; (c) an article, <p>in a concentration equal to or above 0.1% by weight.</p> <p>3. Paragraph 2 shall not apply to:</p> <ul style="list-style-type: none"> • articles placed on the market for the first time before [18 months after date of entry into force] <p>4. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of:</p> <ul style="list-style-type: none"> • 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]. <p>5. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of:</p> <ul style="list-style-type: none"> • medical imaging applications manufactured before [date of entry into force + 7 years]

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

	<ul style="list-style-type: none">• 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] <p>6. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of spare parts for:</p> <ul style="list-style-type: none">• motor vehicles*** placed on the market for the first time before [18 months after date of entry into force] <p>7. The Commission shall review the exemptions in paragraph 4, 5 and 6 and, if appropriate, modify them accordingly.</p>
--	--

*The numerical identifiers specified in the restriction entry do not constitute a comprehensive record of all relevant numerical identifiers available.

**Aerospace and defence applications: All applications of Dechlorane Plus within aerospace and defence.

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

For simplicity, RAC denotes in this opinion all the substances covered by the restriction proposal with the name "Dechlorane Plus".

With regard to the terms used in the entry above, it is important that the Commission clarifies the legal wording and the definitions of e.g. the terms "motor vehicles", "machinery applications", "radiotherapy devices/installations", and "medical imaging applications". In addition, the FORUM noted that the terms "aerospace" and "marine, garden and forestry machinery applications" require more precise definitions. The inclusion of bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) in Annex I of the Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs)¹ could be used as template, particularly with respect to the approach for identifying the automotive and aviation sectors, and spare parts. However, some amendments will be needed, i.e. DIRECTIVE 2007/46/EC being replaced by REGULATION (EU) 2018/858 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles. Further, medical devices and marine applications

¹ <http://data.europa.eu/eli/reg/2019/1021/oj>

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

may not be covered by the legal definitions of the restriction on decaBDE.

The intention of the Dossier Submitter is to allow spare parts to be placed on the market for an indefinite time i.e. until they are no longer required to repair an article. The FORUM also suggests to phrase the conditions of the restriction in a different way so that the intention of the derogations for spare parts are clearer.

1.2. THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that any of the proposed restriction options on **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 synisomers or any combination thereof could be appropriate Union wide measures to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs, as demonstrated in the justification supporting this opinion. However, there are clear differences between the different restriction options in terms of their marginal cost-effectiveness.

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

Dechlorane Plus is a man-made substance and there are no natural sources. The use volumes may be estimated between 90 and 230 tonnes/year in the EU with a central estimate of 160 tonnes/year, while the automotive industry is considered to be the main user of Dechlorane Plus with an estimated consumption of 81 to 161 tonnes in 2020. Dechlorane Plus is imported as a substance and in articles. It is not manufactured in the EU.

Dechlorane Plus is mainly used as a flame retardant in adhesives, sealants and polymers as well as in a minor use as an extreme pressure additive in greases. The main applications of Dechlorane Plus are in motor vehicles, aerospace and defence, marine, garden and forestry machinery, electrical and electronic equipment (including consumer electronics) and medical devices. The Dossier Submitter considers that alternatives exist, but uncertainties remain whether these alternatives are available and feasible for all uses.

Dechlorane Plus was identified by ECHA as a Substance of Very High Concern (SVHC) already in 2018, because of its very persistent and very bioaccumulative properties (vPvB). No safe concentration for a substance with such intrinsic substance properties can be derived. According to Annex I para 6.5 of REACH², the risk to the environment cannot be adequately controlled for PBT/vPvB substances but must be minimised.

Dechlorane Plus is imported into the EU in articles. It is not manufactured in the EU. Even though there are no natural sources of Dechlorane Plus, it is detected in humans, wildlife and environmental samples globally, including the Arctic and Antarctic. Releases of Dechlorane Plus to the environment are principally attributable to the waste life cycle stages of articles. Humans can be exposed to Dechlorane Plus through drinking water, food and air. The unborn child may ingest Dechlorane Plus via the umbilical cord and via breast milk after it is born.

The Dossier Submitter has concluded that a restriction under REACH is the most appropriate risk management option to address the identified risk and proposes to restrict the manufacture, use and placing on the market of Dechlorane Plus in concentrations >0.1% by the end of a transition period of 18 months. Three restriction options are analysed in the impact assessment. The strictest restriction option (RO1) does not include any derogations, whereas RO2 and RO3 propose derogations of varying scope and length for uses in the aerospace and defence and motor vehicle sectors. After the consultation on the Annex XV report the Dossier Submitter refined the scope of the RO2 restriction option (referred to as RO2plus) to include further sectors of use (such as medical imaging). In addition, derogations for use of Dechlorane Plus in spare parts for aircraft, motor vehicles and other complex objects originally manufactured using Dechlorane Plus are also included in RO2, RO2plus and RO3.

Based on the available information the Dossier Submitter concluded that RO1 would prevent the greatest emissions of Dechlorane Plus in the EU within the shortest time but with the highest costs, whilst RO3 would result in the least disruption to industry but with lowest emission reduction. The Dossier Submitter identified RO2 plus as their preferred restriction option.

This EU restriction would be an important step towards reducing the risks from Dechlorane Plus within the EU internal market while also assisting the global regulation under the United Nations Environment Programme (UNEP), the Stockholm Convention, by analysing the impacts in the EU of an equivalent global regulation.

2.2. Summary of opinion

2.2.1. RAC opinion summary

The scope of the proposed restriction option after the consultation on the Annex XV restriction report ("RO2plus") is clear and sufficiently justified and should cover the traded substance Dechlorane Plus as well as the individual isomers. Any substance containing one of the isomers at concentration levels $\geq 0.1\%$ would be within the scope of the restriction. The substances under the scope of the proposed restriction are denoted commonly below as "Dechlorane Plus".

Based on the hazard assessment of ECHA's Member State Committee (MSC) in 2018, Dechlorane Plus is very persistent and very bioaccumulating (vPvB substance) and has a potential for long-range transport. As per PBT/vPvB substances generally, a quantitative risk characterisation for Dechlorane Plus is not appropriate. Based on the estimates provided in Background Document the emissions to the environment are inevitable under reasonably foreseeable conditions of use leading to ongoing exposures of the environment and humans. The measured data provide supporting evidence of these ongoing exposures. The exposures will remain high or even increase if the releases to the environment are not minimised. Consequently, there is a risk which needs to be addressed. The available emission estimations of the Dossier Submitter can be used as a proxy for risk.

Based on the available information on releases, particularly at the waste life-cycle stage, the currently recommended and implemented operational conditions (OCs) and risk management measures (RMMs) are not effective to control the risks from Dechlorane Plus. Because 'waste dismantling and recycling' is assessed to be the major source of release, and at least landfills are likely to be so for many years to come, measures to decrease releases at the waste stage should be implemented in Europe.

A broad restriction with a short transitional time and without any derogations is the most effective measure to minimise the release of Dechlorane Plus to the environment. However, the difference in the estimated effectiveness of the strictest restriction option RO1, without any derogations, and the restriction option proposed by the Dossier Submitter after the consultation on the Annex XV restriction report (termed "RO2plus") is not significant as the difference is within the range of uncertainties in the release estimates. RO2plus, which includes several targeted derogations and transition periods (e.g. five years for aerospace and defence applications; seven years for medical imaging applications; 10 years for radiotherapy devices/installations and for spare parts for motor vehicles and for marine, garden and forestry machinery applications), is reported to have an effectiveness of 89% of total emissions of Dechlorane Plus abated between 2023 and 2042, relative to baseline, whilst RO1 has a reported effectiveness of 91% emission abatement relative to baseline. RAC concludes that the risk option RO3 with only 76% emission reduction effectiveness is not supported.

RAC concludes in line with the Dossier Submitter that a general exemption for uses in motor vehicles and for use in electrical and electronic equipment is not justified. These uses can be expected to represent a significant source of emissions of Dechlorane Plus into the environment and stakeholders have not provided enough data and information how emissions are or could be minimised from these uses.

RAC concludes that a derogation for the use of Dechlorane Plus in spare parts for wide-dispersive uses in marine, forestry and garden equipment could not be supported based on risk considerations. Whilst acknowledging that they are likely to be a minor contributor to overall releases, it is reasonably foreseeable that these uses would result in releases (particularly at the waste life-cycle stage) and the information on conditions of use and risk management measures provided in the consultation on the Annex XV report was insufficient to conclude that releases (at all relevant lifecycle stages) would be minimised.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

Conversely, RAC concludes that a derogation for medical imaging applications and radiotherapy devices/installations could be supported from a risk perspective as reasonably foreseeable conditions of use and risk management measures could be expected to achieve minimisation of releases (e.g., extended producer responsibility).

RAC notes that future releases associated with derogated uses (i.e. service life, end-of-life and waste stage) must be minimised as far as possible by implementing appropriate operational conditions (OCs) and risk management measures (RMMs). RAC emphasises that all actors benefiting from a derogation should ensure that OCs and RMMs that minimise emissions throughout the lifecycle of Dechlorane Plus are implemented. In particular, a mandatory destruction (incineration) scheme and proper control of emissions from waste management facilities and from landfills (e.g. via air and leachate), should be implemented as complementary risk management options for minimising potential releases from derogated uses.

Less hazardous alternatives appear to be available. However, due to the lack of information, it was not possible for RAC to verify the hazards of identified alternatives.

RAC took note of the final advice (18th November 2021) and the support document (1st March 2022) from the Forum which states that in general the proposed restriction is enforceable. However, RAC acknowledges the comments of the FORUM in relation to the revised conditions of the restriction (1st March 2022). The comments state that in general more exemptions make restrictions more complicated to enforce and that the status of second-hand articles and some of the terms used in the conditions of the restriction should be clarified. The FORUM also recommended that the conditions of the restriction for spare parts is redrafted to ensure that it is readily understood.

RAC is of the opinion that it will be difficult to monitor the effect of the restriction via environmental monitoring alone, due to the vPvB properties of Dechlorane Plus and due to continuous emissions from existing landfills and from end-of-life (waste-stage) of articles currently in use. There is a "stock" of Dechlorane Plus in articles and so there will be a delay (latency) before changes in use are observed as changes in releases and environmental contamination. Consequently, it may only be possible to monitor the effect of the restriction via monitoring of the use volumes of articles placed on the market containing Dechlorane Plus in the future.

The uncertainties do not change the overall conclusion that there is a risk from Dechlorane Plus that is not adequately controlled.

2.2.2. SEAC opinion summary

SEAC has developed its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties, the opinion of RAC, Forum's advice on enforceability as well as other available information as recorded in the Background Document.

SEAC supports the view that any necessary action to address risks associated with Dechlorane Plus be implemented on an EU wide basis, based on the key principles of ensuring a consistent level of protection of human health and the environment across the EU and of maintaining the free movement of goods within the union.

SEAC agrees that the proposed restrictions effectively manage the identified risks. SEAC also agrees with the Dossier Submitter that other risk management options are not as appropriate as a restriction under REACH because of limitations in their scope and effectiveness.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

Due to the PBT/vPvB properties of Dechlorane Plus, the Dossier Submitter considered emissions reductions as proxy for both the risk and the benefits of the proposed restrictions. SEAC agrees with this approach.

The Dossier Submitter used a cost-effectiveness approach to assess and compare the proportionality of the various restriction options. SEAC notes that this is in line with SEAC's recommendations for the impact assessment of restrictions and applications for authorisation for PBT/vPvB substances.

The Dossier Submitter proposes the RO2plus restriction option as the most appropriate option. When considering the overall cost per kg of releases prevented by the different restriction options, SEAC considers that all three restriction options assessed by the Dossier Submitter (RO1, RO2plus and RO3) could be proportionate, depending on what the decision-makers consider an acceptable cost to society for abating emissions of Dechlorane Plus.

RO1 has a higher cost per kg of releases prevented than RO2plus. However, SEAC notes that under RO1 releases are abated sooner than under the other restriction options. Implementing RO3 leads to a significantly lower cost per kg of releases prevented than the other two restriction options (and this cost effectiveness value is within the range of previous restrictions). However, SEAC notes that RO3 is the option that leads to the smallest reduction in emissions over the assessment period and starts the emission reduction latest.

SEAC considers that alongside cost effectiveness estimates it is also important to consider the marginal cost-effectiveness of moving from one restriction option to another. The marginal cost-effectiveness analysis performed by SEAC of the different restriction options shows that the marginal cost per additional kg of Dechlorane Plus abated as a result of going from RO3 to RO2plus is €68 000 per kg, which is considered high. Those of going from RO2plus to RO1 are €467 000 per kg, which is significantly higher still. Meanwhile, the marginal costs per additional kg abated by moving from the baseline to RO3 are €700. Whilst there are no benchmarks for these marginal cost-effectiveness figures, as there are none for cost effectiveness analysis for PBT/vPvB substances in general, they give an indication of the added costs to society of progressively stricter restriction options, and thus of the trade-offs involved when deciding on their appropriateness.

Although the Dossier Submitter does not consider this in greater detail, it is in SEAC's view important to complement the discussion on proportionality with consideration of affordability of the restriction for the industry. It is also important to consider other aspects beyond cost-effectiveness that could affect the appropriateness of the risk management options, for instance the social value of certain applications that are proposed to be exempted under RO2plus and RO3.

SEAC concluded that the proposed restrictions would be practicable and monitorable.

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

3.1.1. Description of and justification for targeting (scope)

Summary of proposal:

In the Annex XV restriction report the Dossier Submitter proposed a restriction comprising total ban of Dechlorane Plus on the manufacture, use and placing on the market of Dechlorane Plus as a substance, a constituent in a substance, a mixture or an article without granting any

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

derogations. Table 14 in the Background Document presents this strictest restriction option RO1 and the two alternatives RO2 and RO3.

After receiving additional information in the consultation on the Annex XV restriction report and undertaking further analysis of the effectiveness, practicality and monitorability of different restriction options the Dossier Submitter revised their preferred restriction option from RO1 to a ban with targeted derogations and transition periods, similar to the assessed RO2 but with some additional elements ("RO2plus") (for details see section 2.1.1.). This restriction option provides significant reduction in Dechlorane Plus emissions and thereby reduces potential adverse effects on human health and environment.

The scope of the proposed restriction covers any of its individual anti- and syn-isomers or any combination thereof. The restriction also covers the individual isomers, therefore any substance containing one of the isomers at concentration levels $\geq 0.1\%$ is covered by the restrictions.

The Background Document describes the effectiveness, practicality and monitorability of a series of different options for the length of the transition periods as well as different options for the derogations included within the scope, which are described in Annex E.1 to the Background Document.

RAC conclusion(s):

RAC concludes that the scope of the proposed restriction (and the discarded restriction options) is clear and sufficiently justified and agrees with the Dossier Submitter that it should cover both the trademark substance Dechlorane Plus™ as well as the individual constituent isomers contained therein. Therefore, any substance containing one of the isomers at concentration levels $\geq 0.1\%$ would be within the scope of the restriction. The length of the transition periods and any derogations granted will influence the amount of risk reduction and consequently the effectiveness of the proposed restriction (see section 3.3.1).

Key elements underpinning the RAC conclusion:

RAC's conclusion is based on the Background Document section 1.2.1 and Annex B.1

The scope of the proposed restriction should cover any substance containing any of individual anti- and syn-isomers present in Dechlorane Plus and any combination thereof.

The scope of the different restriction options assessed (based on different lengths of transitional periods and different options for derogations) are clearly described in Annex E.1 to the Background Document. RAC notes that the opinion making on this restriction proposal contributes to the EU's input into the ongoing POP identification process under the Stockholm Convention.

In the consultation on the Annex XV restriction report, no comments were received regarding the scope (see Annex G.5.). However, few comments received acknowledge the need and supported the intention of this restriction to minimise emissions of Dechlorane Plus into the environment (e.g. comments #3529, #3530, #3353, #3355, #3536).

3.1.2. Information on hazard(s)

Summary of proposal:

The hazard assessment of the Dossier Submitter is based on the fact that Dechlorane Plus is a long-range transported (see Annex B.4.2.3 to the Background Document), very persistent (see Annex B.4.1. to the Background Document) and very bioaccumulative (see Annex B.4.3. to the Background Document) substance. The ECHA Member State Committee (MSC) used a

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

weight-of-evidence approach to identify Dechlorane Plus as a vPvB substance. The potential for long range transport occurs through sorption to particles in the atmosphere as well as in seawater. By sorption to particles reaction rates slow down and the half-life especially in air increases which facilitates the potential for long range transport of Dechlorane Plus adsorbed on particles. Long-range transport to remote regions occurs when atmospheric conditions permit (e.g., during dry periods). The MSC identified Dechlorane Plus as a Substance of Very High Concern in 2018 (see Annex B.4 and Section 6 of the MSC Support Document).

According to Annex I para 6.5 of REACH², the risk to the environment and to human health cannot be adequately controlled for PBT/vPvB substances. No safe concentration, thus no threshold, can be determined for PBT/vPvB substances. Due to these intrinsic substance properties, Dechlorane Plus may cause severe and irreversible adverse effects on the environment and on human health if the releases are not minimised.

RAC conclusion(s):

RAC concludes that based on the hazard assessment of ECHA's Member State Committee (MSC) in 2018, Dechlorane Plus is very persistent and very bioaccumulative (vPvB substance). Based on the assessment of the MSC, Dechlorane Plus has a potential for long-range transport.

Consequently, RAC is of the opinion that an assessment of specific human health hazards of Dechlorane Plus are not needed for the justification of the proposed restriction.

Key elements underpinning the RAC conclusion(s):

The RAC opinion on the hazards of the substances is based on the Background Document Section 1.2 and Annex B.8.

Dechlorane Plus has a combination of intrinsic substance properties, including persistence and bioaccumulation, low water solubility, low volatility, potential for long-range transport and high adsorption potential. The two properties of very high concern are persistence and bioaccumulation, which result in the fact that once Dechlorane Plus has entered the environment, it is very difficult or impossible to remove the exposures. If releases of a vPvB substance are not minimised effectively, increase of the exposures is unavoidable and thereby exceedance of effect levels in near or far future is likely. Avoiding or reducing effects may then be difficult due to the irreversibility of the exposure.

In the consultation on the Annex XV restriction report only one comment was received on the hazard of Dechlorane Plus (see Annex G.5. to the Background Document). The Japan Auto Parts Industries Association (JAPIA) claims in their comment (#3332, #3527) that "*no evidence of adverse effects to human health or the environment has been established for Dechlorane Plus. There is also no indication of adverse effects.*". RAC notes, that no scientific background nor scientific argumentation is provided by JAPIA. None of the received comments refers to the identification of Dechlorane Plus as very persistent and very bioaccumulative substance of very high concern (SVHC) by the MSC in 2018.

3.1.3. Information on emissions and exposures

Summary of proposal:

² For substances satisfying the PBT and vPvB criteria, the manufacturer or importer shall use the information as obtained in Section 5, Step 2 when implementing on its site, and recommending for downstream users, risk management measures which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

The Dossier Submitter states that Dechlorane Plus is widely used in the EU and is imported to the EU as substance and in articles. There is no manufacture of Dechlorane Plus within the EU (see Annex A.1 to the Background Document). There were only two REACH registrations for Dechlorane Plus and both of them are part of a joint registration. Imports of bulk Dechlorane Plus have taken place since at least 2010 at 100 - 1000 tonnes/year. One registrant ceased their activities relating to Dechlorane Plus in December 2017. The other registrant (ADAMA Agriculture BV) downgraded the tonnage band to 10 – 100 tonnes/year in October 2020, before ceasing their activities in May 2021.

According to the REACH registration information, Dechlorane Plus is used as a flame retardant in adhesives/sealants and polymers. Furthermore, a survey carried out by the Dossier Submitter indicated that Dechlorane Plus is used as an extreme pressure additive in greases. In these applications Dechlorane Plus 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. Table 7 in Annex A.2.2. to the Background Document summarises the uses of Dechlorane Plus from public sources.

Dechlorane Plus 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. The automotive industry is assumed to be the main user of Dechlorane Plus, with an estimated annual consumption of 81 to 161 tonnes in 2020 (see Annex A.2.4 to the Background Document).

Dechlorane Plus is detected in humans, wildlife and environmental samples from all around the world, including the Arctic and Antarctic. Dechlorane Plus is transported to locations far from production sites and places of use. Humans are exposed to Dechlorane Plus through drinking water, food and air. The unborn child may be exposed to Dechlorane Plus via the umbilical cord and infants via breast milk. Available monitoring data from the EU gave an indication about elevated levels of Dechlorane Plus in urban areas and near point sources such as wastewater treatment plants as well as in humans and wildlife (see Annex B.9.4.2 to the Background Document). Recent studies detected Dechlorane Plus in terrestrial and marine biota, including birds, reindeer, seals and polar bears. The release of Dechlorane Plus is associated with human activities.

Acknowledging the vPvB properties of Dechlorane Plus (see Annex B.4.1 to the Background Document), any further emissions of Dechlorane Plus to the environment will lead to an increasing exposure to humans and to the environment.

The exposure assessment performed by the Dossier Submitter comprises both estimated and monitoring data. For nine different uses of Dechlorane Plus the environmental releases were estimated based on Environmental Release Categories (ERCs) given in the REACH registered substance factsheet and default release factors for such ERCs (see Annex B.9 to the Background Document). The estimated releases and exposure from Dechlorane Plus concern the following nine specific uses and a tenth use category, collating 'other' remaining releases (see section 1.2.5.2 to the Background Document):

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 Dechlorane Plus over their service life
6. Outdoor use of articles containing Dechlorane Plus over their service life
7. Dismantling and recycling of waste/articles containing Dechlorane Plus
8. Disposal of waste/articles containing Dechlorane Plus by incineration
9. Disposal of waste/articles containing Dechlorane Plus by landfill
10. Other sources

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Information from OECD Emission Scenario Documents and Specific Environmental Release Categories (SPERCs) were also used when relevant to obtain more realistic estimations for amounts of Dechlorane Plus released to the environment. Release estimates are on the basis on information from publicly available sources and information provided by stakeholders during the Call for Evidence.

Table 1 gives an overview of the emission sources with lower and upper estimates for releases of Dechlorane Plus to the environment. The lower and upper estimates were given in the section B.9.3 of the Annex to the Background Document for the different scenarios.

Table 1: Summary of emission sources of Dechlorane Plus with lower and upper estimates from the Background Document

Scenario	Share of total – Low emission scenario	Share of total – High emission scenario	Lower estimate (kg/year)	Upper estimate (kg/year)	Section in the Background Document
Manufacture of substance	0%	0%	-	-	-
Formulation of sealants/ adhesives	0.02%	0.3%	1.5	70.2	Annex B 9.3, Table 22
Industrial use of sealants/ adhesives	1.1%	1.0%	85	240	Annex B 9.3, Table 26
Polymer raw materials handling, compounding and conversion	7.3%	5.9%	549.3	1416.6	Annex B 9.3, Table 30
Formulation of greases	0.1%	0.1%	5	12.5	Annex B 9.3, Table 34
Widespread use of articles over their service life - indoor use	1.1%	0.8%	79.2	202.5	Annex B 9.3, Table 38
Widespread use of articles over their service life - outdoor use	3.8%	3.1%	286	731.2	Annex B 9.3, Table 42
Waste dismantling and recycling	76.0%	80.2%	5720	19125	Annex B 9.3, Table 46
Waste incineration	0.1%	0.1%	9	23	Annex B 9.3, Table 50
Landfill	10.5%	8.5%	792	2023.9	Annex B 9.3, Table 54

Emissions of Dechlorane Plus in the EU were estimated to be 7.5 to 23.8 tonnes for 2020 (see

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Annex B.9.3.11 to the Background Document). Around 80% of the emissions are estimated to be from waste dismantling and recycling. The second largest source is landfills. Overall, the main releases of Dechlorane Plus are attributable to the waste stage.

Table 2: Estimated total EU releases for Dechlorane Plus in 2020 from the Annex B.9 to the Background Document

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%

Table 2 shows the overall release estimates for the EU in 2020 (see Annex B.9 to the Background Document) which demonstrates that emissions are mainly to air (e.g. airborne dust) when compared to the other routes with a share around of 78-82% of the total Dechlorane Plus released to the environment. The 'total' Dechlorane Plus refers to the sum of estimated releases to the air, water, agricultural soil and industrial soil. These include any direct releases and takes also account of the redistribution in the STP for emissions to wastewater.

The publicly available data on manufacture in and import of Dechlorane Plus into the EU is not detailed enough to conclude on any historic trends in the EU market, and no information on future volumes has been found. In addition, there is a "stock" of Dechlorane Plus in articles which means that there can be a delay before changes in use are observed as changes in releases and environmental contamination.

Dechlorane Plus is marketed as an alternative to decaBDE, which means that developments in the market for decaBDE impact the sales of Dechlorane Plus. Although the restriction of decaBDE under the Stockholm Convention entered into force, some countries have registered for exemptions or did not ratify the amendment.

RAC conclusion(s):

RAC concludes that the import (no manufacture takes place in the EU) and uses are clearly identified and described and that they give a good basis for the exposure/emissions assessment. The methodology and assumptions for the emissions assessment are well described and reasonable. The reported results are plausible.

RAC has assessed the sections on environmental monitoring and on exposure in the Background Document and in the Annexes and concludes that Dechlorane Plus is detected worldwide in air, landfill leachate, sludge, soil and sediment and in freshwater, marine and terrestrial food chains and that the highest levels are measured near point sources, such as manufacturing plants and e-waste recycling sites.

Key elements underpinning the RAC conclusion(s):

The RAC Opinion is based on the Background Document section 1.2.5 and Annex B.9.

The Dossier Submitter assessed and described in the Background Document monitoring studies for different environmental matrices and biota at various locations in detail and in an elaborated qualitative way. As Dechlorane Plus is stable in the environmental compartments

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

with minimal or no abiotic degradation and it is very bioaccumulative, the environmental stock will remain high or even increase over time if emissions are not minimised. Monitoring studies indicate that Dechlorane Plus is globally distributed and detected in different environmental matrices and biota at different types of locations, comprising from production sites and recycling facilities to urban and remote areas. A number of environmental monitoring studies at recycling sites and landfills supports the finding from the emission estimation that the waste stage is the most important source of emission of Dechlorane Plus to the environment. Levels of Dechlorane Plus in remote areas are generally lower compared to levels reported near production sites or urban centres. Birds have been identified as biovectors for the transport and deposition of POPs through feather loss or decaying carcasses, representing an additional transport pathway for Dechlorane Plus to remote regions. Dechlorane Plus has also been detected in human blood and breast milk in different regions of the world.

RAC notes that in the Background Document Section 1.4 and Annex D.3.2 it was not possible to exclude and report the UK data separately from the EU data for the baseline emission volumes. Therefore, the EU emissions are likely to be slightly overestimated.

The information received during the consultation on the Annex XV restriction report has led to a minor change in the baseline use volumes with slight increase in the use volumes of motor vehicles and a slight decrease in use volumes in aerospace and defence applications and in the other applications (see Box 2, Annex D to the Background Document). However, the total use (90-230 tonnes/year) has not changed. The baseline emission estimates are based on the total emissions and are therefore not affected by the updated use volumes per sector (see Box 4, Annex D to the Background Document).

RAC was informed that the single REACH registrant *ADAMA Agriculture BV* had an active registration of Dechlorane Plus until May 2021 when they notified a "ceased manufacture" to ECHA. As in the Background Document it is stated that there could be other non-EU importers of Dechlorane Plus in the range of <100 tonnes per year and the emissions are mostly linked to the waste stage, it is unlikely that this will have an impact on the emissions to the environment. From the available information under REACH, it is not clear whether manufacture of Dechlorane Plus outside the EU is still taking place. Imports of Dechlorane Plus in articles into the EU may therefore continue to take place.

During the consultation on the Annex XV restriction report comments were received on the tonnage of Dechlorane Plus used (#3332, #3353 and #3355) supporting the Dossier Submitter's analysis in the Background Document that the Automotive Sector is the main user of Dechlorane Plus (see Annex G.5. to the Background Document). The comments focused on clarifying the tonnages used in the automotive and aviation sector, identifying uses and applications of Dechlorane Plus in the different sectors and reporting the concentrations of Dechlorane Plus in the final products. For the automotive sector it is reported that globally the production volume is about 700 tons per year. The use volume for the aviation sector is expected to be in the range of 1-10 tons per year in the EEA. After the consultation on the Annex XV restriction report the quantitative emission estimates were not revised by the Dossier Submitter.

3.1.4. Characterisation of risk(s)

Summary of proposal:

The Dossier Submitter states under section 1.2.6 to the Background Document that it is neither relevant nor scientifically justified to perform a quantitative risk characterisation for PBT/vPvB substances. This is due to the uncertainties regarding long-term fate and behaviour, exposure and adverse effects. Therefore, the risk of PBT/vPvB substances, such as Dechlorane Plus, to the environment or to humans cannot be adequately addressed in a quantitative way. The overall aim for PBT/vPvB substances is to minimise the emissions and consequently to minimise any exposures to humans and to the environment (Annex I para 6.5 of REACH²).

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

RAC conclusion(s):

RAC concludes, as per PBT/vPvB substances generally, that a quantitative risk characterisation for Dechlorane Plus is not appropriate. Based on the emission estimates provided in Background Document, RAC concludes that emissions to the environment are inevitable under reasonably foreseeable conditions of use leading to ongoing exposures of the environment and humans. The measured data reported by the Dossier Submitter provides supporting evidence of these ongoing exposures (see section 1.2.5.4. to the Background Document). The exposures will remain high or even increase if the releases are not minimised. RAC thereby concludes that there is a risk which needs to be addressed. The available emission estimations of the Dossier Submitter can be used as a proxy for risk.

Key elements underpinning the RAC conclusion(s):

The RAC Opinion is based on the Background Document section 1.2.6 and Annex B.10.

It is not possible to derive a reliable threshold for the effects of PBT/vPvB substances. Therefore, any releases should be regarded as a proxy for risk to the environment and human health. Manufacturer or importers of PBT/vPvB substances should recommend risk management measures for downstream users to minimise exposure and emissions to humans and environment throughout the lifecycle of the substance that results from manufacture or identified uses (Annex I para 6.5 of REACH²). As discussed in the hazards section the properties of Dechlorane Plus, notably its vPvB properties, result in an intrinsic hazard. A continuous and irreversible exposure of the environment and humans may lead to unpredictable long-term adverse effects. A risk characterisation where releases and exposures are regarded as a proxy for a risk to the environment and human health is appropriate. Use of Dechlorane Plus causes releases from all life-cycle stages as summarised in section 3.1.4. Releases of vPvB substances should be minimised to reduce adverse effects. Release minimisation is necessary for Dechlorane Plus in all sectors of use.

In the consultation on the Annex XV restriction report no comments were received on the characterisation of the risk of Dechlorane Plus (see Annex G.5. to the Background Document).

3.1.5. Uncertainties in the risk characterisation

Relevant uncertainties relate to the release factors used for different environmental compartments and uses (see Background Document section 3.1 and Annex F.2). Only a few uses of Dechlorane Plus were verified during the Call for Evidence (i.e. the stakeholder consultation during the Call for Evidence and consultation on the Annex XV restriction report). As there could be additional uses of Dechlorane Plus than reported, volumes associated with the identified uses could be uncertain. RAC notes that, in the absence of specific information, the Dossier Submitter used a combination of appropriate default release factors from ECHA Guidance R.16, OECD Emission Scenario Documents (ESD) and industry Specific Environmental Release Categories (SPERCs).

RAC concludes that no uncertainties exist which would have a major impact on the overall conclusions of the risk characterisation.

3.1.6. Evidence whether the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

No detailed assessment of implemented operational conditions (OCs) and risk management measures (RMMs) was presented in the Background Document. In terms of articles and the release of Dechlorane Plus to the environment over their service lifetimes and their waste

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

stage, there are currently no implemented risk management measures that are effective in reducing the release to the environment (Annex B.9.1.2. to the Background Document).

RAC conclusion(s):

RAC concludes in line with the Dossier Submitter that, based on the available information on releases, particularly at the waste life-cycle stage, the currently recommended and implemented operational conditions (OCs) and risk management measures (RMMs) are not effective to control the risk from Dechlorane Plus.

Key elements underpinning the RAC conclusion(s):

The RAC Opinion is based on the Background Document and Annex A.2.4., B.9.1.2 and H.

Since Dechlorane Plus was identified as SVHC by the MSC due to its vPvB properties in 2018, no emission minimisation efforts have been documented by the REACH registrants (e.g. recommendations of operational conditions (OCs) and risk management measures (RMMs) to downstream users). To RAC, this is a strong indicator that current OCs and RMMs are not effective to control the risk from Dechlorane Plus to the environment and human health.

Irrespective of OCs and RMMs at the use stage – releases from the waste stage are expected to comprise the majority of emissions. In the Background Document section B.9 and E.1.3. other Union-wide legislative options for the waste-stage were described including the SCIP database which was launched at ECHAs website in Mid-September 2021. However, the Dossier Submitter concludes, that these are not effective to control the identified risk.

In the consultation on the Annex XV restriction report one comment from the aviation sector (#3355) was received confirming that each formulation containing Dechlorane Plus is accompanied by a safety data sheet (SDS) in which the manufacturer is bound to describe the formulation's chemical constituents, health and safety hazards, precautions, disposal considerations and other helpful information. Industrial users of formulations containing Dechlorane Plus in the aviation and defence sector follow the information on the SDS and local laws to protect human health and the environment. To RAC it remains unclear if the SDS take the vPvB properties of Dechlorane Plus into account and if the SDS supports the minimisation of emissions also at the end of the life cycle and in the waste stage.

3.1.7. Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

The Dossier Submitter considered national regulatory actions not to be adequate to manage the risk of Dechlorane Plus. Union-wide action is proposed by the Dossier Submitter 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 (Background Document, section 1.3).

A short description of different Union-wide legislative options that may have the potential to influence emissions of Dechlorane Plus to the environment is presented in Annex E.1.3 to the Background Document. These legislative options concern waste management, authorisation, RoHS Directive and Industrial Emissions Directive. A mandatory destruction (incineration) scheme and proper control of emissions via air and leachate from landfills and waste management facilities, could be considered as a risk management option for the waste life-stage.

However, the Dossier Submitter concludes, that these presented options are not considered to have the potential to minimise the emission of Dechlorane Plus, as they are currently not

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

considered to be feasible, are not considered as an appropriate risk management option, or not effective in reducing the risk.

RAC conclusion(s):

RAC considers the data in the Background Document on emissions, exposure and environmental monitoring to demonstrate that existing regulatory risk management instruments are not sufficient to address the risk.

Key elements underpinning the RAC conclusion(s):

The RAC Opinion is based on the Background Document and Annex B.9 and E.1.3.

The available data on emissions and exposure as well as data from environmental monitoring show that current regulatory risk management measures are not sufficient to minimise the releases, exposures and the risk resulting from the use of Dechlorane Plus.

3.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter has concluded that action is required on a Union-wide level. Throughout the EU/EEA, Dechlorane Plus is a flame retardant mainly included in polymeric materials used in motor vehicles, aerospace and defence applications, marine, garden and forestry machinery, electrical and electronic equipment, including consumer electronics and medical devices, as well as extreme pressure additives in lubricants on a small scale. Due to the specific properties of Dechlorane Plus as vPvB substance(s), releases and exposures are considered by the Dossier Submitter as a proxy of an unacceptable risk to the environment.

The Dossier Submitter highlights that exposure to Dechlorane Plus may occur from releases to air and water from, among others, point sources, industrial sites or dismantling plants, and via diffuse emissions during the 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 the soil from dismantling, result in Dechlorane Plus exposure of the air, water, sediment, soil and organisms.

Dechlorane Plus is chemically stable in various environmental compartments with minimal or no abiotic degradation and is also very bioaccumulative, therefore environmental stock may increase over time upon continued releases. As Dechlorane Plus is distributed via air and aquatic environment and has long-range transport potential. As a vPvB substance, its effects will occur far beyond the source of release. Dechlorane Plus can be detected all over the world, even in remote areas as the Arctic.

Local end-of-pipe technologies are insufficient to reduce the releases because releases may occur from point sources at industrial sites or dismantling plants, but also via diffuse sources, as several articles are intended for consumer and professional uses. To justify that those releases cannot be managed by national regulatory activities, the Dossier Submitter argues that products containing Dechlorane Plus, such as cars, aircrafts and electric and electronic equipment are imported, produced, used and transported across the Member States.

The Dossier Submitter therefore concludes that only action on a Union-wide basis would effectively reduce the environmental exposure to Dechlorane Plus in the EU, limit its potential for trans-boundary exposure from EU sources and avoid trade and competition distortions.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

RAC and SEAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection of human health and the environment across the EU and of maintaining the free movement of goods within the Union, RAC and SEAC support the view that action is required on an EU-wide basis to address the risk associated with Dechlorane Plus.

Key elements underpinning the RAC and SEAC conclusion(s):

The RAC Opinion is based on the Background Document section 1.3 and Annex C.

RAC considers that EU-wide measures are needed to reduce the releases of Dechlorane Plus into the environment from their manufacturing, use and placing on the market. The uses of Dechlorane Plus are broad and articles containing Dechlorane Plus are imported into the EU and are placed on the market in all EU member states. Therefore, a variety of emission sources conduces to environmental and human exposure. Emissions can occur at every stage of life cycle but are most linked to the waste stage. Due to its vPvB properties and the potential for long-range transport national regulatory actions are not considered adequate to manage the risk of Dechlorane Plus as different environmental and human monitoring data show ongoing exposure of Dechlorane Plus. Risk management action by reducing emissions from Dechlorane Plus to the environment on an EU wide level is needed to limit the risk for human health and the environment.

SEAC notes that during the opinion-making period, there has been a 'ceased manufacture' notice of the main Dechlorane Plus importer to the European Economic Area. Despite this, SEAC cannot conclude that the substance is not currently used or placed on the market as a substance, in mixtures. It is certainly used in articles throughout the European Union. Therefore, SEAC assumes in its assessment that releases and exposure take place in all EU Member States (EU-MS). Emissions can occur at every stage of life cycle but are most linked to the waste stage. Dechlorane Plus is considered very persistent and mobile, and it's ubiquitous in the environment and humans. It also has the potential for long-range transport.

Exposure to Dechlorane Plus can arise from multiple sources such as dust in workplaces, indoor house dust, food, beverages, and outdoor air and water. Further, the foetus can be exposed due to the transfer of Dechlorane Plus through the placenta, and breastfed children are exposed through the intake of breast milk. RAC concludes that risks to human health and the environment are not adequately controlled.

SEAC agrees with the Dossier Submitter that regulatory measures on a national basis will not adequately manage the risks arising from Dechlorane Plus due to its properties. Additionally, its releases and exposure may take place in all Member States. Therefore, SEAC agrees that action is required on an EU-wide basis in order to avoid such releases into the environment, resulting in long-term human and environmental exposure in the Member States and, at the same time, to facilitate the free movement of goods.

Although SEAC agrees that action is needed on an EU-wide basis, it recognises the challenges to estimating the effectiveness and efficiency of an EU-wide measure in case of a long-range transboundary pollutant. Since emissions outside the EEA may travel inside the EEA, and vice versa, this will affect the final environmental stock and exposure levels in the EEA.

3.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of RAC and SEAC

3.3.1. Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

Due to the hazardous intrinsic substance properties and the associated risk of Dechlorane Plus, the aim of this restriction proposal is to minimise the emissions of Dechlorane Plus in Europe. As Dechlorane Plus was identified as vPvB substance, quantification of impacts and risk are not possible which makes the quantification of benefits and the selection of the most appropriate EU wide measure challenging. The benefits are linked to the minimisation of the environmental and human exposures and so to the minimisation of future emissions.

This proposed restriction and its derogation will only affect future uses and consequently future emissions of Dechlorane Plus. It will not reduce emissions e.g. from waste already deposited in landfills. The Dossier Submitter only estimated emissions from sources that will be affected by the restriction (see Background Document section 1.4.2 Emissions).

RAC conclusion(s):

RAC agrees that the proposed restriction is the most appropriate option to reduce the identified risk of Dechlorane Plus in Europe.

However, RAC concludes that, because 'waste dismantling and recycling' is the major source of release, and at least landfills are likely to be so for many years to come, measures to decrease releases at the waste stage should also be implemented in Europe to minimise releases of Dechlorane Plus, including from articles placed on the market before the implementation of the proposed restriction. The XRF and FTIR techniques (see section 3.3.4.1. "monitorability") might allow the development of a rapid screening method to detect Dechlorane Plus containing articles in waste streams and ensure that they are treated appropriately.

Key elements underpinning the RAC conclusion(s):

The RAC Opinion is based on the Background Document section 2 and Annex E.

Due to the properties of Dechlorane Plus, it persists in the environment and accumulates in human and wildlife. Current emissions will affect the future generations and avoiding effects is difficult due to irreversible environmental contamination. For PBT/vPvB substances reduced annual emissions are the most appropriate measures of the effectiveness and the appropriateness of a restriction in Europe.

A requirement for mandatory destruction (i.e. incineration) at end of life and proper control of emissions via air and leachate from landfills and waste management facilities could be considered as an alternative risk management option for the waste life-stage. However, this option is not considered to be practicable because of the implementation challenges associated with harmonising waste management practices across the EU and the identification of the articles containing Dechlorane Plus (Annex E.1.3.1. to the Background Document).

Justification for the opinion of SEAC

Summary of proposal:

Apart from the proposed restriction RO2plus and the initial restriction options: RO1, RO2 and RO3, the Dossier Submitter also analysed a range of diverse risk management options (RMOs) to identify the most appropriate risk management option to address these risks. RMOs analysed are REACH Authorisation, other existing EU legislation, and POP Regulation.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Table 2 below summarises the different restriction options assessed by the Dossier Submitter in the submitted Annex XV report. Parts of the assessment have now been updated in the Background Document and details of the new restriction options are listed further down.

Table 3. Initial restriction options prior to the consultation

	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 Entry into Force (EiF) + 18 months.			
(I) Derogation for aerospace and defence sector applications 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 aerospace and defence equipment/motor vehicles during their lifetime	None	Aerospace and defence sector: For equipment covered by the derogation in RO2 (I) Motor vehicles: For vehicles produced before EIF + 18 months	Aerospace and defence sector: For equipment covered by the derogation in RO3 (I) Motor vehicles: For vehicles covered by the derogation in RO3 (II)

Restriction options

RO1

This restriction option is a ban of Dechlorane Plus from the EEA, without derogations, 18 months after the entry into force of the restriction. It is deemed by the Dossier Submitter as the most effective restriction option to reduce Dechlorane Plus emissions.

RO2plus

This is an amended version of the RO2 option and similarly to RO1 is a ban of Dechlorane Plus, but foresees derogations with various transition periods for:

- Aerospace and defence (five years after Entry into Force)
- Medical imaging applications (seven years after Entry into Force)
- Radiotherapy devices and installations (10 years after Entry into Force)

Additionally, a derogation for spare parts for:

- Aerospace and defence (five years after Entry into Force)
- Medical imaging (seven years after Entry into Force)
- Radiotherapy applications (10 years after Entry into Force)
- Motor vehicle, marine, garden and forestry machinery (18 months after Entry into

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Force)

RO3

As RO1 and RO2, RO3 is a ban of Dechlorane Plus, but foresees a derogation for aerospace and defence applications, including a transition period of 10 years, and a transition period for motor vehicles of five years after entry into force of the restriction. It also foresees a derogation for spare parts for the lifetime of aircraft and motor vehicles produced before the respective derogation deadlines. It is deemed by the Dossier Submitter as the least effective restriction option to reduce Dechlorane Plus emissions. However, it also has the lowest cost.

Table 4. Revised restriction options after the consultation

	RO1	RO2plus	RO3
A restriction on the manufacture, use and placing on the market in the EU of Dechlorane Plus in concentrations > 0.1%, from Entry into Force (EIF) + 18 months.			
(I) Derogation for aerospace and defence sector applications produced before:	None	EIF + 5 years	EIF + 10 years
(II) Derogation for medical imaging applications produced before:	None	EIF + 7 years	None
(III) Derogation for radiotherapy devices/installations produced before:	None	EIF + 10 years	None
(IV) Derogation for motor vehicles produced before:	None	None	EIF + 5 years
(V) Derogation for spare parts for aerospace and defence equipment/motor vehicles	None	Aerospace and defence sector: For equipment covered by the derogation in RO2plus (I) Aerospace and defence: For applications manufactured before EIF + 5 years Motor vehicles: For vehicles produced before EIF + 18 months	Aerospace and defence sector: For equipment covered by the derogation in RO3 (I) Motor vehicles: For vehicles covered by the derogation in RO3 (IV)
(VI) Derogations for spare parts in other applications		Medical imaging: For applications manufactured before	None

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

		<p>EIF + 7 years</p> <p>Radiotherapy: For applications manufactured before EIF + 10 years</p> <p>Marine, garden and forestry machinery: For applications placed on the market before EIF + 18 months</p>
--	--	--

The Dossier Submitter highlights that Dechlorane Plus is used widely in different sectors and for several uses, with emissions occurring during every life cycle step, including manufacture, industrial use, article service life and mainly in the waste, dismantling and recycling phase.

Furthermore, imported articles constitute relevant potential emission sources that cannot be targeted by any REACH risk management measure other than a restriction. Monitoring data show that, whilst there is no known natural source, Dechlorane Plus is already ubiquitously present in humans, wildlife, and the environment, even in remote regions, and its removal is difficult.

Once released to air, wastewater and industrial soil³, the substance will stay in the environment. The main fraction of the substance entering into sewage treatment plants (STP) will adsorb onto sewage sludge that may subsequently be applied to agricultural land as a fertiliser, and smaller fractions are distributed to air and water. Whilst the Dossier Submitter notes that all restriction options would reduce emissions, RO1 would reduce the greatest emissions, as it does not contain any of the derogations or sector specific transitional periods included in other restriction options; therefore, emission abatement occurs most rapidly under this option.

Taking into consideration the information provided during the consultation on the Annex XV report, the Dossier Submitter revised the proposed restriction to extend the transitional periods for specific medical devices, aerospace and defence uses and include derogations for the production of spare parts for several types of articles. The revised restriction option is similar to RO2 (and is hereafter referred to as RO2plus) and comprises additional derogations for medical imaging applications, radiotherapy devices and/or installations, and respective spare parts, as well as spare parts in marine, garden and forestry machinery applications (detailed in Table 4).

The Dossier Submitter concluded that the information from interested parties submitted in the consultation on the Annex XV report does not provide sufficient information to support general derogations for motor vehicles and electric and electronic equipment. Also, a general derogation for electric and electronic equipment spare parts is deemed not justified due to the short life span of many of those articles. Additionally, no information was submitted to

³ The soil surrounding industrial sites.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

justify a derogation for specific long-lived electric and electronic equipment.

A derogation for recycled materials was not justified based on information available for the Annex XV report. This position is retained by the Dossier Submitter after the consultation on the Annex XV report.

Taking the non-restriction scenario as the baseline, a reduction of 91%/year in Dechlorane Plus emissions in EU is estimated with RO1, 89%/year with the RO2plus and 76%/year with RO3, during the period of analysis of 20 years.

In the Dossier Submitter's view, although some existing or proposed EU legislation would have an impact on the risk management of certain sectors, these RMOs were considered as not the quickest or as appropriate to address all of the sectors and products contributing to the identified risk. Therefore, in their view, none of the other risk management measures under consideration would perform similarly.

SEAC conclusion(s):

Choice of risk management option

SEAC agrees that the proposed restriction option (RO2plus) effectively manages the potential risks relating to the different uses and life cycle stages of Dechlorane Plus.

Using a restriction as an EU-wide measure to manage the risks posed by this substance is coherent with the approach taken for other similar substances such as decaBDE⁴. Therefore, SEAC finds this approach useful in terms of consistency of legislation, clarity of the measure to the affected parties, overall practicality, and monitorability.

SEAC therefore agrees with the Dossier Submitter's conclusion that the other risk management options assessed are not as appropriate as a restriction under REACH due to limitations in scope and effectiveness.

The proposed restriction option (RO2plus) covers the placing on the market, current and potential future intentional uses of the substance on its own, in a mixture or in articles. It allows the use of the substance to produce spare parts to extend the life cycle of relevant articles, postponing the waste stage of tonnes of materials, and it proposes different transitional periods for specific sectors with the aim to minimise the impacts in the industry according to the information available at present. Therefore, SEAC recognises that it would be an effective way to reduce the release of the substance into the environment.

The proposed general transitional period seems to be adequate and it is extended by specific derogations where justified.

However, SEAC considers that also including the additional derogations proposed under RO2plus (derogation for medical imaging and radiotherapy devices, including the production of its spare parts) in RO3 could result in RO3 (i.e. RO3plus) also being an appropriate option based on proportionality considerations that are explained in section 3.3.3.4.

SEAC therefore considers that among the different possible REACH restriction options that have been assessed by the Dossier Submitter, all restriction options described above could be appropriate, depending on what the decision makers consider is an acceptable cost to society for abating emissions of Dechlorane Plus. This can only be decided based on policy

⁴<https://echa.europa.eu/pops-legislation>

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

priorities, including the societal value placed on the uses proposed to be derogated.

Scope

Generally, SEAC agrees with the scope as proposed by the Dossier Submitter for reducing releases of Dechlorane Plus.

The substance covered by the proposed restrictions is clearly identified, covering any of its individual anti- and syn-isomers or any combination thereof. The proposed derogations also seem to be clear regarding the time limits and the sectors or types of equipment covered.

The proposed restrictions cover also the individual isomers, therefore any substance containing one of the isomers at concentration levels $\geq 0.1\%$ is covered by the restrictions.

The proposed concentration limit value prevents the intentional use of Dechlorane Plus, minimising emissions, and can be measured by the available analytical methods.

The Dossier Submitter used the consultation on the Annex XV report to refine the scope of the restriction.

Following the Dossier Submitter's assessment of the impacts of time limited derogations they proposed the following derogations:

- aerospace and defence applications, and respective spare parts
- medical imaging applications, radiotherapy devices/installations and spare parts for these articles, and other spare parts
- spare parts for motor vehicles, marine, garden and forestry articles

Similarly, the Dossier Submitter has rejected derogations for:

- motor vehicles
- marine applications
- garden and forestry machinery
- recycling
- a general derogation that covers spare parts all electric and electronic equipment

The derogations foreseen in the proposed restriction (RO2plus) are extensions of transitional periods foreseen for specific sectors or equipment: five years for the aerospace and defence sector, seven years for medical imaging applications and 10 years for radiotherapy devices/installations. The transitional period for these 2 specific categories of medical devices is in line with what the industry claim as the minimum time required to substitute Dechlorane Plus. The transitional period of five years for the aerospace and defence sector is in line with the industry's best-case scenario for substitution. SEAC agrees with Dossier Submitter's analyses of the derogation proposals.

The proposed restriction option includes a derogation to produce spare parts for the lifetime of articles used for applications in aerospace and defence, motor vehicles, marine, garden and forestry machinery, medical imaging and radiotherapy devices/installations, manufactured before the end of the respective transitional period.

SEAC notes that assuring the repair and maintenance of articles placed on the market before the respective transitional period guarantees a longer lifetime for complex articles - such as aircraft, motor vehicles and some electric and electronic equipment - and avoids several tons of diverse materials being discarded as waste prematurely and therefore unnecessarily. Therefore, SEAC agrees with the Dossier Submitter's assessment of the impacts used to support proposed derogations for spare parts production since they would promote more

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

sustainable use of the available resources.

SEAC also considers that based on the proportionality considerations described in section 3.3.3.4, the additional time-limited derogation for motor vehicles and longer derogation for the aerospace and defence sector applications could be warranted.

However, as explained in section 3.3.3.4, it is not possible for SEAC to conclude on which restriction option is more appropriate, considering their proportionality to the risk.

Key elements underpinning the SEAC conclusion(s):

Choice of risk management option

The restriction proposal is targeted at reducing the emissions of Dechlorane Plus and under the Dossier Submitter's proposed restriction option (RO2plus), an emission reduction of nearly 89% is achieved. Overall, SEAC agrees that the proposed scope is appropriate to achieve the aim of reducing the emissions to the environment by covering all identified uses and so, sources of release and limiting the concentration to 0.1 % by weight in other substance, in mixtures and in articles.

However, a relevant emission reduction (of nearly 76% per year) can be achieved through RO3, although this restriction option is less effective than RO2plus at reducing emissions. Similarly, if society would prefer to reduce emissions sooner, RO1 would also be an appropriate option because it is the most effective in reducing Dechlorane Plus emissions.

The Dossier Submitter has only updated RO2plus in the Background Document, but it may be assumed that the derogations relating to 'other applications' (medical imaging, radiotherapy and marine, garden and forestry machinery) will also be included in RO3 once those derogations are deemed as justified.

Therefore, SEAC propose the revised restriction options as presented in Table 4. These also include a refinement in the wording for '(VI) Derogations for spare parts in other applications', triggered by comments (#983 and #990) received in the SEAC draft opinion consultation. These comments provided additional information about the specific applications that would require a derogation. Based on that information, SEAC recommends that the wording of the derogation should be revised to ensure that it is aligned more specifically with the uses reported by industry (power equipment only). Additionally, it is recommended that that forestry machinery is specifically included, to avoid ambiguity.

Table 5. Revised restriction options after the consultation proposed by SEAC

	RO1	RO2plus	RO3
A restriction on the manufacture, use and placing on the market in the EU of Dechlorane Plus (DP) in concentrations > 0.1%, from Entry into Force (EIF) + 18 months.			
(I) Derogation for *aerospace and defence sector applications produced before:	None	EIF + 5 years	EIF + 10 years
(II) Derogation for medical imaging applications produced before:	None	EIF + 7 years	EIF + 7 years

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

(III) Derogation for radiotherapy devices/installations produced before:	None	EIF + 10 years	EIF + 10 years
(IV) Derogation for motor vehicles produced before:	None	None	EIF + 5 years
(V) Derogation for spare parts for aerospace and defence equipment/**motor vehicles	None	Aerospace and defence sector: For equipment covered by the derogation in RO2plus (I) Motor vehicles: For vehicles produced before EIF + 18 months	Aerospace and defence sector: For equipment covered by the derogation in RO3 (I) Motor vehicles: For vehicles covered by the derogation in RO3 (IV)
(VI) Derogations for spare parts in other applications		Medical imaging: For applications manufactured before EIF + 7 years Radiotherapy: For applications manufactured before EIF + 10 years Marine, garden and outdoor power equipment including forestry machinery: For applications placed on the market before EIF + 18 months	Medical imaging: For applications manufactured before EIF + 7 years Radiotherapy: For applications manufactured before EIF + 10 years Marine, garden and outdoor power equipment including forestry machinery: For applications placed on the market before EIF + 18 months

*Aerospace and defence applications: All applications of Dechlorane Plus within aerospace and defence sector.

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

SEAC understands that the concentration limit of 0.1 % was proposed to prevent intentional use of the substance. It also enables proper enforcement and guarantees the availability of analytical methods.

Transitional period

The Dossier Submitter suggests a transitional period of 18 months from the Entry into Force of the proposed restriction, based on information provided by the Call for Evidence and the consultation on the Annex XV restriction report. This is considered a sufficient timeframe for the affected parties to phase out the use of the substance, due to alternatives being already

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

widely available, whilst being short enough to reduce the ongoing releases into the environment. Different, transitional periods are considered as derogations for some applications in the restriction options being discussed.

SEAC usually considers that, on the one hand, transitional periods should be long enough to ensure that the producers, importers and users of substances, mixtures and articles are able to realistically comply with the restriction, e.g. in order to allow for required substitution activities and respective adaptations within supply chains. Also, while articles already placed on the market are outside the scope of the proposed restriction, some arrangements with regard to new articles will be necessary in supply chains (negotiation of contracts etc.).

On the other hand, SEAC considers that the transition period should be short enough to avoid future manufacture, import or use of the concerned substance in the EU such that emission reduction can be achieved without unnecessary delay. SEAC also points out that a short transition period would speed up the transition to alternatives in uses where suitable alternatives are already available and add pressure to develop alternatives in the rest of the uses.

Being at the forefront of the development of alternatives is expected to enhance the competitiveness of the EU industry in the longer term. SEAC also highlights that due to the identification of Dechlorane Plus as SVHC since 2018 and prioritisation for it to be included in REACH Annex XIV since 2019, SEAC expects most actors to have been aware of the substitution requirement. Also, the time from the publication of the restriction intention until the date of application will be several years (~1 year for dossier preparation, ~1 year for opinion making, ~½ year for legislative processes) and should be taken into account for the extension of the transition period.

Furthermore, SEAC considers that a transitional period would be useful to enable progress in the availability of and access to (preferably standardised) analytical methods, thereby improving the enforceability and practicality of the restriction, as mentioned in the Forum advice.

Taking into account the above aspects, SEAC considers that a transitional period of 18 months from the Entry into Force will be needed in general, while in the case of specific applications, longer periods are justified as derogations.

Derogation for aerospace and defence applications

The aerospace and defence sector foresees 10 years, or until 2031, to complete the substitution. This time range takes into account some additional time to deal with eventualities, in case the current substitution programmes were not successful in five years. However, the information provided states in general that it has already been possible to switch from Dechlorane Plus to alternatives for many uses, and for others, the substitution of Dechlorane Plus is ongoing, with likely completion before the Entry into Force of the restriction. Therefore, alternatives are available for several uses.

For cases where the substitution might be more complex, the Dossier Submitter suggests a review clause for the transition time in paragraph 7 of the proposed restriction option (RO2plus). That clause intends to highlight that extended derogations can be accessed for specific applications, for which it is not possible to switch to alternatives within the suggested derogation period. This long substitution period of five years is justified by the required legal approvals and demanded testing regimes of the changes introduced by the substitution process.

The comments received in the consultation on the Annex XV restriction report pointed out that unrealistic transition periods will result in additional costs and made clear that the Dechlorane Plus use volumes are lower than initially estimated by the Dossier Submitter.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

SEAC agree with the Dossier Submitter's assessment of the impacts used to support the conclusion that a derogation is justified for the aerospace and defence sector. SEAC considers that the above elements and the available information are sufficient to justify a proposed derogation. SEAC considers that the derogation proposed in RO2plus is justified, and that the longer derogation in RO3, in line with the aerospace and defence sector expectations, could also be considered an appropriate option, due to proportionality concerns, which are detailed in section 3.3.3.4. However, SEAC notes that if the decision-maker places a particularly high value on a more rapid reduction in emissions, a restriction option without these derogations (i.e. RO1) could also be warranted.

Derogation for medical imaging applications and radiotherapy devices/installations

The use of Dechlorane Plus for these applications was not identified in the original Annex XV restriction dossier. The information provided by the industry states that currently, the sector does not know the full range of uses of Dechlorane Plus in medical devices, but its presence is known in several components such as cables and wiring, electrical connectors, printed circuit boards and in other electrical and non-electrical components.

It is expected that the impact of this derogation on the estimation of both RO2plus and RO3 emission reduction capacity would be limited. It is likely that the increase of the emissions would be much below 0.1 tonnes/year. Although there is no available information to allow an accurate estimation of the increase in emissions due to this derogation proposal, SEAC very much agrees with the Dossier Submitter's comparative analyses provided in section 2.5 (page 66) of the Background Document.

It is pointed out that the use of Dechlorane Plus is particularly difficult to substitute in medical imaging and radiotherapy devices since the materials are usually subject to high magnetic fields, extremely low temperatures, high stress, high power and high frequencies. Dechlorane Plus has not been identified in parts designed specifically by the sector, but rather in parts sourced from suppliers which can be generally classified as -off-the-shelf parts. Typical supply chains of imaging or radiotherapy devices are very complex, with 5 to 7 levels, which make the identification of Dechlorane Plus and the subsequent substitution particularly challenging. The extension of the transitional periods of 7 and 10 years are justified by the complexity of the devices and the required legal approvals and demanding testing regimes of the changes introduced by the substitution process.

The comments received in the consultation on the Annex XV restriction report pointed out that unrealistic transition periods will result in additional costs and will impact the availability of the devices for EU healthcare providers. SEAC acknowledges that these devices could have a critical impact on the diagnosis and treatment of severe diseases, and therefore have a high societal value.

SEAC agree with the assessment of this derogation and considers that the above elements and the available information are enough to justify the proposed derogation.

A comment (#989) received during the SEAC draft opinion consultation requested a derogation also for other complex and long-life EEEs. However, as no additional substantial evidence was provided to support the need for a derogation, no changes were made to the opinion.

Derogation for spare parts

Claims for a derogation for spare parts are generally in all sectors of the industry respondents to the consultation on the Annex XV restriction report. The Dossier Submitter's analysis provided in the Background Document is based on the life cycle of the articles, type approval products, the benefits of extending the life of durable products, and the impact on emissions.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

The emissions associated with use in spare parts will naturally decline over time as new models, which will not contain Dechlorane Plus, replace the older models for which spare parts containing Dechlorane Plus are needed.

Based on this, and after also taking into consideration the expected long-service life and type approval requirements for certain complex articles, the Dossier Submitter concluded that the proposed restriction should contain a derogation for spare parts for motor vehicles, marine, garden and forestry machinery, medical imaging devices, radiotherapy devices/installations, aerospace and defence applications.

Information submitted during the SEAC draft opinion consultation (comments #983, #985 and #987) provides estimations of the Dechlorane Plus use volumes in spare parts for marine power equipment, automobiles and motorcycles, respectively. The submitted information highlights the low use volumes, which supports the Dossier Submitter's arguments for supporting these derogations.

However, a general derogation for spare parts for electrical and electronic equipment (EEE) is not considered justified due to the short lifespans of many of the products. Additionally, for specific long-lived electrical and electronic equipment, as seems to be the case for thermoset plastics used in electronics, where a 20-year derogation for spare parts was claimed to be needed in the consultation on the Annex XV restriction report (comment #989). However, the information submitted in the consultation on the Annex XV restriction report was not sufficient to justify it.

During the consultation on the SEAC draft opinion, SEAC requested additional information to further justify the proposed derogation for spare parts for EEE. Two comments were received on this topic, (comment #989 and #984) and although some information on specific long-life EEE was provided, no substantial evidence on low use volume of spare parts of EEE was received to change the SEAC opinion. Furthermore, it is not clear to SEAC why the use of Dechlorane Plus is mandatory, or in other words, why the substitution of Dechlorane Plus-containing parts is particularly complex.

SEAC considers that the additional information provided is not enough to change the conclusion that a general derogation for spare parts for electric and electronic equipment is not warranted.

Applications for which derogations were considered not justified by the Dossier Submitter

Derogation for motor vehicles (with all applications of DP within land-based vehicles) including marine, garden and forestry machinery⁵

Information provided by the automotive industry sector during the consultation on the Annex XV restriction report claimed that five to seven years is needed to complete the substitution of Dechlorane Plus. The identified articles where the substance is present are wire harnesses, adhesive tape, diallyl prepolymer and greases/lubricants. No information is provided on ongoing substitution projects, nor is there any mention of the type of uses where the substitution could be more complex, except for uses involving PDAP⁶ resins. However, the use volumes of Dechlorane Plus used specifically in PDAP resin and the current use volumes of that resin and expected emissions are not provided.

⁵ Changes in the wording for this derogation were triggered by the comments received in the SEAC draft opinion consultation, as explained in the introduction to table 4.

⁶ polydiallyl phthalate

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

SEAC notes that according to the information provided in the consultation on the Annex XV report, the use volume used in Europe is substantially lower than in Japanese companies, which seem to be an indication that, at least for some specific uses, there are alternatives for Dechlorane Plus for automotive applications.

There is a growing trend in the use volumes of PDAP resin due to the growth of electric vehicle production and its heat resistance and electrical properties. This makes the material relevant for next-generation electric vehicles for which there is an increasing demand.

According to the information submitted in the consultation on the Annex XV report, the best timeline scenario for the substitution of DP in these applications is five years. However, no information was originally provided on ongoing efforts to substitute Dechlorane Plus in the PDAP resins formulation.

In the consultation on the SEAC draft opinion additional information was provided, and it is now foreseen that substitution can be achieved in three years. However, no additional details were provided related to the substitution efforts, the requirements for the alternatives, the use volumes of Dechlorane Plus involved, and specific uses for which these resins are essential. Therefore, no change was made to the opinion.

Although a credible substitution plan has been presented for the substitution of Dechlorane Plus in motor vehicles, in SEAC's view, it is likely that not all affected uses will need two years for material development, because some alternatives might already be available for certain players.

Additionally, there is information on the existence of alternatives and their availability for other sectors with high technical requirements. The information provided suggests that several companies already switched to alternatives, although some of them to regrettable alternatives, and it seems that in Europe Dechlorane Plus is rarely used.

During the consultation on the SEAC draft opinion, SEAC requested additional information to further justify the proposed derogations for motor powered vehicles and machinery. Six comments were received requesting derogations for automotive vehicles in general (#982), marine power equipment (#983), automobiles (#985), specifically for motorcycles (#986) and agricultural machinery (#987), and finally for marine, garden and outdoor power equipment (#990). Although some updates on the estimated time for substitution of Dechlorane Plus were received, there was not enough substantial evidence to change the opinion regarding the need for the derogation.

Therefore, SEAC agree with the Dossier Submitter's conclusion that without more detailed information on the specific uses and requirements a general derogation would not be justified for this sector.

However, SEAC considers that including a time-limited derogation proposed under RO3 for motor vehicle sector could be appropriate, due to concerns regarding proportionality that are covered in detail in section 3.3.3.4.

Derogation for electric and electronic equipment

Based on information provided during the consultation on the Annex XV restriction report a transition period of three to five years is requested for electrical and electronic equipment in general, at least seven years for more complex equipment such as "industrial and infrastructure equipment", and nine years transition time for thermoset plastic used in specific electronic components.

SEAC notes that derogations based on the RoHS directive scope are accepted for specific uses where it is deemed that there are no alternatives technically feasible. A maximum of five years for products in categories 1 to 7 - large household appliances, small household

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

appliances, IT and telecommunications equipment, consumer equipment, lighting equipment, electrical and electronic tools, toys, leisure and sports equipment - and a maximum of seven years for articles in categories 8 and 9 - medical devices, monitoring and control instruments including industrial monitoring and control instruments.

However, the provided information does not allow an estimation of the use volumes of Dechlorane Plus in the electric and electronic equipment in general, nor the estimation of the emissions. Additionally, there is a lack of information on the use volumes of the substance involved, availability of alternatives and on the specific uses where substitution is more challenging.

During the consultation on the SEAC draft opinion, SEAC requested additional information to further justify the proposed derogation for EEE. Two comments were received on this topic (comments #984 and #989) and although some information was submitted on specific products where a derogation is requested, there was not enough substantial evidence to change the opinion.

Therefore, SEAC agree with the Dossier Submitter's analysis that concludes that without more detailed information on the uses and requirements where the substitution is more complex, SEAC has no grounds to justify a general derogation proposal for this sector.

Derogation for recycling

No information was provided from the recycling sector to the Dossier Submitter during the preparatory phase of the Annex XV report indicating that specific problems related to the current restriction could arise. The main contributors to waste containing Dechlorane Plus are the wastes from electrical and electronic equipment and end of life vehicles, both contribute to total plastic waste streams in the EU with 9% and 5%, respectively. Therefore, it is likely that the concentration of Dechlorane Plus in the final recycled materials could be significantly diluted to below the specific concentration limit. In addition, even if not widely adopted by recyclers, techniques to effectively separate waste containing Dechlorane Plus, and treat them separately, are available. Also, in the decaBDE restriction assessment, a similar restriction proposal, where the use volumes involved were one order of magnitude higher, it was concluded that recyclers would be able to meet the 0.1% w/w concentration limit, and no derogation for recycled materials was deemed as justified.

As the information provided in the consultation on the Annex XV restriction report confirms the information and conclusions in the BD related recycling, SEAC agree with the Dossier Submitter analysis and conclusion that a derogation for recycling is not justifiable.

Other EU wide legislative measures

The Dossier Submitter provides a short overview of possible EU wide legislative measures with the potential to control the releases from Dechlorane Plus, other than the proposed restriction. SEAC agrees with the line of argumentation presented by the Dossier Submitter with regards to Waste Management, Authorisation, POPs, RoHS directive, IED, and Ecodesign directive being harder to implement, slower or less effective or less appropriate to reducing emissions from Dechlorane Plus.

Waste management

The Dossier Submitter considers that a mandatory incineration scheme could be an appropriate risk management option for the waste life stage. However, the lack of harmonisation of waste management practices across the EU and the difficulty to identify Dechlorane Plus containing waste are relevant arguments to conclude that this option is not feasible. The lack of incineration capacity of some Member States is also an issue for this RMO implementation.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

Authorisation

Dechlorane Plus is an SVHC and was prioritised by ECHA to be included in Annex XIV of REACH in the 9th draft recommendation. However, due to regulatory uncertainty resulting from the nomination of the substance to the Stockholm Convention, the Dossier Submitter concludes that this option is not appropriate⁷. Additionally, the consideration of the authorisation as an RMO that is appropriate to deal with the identified risk is not aligned with the Commission's previous decision related to the decaBDE. SEAC notes that authorisation cannot address the inherent risk of the imported articles containing Dechlorane Plus.

Stockholm Convention on POPs

Regarding the POP Regulation, Norway proposed to include Dechlorane Plus in the POP Regulation in 2019. Recently, in January 2022⁸, the POPs Review Committee, by consensus, adopted the risk profile of the substance and its elimination is in consideration. However, the POP Regulation is not considered the quickest way to achieve significant emission reduction. In addition, SEAC agrees with the Dossier Submitter that the REACH restriction conclusions can be used to inform the Stockholm Convention process. Even if Dechlorane Plus does not fulfil the criteria for an eventual possible elimination, the substance can still pose an unacceptable risk in the European Union due to other properties, and therefore should be the subject of a restriction.

Restriction of Hazardous Substances (RoHS) Directive

Dechlorane Plus is not currently listed as a restricted substance under RoHS. Additionally, although the Directive applies to some types of electric and electronic equipment that may contain Dechlorane Plus, it does not apply to all relevant applications of Dechlorane Plus. Therefore, SEAC agree that the RoHS Directive is ineffective in reducing the emissions of Dechlorane Plus.

Industrial Emissions Directive (IED)

IED has no effect on the service life emissions or releases from the waste stage of Dechlorane Plus -containing articles, which is considered a key life cycle stage that could create a substantial part of the emissions. Therefore, SEAC concludes that IED is not an appropriate to minimising all environmental emissions from Dechlorane Plus.

Ecodesign Directive

The Dossier Submitter highlight that currently the use of halogenated flame retardants is not allowed in the enclosure and stand of electronic displays by the Commission Regulation (EU) 2019/2021 that lays down Ecodesign requirements for electronic displays pursuant to the Ecodesign Directive. The ban is questioned by The International Bromine Council which has filed a legal challenge under consideration by courts. Notwithstanding that, the Ecodesign Directive does not apply to relevant applications of Dechlorane Plus. Therefore, SEAC finds it ineffective in reducing the emissions of Dechlorane Plus.

⁷ A Common Understanding states that if a substance is included in Annex XIV and subsequently banned under the Stockholm Convention, not only should all existing authorisations be withdrawn but all applications for authorisation should be refused.

⁸ Press release:
<http://www.brsmeas.org/Implementation/MediaResources/PressReleases/POPRC17PressRelease/tabid/9089/language/en-US/Default.aspx>

3.3.2. Effectiveness in reducing the identified risk

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter assessed in its original proposal three different risk management options (see Annex E.1 to the Background Document). It is concluded by the Dossier Submitter, that a restriction on the manufacture, use and placing on the market of Dechlorane Plus in concentrations >0.1% by the end of a transition period of only 18 months is the most effective risk management option as it gives the highest environmental and human health benefits related to reduced risk associated with the use of Dechlorane Plus.

In the Background Document section 2.1.1. and Annex E.1. the Dossier Submitter describes three restriction options. Under RO1, there are no derogations proposed, which would mean that all uses of Dechlorane Plus must cease by the end of the transition period (EiF + 18 months). RO2 allows for continued use of Dechlorane Plus 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. RO3 allows a 10-year derogation for the use in the aerospace and defence sector and a 5-year derogation for the use in motor vehicles, in addition to the use in spare parts.

After the consultation on the Annex XV restriction report the Dossier Submitter proposes a revised scope for the restriction including derogations similar to the original RO2 but with some additional elements ("RO2plus"). The main difference is that the new proposal also contains: (1) a derogation that allows for continued use of Dechlorane Plus 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 spare parts in the following use areas; medical imaging devices and radiotherapy devices/installations and marine and garden/forestry engines. Uses described under (1) and (3) are minor use areas and should not affect the result of the emission characterisation to a significant degree.

In section 2.1.3. the Dossier Submitter justifies rejected requests for derogations e.g. for electrical and electronic equipment and for a general exemption for uses in motor vehicles (for details see 2.1.1.). Not allowing a general derogation for the use of Dechlorane Plus in motor vehicles will ensure a high level of emission reduction as this is the main use area representing a significant source of emissions of Dechlorane Plus to the environment. It follows therefore that the restriction option RO2, revised with a few minor adjustments is chosen by the Dossier Submitter as the most appropriate EU-wide measure and consequently as the proposed restriction ("RO2plus").

The overall emission reduction capacity of each RO was estimated by subtracting the total emission under each scenario from the total emissions under the baseline scenario.

Table 6: Revised emission reduction estimates under each restriction scenario after the consultation on the Annex XV restriction report (see Box 8, Annex E.5.3. to the Background Document)

Sector/use	Baseline emissions (t/y)	Annual reduction (t/y)		
		RO1	RO2plus	RO3
Motor vehicles	6.9 - 21.8	6.3 - 19.8	6.2 - 19.5	5 - 15.9

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Sector/use	Baseline emissions (t/y)	Annual reduction (t/y)		
		RO1	RO2plus	RO3
Aerospace and defence	0.2 - 0.6	0.2 - 0.6	0.1 - 0.4	0.1 - 0.3
Other applications	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 - 22.0
Scenario emission reduction capacity	-	91%	89%	76%

RAC conclusion(s):

RAC concludes that the release estimates over a period of 20 years with and without the three different risk management options are considered as reliable.

RAC concludes that the estimation of the annual reduction capacity of each restriction option is plausible.

RAC concludes that a broad restriction with a short transitional time and without any derogations is the most effective measure to minimise the release of Dechlorane Plus to the Environment.

RAC concludes that the difference in the estimated effectiveness of the strictest restriction option RO1, without any derogations, and the restriction option proposed by the Dossier Submitter after the consultation on the Annex XV restriction report (termed "RO2plus") is not significant as the difference is within the range of uncertainties in the release estimates.

RAC concludes that RO2plus with targeted derogations and transition periods is effective for the minimisation of future releases from both in-service uses and the waste lifecycle stage, including landfill. RO2plus, which includes several targeted derogations and transition periods (e.g. five years for aerospace and defence applications; seven years for medical imaging applications; 10 years for radiotherapy devices/installations and for spare parts for motor vehicles and for marine, garden and forestry machinery applications), is reported to have an effectiveness of 89% of total emissions of Dechlorane Plus abated between 2023 and 2042, relative to baseline, whilst RO1 has a reported effectiveness of 91% emission abatement relative to baseline.

RAC concludes that the risk option RO3 with only 76% emission reduction effectiveness is not supported.

RAC concludes in line with the Dossier Submitter that a general exemption for uses in motor vehicles and for use in electrical and electronic equipment is not justified. These uses can be expected to represent a significant source of emissions of Dechlorane Plus into the environment and stakeholders have not provided enough data and information how emissions are or could be minimised from these uses.

RAC concludes that a derogation for the use of Dechlorane Plus in spare parts for wide-dispersive uses in marine, forestry and garden equipment could not be supported based on risk considerations. Whilst acknowledging that they are likely to be a minor contributor to overall releases, it is reasonably foreseeable that these uses would result in releases (particularly at the waste life-cycle stage) and the information on conditions of use and risk management measures provided in the consultation on the Annex XV report was insufficient

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

to conclude that releases (at all relevant lifecycle stages) would be minimised.

Conversely, RAC concludes that a derogation for medical imaging applications and for radiotherapy devices/installations could be supported from a risk perspective as reasonably foreseeable conditions of use and risk management measures could be expected to achieve minimisation of releases (e.g., extended producer responsibility).

RAC agrees that the proposed restriction is effective in reducing the identified risk of Dechlorane Plus in Europe. However, RAC notes that future releases associated with derogated uses (i.e. service life, end-of-life and waste stage) must be minimised as far as possible by implementing appropriate operational conditions (OCs) and risk management measures (RMMs).

RAC emphasises that all actors benefiting from a derogation should ensure that OCs and RMMs that minimise emissions throughout the lifecycle of Dechlorane Plus are to be implemented. In particular, a mandatory destruction (incineration) scheme and proper control of emissions from waste management facilities and from landfills (e.g. via air and leachate), should be implemented as complementary risk management options for minimising potential releases from derogated uses.

Key elements underpinning the RAC conclusion(s):

The RAC Opinion is based on the Background Document section 2, Annex D, E and G.5.

As Dechlorane Plus is a vPvB substance, emissions are a proxy for risk.

As REACH recital 70 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.*" In general, a restriction with the shortest transitional period and without derogations will be effective as soon as possible to minimise the potential for adverse effects on human health and the environment. In contrast, a restriction containing derogations for continued uses in spare part would only correspond to a gradual phase-out over time, until these spare parts are no longer required.

By restricting the use of Dechlorane Plus in the main use sectors (e.g. automotive, aviation, electric/electronic) the emissions to the environment and the ongoing increase in the existing pollution stock are expected to be significantly reduced. From a risk perspective, a restriction with carefully selected and justified time limited derogations is an effective measure to control in future the risk and to gradually phase-out over time. Even when there are derogations granted for PBT/vPvB substances releases from derogated uses should be minimized as far as possible. Manufacturers and importers of a SVHC included on the Candidate List due to its vPvB properties should recommend appropriate operational conditions (OCs) and risk management measures (RMMs) to downstream users of the derogated uses to minimize emissions throughout the lifecycle.

The restriction affects future use of Dechlorane Plus. It will not reduce emissions from products already in use or, for instance, emissions from waste already deposited in landfills. All restriction options result in high emission reduction.

The expected achievable emission reduction for each restriction option was estimated using both the low and high baseline tonnages (see Annex D to the Background Document). The average annual emission reductions for each RO were estimated by dividing the total emissions by the number of years in the analytical period (20 years). All restriction options result in emission reductions in the range of 75% - 91% of the baseline emissions.

The difference of the emission reduction capacity between the strictest RO1 without any

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

derogations granted and the proposed RO2plus is in the range of 200-400 kg/y. The difference of the emission reduction capacity between the strictest RO1 without any derogations granted and RO3 is in the range of 1.3 t/y and 4.2 t/y. The following Table gives an overview about the ranges of the emission reduction capacity of the different RO compared to the Baseline emissions.

Table 7: Annual emission reduction of the different RO compared to the Baseline emissions

Baseline emissions for all uses (t/y)	Annual emission reduction compared to the baseline emissions (t/y)		
	RO1	RO2plus	RO3
9.1 – 28.8	0.8 – 2.6	1 - 3	2.2 – 6.8

Several requests for derogations from the proposal for a general restriction on Dechlorane Plus were submitted by stakeholders during the consultation on the Annex XV restriction report. Derogations were requested for the aerospace and defence sector, for medical devices (medical imaging and radiography devices), for the motor vehicles sector, the electric and electronic sector and also for marine applications, garden and forestry machinery. RAC notes, that none of these requests were supported by data and information on use volumes, already implemented operational conditions (OCs) and risk management measures (RMMs) to minimise the emissions, or how much emissions must be expected by the requested transitional periods and derogations. Information from stakeholders submitted in the consultation on the Annex XV restriction report also does not give clear picture of whether they have started a substitution process or not. Based on the very limited data and information on use volumes and emissions caused, it is not possible for RAC to make accurate estimates of releases or whether releases are likely to be minimised. The following estimations of the emissions associated with each of the derogations proposed by the Dossier Submitter after the consultation on the Annex XV restriction report are associated with uncertainties.

For the aerospace and defence section the Dossier Submitter considered in the Annex XV restriction report (the original proposal) that a transitional period of five years and a derogation for spare parts will result in only insignificantly lower emission reduction compared to RO1. The relative effectiveness of the restriction for this specific sector is reduced by 50 % to 30 %, however this sector is only a minor contributor to the overall releases (see Table 3).

For medical imaging and radiography devices it can be considered that the total number of existing and newly installed devices will be very small in comparison to electronic devices and machinery. Consequently, it is reasonable to assume on a qualitative basis that the time-limited derogation proposed of 7 and 10 years and a derogation for spare parts for these specific medical devices will not significantly contribute to the remaining emissions of Dechlorane Plus in Europe. In addition, given that maintenance and repair activities will likely be undertaken by either the original equipment manufacturer or their authorised agents. Comments, received during the consultation on the Annex XV restriction report from the medical sector, were describing risk management measures to minimise emissions from the waste stage under the WEEE Directive (#3352, #3537). Further operational conditions (OCs) and risk management measures (RMMs) were indicated for workers when handling during assembly and maintenance. It is also mentioned that emissions of Dechlorane Plus during the service life of the product are not expected as the use is within plastic parts within the equipment and dusts from wear are not expected to arise. RAC concludes that it is likely that the lifecycle of parts containing Dechlorane Plus can be closely controlled, including ensuring appropriate disposal (i.e. incineration) at the end of their service life by implementing appropriate OCs and RMMs. As such, these uses can be expected to achieve minimisation of releases.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

For motor vehicles, the difference in emission reductions between RO1 and RO2plus is assumed to be only 0.1 – 0.3 tonnes per year. This difference is purely due to the derogation for spare parts. For details see Annex E.3.1 to the Background Document and Table 3.

For marine, garden and forestry applications included by the Dossier Submitter in RO2plus it can be considered that the volume used is significantly lower than that of motor vehicles. Consequently, the volume used for spare parts will be small. The time-limited derogation for spare parts in marine applications is not expected to notably change the overall emission reduction capacity and the difference is likely \ll 0.1 tonnes/year (qualitative estimation). Nevertheless, whilst acknowledging that they are likely to be a minor contributor to overall releases, RAC concludes that the derogation proposed by the Dossier Submitter for use of Dechlorane Plus in spare parts for wide-dispersive uses in marine, forestry and garden equipment in RO2plus could not be supported based on risk considerations as it is reasonably foreseeable that these uses would result in releases (particularly at the waste life-cycle stage) and the information on conditions of use and risk management measures provided in the consultation on the Annex XV report was insufficient to conclude that releases (at all relevant lifecycle stages) would be minimised. The comments received from the marine, garden and forestry sectors did not include data and information on amounts used of Dechlorane Plus or expected emissions nor information on risk management measures or operation conditions implemented to result in minimisation of releases (#3535, #3533). The comments also mentioned that Dechlorane Plus is widely used, not only in the EU, in various applications.

For electrical equipment and electronics, a derogation for spare parts was rejected by the Dossier Submitter, as many electronic devices and electrical equipment has a short lifespan. A derogation for spare parts for specific long-lived devices could conceivably be warranted. However, no information to base such a derogation on was submitted in the consultation on the Annex XV report.

The Dossier Submitter analysed alternatives for the main uses of Dechlorane Plus and summarised the available alternatives in a table by using a colour-code system. Additionally, a short summary was given under the table to all identified alternatives. Identified alternatives to Dechlorane Plus as flame retardant are chlorendic anhydride, ammonium polyphosphate, aluminium hydroxide and ethane-1,2-bis(pentabromophenyl) (EBP). Long chain chlorinated paraffins (LCCPs), tricresyl phosphate and diallyl chlorendate were identified as alternatives to Dechlorane Plus as extreme pressure additives.

Some alternatives were concluded by the Dossier Submitter to be suitable due to their technical feasibility, but other of the alternatives are currently under REACH Substance Evaluation due to their potential PBT/vPvB properties or have a harmonised classification. Therefore, part of the alternatives might have a potential for regrettable substitution due to environmental or human health concerns. RAC's analysis is limited to the alternatives explored by the Dossier Submitter but further alternatives may exist. Due to the lack of data and information and due to ongoing hazard assessment, it was not possible for RAC to verify the hazards of identified alternatives.

During the consultation on the Annex XV restriction report, comments were received on the possibility to substitute Dechlorane Plus (#3332, #3352, #3353, #3355) (see Annex G.5. to the Background Document). The comments noted that the key functions and applications of Dechlorane Plus are not fully known. The comments also focused on the availability of alternatives and the challenges for substitution. Another comment received in the consultation indicates that the proposed restriction will not have an impact on the recycling industry (#3398).

3.3.3. Socio-economic impact

Justification for the opinion of SEAC

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

3.3.3.1. Costs

Summary of proposal:

In order to define cost components, the Dossier Submitter has performed extensive research to collect data, covering various literature studies where Dechlorane Plus was mentioned, studies analysing consumer articles for Dechlorane Plus content, REACH registration data, and data from EU authorities and downstream user groups. By including information from stakeholder surveys, interviews and the Call for Evidence⁹, it was possible for the Dossier Submitter to quantify some cost components (although the Dossier Submitter would have wished for more extensive data on costs).

The costs assessed by the Dossier Submitter include:

- substitution costs for industry (quantified)
- lost profits and job losses (partially quantified)
- enforcement costs for authorities (qualitatively described)

It was only possible for the Dossier Submitter to quantify the substitution costs and lost profits (E.4.) partially, due to the limitations of the available data. Following this the cost sections and related calculations have, to a large extent, been based on alternatives analysis and behavioural assumptions.

As limited data on specific alternatives have been supplied during the consultation on the Annex XV report, the estimation of impacts rests on the assessment of alternatives. The assessed costs are based on 2020 prices, subject to a 4% discount rate, and a 20-year assessment period, starting in 2023.

Analysis of the alternatives

The Dossier Submitter conducted a detailed and in-depth assessment of alternatives and their suitability. They started from a list of 200 substances and methodically eliminated them down to a few, shortlisted ones. These alternatives are all technically and economically feasible according to the Dossier Submitter. However, they expressed uncertainty regarding whether these would be suitable for all applications within the uses described. Since the industry has not yet fully moved to those alternatives, this seems to suggest that there may be other technical criteria that are not fulfilled which prevent the substitution.

According to the Dossier Submitter, there are three potential alternatives, technically and economically feasible, for Dechlorane Plus as a flame retardant, though one of these (EBP) might be a regrettable substitute, and two suitable alternatives for the extreme pressure additive use.

However, the limited number of stakeholders providing information in regard to alternatives in both the consultation on the Annex XV restriction report and Call for Evidence, expressed that there are no suitable alternatives. It has not been possible to find information on why no alternatives are considered feasible, as the only reasoning stated by stakeholders was lack of awareness of potential alternatives. The Dossier Submitter considers that no technical criteria from uses provided by the stakeholders were so specific that other flame-retardants or lubricants could not meet them.

⁹ <https://echa.europa.eu/documents/10162/724b8c08-98fc-a992-49fd-aa329de4437d>

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

The alternative assessment was performed separately for each function, i.e. flame retardant and extreme pressure additive. The shortlist of alternatives to Dechlorane Plus as flame retardant was identified based on literature research and the hazard profile of the substances.

Shortlisted alternatives to Dechlorane Plus (DP) as a flame retardant identified by the Dossier Submitter:

- (i) ammonium polyphosphate;
- (ii) aluminium hydroxide;
- (iii) ethane-1,2-bis(pentabromophenyl) (EBP).

Alternatives to Dechlorane Plus as an extreme pressure additive for grease/lubricants were identified based on experts' opinions and published literature, as well as on the hazard profiles.

Shortlisted alternatives to Dechlorane Plus (DP) as extreme pressure additive identified by the Dossier Submitter:

- (i) long chain chlorinated paraffins (LCCPs);
- (ii) tricresyl phosphate (TCP);
- (iii) diallyl chlorendate.

To establish the total annual cost of chemicals for each flame retardant alternative, tonnage data was combined with price information. As presented in table 5 (104, E.4.2.1.), the costs of the most likely alternatives are all lower than those of Dechlorane Plus.

Table 8. Available information on the most likely alternatives to Dechlorane Plus as a flame retardant

Flame retardant	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%	2675	31%	50% - 80%
Ethane-1,2-bis (pentabromophenyl) (EBP)	30%	5782	17%	60% - 100%

While aluminium hydroxide is the cheapest alternative, the majority of users are expected to implement this as an alternative. However, due to various technical criteria one alternative is unlikely to fit for all uses. In order to make evaluation on the flame retardants cost of chemicals following a potential restriction, it was attempted to estimate how much of the respective alternatives and Dechlorane Plus there will be used under each restriction scenario. To do so the information from table 5 was combined with the expected behavioural responses and the linked timeline for when substitution will take place. The results are given in table 6, where the volumes of substituted Dechlorane Plus and

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

corresponding rise in alternatives is portrayed. The lower amount of substituted Dechlorane Plus under RO1 than RO2 is due to the higher share of relocations, both permanently and temporary ones, happening under RO1.

Table 9. DP use substituted (not ceased) and increased use of alternatives compared to the baseline, tonnes per year

Substance	RO1	RO2plus	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

With respect to the use of Dechlorane Plus as an extreme pressure additive in lubricants (2% of the total use), the Dossier Submitter was unable to define the change in the cost of chemicals due to a lack of information on loading factors. However, as the prices for relevant alternatives are significantly lower than the price for Dechlorane Plus, it seems plausible that the loading element of alternatives would have to be considerably higher than Dechlorane Plus's loading amount in order for the cost of chemicals to be of significance.

Additionally, the Dossier Submitter suggests that substitution is already taking place in the industry; however, no known industry players have made the transition to date.

The Dossier Submitter suggests that the transition may be more difficult and expensive than presently expected, as there may be additional substitution costs that are not currently accounted for, but without data this cannot be concluded. They make several suggestions for why there has been no transition:

- the alternatives may not actually be able to fulfil all the technical criteria,
- there might be undisclosed costs related to R&D, operating activities or other investments, which the cost of chemicals does not cover.
- some companies might be in the process of implementing alternatives but not finished with the operation just yet.

Comments received during consultation on the Annex XV restriction report suggest that there are no suitable alternatives presently available for all uses. However, alternatives to wire harnesses and tape on the EU market are mentioned. No evidence is provided or reasons given to support the claim of the lack of alternatives.

As a result, the Dossier Submitter is not able to provide a robust conclusion on the availability of suitable alternatives for all applications. At the same time, it has not been possible to determine any specific reasons, technical or economic, for why alternatives to Dechlorane Plus are considered infeasible by the stakeholders, apart from lack of knowledge of any alternatives.

Additionally, there was no information made available during consultation on what feasible

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

alternatives consists of. Therefore, the Dossier Submitter could not draw robust conclusions as to which substances will be adopted as alternatives, due to this uncertainty.

Substitution costs

The Background Document does not contain a lot of information about practical availability and technical feasibility of alternatives to Dechlorane Plus, and consequently on substitution costs. It has not been possible for the Dossier Submitter to establish costs related to R&D, raw materials, investment or energy. It was also not possible to establish increased operational costs (which transitioning to alternatives can include) either. The options for estimating the cost of transitioning to alternatives are thus limited.

Through the consultation, JAPIA¹⁰ (#3527) provided information that a restriction will impose a one-off cost, related to R&D and testing of motor vehicles, to the automotive parts industry. They set an estimate of €0.7 – €21 million per company. Whether these costs would be passed on to the European consumers is unknown. The European stakeholders from motor vehicles industries submitted no information in relation to this. Considering new information from the consultation on potential alternatives, the Dossier Submitter suggests that the costs are likely to be lower for European based companies, as inorganic alternatives are more accessible for the European companies than the Japanese.

During the consultation, JBCE (#989) has mentioned that costs of redesigns of new components are to be expected. IMEC (#983) has similarly commented on how costs related to re-design, re-testing and re-manufacturing of spare parts are anticipated to occur. However, as no specific data or additional information on these areas has been submitted, the opinion has not been adjusted further in this respect.

No information was submitted from either the aerospace and defence sector nor from the other industry sectors during the third-party consultation. However, one-off costs are expected to be incurred at least for some uses.

As the Dossier Submitter did not receive adequate data on substitution costs, the cost of chemicals for flame retardants were investigated. This was done by comparing the prices and loading factors for potential flame retardant alternatives, identified in section E.2. and Annex H.3. Based on the available information the Dossier Submitter suggests the cost of chemicals as an indicator of substitution cost.

Market responses

The expected behavioural responses to the 3 restriction options have been divided by sectors, covering “other applications” and the main user groups “motor vehicles” and “aerospace and defence” as presented in table 7 below.

Table 10. The expected behavioural responses

Behavioural Responses	Share of Dechlorane Plus Volume					
	Motor vehicle sector			Aerospace and defence sector		
	RO1	RO2plus	RO3	RO1	RO2plus	RO3

¹⁰ Japan Auto Parts Industries Association

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Switch to an alternative, including transfer of market shares between EU actors.	50%	50%	95%	20%	70%	95%
Temporary cease parts of production until an alternative is found	40%	45%	5%	70%	30%	5%
Relocation (requires non-EU customers) and permanently reduced production	10%	5%	0%	10%	0%	0%

The consultation on the Annex XV restriction report did not provide any information on the behavioural responses set out in the table or why these options are expected to be suitable. The behavioural responses of the Dossier Submitters proposed restriction option correspond to those indicated in RO2plus.

For the behavioural response section, “other applications”, it was in the original analysis set as an assumption, that all users would be able to switch to an alternative for all restriction options. However, the consultation revealed that some actors using Dechlorane Plus in electronics, medical devices, marine applications and motorised machinery would be unable to substitute within Eif + 18 months. Nevertheless, as no information on use volumes were provided, the Dossier Submitter did not refine their assumptions further. Therefore, the assessments will be incorrect for some applications and more correct for others, with potential impacts qualitatively assessed in the following sections.

Profit losses

Stakeholders supplied limited information during the development of the restriction proposal in respect to temporary or permanent reduction of production of Dechlorane Plus-dependent products within the EU. It was estimated that production halts are expected to happen following a restriction, with the effects depending on the use groups of Dechlorane Plus. The information from the consultation was set up against the previously made estimations.

The Dossier Submitter suggests that profit losses will only be temporary, until the substitution happens. They are also likely to be overestimated, based on their analysis. They assume that Dechlorane Plus will be substituted by the Entry into Force or the end of derogation period (where applicable).

To make an estimate on potential lost profits the Dossier Submitter combined statistics from Eurostat with previously defined expected behavioural responses. The behavioural responses, which were based on data from expert judgements, have been pooled within scenarios built upon contextual information. Following a restriction, the users of Dechlorane Plus are expected to:

- Switch to an alternative,
- Temporarily cease parts of production,
- Relocate, or
- Permanently reduce production

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

The behavioural responses set out in the tables above were combined with Structural Business Statistics and PRODCOM from Eurostat, to estimate the sales at risk. For the motor vehicles and aerospace and defence sectors, the average turnover for relevant PRODCOM codes in the period of 2015 and 2019 (uplifted to 2020) were defined in € million per year - excluding knock-on effects, as presented in table 8 below.

Table 11. Structural Business Statistics and PRODCOM from Eurostat

Sector	Relevant PRODCOM code	Description	Turnover at risk, € million per year
Motor vehicles	22299160	Plastic parts and accessories for all land vehicles (excluding for locomotives or rolling stock)	31 521
	29311000	Insulated ignition wiring sets and other wiring sets of a kind used in vehicles, aircraft or ships	
Aerospace and defence	22299180	Plastic parts for aircraft and spacecraft	2 577
	29311000	Insulated ignition wiring sets and other wiring sets of a kind used in vehicles, aircraft or ships	

Sources: PRODCOM (accessed: 2020)

Note: PRODCOM code 29311000 is cross-sectoral and has been split between land vehicles (80%), aircrafts (10%) and ships (10%).

Table 12. Profit at risk, EAV¹¹ in € million per year

Sector	RO1	RO2plus	RO3
Automotive	262	167	5
Aviation	41	9	2
Other, including imported articles	0	0	0
Total profits at risk	303	175	6

The potential lost profits are higher under RO1 and RO2plus than under RO3, due to longer transition period for usage of Dechlorane Plus and the share of affected sales. The estimates do not include distributional effects, as transfers from one company to another have been accounted for in the behavioural responses, which the calculations are based upon.

The analysis of lost profits is based on assumptions around the necessary time needed for substitution to happen and depends on the value of the products rather than the product amount used. It is difficult to estimate the profit losses accurately, because the reliance on Dechlorane Plus might differ throughout the supply chain.

The considerations on availability and implementation of alternatives, is also relevant in respect to the estimation of lost profit. The Dossier Submitter makes the point that if feasible alternatives exist, this could shorten the substitution time, resulting in lower profit loss under RO1 and RO2plus than currently estimated. On the other hand, there may be some profit losses from other parts in the supply chain that have not been taken into account, which could lead to an underestimation. However, it is deemed unlikely considering the information from stakeholders given below.

¹¹ 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%)

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

It was previously indicated by stakeholders that around 93% of Dechlorane Plus is used in wired and printed circuit boards, and other plastic and rubber parts; with a large quantity being used by the motor vehicles (67%) and aerospace and defence (85%) sectors. New information from the consultation indicates new alternatives for wire harnesses and tape might be available on the EU market. During the consultation ACEA¹² reported that around 90% of Dechlorane Plus used within the automotive industry comes from wire harness, tape and adhesives.

There may still occur production halts despite the existence of alternatives. However, in the light of this information, the potential lost profits are considered by the Dossier Submitter likely to be overestimated in the original analysis, in respect to the motor vehicle industry. Since the motor vehicles industry is responsible for a large amount of the emissions and hence the estimated lost profit, the potential overestimation is reflected throughout the analysis.

The information provided by stakeholders in the consultation does not reflect if the motor vehicle sector has started a substitution process. In respect to the aerospace and defence sector, no new information was submitted that would influence the lost profit calculations, so the information in the table 8 above (table 110, E.4.3.1) is considered representative.

For applications related to other segments, including electronics, marine applications, medical devices and other machinery various losses are expected to occur within the category, but not for all uses. Because the proposed restriction includes a derogation for the medical industry, there will not be any production halts and hence no losses, while the electronics sector needs to implement alternatives within the given transition period in order not to experience production halts.

As no further information has been supplied that is relevant for approximating costs induced by production halts for the "other applications" category, the Dossier Submitter has been unable to put a price on this. However, it is possible that there will be production halts, followed by lost profits, for at least some uses within the sector.

The consultation has revealed factors indicating both lower and higher profits than the Dossier Submitters original estimations. Between 83 % - 95 % of the lost profit in the original analysis related to the motor vehicle industry, meaning the actual net loss is most likely lower than what is presented in table 8 above. As there are strong similarities between previous restriction option (RO2) and the current proposed restriction option (RO2plus), the lost profits are now likely to be much lower than €175 million per year.

Administrative/enforcement costs

Enforcement of a restriction, regardless of the option, is expected to be carried out along the existing restrictions which affect similar products– e.g. decaBDE, allowing tests to be carried out jointly.

The enforcement costs are in any scenario unlikely to be significant compared to other costs from the restriction, which is why these have not been investigated further.

SEAC conclusion(s):

While the performed analyses are executed with many considerations in mind, they are based on a number of uncertain parameters and assumptions. This is the case for all parts related to the cost section, covering alternatives, substitution costs and lost profits. It is important to note that it has been attempted to underpin the analysis further, with more adequate and

¹² ACEA – European Automotive Manufacturers Association

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

precise data, by requesting Dechlorane Plus users to submit information. This has been successful, to the extent that the Dossier Submitter has received some information.

There are still uncertainties, but SEAC finds the assumptions that the calculations are based upon to appear reasonable. More specific data would have made it possible to make even firmer calculations but considering the available information and the reliability of the applied sources, it is SEAC's view that the Dossier Submitter overall has managed to make suitable and reasonable estimations.

In SEAC's view, the Dossier Submitter's research into alternatives to Dechlorane Plus as a flame retardant and extreme pressure additive is thoughtful. The criteria to select the alternatives' shortlist is acceptable, taking into account the diversity of materials and applications that demand the use of Dechlorane Plus and the lack of information provided by the industry. However, the approach has led to generic alternatives, for which no information is available on their feasibility for the most demanded uses, as well as on costs of eventual substitution.

Substitution costs

R&D costs, investment costs, and potential increased operational costs, have been left out of the substitution analysis due to a lack of information. The Dossier Submitter's estimated cost of chemicals has proven to be the main indicator of substitution costs, as limited knowledge has been obtained from industry or other sources. It appears in the dossier that the costs of alternatives may be lower than those of Dechlorane Plus; however, SEAC cannot actually confirm this.

Excluding additional costs and assuming the cost of chemicals to cover all costs, creates some risk of simplification, as R&D cost or cost of implementation may be significant. The Dossier Submitter acknowledges this, despite not being able to make estimations including these additional costs.

SEAC supports the Dossier Submitter's efforts, and agrees that the current information does not allow for a quantification of the total substitution costs. However, given the available data the Dossier Submitter has managed to highlight relevant issues related to the substitution of Dechlorane Plus, including one-off costs related to R&D, and to estimate the cost of alternatives, which SEAC considers useful.

Lost profits

The lost profit analysis is based on "assumed behavioural responses" and statistics from Eurostat sources, whereby the Dossier Submitter managed to approximate cost components to make quantitative analysis.

Therefore, the analysis includes some uncertain elements, but by combining insights from the consultation on the Annex XV restriction report and comparing the two parts, the assessment appears more robust.

SEAC considers the result a good approximation, though there still are uncertain elements in the cost assessment. However, it seems the costs currently are more likely to be overestimated than underestimated. SEAC agrees the costs of the restriction are likely to be lower than €175 million per year and agrees with the performed analysis.

Enforcement costs

SEAC finds that due to current efforts to implement restrictions affecting similar substances, e.g. decaBDE, the enforcement costs are likely not to be significant, compared with other costs related to implementation of the restriction proposal.

Forum agrees with this, with the assumption that the costs will fall within the accustomed

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

range for testing chlorinated POPs, due to similarities in laboratory equipment and test methods.

Manufacture, importing and production of Dechlorane Plus

There are only two REACH registrations for Dechlorane Plus (EC 236-948-9) and both of them are part of a joint dossier. From the submitted information it is clear that imports of bulk Dechlorane Plus have taken place since at least 2010 at 100-1000 tpa. Manufacture of Dechlorane Plus in the EU has never been reported to ECHA. Furthermore, at any given time, only one of the two registrants imported the substance into the EU. One registrant ceased their activities relating to Dechlorane Plus in December 2017 and the other in May 2021.

From the available information under REACH, it is not clear whether manufacture of Dechlorane Plus outside the EU is still taking place. However, imports of Dechlorane Plus in articles into the EU may still continue, which is why the restriction still is relevant and important. The price of Dechlorane Plus may potentially rise if the users have to import the substance from outside EU, leading to more incentives to substitute.

The consultation has produced interest in the restriction from the motor vehicles, electronics, medical and aerospace and defence industries, but none of these insights have related to the ceasing of production.

Summary

SEAC acknowledges the Dossier Submitter's difficulties with receiving adequate data and robust cost information and agrees with the Dossier Submitter's approach to estimate costs. SEAC appreciates the inclusion of a sensitivity analysis to reflect on the uncertainties. Additional information on costs would have made it possible to develop the analysis further; however, SEAC concludes that the efforts made by the Dossier Submitter are adequate and supports the estimations made.

Key elements underpinning the SEAC conclusion(s):

Because of the limited data many elements have not been possible to estimate, e.g. costs related to the substitution process. Therefore, many assumptions have been made in order to make some cost estimations. Extensive research has been the basis for the assumptions the cost estimations are based upon. The assumptions have been supported with data from the consultation on the Annex XV restriction report when possible, underpinning the analysis. Due to the extent of the research and validity of the applied sources, SEAC accepted the assumptions as a valid foundation for the estimated costs. The cost estimations themselves follow a clear procedure, which is easy and reasonable to follow, and SEAC supports the Dossier Submitters efforts. Therefore, SEAC finds the cost assessment overall sufficient to support the restriction proposal from an economic viewpoint.

Alternatives

SEAC reviewed the evidence and analysis provided by the Dossier Submitter regarding the existence and availability of alternatives to Dechlorane Plus, focusing on the following main known uses:

1. As flame retardant in polymeric materials and also in paints and textile coatings.
2. As extreme pressure additive in greases/lubricants.

The alternative assessment was performed separately for each use. Apart from the chlorendic anhydride, indicated as an alternative by Dechlorane Plus's European importer, the shortlist of alternatives to Dechlorane Plus as flame retardant was identified based on literature

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

research and the hazard profile of the substances.

Alternatives to Dechlorane Plus as an extreme pressure additive for grease/lubricants were identified based on experts' opinions and published information, as well as on the hazard profiles. As no relevant information comes from the consultation on the Annex XV restriction report and the function of the substance is not clear in such matrixes, there is a lack of evidence on the availability and feasibility of alternatives. SEAC notes that the cost of alternatives is estimated to be lower than Dechlorane Plus, but this is not confirmed.

Substitution cost and cost of chemicals

SEAC identified shortcomings in the Dossier Submitter's assessment of substitution costs which are based on the estimated cost of chemicals, which in turn are based on expected behavioural responses, information on alternatives and statistics.

The Dossier Submitter acknowledges the existence of potential cost elements other than cost of chemicals, but it has not been possible to quantify these, as the information has been insufficient. Due to lack of information on feasible alternatives, and consequently on research and development costs - including reformulation costs, SEAC agrees with the approach taken by the Dossier Submitter to illustrate the qualitative substitution costs through the assessment of cost of chemicals, while including a "buffer" and sensitivity analysis for other parts of the analysis. SEAC agrees that additional costs are expected to appear, but as only one stakeholder submitted numerical information on actual substitution costs, it is SEAC's opinion the costs must be affordable.

Although potential alternatives are cheaper than Dechlorane Plus when looking at the cost of chemicals alone, this is an incomplete picture. It excludes other cost elements e.g. the number of products affected by a restriction, or the cost per reformulation beyond the market price of the alternatives, and its impact on the costs of the final materials. During the consultation, information on other costs, such as one-off costs, likely to be incurred during substitution process were presented. JAPIA managed to include some cost estimations, but these were within a wide range, and more specific impacts are unknown.

Lost profits

As the lost profit estimations are partially based on "expected behavioural responses" the actual reactions from stakeholders might differ from the estimated ones and thereby influence the analysis. However, as no stakeholders from either the motor vehicles or aerospace and defence sectors have made any objections to these, SEAC finds the expected behavioural responses to be appropriate assumptions. The actual reactions to the suggested restriction are thus expected to correspond with the estimated reactions under RO2.

In terms of the "other applications" category there are some users who will face difficulties with implementing alternatives within the given timeframe. But as the Dossier Submitter has been unable to find any data on use volumes, it was not possible to make more correct estimations. SEAC finds that despite the uncertainty surrounding the use category, the number of users in the group are limited, and with some being granted derogations, the influence on the overall analysis will be limited.

It is noted by SEAC that the actual profits at risk will depend on the availability of alternatives, and the related implementation process. In the consultation on the Annex XV restriction report it was indicated that new alternatives to wire harness and tape might be available in the EU market, which is of great relevance as 93% of Dechlorane Plus are estimated to be used within wired and printed circuit boards and other plastic/rubber parts; with the main users being the motor vehicles and aerospace and defence sectors.

If there are alternatives available, the estimated potentially lost profits are likely to be

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

overestimated, because the motor vehicles and aerospace and defence are the main users of the substance.

SEAC agrees that it is not possible to draw completely firm conclusions on the defined central estimates and ranges of costs, as provided information does not allow for this - but the performed analysis addresses the uncertainties well. Assuming the alternatives are applicable, and accepting the uncertainties of the cost effectiveness and qualitative arguments, i.e. following the sensitivity analysis, SEAC agrees the costs are likely to fall within the range defined by the Dossier Submitter.

Enforcement costs

Enforcement costs were not quantitatively assessed by the Dossier Submitter following the claim that implementation can be carried out in parallel with enforcement of existing restrictions affecting similar products. SEAC tends to agree that additional spending for enforcement might be needed but with little relevance in the total costs of this restriction. SEAC notes Forum's assumptions that the costs should be in the order of the usual testing costs for chlorinated POPs, as the laboratory equipment and the test methods for Dechlorane Plus will be similar. Therefore, if, as assumed by the Dossier Submitter, the enforcement can be carried out in parallel with enforcement of existing restrictions affecting similar products, e.g. decaBDE, the enforcement costs will likely be low. Essentially, these costs would be the additional costs of testing for the presence of one more substance.

Other costs

As there is no drop-in alternative available, the Dossier Submitter acknowledges additional costs that are likely to be incurred by the industry following substitution, e.g. R&D and investment costs, but these costs are not quantified.

During the consultation information was received that one-off costs and production halt costs are to be expected, which SEAC finds likely to be unavoidable, but further details of the extent are unknown.

While JAPIA suggested the one-off costs will fall in between €0.7 million to €21 million per company, no stakeholders from the European motor vehicles industry or aerospace and defence and other applications submitted any data. Considering the possible alternatives on the European market, the one-off costs are likely to be lower, but it is assumed at least some of these market players will face some one-off costs as well. SEAC agrees that while there most likely will be some undisclosed costs related to the restriction, they are less significant compared to the other costs, following the lack of interest during the consultation.

3.3.3.2. Benefits

Summary of proposal:

In 2018 Dechlorane Plus was identified as a very persistent and very bioaccumulative (vPvB) substance. As Dechlorane Plus is both very bio accumulative and chemically stable in various environmental compartments with limited, if any, abiotic degradation, the environmental stock may increase over time. According to ECHA¹³ guidelines on PBT/vPvB substances, the effects of the accumulation of these substances are unpredictable in the long-term, and difficult to reverse.

¹³ Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC. Available at: https://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpVB_substances_seac_en.pdf

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

While the effects of Dechlorane Plus are yet to be explored thoroughly, the Dossier Submitter notes that the substance is currently being investigated under the Stockholm Convention. The half-lives of Dechlorane Plus in soil is predicted to be 10 years, therefore the effects and impacts of increasing environmental stock might particularly affect future generations.

Subsequently, the main benefit for the society from a restriction, which limits the amount of emissions and exposure to Dechlorane Plus, is to avoid possible effects on humans, wildlife and environment.

As risks of PBT/vPvB substances cannot be quantified, benefits of risk management are delivered through emission reductions and avoided increase in environmental stocks. The Dossier Submitter has taken a cost-effectiveness analysis approach, whereby emission reductions are used as a proxy for benefits, in line with SEAC's PBT/vPvB approach. When applying a static exposure model the modelled emissions of Dechlorane Plus will fall within the same year as the modelled substance is used. This means that the emissions reductions will happen at the same time as the use ceases. Furthermore, most of modelled emissions will happen within the analytical period. As a result, the estimated emission reductions are likely to be close to the actual (expected) emission reductions.

The emission ranges and reduction opportunities were identified by applying stakeholder reported use volumes within a static model. The emissions calculations include only the emissions impacted by the restriction, as historical emissions are left out of the baseline and estimates of reduction.

All restriction options are limiting the emissions significantly as the total baseline emissions for all uses are estimated between 9.1 – 28.8 tonnes per year, as displayed in table 10 below:

Table 13. Emission reduction under each restriction scenario, tonnes per year

Sector/use	Baseline emissions (t/y)	Annual reduction (t/year)		
		RO1	RO2plus	RO3
Motor vehicles	6.9 – 21.8	6.3 – 19.8	6.2 – 19.5	5 – 15.9
Aerospace and defence	0.2 – 0.6	0.2 – 0.6	0.1 – 0.4	0.1 – 0.3
Other applications	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%

The expected emissions reductions for the different ROs have been estimated and are presented in table 10 above (table 111, E.5.3. in Background Document). RO1 has thus the biggest emission reduction capacity, which by proxy, will lead to the highest level of environmental benefit, while RO3 has the lowest potential with 76%. The elements influencing a reduction in emissions following a restriction on Dechlorane Plus are the restriction scope, transition period lengths and derogations granted.

The Dossier Submitter has adjusted his currently proposed restriction option (RO2plus) which is similar to RO2. The differences are in additionally proposed derogations covering medical

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

imaging and radiography devices, in addition to spare parts for medical imaging, radiotherapy devices, installations and marine, garden and forestry machinery applications.

The reason for the emission reduction difference of 0.1-0.3 tonnes per year between RO1 and RO2plus was due to motor vehicles spare parts.

As a large quantity of Dechlorane Plus is used in motor vehicles the derogations for other sectors are of limited impact. Because of that, the derogation time for spare parts is not expected to change emission reduction capacity when compared to RO2plus.

Many comments were received, during the consultation on the Annex XV restriction report, concerning the "other applications" category. Information was received that Dechlorane Plus is used within the electric and electronic equipment industry, in addition to machinery used for gardening, forestry, construction, and other industrial applications. These users are expected to make up most of the category covering the "other applications".

In the light of this broad group of users, the proposed derogation for medical imaging and radiography devices is unlikely to have a significant influence on emissions. This means the emissions of the proposed restriction option and RO2 are similar, despite the additional derogations included in the proposed restriction.

The Dossier Submitter's current proposal (RO2plus) represents an emission reduction capacity similar to RO2, at around 89% of the emitted Dechlorane Plus, which is expected to be reduced between 2023 and 2042.

SEAC conclusion(s):

The restriction proposal aims to minimise the emissions, as Dechlorane Plus persists in the environment and accumulates in humans and wildlife, leading to possible transgenerational effects. The approach taken to evaluate the benefits of the restriction, by using emission reductions and factors of concerns as a proxy for potential benefits, is in line with SEACs current framework for evaluating vPvB substances.

SEAC agrees with the Dossier Submitter's approach to estimate the benefits of the restriction. Dechlorane Plus is listed as vPvB, has a long-range transport potential and wide dispersive use (see Annex A.2. Uses). Dechlorane Plus is already present in the environment, though knowledge about its effects on the environment and humans is limited. As there is inadequate knowledge, there is no known safe level of exposure.

Following this line of thought, SEAC supports the overall approach taken by the Dossier Submitter and agrees that emission reductions should be considered a proxy for risks, which is an approach in line with SEAC guidelines.

Key elements underpinning the SEAC conclusion(s):

Dechlorane Plus is very persistent and very bio accumulative. Emissions will stay in the environment and add up, leading the stock to grow, which may lead to transgenerational, unpredictable consequences.

The Dossier submitter has described Dechlorane Plus's many properties as a vPvB and PBT substance and why these are of concern, underpinning the benefits of a potential restriction by reducing emissions.

To improve the analysis, information on the flows of the substance and the impact on actual stocks would be relevant.

The approach taken to evaluate the benefits of a restriction, by using emission reductions and

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

factors of concerns as a proxy for potential benefits, is in line with SEACs current framework for evaluating vPvB substances.

SEAC took note that RAC is of the opinion that an assessment of the human health hazards of Dechlorane Plus is not needed for the justification of the proposed restriction, because of the hazard assessment of ECHA's Member State Committee defining Dechlorane Plus as vPvB. RAC is of the opinion that there is a risk to address from emissions and ongoing exposure. Due to the vPvB properties, emission estimates as a proxy for risk are accepted. The given emissions are deemed relevant and plausible by RAC.

The Dossier Submitter noted that the actual emissions for RO2plus will differ slightly from the estimated emissions, because of the proposed derogations concerning medical imaging and radiography devices, as well as for spare parts for several other elements from the category "other applications." However, the amount of used Dechlorane Plus is very limited within these use areas compared to the amount used for motor vehicles. Therefore, the emissions are not expected to influence the estimated emissions for RO2plus, which has a reduction capacity of 89 %. SEAC agrees with these considerations and the completion of emission estimations.

3.3.3.3. Other impacts

Summary of proposal:

The Dossier Submitter does not expect a restriction of Dechlorane Plus to have substantial, social impacts, apart from job losses.

The potential impact on employment depends on the possibility of production halts, or permanent reduction in production and/or relocation outside of EU.

In order to make some estimation of whether there will be job losses, the Dossier Submitter has applied a similar approach as when estimating profit losses. By using data and NACE data codes from Eurostat the estimations in the table below were made:

Table 14. Assessment of job losses across industries

Sector	Relevant jobs within the EU	Share of relevant jobs at risk		
		RO1	RO2plus	RO3
Motor vehicles	80 580	9.1%	5.8%	0.2%
Aerospace and Defence	9 924	15.7%	3.3%	0.6%
Other applications	0	0%	0%	0%

The Dossier Submitter believes that job losses will not be equally distributed across the period but will rather be concentrated in the period before the market switches to alternatives as human resources are redistributed. ECHA (2016)¹⁴ guidance on estimations of job losses, was applied in order to make estimation on the average annual number of jobs at risk and multiplied this by the average gross salary in the EU. The resulting net present values, from 2023 – 2042, across all three ROs are in table 12 below.

Table 15. Net present values of the estimated job losses (2023 – 2042)

¹⁴ The social cost of unemployment. Accessed at: [af3a487e-65e5-49bb-84a3-2c1bcbcb35d25 \(europa.eu\)](https://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&plugin=1&code=af3a487e-65e5-49bb-84a3-2c1bcbcb35d25)

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Sector	RO1		RO2plus		RO3	
	Average annual jobs at risk	Societal value (€ million/year)	Average annual jobs at risk	Societal value (€ million/year)	Average annual jobs at risk	Societal value (€ million/year)
Motor vehicles	368	18.6	234	12	7	0.3
Aerospace and defence	78	3.9	16	0.8	3	0.2
Other Applications	0	0	0	0	0	0
Total	446	23	251	13	10	0.5

As mentioned above, the EU employment will be affected if there are production halts or permanent reductions/relocations outside the EU. However as most of the estimated jobs at risk are from the motor vehicles segment, the estimated losses of €13 million per year under RO2plus are likely overestimated, as the consultation have revealed how potential alternatives for this segment might exists on the EU market already.

In terms of distributional impacts, the main sectors affected (the motor vehicles and aerospace and defence) are large and strong in the EU, and in the Dossier Submitter's view they will not be largely affected. The actors that would be disproportionately affected are SMEs in the supply chain for parts and materials, especially under RO1 and RO2plus. However, they do not make any attempt at quantifying or qualitatively assessing these impacts.

SEAC conclusion(s):

SEAC agrees with the Dossier Submitter that the societal impacts are of limited influence. SEAC agrees with the assumption that the costs will indeed fall below the estimated €13 million per year, due to the potentially existing alternatives within the European market.

Key elements underpinning the SEAC conclusion(s):

The data received by the Dossier Submitter during the consultation on the Annex XV restriction report did not indicate any social and wider economic impacts relevant for the "other applications" sector, for SEAC to consider. SEAC agrees with the estimations made by the Dossier Submitter.

3.3.3.4. Overall proportionality

Summary of proposal:

The main societal trade-off arising from the restriction proposal is between the costs to society of a potential restriction and the environmental benefits of reducing the emissions of Dechlorane Plus. The stricter the restriction, the higher will be the potential benefits and costs. Because Dechlorane Plus is a PBT/vPvB substance¹⁵, it is not possible to perform a traditional

¹⁵ <https://echa.europa.eu/documents/10162/97b3c3bf-f38a-f3e2-6b53-45654bcc02dc>

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

cost-benefit analysis to assess the restriction proposal's proportionality. Instead, the Dossier Submitter has compared the cost-effectiveness of their proposal to a similar previous restriction on decaBDE.

Cost-effectiveness

The Dossier Submitter has assessed the total costs of the restriction options, where the largest element is lost profits - under all three scenarios. The table 13 below provides a summary of costs associated with the restriction options as estimated by the Dossier Submitter.

Table 16. Summary of costs associated with the restriction options, 2023-2042, Euro million per year

Type of cost	RO1	RO2plus	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 previously noted, RO1 offers the largest reduction in emissions and leads by proxy to the highest environmental benefits. However, RO1 is also the option that will incur the most costs, while RO2plus and RO3 will cost much less but will also reduce fewer emissions.

Furthermore, emissions reduction will come with a delay, as in RO1 there is an 18-month transition period for all uses and RO2plus and RO3 have industry specific derogations of 5, 7 and 10 years

Based on new information from the consultation on the Annex XV restriction report, the Dossier Submitter finds that the substitution costs estimated for Dechlorane Plus (which do not include R&D, investment and other substitution related costs) are likely to be underestimated, while the lost profits and jobs at risk are likely to be overestimated. As lost profits and jobs at risk are expected to be the dominant cost elements, the net cost of all restriction options will likely be substantially lower than estimated by the Dossier Submitter, despite the potential underestimation of substitution costs.

Because the proposed restriction option (RO2plus) is similar to RO2, it is concluded that the net cost of the suggested restriction option is likely to be less than the estimated €180 million per year. In order to allow a comparison of the above estimated costs, a cost-effectiveness ratio has been calculated for each of the restriction options. Table 14 shows the cost per kg of Dechlorane Plus releases prevented by each restriction option over their emission reduction capacity.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Table 17. Cost-effectiveness ranges for the assessed restriction options, € per kg

Sector/use	Cost effectiveness €/kg DP		
	RO1	RO2plus	RO3
All uses	13 000 – 39 000	8 000 – 23 000	0 – 1 000
Central estimate	~20 000	~10 000	~500
Scenario emission reduction capacity	91% of baseline emissions	89% of baseline emissions	76% of baseline emissions

Previous study on cost-effectiveness in chemicals regulation

The Dossier Submitter reviewed a study by Oosterhuis and Brouwer (2015)¹⁶, where a comprehensive list of cost-effectiveness estimates of different types of risk reduction measures for a large number of substances are presented. The outcome of the paper influenced the ECHA (2016)¹⁷ PBT/vPvB approach, which the Dossier Submitter also considered in their assessment.

In the Oosterhuis and Brouwer study, the authors discuss three areas of cost-effectiveness and determine that costs below €1 000 per kg are widely considered to be proportionate, whereas costs above €50 000 per kg are typically seen as excessive and likely to be viewed as disproportionate. Between these values they describe a “grey zone”, in which costs of abatement may or may not be considered proportionate. Based on this approach, the Dossier Submitter deems RO3 as being clearly below the “lower bound” and therefore clearly proportionate, while the cost-effectiveness of RO1 and RO2plus falls within the “grey zone”; in particular RO2plus is likely to be equal to or lower than €10 000 and therefore within the paper’s determined “grey zone”.

DecaBDE vs Dechlorane Plus

To allow for a meaningful assessment of cost-effectiveness the Dossier Submitter has compared the restriction options for Dechlorane Plus to the previous restriction on decaBDE, which is in many ways similar to Dechlorane Plus. In the case of decaBDE the cost of reducing emissions was estimated at 484 €/kg (corresponding to 508 €/kg in 2020 prices).

The Dossier Submitter stresses however that the decaBDE estimations relied only on the incremental costs of alternatives and hence did not include costs related to R&D, investments and profit or job losses. In the Background Document, it is also highlighted that there is greater uncertainty about the availability of alternatives for Dechlorane Plus than there was for decaBDE. Despite this uncertainty, the Dossier Submitter speculates that, if the cost assessment of restricting decaBDE had considered the same elements as that of restricting

¹⁶ Oosterhuis F. and Brouwer R. (2015): *Benchmark development for the proportionality assessment of PBT and vPvB substances*
Available at: [Benchmark development for the proportionality assessment of PBT and vPvB substances. — Vrije Universiteit Amsterdam \(vu.nl\)](https://www.vrijeuniversiteit.nl/en/research/10162/17091/evaluation_pbt_vpVB_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3?t=1472819309457)

¹⁷ See: https://echa.europa.eu/documents/10162/17091/evaluation_pbt_vpVB_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3?t=1472819309457

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

Dechlorane Plus, then the cost-effectiveness of both restrictions would be of the same order of magnitude.

Overall proportionality

The information provided during the consultation led to some additional derogations being added to RO2plus, but this has not affected the expected emission reduction capacity for any of the three restriction options assessed by the Dossier Submitter. The central cost-effectiveness figures are ~€20 000 for RO1, ~€10 000 for RO2plus and ~€500 for RO3 per kg of Dechlorane Plus emission reduced. While RO1 provides the largest reduction in emissions and therefore the highest level of protection to human health and environment, the costs of RO3 are the lowest in terms of cost-effectiveness (corresponding to that found in the previous restriction on decaBDE).

After the consultation, the Dossier Submitter considered that if there are alternatives available for most of the volume used, and a potential lack of alternatives only for certain uses, then this will not significantly affect the production of critical parts. Therefore, the costs for RO2plus could be significantly lower than the current estimate of €10 000 per kg of emissions reduced. However, currently there is no data to support that conclusion. Indeed, the Dossier Submitter did not receive any significant new information in the consultation that would have allowed them to assess the impacts on industry in more detail. The Dossier Submitter concludes that this lack of information may also be considered an indication that the costs of substituting Dechlorane Plus are indeed manageable for most of the industry affected.

RAC and SEAC conclusion(s):

RAC concludes that the proposed restriction option after the consultation on the Annex XV restriction report ("RO2plus") addresses the identified risk related to the use of Dechlorane Plus within an acceptable time period, with targeted derogations and with an acceptable effectiveness. However, the proposed derogations for marine, forestry and garden equipment cannot be supported based on risk considerations.

The PBT/vPvB properties of Dechlorane Plus are an important element influencing the proportionality of a potential restriction, as the impacts on human health and the environment that may occur from these properties are uncertain. Following this line of thought, SEAC agrees that emissions of Dechlorane Plus should be minimised to as low as reasonably practical; all of the proposed restriction options cut emissions substantially, but as the marginal abatement cost is increasing, there is a trade-off to be made between more reduction in emissions and the incremental cost.

To assess and compare the proportionality of the various restriction options, the Dossier Submitter has used a cost-effectiveness approach, as it was not possible to perform a traditional cost-benefit analysis. This is in line with SEAC's recommendations¹⁸ for PBT/vPvB substances. In order to analyse the cost-effectiveness despite the encountered lack of data,

¹⁸ See: https://echa.europa.eu/documents/10162/17091/evaluation_pbt_vpnb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3?t=1472819309457

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

the Dossier Submitter has relied on estimates reported in the literature, previous restrictions, statistics and assumptions to facilitate their estimations and calculations. Overall, SEAC considers this a reasonable approach and concludes that on this basis meaningful estimates can be provided to the decision maker. There are, however, some uncertainties and critical assumptions related to the assessment of the alternatives, costs, and benefits that the decision maker may wish to take into account.

- The consultation resulted in new information that indicates the availability and affordability of alternatives for several uses in different industrial sectors, including the ones with the largest use amounts.
- It was also noted that substitution might already be taking place, within some industries. This is an important factor influencing not only the time and cost of substitution, but also the relevance of the restriction options.
- If alternatives are readily available, this will make it easier and less costly to substitute, and derogations and long transition periods are less justified than in a situation in which there are no alternatives available.
- If there are suitable and affordable alternatives, abating emissions becomes less costly and easier to achieve. On the other hand, abatement may already have taken place in those uses in which alternatives are most readily available and therefore the cost-effectiveness of further reductions in emissions may be less favourable. (This follows directly from the marginally increasing abatement cost curve -see below in the section on key elements underpinning the conclusions- and is sometimes referred to as “low-hanging fruit” implication.)

Originally, the Dossier Submitter presented three restriction options, but following the information received during the consultation, additional arguments and a new restriction option have been added. The new restriction option RO2plus is similar to RO2 but includes different derogations to accommodate concerns from the industry organisations. SEAC scrutinised the various restriction options including the newly added RO2plus, and extended the comparison with previous restrictions, by looking into other relevant restrictions under REACH.

The Dossier Submitter proposes RO2plus as the most appropriate option. When considering the overall cost per kg of releases prevented by the different restriction options, SEAC considers that all three restriction options could be proportionate, depending on what the decision-makers consider an acceptable cost to society for abating emissions of Dechlorane Plus. Based on table 14, RO1 has a higher cost per kg of releases prevented than RO2plus. However, SEAC notes that under RO1 releases are abated sooner. RO3 leads to a significantly lower cost per kg of releases prevented than the other two options and this figure is within the range of previous restrictions implemented already. However, SEAC notes that RO3 is the option that leads to the smallest reduction in emissions over the assessment period and starts the emission reduction latest.

SEAC considers it is important that decision-makers take into account the marginal cost-effectiveness of moving from one restriction option to another (thus, of bringing forward the emissions reductions by removing and/or shortening sectoral transitional periods). The analysis performed by SEAC shows that the marginal costs per additional kg of Dechlorane Plus removed of going from RO3 to RO2plus are €68 000 per kg, which are considered high. Those of going from RO2plus to RO1 are €467 000 per kg, which are significantly higher. Meanwhile, the marginal costs per additional kg abated by moving from the baseline to RO3

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

are €700. Whilst there are no benchmarks either for these marginal cost-effectiveness figures, they give an indication of the added costs to society of progressively stricter restriction options, and thus of the trade-offs involved.

Although the Dossier Submitter does not consider this in greater detail, it is in SEAC's view important to complement the discussion on proportionality with consideration of affordability of the restriction for the industry. Since no information was provided or concerns raised during consultation on the impact of this restriction on EU industry, SEAC can assume that implementing this restriction will not cause a significant financial challenge for the industry.

It is also important to consider other aspects beyond the cost-effectiveness that could affect the appropriateness of the risk management options, which are discussed in section 3.3.1, for instance the social value of certain applications that are proposed to be exempted under RO2plus and RO3.

Key elements underpinning the RAC and SEAC conclusion(s):

Emissions from Dechlorane Plus occur at all life cycle stages. Considering the broad use of the substances in different sectors, a restriction with carefully selected and justified derogations is from a risk perspective an effective measure. The proposed RO2plus with time limited derogations for the aerospace and defence sector and specific medical devices (medical imaging applications and radiotherapy devices/installations) as well as derogations for use in spare parts for the aerospace and defence sector, specific medical devices (medical imaging applications and radiotherapy devices/installations) and motor vehicles result in an annual emission reduction capacity of 89% when compared to the baseline emissions. This results in an annual emission reduction of about 1-3 tonnes/year.

To assess the proportionality of all restriction options, SEAC has looked at measures beyond the cost-effectiveness analysis presented by the Dossier Submitter. To enrich the assessment and highlight the trade-off between the costs and benefits of the different restriction options, an incremental marginal cost-effectiveness analysis and abatement cost curve have been produced. Moreover, SEAC extended the comparison with previous restrictions, by looking into other relevant restrictions under REACH. The following sections account for these additions, whereby the scope of the analysis of the restriction options is extended to conclude on proportionality.

SEAC underlines that it is currently not possible to estimate benefits of abating PBT/vPvB substances, and hence impossible to determine the proportionality through a cost-benefit analysis. As a reference point SEAC notes that SEAC PBT/vPvB approach paper¹⁹ states: "To assess whether the regulatory action results in net benefits for the society, **it would be desirable** to have a comparator or a "benchmark" on the level of costs that are deemed to be worthwhile taking when reducing emissions of PBTs and vPvBs." Following this SEAC concludes that "Based on the available information, it does not seem to be currently possible to set any benchmark level for the acceptable level of cost effectiveness or other indicator of benefits that would be applicable for all PBTs and vPvBs". This applies also to the figures proposed in the Oosterhuis and Brouwer study, which are therefore not used as benchmarks

¹⁹ See: https://echa.europa.eu/documents/10162/17091/evaluation_pbt_vpVB_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3?t=1472819309457

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

by SEAC.

Due to the PBT/vPvB properties of Dechlorane Plus and unknown safe level of exposure, it is not meaningful to quantify the benefits of the proposed restriction in different ways than through the quantification of reduced emissions. SEAC has reviewed the cost assessment the Dossier Submitter had made based on the limited information available, and takes note that RAC agree with the emission reductions as calculated by the Dossier Submitter. Therefore, SEAC considers the cost-effectiveness ratios presented by the Dossier Submitter to be reasonable estimates and uses them in its own evaluation of the options proposed. However, SEAC notes that the Dossier Submitter considers that the costs are likely to be over-estimated and therefore lower than the figures used in calculating the cost effectiveness ratios; an assumption SEAC agrees with.

DecaBDE comparison

The Dossier Submitter has applied a cost-effectiveness approach to assess the proportionality of the restriction options. Assessing proportionality by including consideration of the cost-effectiveness of the restriction is usual in similar cases, and SEAC agrees with the Dossier Submitters' approach.

In the Background Document, the Dossier Submitter has compared the previous Dechlorane Plus restriction proposal to decaDBE, as it was argued that the two share substance similarities and the proposed restriction is somewhat similar.

In the case of decaDBE the central cost-effectiveness estimate was 484 €/kg of emissions prevented (508 €/kg updated to 2020 level), based on substitution costs for switching to drop in alternatives, and on price and loading information.

Therefore, these costs were not just lower than those of Dechlorane Plus, but also more transparent due to the availability of drop-in alternatives. As there are no drop-in alternatives available for Dechlorane Plus, that cost-effectiveness estimation method cannot be applied. SEAC finds the comparison of the restrictions credible but notes that additional restriction comparisons would have made the analysis more substantial and tangible.

Cost-effectiveness analysis and other restrictions

Comparisons with other PBT/vPvB restriction substances are appropriate; however, SEAC underlines that cost estimations founded on profit and job losses make it challenging to compare the cost-effectiveness to previous restrictions. This is because the applied cost categories are not used in the costs assessment of other restriction proposals. The related uncertainties and potential overestimations of the costs make it additionally challenging to make a comparison to previous restrictions.

Table 15 below shows some relevant restrictions, which the proposals for a restriction of Dechlorane Plus can be compared to.

Table 18. Comparison of the cost-effectiveness of the proposed restriction and previous restrictions under REACH, central estimates.

Restrictions under REACH	Central value (€/kg)
Proposed restriction for Dechlorane Plus (RO1)	18 600 (likely lower)
Proposed restriction for Dechlorane Plus (RO2plus)	10 600 (likely lower)
Proposed restriction for Dechlorane Plus (RO3)	700 (likely lower)
Lead stabilisers in PVC	308
Mercury in measuring devices	4 100

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Phenylmercury compounds	649
PFOA	1 649
PFOA-related substances	734
D4, D5 in wash-off	415
D4, D5, D6	464
DecaBDE	464

Setting the estimated cost-effectiveness of Dechlorane Plus side by side with other previous restrictions, the costs of Dechlorane Plus are at the high end. When comparing the costs of previous restrictions to the costs of the various Dechlorane Plus restriction options directly, SEAC agrees that RO3 appears to be in line with previous restrictions, while RO2 (and hence RO2plus) are at the higher end, and RO1 appears even more costly.

SEAC notes, however, that the Dossier Submitter's anticipation of the costs being lower than currently estimated means the costs of the proposed restriction are likely to be closer to the cost of previous restrictions in the table above. This means that the costs of RO2plus may be, to some extent, in the same order of magnitude as PFOA and mercury in measuring devices, as displayed in the table above.

SEAC finds it appropriate to compare the costs of Dechlorane Plus with those estimated for PFOA, ranging from 0 to 6 551 €/kg, and Mercury in measuring devices ranging from 0 to 19 200 €/kg.

SEAC suggests that these restrictions could have been included as a point of reference in the Background Document provided by the Dossier Submitter for further comparison.

In terms of assessing proportionality through comparing different restriction options, SEAC underlines that although it is possible to draw some parallels, precise comparability with cost-effectiveness of other restrictions is not possible. The highlighted costs differ between the previous restrictions and that of Dechlorane Plus, in terms of the foundation of costs estimations and knowledge concerning availability of alternatives. Additionally, the cost-effectiveness of previous restrictions cannot be considered benchmarks.

Nevertheless, the cost-effectiveness of RO3 is likely in the same order of magnitude as some previous, notably PFOA and PFOA related restrictions, and hence may be tolerable to society. If the costs of RO2plus are, as expected, overestimated, this restriction option is also within the same order of magnitude as previous restrictions, and may also be tolerable to society. The cost-effectiveness ratio for RO1 is likely outside of the range of that of previous restrictions. However, this does not necessarily mean that it would not be tolerable for society.

Incremental marginal cost effectiveness analysis

In order to allow a more complete comparison of the different Restriction Options proposed and analysed by the Dossier Submitter, SEAC has performed an incremental marginal cost effectiveness analysis, which is presented in table 16 below, and illustrated in the graphs that follow. The analysis highlights the ratio of difference in cost and emission change for various restriction options. By applying the incremental cost-effectiveness ratio, it is possible to assess the additional cost per unit of emission reduction gained from each restriction option.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON
DECHLORANE PLUS

Table 19. Incremental marginal cost effectiveness analysis

Incremental marginal cost effectiveness analysis	Central emission reduction estimate* [t/y]	Total costs, 2023 – 2042, [€m/y]	Cost-effectiveness ratio [€/kg]	Incremental change in cost [€m/y]	Incremental change in emissions [t/y]	Marginal cost-effectiveness [€/kg]
Restriction option 1	17.25	320	18 600	140	0.30	467 000
Restriction option 2+	16.95	180	10 600	170	2.50	68 000
Restriction option 3	14.45	10	700	10	14.45	700

Note: According to the Dossier Submitter the effects of the proposed restriction option (RO2plus) are likely to be similar to those of the RO2.

*For simplicity, this analysis has been performed based on central estimates

As the table shows (see 'Incremental change in cost' column), RO1 costs €140m per year more than RO2plus, which costs €170m per year more than RO1. RO1 costs €10 m per year more than the baseline. Regarding their emission reduction capacity, RO1 leads to a reduction of 0.3 t/year more than RO2plus, which in turn leads to a reduction of emissions of 2.5 t/y more than RO3. RO3 reduces emissions by 14.45 t/y in comparison to the baseline (see 'Incremental change in emissions' column).

Marginal cost-effectiveness is calculated by dividing the incremental change in cost by the incremental change in emissions for each RO, and shows the cost per kg of emissions reduced as a product of moving from one RO to the next.

This information has also been plotted onto an abatement cost curve. By combining the total cost and total emission reduction potential for the various restriction options, the costs of reducing emissions by moving from one RO to the next are illustrated below.

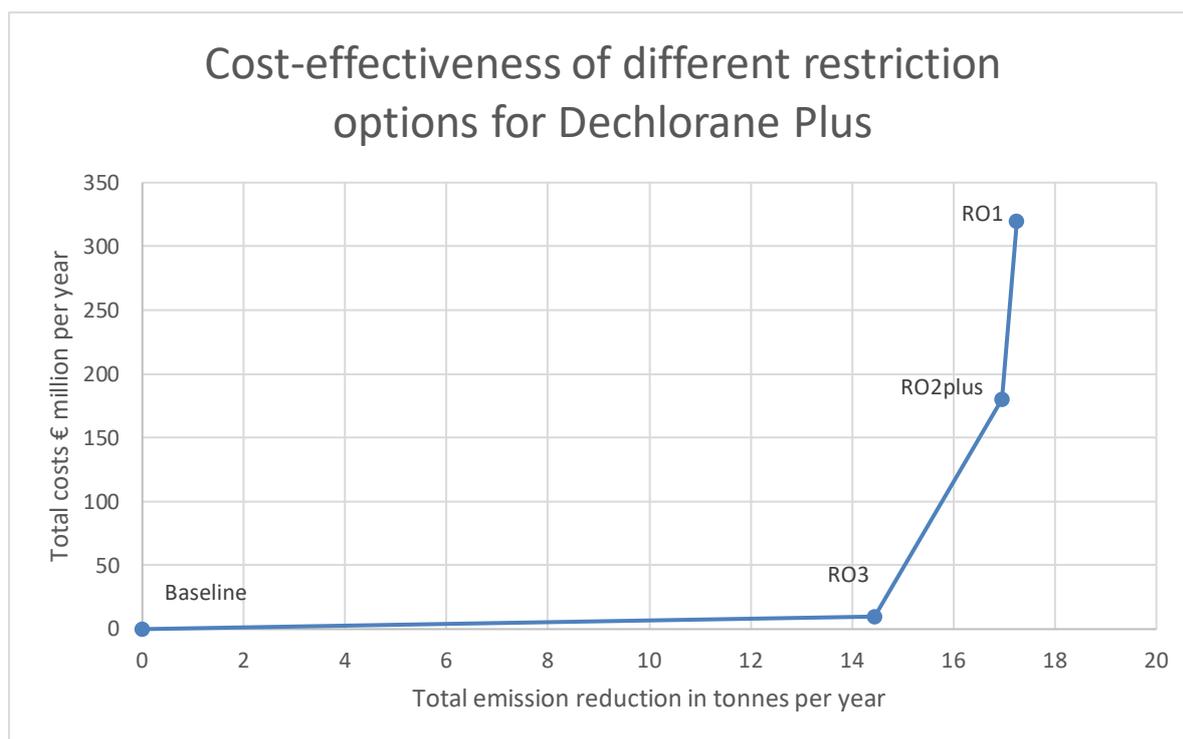


Figure 1

Figure 1 displays the costs of reducing 14.45 tonnes of emissions per year in RO3, compared with reducing 16.95 t/year and 17.25 t/year in RO2plus and RO1 respectively. The curve shows a steep cost rise from RO2plus to RO1, presenting the incremental change in emissions from RO1 to RO2plus as expensive, as the reduction of the additional 0.3 tonnes will cost €140 million per year.

The rise from RO3 to RO2plus is less steep; an additional 2.5 tonnes of emissions are reduced in RO2plus compared to RO3, for the cost of €170 million per year. That means the additional cost of avoiding a kg of emissions per year between RO2plus and RO3 is €68 000, one order of magnitude below the additional cost of avoiding a kg of emissions per year between RO1 and RO2plus, at €467 000.

The move from the baseline to RO1 is more gradual, as 14.45 tonnes of emissions per year are reduced at an annual cost of €10 million per year.

SEAC considers that this analysis highlights that from a cost-effectiveness perspective RO3 is the most favourable option, as the cost per amount of reduced emission is the lowest. However, the amount of emissions reduced is also the lowest under this restriction option, as more emissions are reduced under RO1 and RO2plus.

As analysed above, comparing with previous restrictions the overall cost-effectiveness of both RO2plus and RO3 is within the range of that of previous restrictions. However, SEAC notes that the marginal costs per additional kg of Dechlorane Plus removed of going from RO3 to RO2plus are €68 000 per kg, which are considered high. Those of going from RO2plus to RO1 are €467 000 per kg, which are significantly higher. Meanwhile, the marginal costs per additional kg abated by moving from the baseline to RO3 are €700. Whilst there are no benchmarks either for these marginal cost-effectiveness figures, they give an indication of the added costs to society of progressively stricter restriction options, and thus of the trade-offs involved.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

The marginal cost-effectiveness for each restriction option is presented in the figure below.

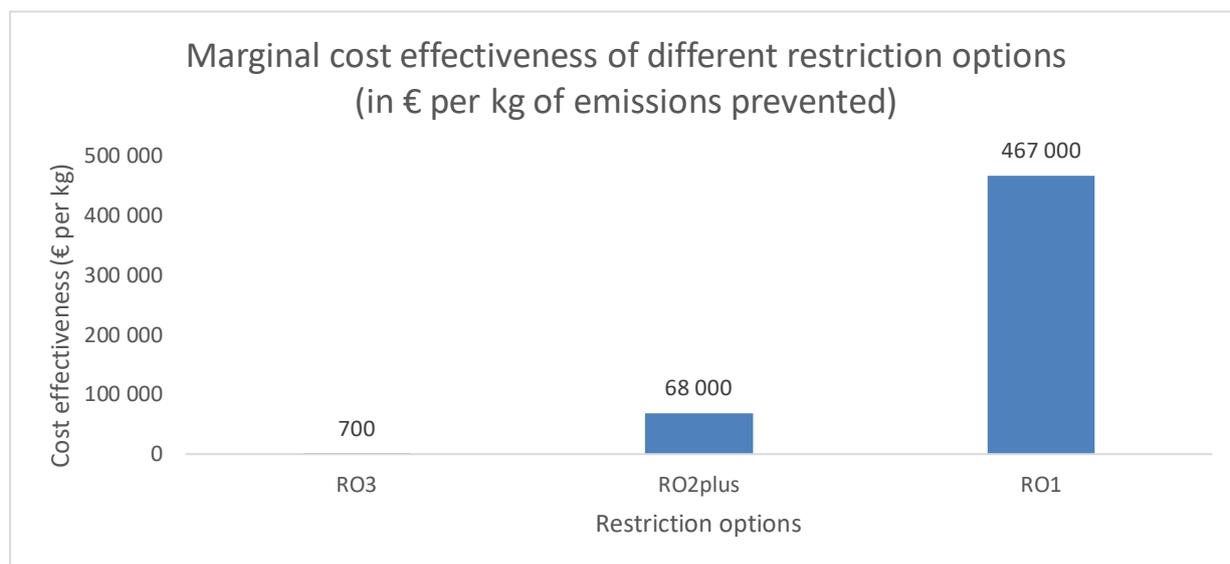


Figure 2. The marginal cost-effectiveness of RO1, RO2plus and RO3

Affordability

During the consultation only one comment was received, from the Japanese motor vehicle industry, which suggested one-off costs of introducing the restriction, but no information was provided from the EU. Additionally, the substance is used for more applications in Japan than in the EU, which suggests that the costs are likely to be lower for EU-based companies, making the restriction more affordable for that sector. No information on costs was received for other sectors.

SEAC assumes that if EU industry would be facing genuine affordability issues from this restriction, they would have provided comments and objections through the third-party consultation. Since these were not forthcoming, it can be assumed that overall, the restriction presents no concerns regarding affordability for the industry.

Final remarks:

The Dossier Submitter proposes RO2plus as the most appropriate option. When considering the overall cost per kg of releases prevented by the different restriction options, SEAC considers that all the restriction options could be proportionate, depending on what the decision-makers consider is a tolerable cost to society for abating emissions of Dechlorane Plus. RO1 has a higher cost per kg of releases prevented than RO2plus. However, SEAC notes that under that option, releases are abated sooner. RO3 leads to a significantly lower cost per kg of releases prevented than the other two options, and this figure is within the range of previous restrictions implemented already. However, SEAC notes that it is the option that reduces the fewest emissions over the assessment period, and starts the emission reduction latest.

SEAC considers that it is important that decision-makers take into account the marginal cost-effectiveness of moving from one restriction option to another (thus, of moving forward the emissions reductions by removing and/or shortening sectoral transitional periods). The

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

analysis performed by SEAC shows that the marginal costs per additional kg of Dechlorane Plus removed of going from RO3 to RO2plus are €68 000 per kg, which are considered high. Those of going from RO2plus to RO1 are €467 000 per kg, which are significantly higher. Meanwhile, the marginal costs per additional kg abated by moving from the baseline to RO3 are €700. Whilst there are no benchmarks either for these marginal cost-effectiveness figures, they give an indication of the added costs to society of progressively stricter restriction options, and thus of the trade-offs involved.

As there are no established thresholds for when the restriction can be considered proportionate, SEAC deems it appropriate to also consider in the assessment of the appropriateness of the different options the available evidence concerning the properties of Dechlorane Plus as a PBT/vPvB substance.

As Dechlorane Plus is a stock pollutant characterised by PBT/vPvB properties, the environmental and the human health impacts that may occur from the substance are unknown. The chemical is very mobile, has long-range transport potential and is able to contaminate remote regions. Today it is already ubiquitously present in the environment. As the emissions are irreversible, these will stay in the environment and accumulate in the future. Currently there is only limited information about the substance's potential effects, but if the substance is harmful, impacts on human health and environment might be rather costly and potentially permanent.

It is therefore in line with REACH to minimise the emissions as much as possible, as there is no known safe level of exposure. For the time being, end-of-pipe technologies to reduce releases are not generally effective or cost-effective, because the emissions occur essentially at articles' end of life. Therefore, it is likely that remediation costs are likely to have much higher costs than the than the costs of implementing the proposed restriction.

As there is limited knowledge concerning the harms of Dechlorane Plus in the environment, there may be potential harmful effects in the future linked to concurrent emissions.

Considering this possibility, as well as the potential costs of removing the substance from the environment once emitted, it seems preferable to reduce future emissions now. Avoiding harmful effects and future costs is a benefit which society may very well be willing to pay for, though it is linked with some present costs. This unknown willingness-to-pay affects whether the costs associated with RO1, 2, 2plus and 3 are seen as excessive or bearable.

3.3.3.5. Uncertainties in the proportionality section

There are several elements of uncertainty related to proportionality covering:

- Lack of robust data on costs of substitution.
- Uncertainties of the cost's estimation grounded on profit and job losses.
- Emission reduction achieved and any related environmental impacts.
- Availability and risks of alternatives.
- Impact of the changes on the activity of the industries

As the Dossier Submitter has been unable to collect sufficient information concerning substitution costs, estimation was only possible using cost of chemicals. As noted above this leads to some certainty and transparency issues, but SEAC acknowledge the attempts made

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

by the Dossier Submitter and supports the alternative way of focusing on lost profits instead.

Looking more closely at the identified costs-effectiveness values, these are mainly based on the categories "jobs at risk" and "profit at risk," leaving out a whole lot of potential costs like R&D and investments.

The lost profits and potentially lost profits have been set as a cost indicator, in the absence of enough robust knowledge and data related to substitution costs. The potentially lost profits have been included as a sort of "buffer" for the potentially significant costs related to the alternatives, as information about these are scarce. Still, the many assumptions and uncertainties related to the categories have led the Dossier Submitter to perform a sensitivity analysis (discussed later under in 3.4) to work around this. In the sensitivity analysis the overall conclusions do not change, despite the great uncertainty related to especially lost profit, as most of the values fall within the range identified in the main analysis. SEAC approves of the use and result of the sensitivity analysis.

SEAC finds two potential issues regarding the alternatives and the risk of these:

- It is unknown if the alternatives which the Dossier Submitter have suggested are in practice technically and economically feasible
- The consultation has supplied limited information in respect to current use of alternatives.

Although the consultation revealed there might be an available alternative for a major user category within the EU, this was not confirmed as being used at the moment by the stakeholders. Even though the general information regarding alternatives is sparse, it is important to note there was no explanation provided by stakeholders on why the alternatives, which the Dossier Submitter has identified, would not be feasible.

In SEAC's view, Dechlorane Plus is imported in articles, further manufacture outside the EU may continue, and there is nothing stopping new manufacture to start. Hence the need for this restriction to prevent this.

3.3.4. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers that enforcement authorities could check documentation from the supply chain confirming that the articles do not contain Dechlorane Plus. Enforcement activities should cover the manufacture, import of Dechlorane Plus as such, in mixtures and in articles, and the use of Dechlorane Plus in production of articles in the EU. In addition, it is envisaged they will verify if the articles contain Dechlorane Plus 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 proposed concentration limit of 0.1% w/w would therefore enhance the enforceability.

The Dossier Submitter considers that practicability cannot be fully evaluated due to the uncertainties related to the availability and feasibility of alternatives to substitute Dechlorane Plus. Therefore, in this context, extended transition periods would increase the practicality, as the likelihood to identify and implement alternatives would also increase. Based on this,

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

the Dossier Submitter deemed RO3 as the most practical restriction option for the industry.

Regarding enforceability, the Dossier Submitter considers the restriction enforceable. Enforcement through documentation check and testing are deemed feasible and facilitated by the proposed 0.1% w/w concentration limit and by the availability of reference standards for the determination and quantification of Dechlorane Plus.

Given that, the absence of an EU standard analytical method is not considered as a hindrance to the enforceability of the proposed restriction.

RAC and SEAC conclusion(s):

RAC concludes that the proposed restriction is practicable and enforceable.

RAC took note of the final advice (18th November 2021) and the support document (1st March 2022) from the Forum which states that in general the proposed restriction is enforceable. The FORUM noted that the terms "aerospace" and "marine, garden and forestry machinery applications" require more precise definitions. RAC acknowledges the comments of the FORUM in relation to the revised conditions of the restriction (1st March 2022), which states that in general more exemptions make restrictions more complicated to enforce and that the status of second-hand articles and some of the terms used in the conditions of the restriction should be clarified. The FORUM also recommended that the conditions of the restriction for spare parts is redrafted to ensure that it is readily understood.

SEAC's view is that the proposed restriction would be implementable and manageable.

Key elements underpinning the RAC and SEAC conclusion(s):

RAC:

The RAC Opinion is based on the Background Document section 2.2 and Annex E.2.

The Dossier Submitter confirmed that analytical methods for qualitative and quantitative determination of halogenated flame retardants including Dechlorane Plus, and its anti- and syn-isomers, have been described extensively in the literature in the past decade.

The FORUM states in their final advice (18th November 2021) and the support document (1st March 2022), that no international standard methods for determination of Dechlorane Plus and its isomers exists today, but standards for determination of other halogenated flame retardants like bromophenyl ethers in different matrices such as, waste, electronic products and water are well established. These methods are based on the same analytical approach as used for determination and quantification of Dechlorane Plus. The typical Limit of Quantification (LOQ) is significantly lower than the concentration limit proposed in the restriction entry. Therefore, the available techniques are sensitive enough to produce reliable analytical results for all relevant matrices to enable compliance monitoring and enforcement.

The FORUM also confirmed that sampling should be feasible for inspectors. Although there are some concerns regarding some types of articles, for example automotive and even more for aviation products.

The FORUM states that more exemptions make restrictions more complicated to enforce. It is not clear what exactly is included in the definition of aerospace and the definition of marine,

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

garden and forestry machinery. Garden machinery could be from an enforcement point of view common products in retail shops for consumers. The FORUM suggests to phrase the conditions of the restriction in a different way so that the intention of the derogations for spare parts are clearer.

SEAC:

Clarity of the scope:

Forum considered that the initial scope as well as the wording of the restriction is generally clear, and according to the current wording, the use of substances, mixtures and articles already placed on the market is not restricted. It is possible that, as a consequence of the introduction of derogations, guidance may be needed to identify which industry sectors are affected.

Feasibility of Alternatives

Apart from some complex uses, the fact that the industry did not report major issues, can be interpreted that alternatives are already identified for most of the uses. In this sense, SEAC considers that the current restriction might be an incentive to accelerate the substitution process of Dechlorane Plus.

However, substitution in more complex applications may take more time than the proposed transition time. In SEAC view, the proposed derogations will increase the practicality of the restriction.

Enforcement

SEAC notes Forum's opinion that this restriction can be regarded as enforceable and sampling should be feasible.

Notwithstanding concerns with some type of articles in aerospace and defence sectors, the Forum recommends that a standard procedure should be developed (also concerning extraction) for the analytical methods.

In SEAC's view the enforcement of this restriction will not be limited by testing issues since the concentration limit proposed by the Dossier Submitter seems not to be an issue for the detection and quantification of Dechlorane Plus concentration with analytical techniques available. The concentration limit of 0,1 % coincides with the concentration limit triggering notification and information requirements under REACH and is significantly above the limit of quantification. The quantification is possible since reference materials are also available. Therefore, SEAC expect that the lack of standardised analytical methods will not jeopardise the enforceability of the restriction.

Enforcement actions by documentation checks from the supply chain are also likely. Although the industry claims that frequently there is a lack of information on the content of imported articles, the EoF of this restriction may oblige the European companies to be more demanding on this type of information in the supply chain.

3.3.4.1. Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers the proposed restriction to be monitorable. Initial screening for chlorine in materials is reported using X-ray fluorescence (XRF). This rapid technique can be used as an efficient method to determine potential content of Dechlorane Plus in waste streams. However, XRF can only be used for crude identification because it does not distinguish chlorine (Cl) in polymers from Cl in Dechlorane Plus. Therefore, such method is most used as a first step for identifying materials for further assessment by more targeted approaches using mass-spectrometry or for crude sorting and separation of waste to separate out e.g. waste fractions heavily contaminated with halogenated compounds. Other spectroscopic techniques like Fourier Transform Infrared Spectroscopy (FTIR) will be able to distinguish polymeric bound chlorine from chlorine bound in Dechlorane Plus.

RAC and SEAC conclusion(s):

RAC took note of the final advice (18th November 2021) and the support document (1st March 2022) by The Forum which states that in general the proposed restriction enforceable.

RAC is of the opinion that it will be difficult to monitor the effect of the restriction via environmental monitoring alone, due to the vPvB properties of Dechlorane Plus and due to continuous emissions from existing landfills and from end-of-life (waste-stage) of articles currently in use. There is a "stock" of Dechlorane Plus in articles and so there can be a delay before changes in use are observed as changes in releases and environmental contamination. Consequently, it may be only possible to monitor the effect of the restriction via monitoring of the use volumes of articles placed on the market containing Dechlorane Plus in the future.

SEAC agrees that the restriction is monitorable.

Key elements underpinning the RAC and SEAC conclusion(s):

RAC:

The RAC Opinion is based on the Background Document section 2.6 and Annex E.6.

Precise determination and quantification of Dechlorane Plus and its isomers have been reported in almost all environmental matrixes, including samples of human serum, and in consumer products, building materials and waste, using quantitative target screening methods with reference standard solutions for identification and quantification.

The persistent and very persistent properties of PBT/vPvB substances in general cause problems to monitor the success of a restriction with environmental monitoring. As such for substances which persist for a very long time in the environment the exposure remains even after emissions have been ceased and minimized. Consequently, it may take decades to prove decreasing levels in environmental matrices and in human beings. In the case of Dechlorane Plus, in addition to the vPvB properties, the continuous emissions from the waste-stage of articles and from landfills will deteriorate the monitorability via environmental monitoring.

The Dossier Submitter derived new estimates for the volumes used per sector, based on new

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

information received in the consultation on the Annex XV restriction report (see Box 1, Background Document section B.2.4.). RAC notes that for the medical sector and the marine, garden and forestry sectors no use volumes are available and are only estimated pooled within “other applications”. The success of this restriction may be monitored via the use volumes within the different sectors e.g. motor vehicles, aerospace and defence and other applications, including imported articles. The Dossier Submitter assumes around 30 tonnes of Dechlorane Plus were imported to the EU in articles in 2019 (see Background Document section A.1.1.1.). Due to the conflicting information provided by different stakeholders this approach of monitorability is imperilled to high uncertainty.

The FORUM confirms that sampling of articles should be feasible for inspectors, although there are some concerns regarding some types of articles, for example automotive and even more for aviation products. XRF and FTIR can be used as a rapid screening method but is not a needed step in the analysis and so it will not affect the monitorability.

SEAC:

The SEAC Opinion is based on the Annex E section E.7.2 and in the Forum advice.

Due to the characteristics of PBT/vPvB substances, risks cannot be adequately addressed in a quantitative way. Therefore, emissions and subsequent exposure, are considered as a proxy for risk. Monitoring the effectiveness of the proposed restriction in reducing the emissions can, in the first instance, be carried out by monitoring the emissions from waste treatment plants and industrial sites, as well as in the respective industrial soils. However, decreasing levels may take a long time to detect due to the very persistent properties of Dechlorane Plus.

However, the Dossier Submitter indicates that analytical methods to identify and quantify Dechlorane plus are available. The Dossier Submitter indicates the limit of quantification of Dechlorane Plus is significantly lower than the proposed 0.1% w/w concentration limit in the restriction entry. Thus, it is expected that monitoring the presence the substance above the proposed limit is feasible.

No comments on the monitorability were received during the consultation, and the Forum does not identify special issues on the monitorability of this restriction. However, the Forum raised some concerns regarding the sampling in very complex articles as automotive and aviation products.

3.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

3.4.1. RAC

Summary of proposal:

A number of uncertainties have been identified and described by the Dossier Submitter in the Background Document (section 3 and Annex F). Regarding the use volumes, differences in the total volume manufactured and used were reported by stakeholders. These uncertainties are captured in the large tonnage band taken forward for the exposure assessment.

Owing to a lack of site-specific exposure information for the EU, a generic approach closely aligned with ECHA Guidance R16 has been used for the exposure assessment. The approach involves a number of assumptions and, where appropriate, a realistic worst-case approach

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

has been chosen in line with ECHA Guidance R16. Uncertainties in the use volumes, both at a given site (local scale) and EU-wide, are a driving factor for the results of the exposure assessment. The limited information on volumes used combined with the lack of information on fractions of Dechlorane Plus released to air, water, and soil from the various processes using Dechlorane Plus and lifecycle stages, creates uncertainties in the exposure assessment. The Dossier Submitter therefore used 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.

Uncertainties are introduced when dynamics are introduced to the modelling estimating the baseline emissions (see Annex F2 to the background document). For the baseline emissions of Dechlorane Plus, it has not been possible to capture continued emissions from articles already in use, nor the continued emissions after the end of the analytical period. These exclusions will, to some extent, balance each other out, so it is not expected that this will have a large impact on the overall results. The exposure model underlying the baseline modelling is static and does not pick up emissions from use of Dechlorane Plus prior to 2020. This leads to an underestimation of emissions in the beginning of the analytical period for the different restriction options, i.e. higher emissions should be observed due to continued emissions from historic use. This is in particular the case for emissions from landfills. Furthermore, the model also implicitly assumes that emission ceases when use of the substance in restricted uses ceases. In reality, parts of the emissions will occur during the service life of the articles and a significant share of the emissions would occur at the waste stage. The reduction in emissions as compared to the baseline will therefore in reality be more spread throughout the analytical period.

RAC conclusion(s):

RAC agrees with the identified uncertainties and the sensitivity analysis performed by the Dossier Submitter. RAC concludes that the uncertainties do not change the overall conclusion that there is a risk from Dechlorane Plus that is not adequately controlled within the EU.

Key elements underpinning the RAC conclusion(s):

The RAC Opinion is based on the Background Document section 3.1 and Annex F.

The main uncertainties in the restriction proposal are related to the use volumes of Dechlorane Plus. Uncertainties in the use volumes, both at a given site (local scale) and EU-wide, is a driving factor for the results of the exposure assessment. The limited information on volumes used combined with the lack of information on fractions of Dechlorane Plus released to air, water, and soil from the various processes using Dechlorane Plus and lifecycle stages, creates uncertainties in the exposure assessment. Therefore, an approach based on 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 was used by the Dossier Submitter to capture such uncertainties.

The overall emission reduction capacity of each RO was estimated by subtracting the total emission under each scenario from the total emissions under the baseline. This means that the inaccuracies in the timing of the emission reductions will have less impacts on the emission reduction capacities of the ROs. The longer the analytical period used in the analysis, the more accurate the total emission reductions will be.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

From the available information it is not clear whether manufacture of Dechlorane Plus outside the EU is still taking place. There was one active registration of Dechlorane Plus (*ADAMA Agriculture BV*) and they notified a cease of manufacture to ECHA in May 2021. RAC notes that individual importers can only import currently below 1 tpa, as there are no active registrations. However, currently the amounts and use volumes of Dechlorane Plus imported into the EU are uncertain. It is noted that in case the substance is added into the Stockholm Convention, a monitoring of the volumes will be established among all parties to the Convention. This may reduce the uncertainties for the future volumes imported to the EU to some extent.

Due to the very limited data and information received in the consultation on the Annex XV restriction report the amounts and use volumes are still subject to uncertainties. Consequently, also the effectiveness of the proposed restriction with regard to the reduction of releases and significance of the derogations for the aerospace and defence sector, for medical imaging applications, for radiotherapy devices/installations, for the motor vehicles sector and for marine applications to the effectiveness are uncertain to the corresponding degree, as the emission estimates are directly related to the estimated volumes. The uncertainties in evaluating a proposed derogation increases if the use sector represents wide-dispersive uses with shorter life-time of the articles and lower likely control at the waste lifecycle stage under reasonably foreseeable conditions of use as e.g. for the marine, garden and forestry sectors. Without data and information neither on use volumes, expected emissions nor implemented operational conditions (OCs) and risk management measures (RMMs) are the uncertainties in the risk considerations for such sectors very high. Estimation of the effectiveness of the restriction for the largest source of baseline releases, namely dismantling and landfills, also encompasses uncertainties.

The Dossier Submitter proposes a review clause to evaluate the need for derogations after the end of the proposed derogation periods.

3.4.2. SEAC

Summary of proposal:

Sensitivity analysis:

The uncertainties of the analyses have been tested in a sensitivity analysis, presented in table 118 section F.3. The results show most of the sensitivity values falling within the range defined in the core analysis; uncertainties caused by single input factors are hence not likely to change the overall conclusion.

Input variables are considered highly uncertain by the Dossier Submitter. Use volumes were a key uncertainty but they were not tested in the sensitivity analysis. Sensitivity analysis details are in Annex F.2 and H.6.

Dossier Submitter states that their sensitivity analysis shows that only a few tested parameters have significant effect (where they define it as an absolute value of higher than 10%) on the cost-effectiveness of the restriction option.

The highest impact in cost-effectiveness is in the overall sales value where percentage variations in sales translate to almost one-to-one in the cost-effectiveness estimates.

OPINION ON AN ANNEX XV REPORT PROPOSING RESTRICTIONS ON DECHLORANE PLUS

The second highest impact is the profit margin for the automotive sector.

Although Dechlorane Plus's use volumes and emissions were identified as a key uncertainty, it has not been tested in the sensitivity analysis, but that uncertainty is reflected in the broad tonnage band used in the analysis.

The table below presents clearly the summary of key results from the sensitivity analysis.

Table 20. Summary of the key results from sensitivity analysis

Variation	RO1	RO2plus	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 – 15 000	0 – 1 000
Range from the core analysis (Low, High)	13 000 – 39 000	8 000 – 23 000	0 – 1 000

SEAC conclusion(s):

SEAC concludes that the uncertainties have been adequately assessed and presented by the Dossier Submitter. SEAC considers that major uncertainties are related to the availability of technical and economically feasible alternatives, which are conditional on the cost analysis by using potential profits losses as the primary economic cost component.

Key elements underpinning the SEAC conclusion(s):

Other relevant uncertainties are the estimation of the baseline for the use of Dechlorane Plus in Europe for the 20 years period of analysis and the estimation of the expected responses of the industry to the restriction.

The former is tested directly in the sensitivity analyses which show that uncertainty has a lower impact on the cost-effectiveness of the restriction options, and the latter is reflected in the potential profit losses where a change of +/- 50% was tested. In SEAC view, the use of this large interval is justified by the high degree of uncertainty of this estimation.

The consultation on the Annex XV restriction report did not provide relevant information on the availability and feasibility of alternatives and the substitution costs. One submitter (#3332, #3527) provided some substitution costs for the Japanese auto parts industry (#3527), but this claim could not be further scrutinised.

REFERENCES

See Background Document