

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

Draft Opinion

on an Annex XV dossier proposing restrictions on

1,6,7,8,9,14,15,16,17,17,18,18-
Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene
(Dechlorane Plus) [covering any of its individual anti- and synisomers or any
combination thereof]

ECHA/RAC/[Opinion N° (same as opinion number)]

ECHA/SEAC/[Opinion N° (same as opinion number)]

Compiled version prepared by the ECHA Secretariat of RAC's opinion
(adopted [xx Month 20xx]) and SEAC's opinion (adopted [xx Month
20xx])

Draft date: 16/03/2022

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
DECHLORANE PLUS™

[Date]

[RAC opinion number]

[Date]

[SEAC opinion number]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier 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 synisomers 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 documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <https://echa.europa.eu/restrictions-under-consideration> on **23/06/2021**. Interested parties were invited to submit comments and contributions by **03/01/2022**.

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 **[date of adoption of the opinion]**.

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.] [a simple majority]** of all members having the right to vote. [The minority position(s) including their grounds are made available in a separate document which has been published at the same time as the opinion.]⁴

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 **16/03/2022**. Interested parties were invited to submit comments on the draft opinion by **15/05/2022**.

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 **[date of adoption of the opinion]**. [The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]**]¹.

[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.] [No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and]³ 71(1)]⁶.

The opinion of SEAC was adopted **by [consensus.] [a simple majority]** of all members

¹ Delete the unnecessary part(s)

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having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion.]⁶.

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1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Table 1. Proposed restriction

| | |
|--|---|
| <p>XX. 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]</p> <p>CAS No 13560-89-9; 135821-74-8; 135821-03-3</p> <p>EC No 236-948-9; -; -</p> | <p>Conditions of the restriction</p> <ol style="list-style-type: none"> 1. Shall not be manufactured or placed on the market as a substance on its own from [18 months after entry into force]. 2. Shall not, from [18 months after entry into force], be used in the manufacture of, or placed on the market in: <ol style="list-style-type: none"> (a) another substance, as a constituent; (b) a mixture; (c) an article, in a concentration equal to or above 0,1% by weight. 3. Paragraph 2 shall not apply to: <ul style="list-style-type: none"> • articles placed on the market for the first time before [18 months after date of entry into force] 4. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of: <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]. 5. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of: <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] |
|--|---|

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| | |
|--|---|
| | <ul style="list-style-type: none">• 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 DP within aerospace and defence.

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

1.1. THE OPINION OF RAC

See RAC opinion

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 MAKING

2.1. Summary of proposal

Dechlorane Plus is mainly used as a flame retardant in adhesives, sealants and polymers as well as an extreme pressure additive in greases. The concentration of Dechlorane Plus in polymers and adhesive formulations are in the range of 13%-20% and 5%-30%, respectively, and between 20% and 25% in greases.

Dechlorane Plus was identified by ECHA as a Substance of Very High Concern (SVHC) in 2018 because of its very persistent and very bioaccumulative properties (vPvB). As of 2020, Dechlorane Plus use volumes are estimated to be between 90 and 230 tonnes/year in the EU, with a central estimate of 190 tonnes/year. The automotive sector is thought to be the principal user of Dechlorane Plus with 81 to 161 tonnes used in 2020.

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 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 in all uses.

The Dossier Submitter concluded that the risks posed by Dechlorane Plus are not adequately controlled and that a comprehensive restriction under REACH is therefore the most appropriate risk management option to address the identified risk.

The impact of three restriction options was analysed in the Annex XV report. All three options proposed 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. However, the options differed with respect to the inclusion of certain derogations for specific uses and the duration of transitional periods prior to the conditions of the restriction entering into effect. 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 RO2 plus) 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 its preferred restriction option.

The proposal is coordinated with regulatory activities on Dechlorane Plus under the Stockholm Convention. An EU restriction would be an important step towards reducing the risks from Dechlorane Plus within the EU internal market. It would also assist the global

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regulation in the POPs Convention by analysing the impacts in the EU of an equivalent global regulation.

2.2. Summary of SEAC opinion

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.

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 appreciate 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 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.

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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.

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3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

See RAC opinion.

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

Justification for the opinion of SEAC and RAC

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 as 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 from the air, water, sediment, soil and organisms.

As Dechlorane Plus is mobile in the air and aquatic environment, has a long-range transport potential and could be distributed easily within and between environmental compartments by aqueous and air media (although, due to its high adsorption potential, sediment and soil are more likely to contain Dechlorane Plus than water). Thus, its effects will occur beyond the source of release. Dechlorane Plus can be detected in 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 emissions, 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.

SEAC and RAC 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, SEAC supports the view that any necessary action to address risks associated with

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Dechlorane Plus be implemented on an EU wide basis.

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

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

3.3.1. Scope including derogations

Justification for the opinion of RAC

See RAC opinion

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.

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.

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Table 2. 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 (5 years after Entry into Force)
- Medical imaging applications (7 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 (5 years after Entry into Force)
- Medical imaging (7 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 Force)

RO3

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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 5 years after 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.

Table 3. 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 | <p>Aerospace and defence sector: For equipment covered by the derogation in RO2plus (I)</p> <p>Aerospace and defence: For applications manufactured before EIF + 5 years</p> <p>Motor vehicles: For vehicles produced before EIF + 18 months</p> | <p>Aerospace and defence sector: For equipment covered by the derogation in RO3 (I)</p> <p>Motor vehicles: For vehicles covered by the derogation in RO3 (IV)</p> |
| (VI) Derogations for spare parts in other applications | | <p>Medical imaging: For applications manufactured before EIF + 7 years</p> <p>Radiotherapy: For</p> | None |

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| | | <p>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 soil², 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.

However, 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 RO2 plus) 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).

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

² The soil surrounding industrial sites.

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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 sufficiently 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 decaBDE³. 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 priorities, including the societal value placed on the uses proposed to be derogated

³<https://echa.europa.eu/pops-legislation>

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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 the following 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, 7 years for medical imaging applications and 10 years for radiotherapy devices/installations. The transitional period for these two 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 sustainable use of the available resources.

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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 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.

Table 4. 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 |
| (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 | None | Aerospace and defence sector: For equipment | Aerospace and defence sector: For |

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| | | | |
|--|--|---|---|
| equipment/motor vehicles | | covered by the derogation in RO2plus (I) Motor vehicles: For vehicles produced before EIF + 18 months | 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 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 forestry machinery: For applications placed on the market before EIF + 18 months |

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 stakeholders, during the preparation of the dossier and the third-party consultation. This is considered a sufficient timeframe for the affected parties to phase out the use of the substance, due to alternatives being already 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

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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, it 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 airspace 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 5 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 5 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 third-party consultation 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.

SEAC agree with the Dossier Submitter's assessment of the impacts used to support the conclusion that a derogation is justified for this 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

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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 is considered 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 third-party consultation 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.

Derogation for spare parts

Claims for a derogation for spare parts are generally in all sectors of the industry respondents to the third-party consultation. 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.

The emissions from spare parts will naturally decline over time as new models which would not contain Dechlorane Plus will replace older models. Also, taking into consideration the expected long-life cycle and type of approval of products, motor vehicles, marine, garden and forestry machinery, medical imaging devices, radiotherapy devices/installations, aerospace and defence applications, are sectors where a derogation for spare parts is justified in the Dossier Submitter's view.

A general derogation for spare parts for electric and electronic devices is not considered justified due to the short lifespan of many of the products. For specific long-lived electric and electronic devices, as seems to be the case for thermoset plastics used in electronics, where a 20-years derogation for spare parts is claimed to be needed, the submitted information is not sufficient to justify it.

SEAC agrees with the assessment of this derogation and considers that the above elements and the available information are enough to justify the proposed derogation. SEAC also agrees with the conclusion to reject a general derogation for spare parts for electric and electronic equipment in general.

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

Derogation for automotive applications (includes motorcycles, trucks, machines and agricultural equipment)

Information provided by the automotive industry sector during the third-party consultation claims 5 to 7 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 PDAP⁴ resins. However, the use volumes of Dechlorane Plus used specifically in PDAP resin and the current use volumes of that resin and expected emissions is not provided.

SEAC notes that according to the information provided in the third-party consultation, 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. However, no information was provided on ongoing efforts to substitute Dechlorane Plus in the PDAP resins formulation.

For the use of Dechlorane Plus in PDAP resins it is claimed that an unlimited derogation as well as to “extend the application of PDAP resin for at least five years” are needed. The provided ground for this exemption is the excellence of PDAP resins' heat resistance and electrical properties that make this material relevant for next-generation electric vehicles for which there is increasing demand.

For PDAP resin, besides the lack of information on the use volumes, SEAC also notes the lack of detailed requirements for the alternatives, and no information was provided for emissions and specific uses.

Although a credible substitution plan has been presented, 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.

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.

⁴ polydiallyl phthalate

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Derogation for electric and electronic equipment

Based on information provided during the third-party consultation a transition period of 3 to 5 years is requested for electrical and electronic equipment in general, at least 7 years for more complex equipment such as "industrial and infrastructure equipment", and 9 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 5 years for products in categories 1 to 7 - large household appliances, small household appliances, IT and telecommunications equipment, consumer equipment, lighting equipment, electrical and electronic tools, toys, leisure and sports equipment - and a maximum of 7 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. Also, there is a lack of information on the specific uses where substitution is more challenging, the use volumes of the substance involved, and availability of alternatives.

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 third-party consultation 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

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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.

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 appropriate⁵. 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 2022⁶, 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

⁵ 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.

⁶ Press release:

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

(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.

3.3.2. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

See RAC opinion

RAC conclusion(s):

See RAC opinion

Key elements underpinning the RAC conclusion(s):

See RAC opinion

3.3.3. Socio-economic impact

Justification for the opinion of SEAC

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 Evidence⁷, 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 stakeholder and public

⁷ <https://echa.europa.eu/documents/10162/724b8c08-98fc-a992-49fd-aa329de4437d>

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consultation, 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, 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 stakeholder consultation 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.

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.

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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 5. 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 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 6. 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

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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 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 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 public consultation, JAPIA⁸ (#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

⁸ Japan Auto Parts Industries Association

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companies, as inorganic alternatives are more accessible for the European companies than the Japanese.

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 7. The expected behavioural responses

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

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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

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 8. 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%).

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Table 9. Profit at risk, EAV⁹ 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.

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 public consultation indicates new alternatives for wire harnesses and tape might be available on the EU market. In the stakeholder consultation ACEA¹⁰ 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 public 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

⁹ 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%)

¹⁰ ACEA – European Automotive Manufacturers Association

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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 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 make suitable and reasonable estimations.

In SEAC's view, the Dossier Submitter's research for 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

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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 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 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.

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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 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 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 stakeholders' consultation 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

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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 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 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

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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 public 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 public 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 ECHA¹¹ guidelines on PBT/vPvB substances, the effects of the accumulation of these substances are unpredictable in the long-term, and difficult to reverse.

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

¹¹ 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

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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 10. 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 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 public consultation, 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

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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 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 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

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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 11. 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)¹² 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.

¹² The social cost of unemployment. Accessed at: [af3a487e-65e5-49bb-84a3-2c1bcbc35d25 \(europa.eu\)](https://af3a487e-65e5-49bb-84a3-2c1bcbc35d25.europa.eu)

Table 12. Net present values of the estimated job losses (2023 – 2042)

| 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 stakeholder consultations 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

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costs. Because Dechlorane Plus is a PBT/vPvB substance¹³, it is not possible to perform a traditional 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 13. 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 RO 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, 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.

¹³ <https://echa.europa.eu/documents/10162/97b3c3bf-f38a-f3e2-6b53-45654bcc02dc>

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Table 14. 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)¹⁴, 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)¹⁵ 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 Dechlorane Plus, then the cost-effectiveness of both restrictions would be of the same order of magnitude.

¹⁴ 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/~/media/Files/Research/2015/Benchmark-development-for-the-proportionality-assessment-of-PBT-and-vPvB-substances.pdf)

¹⁵ See: https://echa.europa.eu/documents/10162/17091/evaluation_pbt_vpVB_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3?t=1472819309457

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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):

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 recommendations¹⁶ for PBT/vPvB substances. In order to analyse the cost-effectiveness despite the encountered lack of data, 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

¹⁶ See: https://echa.europa.eu/documents/10162/17091/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3?t=1472819309457

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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 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):

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

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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 paper¹⁷ 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 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

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

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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 proposal for Dechlorane Plus can be compared to.

Table 15. 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 |
| 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 on 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.

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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.

Table 16. 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.

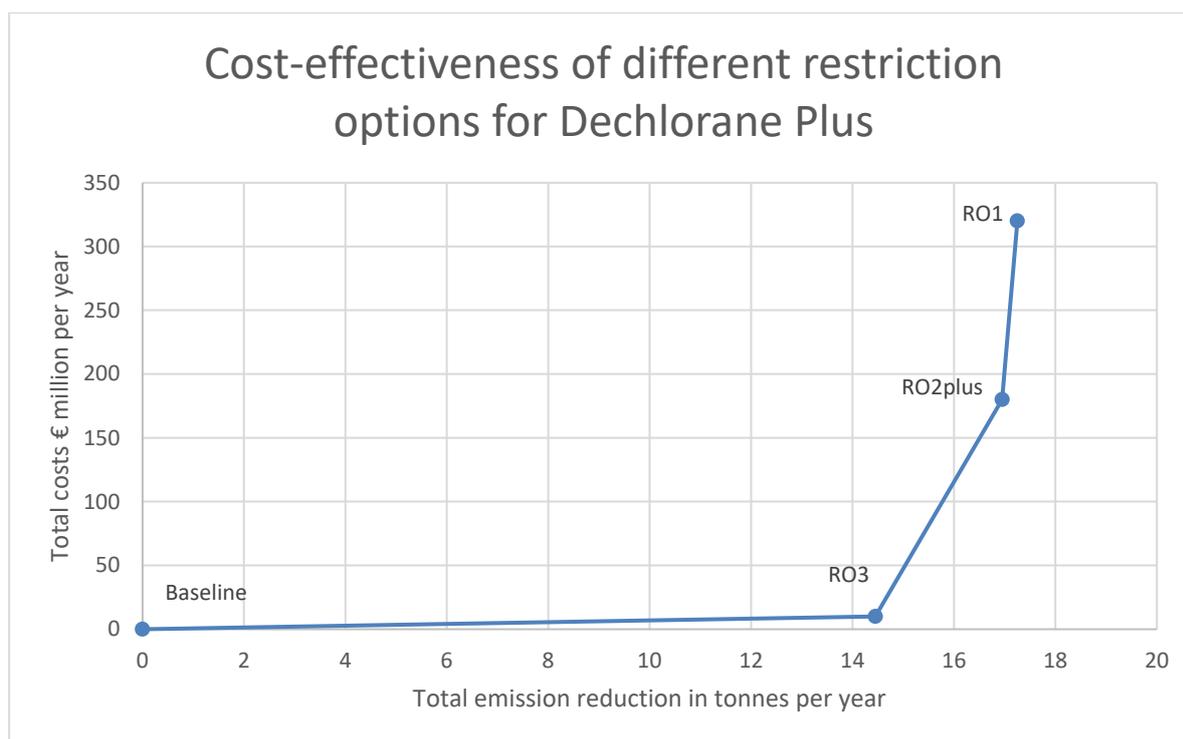


Figure 1

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, €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.

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

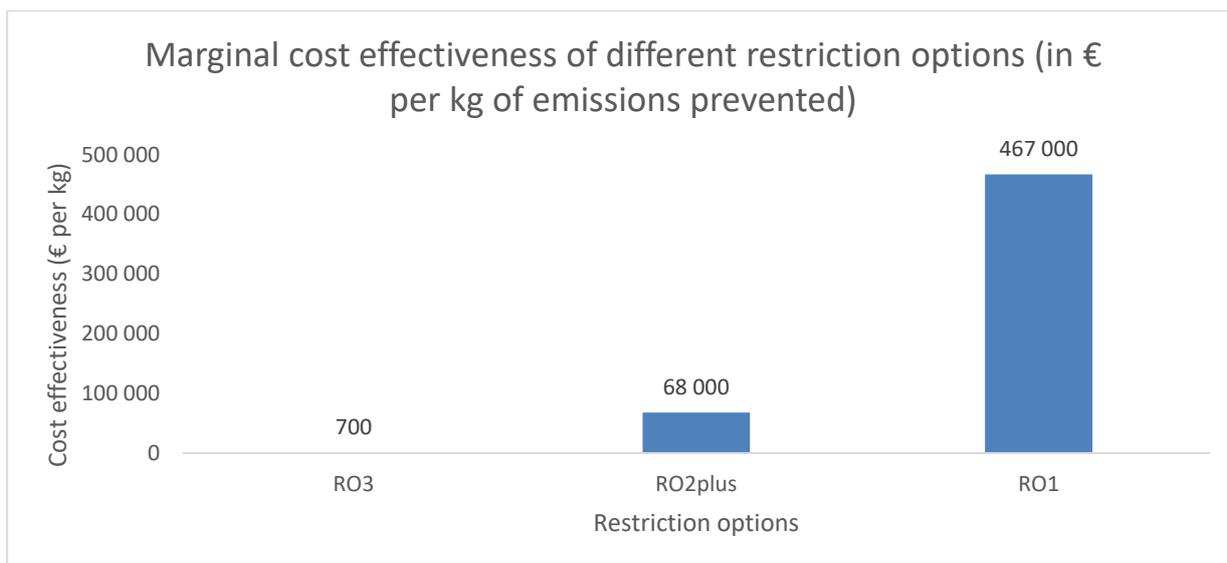


Figure 2. The marginal cost-effectiveness of RO1, RO2plus and RO3

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 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.

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

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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 still continue and also 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 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, the Dossier Submitter deemed RO3 as the most practical restriction option for the industry.

Regarding enforceability, the Dossier Submitter considers the restriction to be enforceable. Enforcement through documentation check and testing are deemed feasible and facilitated by the proposed 0.1% w/w concentration 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):

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

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

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 and concludes that the available techniques are sensitive enough to produce reliable analytical results for all relevant matrices to enable compliance monitoring.

Although X-Ray Fluorescence spectroscopy (XRF) and Fourier Transform Infrared Spectroscopy (FTIR) are deemed as not the most appropriate for quantitative analyses,

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both are techniques that can be used for initial screening of chlorine in materials, but FTIR techniques needs to be developed before could be used based as a rapid screening method.

RAC and SEAC conclusion(s):

SEAC agree that the restriction is monitorable.

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

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:

See RAC opinion

RAC conclusion(s):

See RAC opinion

Key elements underpinning the RAC conclusion(s):

See RAC opinion

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.

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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.

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 17. 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.

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The third-party consultation 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

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