Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV restriction report proposing restrictions on

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

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

ECHA/SEAC/[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])

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Draft date: 18/03/2022

18/03/2022

RES-O-0000007082-81-01/F

[Date]

[SEAC opinion number]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

Chemical name(s): 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™) [covering any of its individual anti- and syn-isomers or any combination thereof]

EC No.: 236-948-9

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

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

PROCESS FOR ADOPTION OF THE OPINIONS

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

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Michael NEUMANN

Co-rapporteur, appointed by RAC: Manuel FACCHIN

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

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

The opinion of RAC was adopted **by consensus** of all members having the right to vote.

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

[The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.**] [**No comments were received from interested parties during the consultation in accordance with Article 69(6)(a).**]**[4].

[The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.**] [**No socio-economic analysis, or the information which can contribute to one, were received from interested parties during the consultation in accordance with Article 69(6)(b).**]**[4].

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

The opinion of SEAC

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

[1] Delete the unnecessary part(s)

71(1)**]**[6].

The opinion of SEAC 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**.]**[6].

Contents

Tables

1. OPINION OF RAC AND SEAC

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

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

The restriction proposed by the Dossier Submitter is:

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [12.2.1.1^{6,9}.0^{2,13}.0^{5,10}] octadeca-7,15-diene ("Dechlorane Plus"™) [covering any of its individual anti- and syn-isomers or any combination thereof] CAS No 13560-89-9; 135821-74-8; 135821-03-3 EC No 236-948-9; -; -	1. Shall not be manufactured, or placed on the market as a substance on its own from [18 months after entry into force]. 2. Shall not, from [18 months after entry into force], be used in the manufacture of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article, in a concentration equal to or above 0.1% by weight. 3. Paragraph 2 shall not apply to: • articles placed on the market for the first time before [18 months after date of entry into force] 4. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of: • aerospace and defence applications* before [date of entry into force + 5 years]. • spare parts for aerospace and defence applications manufactured before [date of entry into force + 5 years]. 5. Paragraphs 1 and 2 shall not apply to

	manufacture, use and placing on the market of: • medical imaging applications manufactured before [date of entry into force + 7 years] • Radiotherapy devices/installations manufactured before [date of entry into force + 10 years] • spare parts for medical imaging applications manufactured before [date of entry into force + 7 years] • spare parts for radiotherapy applications manufactured before [date of entry into force + 10 years] 6. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of spare parts for: • motor vehicles** placed on the market for the first time before [18 months after date of entry into force] • marine, garden and forestry machinery applications placed on the market for the first time before [18 months after date of entry into force] 7. The Commission shall review the exemptions in paragraph 4, 5 and 6 and, if appropriate, modify them accordingly.

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

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

1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on **1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™) covering any of its individual anti- and synisomers or any combination thereof** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as

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

The restriction proposed by RAC:

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [12.2.1.1^{6,9}.0^{2,13}.0^{5,10}] octadeca-7,15-diene ("Dechlorane Plus"™) [covering any of its individual anti- and syn-isomers or any combination thereof] CAS No 13560-89-9; 135821-74-8; 135821-03-3* EC No 236-948-9; -; -	1. Shall not be manufactured, or placed on the market as a substance on its own from [18 months after entry into force]. 2. Shall not, from [18 months after entry into force], be used in the manufacture of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article, in a concentration equal to or above 0.1% by weight. 3. Paragraph 2 shall not apply to: • articles placed on the market for the first time before [18 months after date of entry into force] 4. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of: • aerospace and defence applications** before [date of entry into force + 5 years]. • spare parts for aerospace and defence applications manufactured before [date of entry into force + 5 years]. 5. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of: • medical imaging applications manufactured before [date of entry into force + 7 years]

	• Radiotherapy devices/installations manufactured before [date of entry into force + 10 years] • spare parts for medical imaging applications manufactured before [date of entry into force + 7 years] • spare parts for radiotherapy applications manufactured before [date of entry into force + 10 years] 6. Paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market of spare parts for: • motor vehicles*** placed on the market for the first time before [18 months after date of entry into force] 7. The Commission shall review the exemptions in paragraph 4, 5 and 6 and, if appropriate, modify them accordingly.

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

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

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

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

With regard to the terms used in the entry above, it is important that the Commission clarifies the legal wording and the definitions of e.g. the terms “motor vehicles”, “machinery applications”, “radiotherapy devices/installations”, and “medical imaging applications”. In addition, the FORUM noted that the terms “aerospace” and “marine, garden and forestry machinery applications” require more precise definitions. The inclusion of bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) in Annex I of the Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs)[2] could be used as template, particularly with respect to the approach for identifying the automotive and aviation sectors, and spare parts. However, some amendments will be needed, i.e. DIRECTIVE 2007/46/EC being replaced by REGULATION (EU) 2018/858 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles. Further, medical devices and marine applications

[2] http://data.europa.eu/eli/reg/2019/1021/oj

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

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

1.2. THE OPINION OF SEAC

See SEAC opinion

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

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

Dechlorane Plus is mainly used as a flame retardant in adhesives, sealants and polymers as well as in a minor use as an extreme pressure additive in greases. It is used in motor vehicles, aerospace and defence applications, marine, garden and forestry machinery as well as in the production of electrical and electronic equipment, including consumer electronics and medical devices. Alternatives for uses of Dechlorane Plus exist. However, there is some uncertainty whether the alternatives are available and feasible for all uses.

Dechlorane Plus is mainly released to the environment during the waste life-cycle stages of articles. It is detected in humans, wildlife and in the environment around the world, including the Arctic and Antarctic. Humans are exposed through drinking water, food and air. The unborn child may be exposed via the umbilical cord whilst infants are exposed via breast milk.

Dechlorane Plus was identified by ECHA as a Substance of Very High Concern (SVHC) already in 2018, because of its very persistent and very bioaccumulating properties (vPvB). No safe concentration for a substance with such intrinsic substance properties can be derived. According to Annex I para 6.5 of REACH[3], the risk to the environment cannot be adequately controlled for PBT/vPvB substances but must be minimised.

The Dossier Submitter has concluded that a restriction under REACH is the most appropriate risk management option to address the identified risk and proposes to restrict the manufacture, use and placing on the market of Dechlorane Plus in concentrations >0.1% by the end of a transition period of 18 months. Three restriction options are analysed in the impact assessment. While the strictest restriction option (RO1) would not include any derogations, RO2 and RO3 contain derogations of varying scope and length for uses in the aerospace and defence sector and motor vehicle sectors including derogations for spare parts for the remaining lifetime.

The Dossier Submitter proposed, after analysis of the available information in the consultation on the Annex XV restriction report, RO2 with some additional elements (called by RAC “RO2plus”), containing a ban with time limited derogations for the aerospace and defence sector and medical imaging devices and radiotherapy devices/installations and containing derogations for use in spare parts for the aerospace and defence sector, medical imaging devices and radiotherapy devices/installations, motor vehicles and marine, garden and forestry machinery applications.

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

2.2. Summary of opinion

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

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

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

A broad restriction with a short transitional time and without any derogations is the most effective measure to minimise the release of Dechlorane Plus to the environment. However, the difference in the estimated effectiveness of the strictest restriction option RO1, without any derogations, and the restriction option proposed by the Dossier Submitter after the consultation on the Annex XV restriction report (termed "RO2plus") is not significant as the difference is within the range of uncertainties in the release estimates. RO2plus, which includes several targeted derogations and transition periods (e.g. 5 years for aerospace and defence applications; 7 years for medical imaging applications; 10 years for radiotherapy devices/installations and for spare parts for motor vehicles and for marine, garden and forestry machinery applications), is reported to have an effectiveness of 89% of total emissions of Dechlorane Plus abated between 2023 and 2042, relative to baseline, whilst RO1 has a reported effectiveness of 91% emission abatement relative to baseline. RAC concludes that the risk option RO3 with only 76% emission reduction effectiveness is not supported.

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

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

Conversely, RAC concludes that a derogation for medical imaging applications and radiotherapy devices/installations could be supported from a risk perspective as reasonably foreseeable conditions of use and risk management measures could be expected to achieve

minimisation of releases (e.g., extended producer responsibility).

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

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

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

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

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

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

3.1.1. Description of and justification for targeting (scope)

Summary of proposal:

In the Annex XV restriction report the Dossier Submitter proposed a restriction comprising total ban of Dechlorane Plus on the manufacture, use and placing on the market of Dechlorane Plus as a substance, a constituent in a substance, a mixture or an article without granting any derogations. Table 14 in the Background Document presents this strictest restriction option RO1 and the two alternatives RO2 and RO3.

After receiving additional information in the consultation on the Annex XV restriction report and undertaking further analysis of the effectiveness, practicality and monitorability of different restriction options the Dossier Submitter revised their preferred restriction option from RO1 to a ban with targeted derogations and transition periods, similar to the assessed

RO2 but with some additional elements ("RO2plus") (for details see section 2.1.1.). This restriction option provides significant reduction in Dechlorane Plus emissions and thereby reduces potential adverse effects on human health and environment.

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

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

RAC conclusion(s):

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

Key elements underpinning the RAC conclusion:

The RAC Opinion is based on the Background Document section 1.2.1 and Annex B.1

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

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

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

3.1.2. Information on hazard(s)

Summary of proposal:

The hazard assessment of the Dossier Submitter is based on the fact that Dechlorane Plus is a long-range transported (see Annex B.4.2.3 to the Background Document), very persistent (see Annex B.4.1. to the Background Document) and very bioaccumulating (see Annex B.4.3. to the Background Document) substance. The ECHA Member State Committee (MSC) used a weight-of-evidence approach to identify Dechlorane Plus as a vPvB substance. The potential for long range transport occurs through sorption to particles in the atmosphere as well as in seawater. By sorption to particles reaction rates slow down and the half-life especially in air increases which facilitates the potential for long range transport of Dechlorane Plus adsorbed on particles. Long-range transport to remote regions occurs when atmospheric conditions permit (e.g., during dry periods). The MSC identified Dechlorane Plus as a Substance of Very

High Concern in 2018 (see Annex B.4 and Section 6 of the MSC Support Document).

According to Annex I para 6.5 of REACH[3], the risk to the environment and to human health cannot be adequately controlled for PBT/vPvB substances. No safe concentration, thus no threshold, can be determined for PBT/vPvB substances. Due to these intrinsic substance properties, Dechlorane Plus may cause severe and irreversible adverse effects on the environment and on human health if the releases are not minimised.

RAC conclusion(s):

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

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

Key elements underpinning the RAC conclusion(s):

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

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

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

3.1.3. Information on emissions and exposures

Summary of proposal:

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

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

registrant (ADAMA Agriculture BV) downgraded the tonnage band to 10 – 100 tonnes/year in October 2020, before ceasing their activities in May 2021.

According to the REACH registration information, Dechlorane Plus is used as a flame retardant in adhesives/sealants and polymers. Furthermore, a survey carried out by the Dossier Submitter indicated that Dechlorane Plus is used as an extreme pressure additive in greases. In these applications Dechlorane Plus is used in motor vehicles, aerospace and defence applications, marine, garden and forestry machinery, electrical and electronic equipment, including consumer electronics and medical devices. Another confirmed minor use is in fireworks. Table 7 in Annex A.2.2. to the Background Document summarises the uses of Dechlorane Plus from public sources.

Dechlorane Plus is estimated to currently be used in volumes of between 90 and 230 tonnes/year in the EU, with a central estimate of 160 tonnes/year. The automotive industry is assumed to be the main user of Dechlorane Plus, with an estimated annual consumption of 81 to 161 tonnes in 2020 (see Annex A.2.4 to the Background Document).

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

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

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

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

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

during the preparation of the Annex XV restriction report.

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

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

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

Emissions of Dechlorane Plus in the EU were estimated to be 7.5 to 23.8 tonnes for 2020 (see Annex B.9.3.11 to the Background Document). Around 80% of the emissions are estimated to be from waste dismantling and recycling. The second largest source is landfills. Overall, the main releases of Dechlorane Plus are attributable to the waste stage.

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

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

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

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

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

RAC conclusion(s):

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

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

Key elements underpinning the RAC conclusion(s):

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

The Dossier Submitter assessed and described in the Background Document monitoring studies for different environmental matrices and biota at various locations in detail and in an elaborated qualitative way. As Dechlorane Plus is stable in the environmental compartments with minimal or no abiotic degradation and it is very bioaccumulative, the environmental stock will remain high or even increase over time if emissions are not minimised. Monitoring studies indicate that Dechlorane Plus is globally distributed and detected in different environmental matrices and biota at different types of locations, comprising from production sites and

recycling facilities to urban and remote areas. A number of environmental monitoring studies at recycling sites and landfills supports the finding from the emission estimation that the waste stage is the most important source of emission of Dechlorane Plus to the environment. Levels of Dechlorane Plus in remote areas are generally lower compared to levels reported near production sites or urban centres. Birds have been identified as biovectors for the transport and deposition of POPs through feather loss or decaying carcasses, representing an additional transport pathway for Dechlorane Plus to remote regions. Dechlorane Plus has also been detected in human blood and breast milk in different regions of the world.

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

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

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

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

3.1.4. Characterisation of risk(s)

Summary of proposal:

The Dossier Submitter states under section 1.2.6 to the Background Document that it is neither relevant nor scientifically justified to perform a quantitative risk characterisation for PBT/vPvB substances. This is due to the uncertainties regarding long-term fate and behaviour, exposure and adverse effects. Therefore, the risk of PBT/vPvB substances, such as Dechlorane Plus, to the environment or to humans cannot be adequately addressed in a quantitative way. The overall aim for PBT/vPvB substances is to minimise the emissions and consequently to minimise any exposures to humans and to the environment (Annex I para 6.5 of REACH[3]).

RAC conclusion(s):

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

Key elements underpinning the RAC conclusion(s):

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

It is not possible to derive a reliable threshold for the effects of PBT/vPvB substances. Therefore, any releases should be regarded as a proxy for risk to the environment and human health. Manufacturer or importers of PBT/vPvB substances should recommend risk management measures for downstream users to minimise exposure and emissions to humans and environment throughout the lifecycle of the substance that results from manufacture or identified uses (Annex I para 6.5 of REACH[3]). As discussed in the hazards section the properties of Dechlorane Plus, notably its vPvB properties, result in an intrinsic hazard. A continuous and irreversible exposure of the environment and humans may lead to unpredictable long-term adverse effects. A risk characterisation where releases and exposures are regarded as a proxy for a risk to the environment and human health is appropriate. Use of Dechlorane Plus causes releases from all life-cycle stages as summarised in section 3.1.4. Releases of vPvB substances should be minimised to reduce adverse effects. Release minimisation is necessary for Dechlorane Plus in all sectors of use.

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

3.1.5. Uncertainties in the risk characterisation

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

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

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

Summary of proposal:

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

reducing the release to the environment (Annex B.9.1.2. to the Background Document).

RAC conclusion(s):

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

Key elements underpinning the RAC conclusion(s):

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

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

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

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

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

Summary of proposal:

The Dossier Submitter considered national regulatory actions not to be adequate to manage the risk of Dechlorane Plus. Union-wide action is proposed by the Dossier Submitter to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States (Background Document, section 1.3).

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

However, the Dossier Submitter concludes, that these presented options are not considered

to have the potential to minimise the emission of Dechlorane Plus, as they are currently not considered to be feasible, are not considered as an appropriate risk management option, or not effective in reducing the risk.

RAC conclusion(s):

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

Key elements underpinning the RAC conclusion(s):

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

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

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

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter concluded that action is required on a Union-wide level. In 2018 Dechlorane Plus was identified as SVHC based on its very persistent and very bioaccumulative (vPvB) properties according to Article 57(e) of Regulation (EC) No 1907/2006 (REACH). Dechlorane Plus is chemically stable in various environmental compartments with minimal or no abiotic degradation and is also very bioaccumulative, therefore environmental stock may increase over time upon continued releases. The substance is also widely dispersed in both the aquatic and terrestrial food chains, including top predators. It is frequently detected in remote regions which shows that the compound is transported over long distances from point sources and production facilities. Humans are also exposed to Dechlorane Plus through drinking water, food and air. It was shown that Dechlorane Plus is transferred to the foetus during pregnancy via blood, and after delivery via breast feeding. There is no EU manufacture of Dechlorane Plus, but it is imported as substance (e.g. in amounts below 1 tpa) and in articles to the EU. The substance is used in a wide range of products. There is a potential for releases of Dechlorane Plus to the environment during processing and use, as well as from waste disposal and recycling activities. Articles imported in one Member State may be transported to and used in other Member States. An EU wide restriction will therefore be an important step to reduce the risk from Dechlorane Plus within the EU internal market.

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, RAC support the view that action is required on an EU-wide basis to address the risk associated with Dechlorane Plus.

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

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

RAC considers that EU-wide measures are needed to reduce the releases of Dechlorane Plus into the environment from their manufacturing, use and placing on the market. The uses of Dechlorane Plus are broad and articles containing Dechlorane Plus are imported into the EU

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

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

Justification for the opinion of SEAC and RAC

3.3.1. Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

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

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

RAC conclusion(s):

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

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

Key elements underpinning the RAC conclusion(s):

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

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

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

Justification for the opinion of SEAC

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

SEAC conclusion(s):

Add conclusion of SEAC

Key elements underpinning the SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

3.3.2. Effectiveness in reducing the identified risk

Justification for the opinion of RAC

Summary of proposal:

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

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

After the consultation on the Annex XV restriction report the Dossier Submitter proposes a revised scope for the restriction including derogations similar to the original RO2 but with some additional elements (“RO2plus”). The main difference is that the new proposal also contains: (1) a derogation that allows for continued use of Dechlorane Plus in medical imaging devices and radiotherapy devices/installations for limited time periods (EiF + 7 and 10 years respectively), (2) a review clause for these use areas to assess if further derogations will be needed after the end of the proposed derogation periods, (3) derogations for use in spare parts in the following use areas; medical imaging devices and radiotherapy devices/installations and marine and garden/forestry engines. Uses described under (1) and (3) are minor use areas and should not affect the result of the emission characterisation to a significant degree.

In section 2.1.3. the Dossier Submitter justifies rejected requests for derogations e.g. for

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

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

Table 3: Revised emission reduction estimates under each restriction scenario after the consultation on the Annex XV restriction report (see Box 8, Annex E.5.3. to the Background Document)

Sector / use	**Baseline emissions (t / y)**	**Annual reduction (t / y)**		
		RO1	**RO2plus**	**RO3**
Motor vehicles	6.9 - 21.8	6.3 - 19.8	6.2 - 19.5	5 - 15.9
Aerospace and defence	0.2 - 0.6	0.2 - 0.6	0.1 - 0.4	0.1 - 0.3
Other applications	2 - 6.4	1.8 - 5.8	1.8 - 5.8	1.8 - 5.8
All uses	**9.1 - 28.8**	**8.3 - 26.2**	**8.1 - 25.8**	**6.9 – 22.0**
Scenario emission reduction capacity	**-**	**91%**	**89%**	**76%**

RAC conclusion(s):

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

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

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

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

RAC concludes that RO2plus with targeted derogations and transition periods is effective for the minimisation of future releases from both in-service uses and the waste lifecycle stage, including landfill. RO2plus, which includes several targeted derogations and transition periods (e.g. 5 years for aerospace and defence applications; 7 years for medical imaging applications; 10 years for radiotherapy devices/installations and for spare parts for motor vehicles and for marine, garden and forestry machinery applications), is reported to have an effectiveness of 89% of total emissions of Dechlorane Plus abated between 2023 and 2042,

relative to baseline, whilst RO1 has a reported effectiveness of 91% emission abatement relative to baseline.

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

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

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

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

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

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

Key elements underpinning the RAC conclusion(s):

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

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

As REACH recital 70 states that "*… substance for which it is not possible to establish a safe level of exposure, measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with a view to minimising the likelihood of adverse effects."* In general, a restriction with the shortest transitional period and without derogations will be effective as soon as possible to minimise the potential for adverse effects on human health and the environment. In contrast, a restriction containing derogations for continued uses in spare part would only correspond to a gradual phase-out over time, until these spare parts are no longer required.

By restricting the use of Dechlorane Plus in the main use sectors (e.g. automotive, aviation, electric/electronic) the emissions to the environment and the ongoing increase in the existing pollution stock are expected to be significantly reduced. From a risk perspective, a restriction with carefully selected and justified time limited derogations is an effective measure to control

in future the risk and to gradually phase-out over time. Even when there are derogations granted for PBT/vPvB substances releases from derogated uses should be minimized as far as possible. Manufacturers and importers of a SVHC included on the Candidate List due to its vPvB properties should recommend appropriate operational conditions (OCs) and risk management measures (RMMs) to downstream users of the derogated uses to minimize emissions throughout the lifecycle.

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

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

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

Table 4: Annual emission reduction of the different RO compared to the Baseline emissions

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

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

For the aerospace and defence section the Dossier Submitter considered in the Annex XV restriction report (the original proposal) that a transitional period of 5 years and a derogation for spare parts will result in only insignificantly lower emission reduction compared to RO1. The relative effectiveness of the restriction for this specific sector is reduced by 50 % to 30 %, however this sector is only a minor contributor to the overall releases (see Table 3).

For medical imaging and radiography devices it can be considered that the total number of

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

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

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

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

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

Some alternatives were concluded by the Dossier Submitter to be suitable due to their technical feasibility, but other of the alternatives are currently under REACH Substance Evaluation due to their potential PBT/vPvB properties or have a harmonised classification. Therefore, part of the alternatives might have a potential for regrettable substitution due to

environmental or human health concerns. RAC's analysis is limited to the alternatives explored by the Dossier Submitter but further alternatives may exist. Due to the lack of data and information and due to ongoing hazard assessment, it was not possible for RAC to verify the hazards of identified alternatives.

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

3.3.3. Socio-economic impact

Justification for the opinion of SEAC

3.3.3.1. Costs

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

SEAC conclusion(s):

Add conclusion of SEAC

Key elements underpinning the SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

3.3.3.2. Benefits

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

SEAC conclusion(s):

Add conclusion of SEAC.

Key elements underpinning the SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

3.3.3.3. Other impacts

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

SEAC conclusion(s):

Add conclusion of SEAC.

Key elements underpinning the SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

3.3.3.4. Overall proportionality

Summary of proposal:

The main societal trade-off for the restriction proposal is between the costs of a potential restriction and the environmental benefits of reducing the emissions of Dechlorane Plus. The stricter a restriction, the higher will level of lost cost be. Because Dechlorane Plus is a PBT/vPvB substance, it is not possible to perform a traditional cost-benefit analysis in order to test the restriction proposal's proportionality. Instead, the Dossier Submitter has looked towards comparators, in the shape of previous studies and implemented regulations, in order to assess the cost-effectiveness of the restriction options.

RAC conclusion(s):

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

Key elements underpinning the RAC conclusion(s):

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

3.3.3.5. Uncertainties in the proportionality section

See SEAC opinion

3.3.4. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers that enforcement authorities could check documentation from the supply chain confirming that the articles do not contain Dechlorane Plus. Enforcement activities should cover the manufacture, import of Dechlorane Plus as such, in mixtures and in articles, and the use of Dechlorane Plus in production of articles in the EU. In addition, it is envisaged they will verify if the articles contain Dechlorane Plus by testing. Currently, 0.1% w/w is the limit that triggers the notification requirement under article 7(2)27 of REACH and the information requirement under article 33 of REACH. The proposed concentration limit of 0.1% w/w would therefore enhance the enforceability.

RAC conclusion(s):

RAC concludes that the proposed restriction is practicable and enforceable.

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

Key elements underpinning the RAC conclusion(s):

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

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

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

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

The FORUM states that more exemptions make restrictions more complicated to enforce. It is not clear what exactly is included in the definition of aerospace and the definition of marine, garden and forestry machinery. Garden machinery could be from an enforcement point of view common products in retail shops for consumers. The FORUM suggests to phrase the conditions of the restriction in a different way so that the intention of the derogations for spare parts are clearer.

3.3.4.1. Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

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

spectroscopic techniques like Fourier Transform Infrared Spectroscopy (FTIR) will be able to distinguish polymeric bound chlorine from chlorine bound in Dechlorane Plus.

RAC conclusion(s):

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

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

Key elements underpinning the RAC conclusion(s):

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

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

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

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

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

3.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

3.4.1. RAC

Summary of proposal:

A number of uncertainties have been identified and described by the Dossier Submitter in the Background Document (section 3 and Annex F). Regarding the use volumes, differences in

the total volume manufactured and used were reported by stakeholders. These uncertainties are captured in the large tonnage band taken forward for the exposure assessment.

Owing to a lack of site-specific exposure information for the EU, a generic approach closely aligned with ECHA Guidance R16 has been used for the exposure assessment. The approach involves a number of assumptions and, where appropriate, a realistic worst-case approach has been chosen in line with ECHA Guidance R16. Uncertainties in the use volumes, both at a given site (local scale) and EU-wide, is a driving factor for the results of the exposure assessment. The limited information on volumes used combined with the lack of information on fractions of Dechlorane Plus released to air, water, and soil from the various processes using Dechlorane Plus and lifecycle stages, creates uncertainties in the exposure assessment. The Dossier Submitter therefore used a combination of relevant release factors from OECD Emission Scenario Documents (ESD), industry Specific Environmental Release Categories (SPERCs) and default release factors from ECHA Guidance R16.

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

RAC conclusion(s):

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

Key elements underpinning the RAC conclusion(s):

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

The main uncertainties in the restriction proposal are related to the use volumes of Dechlorane Plus. Uncertainties in the use volumes, both at a given site (local scale) and EU-wide, is a driving factor for the results of the exposure assessment. The limited information on volumes used combined with the lack of information on fractions of Dechlorane Plus released to air, water, and soil from the various processes using Dechlorane Plus and lifecycle stages, creates uncertainties in the exposure assessment. Therefore, an approach based on combination of relevant release factors from OECD Emission Scenario Documents (ESD), industry Specific Environmental Release Categories (SPERCs) and default release factors from ECHA Guidance R16 was used by the Dossier Submitter to capture such uncertainties.

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

From the available information it is not clear whether manufacture of Dechlorane Plus outside

the EU is still taking place. There was one active registration of Dechlorane Plus (*ADAMA Agriculture BV)* and they notified a cease of manufacture to ECHA in May 2021. RAC notes that individual importers can only import currently below 1 tpa, as there are no active registrations.However, currently the amounts and use volumes of Dechlorane Plus imported into the EU is uncertain. It is noted that in case the substance is added into the Stockholm Convention, a monitoring of the volumes will be established among all parties to the Convention. This may reduce the uncertainties for the future volumes imported to the EU to some extent.

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

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

3.4.2. SEAC

Summary of proposal:

Add summary of Dossier Submitter proposal from the uncertainties section of the Annex XV restriction report.

SEAC conclusion(s):

Add conclusion of SEAC.

Key elements underpinning the SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]