

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

Opinion

on an Annex XV dossier proposing restrictions on
Medium-chain chlorinated paraffins (MCCP) and other substances
that contain chloroalkanes with carbon chain lengths within the
range from C14 to C17

ECHA/RAC/RES-O-000007283-75-01/F
**ECHA/SEAC/[reference code to be added after the
adoption of the SEAC opinion]**

9 June 2023

[reference code to be added after the adoption of the SEAC opinion]

**Opinion of the Committee for Risk Assessment
and**

Opinion of the Committee for Socio-economic Analysis

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

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

Chemical name(s): Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17

EC No.: -

CAS No.: -

This document presents the opinion adopted by RAC 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

ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <https://echa.europa.eu/restrictions-under-consideration> on **21 September 2022**. Interested parties were invited to submit comments and contributions by **22 March 2023**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Laure GEOFFROY

Co-rapporteur, appointed by RAC: Railii MOLDOV

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 **8 June 2023**.

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

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

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: John JOYCE

Co-rapporteur, appointed by SEAC: Stéphane JOMINI

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 **9 June 2023**.

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

The draft opinion 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.

The draft opinion was published at <https://echa.europa.eu/restrictions-under-consideration> on **14 June 2023**. Interested parties were invited to submit comments on the draft opinion by **14 August 2023**.

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]**]

[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 71(1)]]

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.]

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1. OPINION OF RAC AND SEAC¹

The Dossier Submitter proposed two Annex XVII restriction entries, as reported in the following tables.

Table 1: Proposed REACH Annex XVII entry (option A)²

Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
Linear chloroalkanes with the following molecular formulae: C ₁₄ H _{30-y} Cl _y where y = 3 to 11 C ₁₅ H _{32-y} Cl _y where y = 3 to 8 C ₁₆ H _{34-y} Cl _y where y = 3 to 8 C ₁₇ H _{36-y} Cl _y where y = 6 to 9	<ol style="list-style-type: none">1.<ol style="list-style-type: none">a. Substances containing chloroalkanes listed in column 1 shall not be manufactured if the overall concentration of the chloroalkanes listed in column 1 is [equal to or greater than 0.1 % (w/w)].b. Chloroalkanes listed in column 1 shall not be placed on the market in substances, in mixtures and in articles if their overall concentration in such substances, mixtures and articles is [equal to or greater than 0.1 % (w/w)].<p>Paragraph 1 shall apply [2 years] after entry into force of the restriction.</p>2. Substances containing chloroalkanes listed in column 1 shall not be used for the formulation of mixtures and production of articles if the [overall concentration] of the chloroalkanes listed in column 1 is [equal to or greater than 0.1 % (w/w)]. Paragraph 2 shall apply [2 years after entry into force of the restriction].3. Paragraphs 1 and 2 shall not apply to articles already in use and second-hand articles which were in end-use in the Union before [date of entry into force].4. Paragraphs 1 and 2 shall not apply to reference materials and standards for analytical purposes.5. [Within three months after entry into force of the restriction, the European Chemicals Agency shall publish and maintain on its website an indicative list of identifiers describing substances that may contain the chloroalkanes listed in column 1].6. [Within six months after entry into force] of the restriction, the suppliers of substances containing the chloroalkanes listed in column 1 or, of substances referred to in paragraph 5, shall conclude and identify the substances as PBT and/or vPvB unless they can demonstrate to the Competent Authorities that the overall upper concentration of the chloroalkanes listed in column 1 is [lower than 0.1 % (w/w)], by

¹ Do not delete any of the headings in this document under any circumstances. This is important to keep in mind for the combination of the RAC and SEAC opinion towards the end of the opinion-making process.

² As reported in the coming sections, option A is a combination of RO3 and RO5.

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Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
	<p>providing the following information (i) the overall upper concentration level of the chloroalkanes listed in column 1 in the composition(s). The upper concentration level should be determined using representative batches (typically five batches) manufactured according to the same technical specifications by the same manufacturer. The level should be determined using validated analytical methods and statistical calculations, and (ii) a description of the analytical methods used, and the results obtained to derive the overall upper concentration level mentioned above.</p> <p>7. [Within 6 months after entry into force] of the restriction, the supplier placing on the market substances, mixtures, or articles [containing chloroalkanes listed in column 1 or referred to in paragraph 5], irrespective of the concentration, shall inform their downstream users and customers of (i) the presence and overall concentration of the chloroalkanes listed in column 1, and (ii) the appropriate risk management measures and operating conditions to minimise the releases and exposure in case of presence of chloroalkanes listed in column 1.</p>

Table 2: Proposed REACH Annex XVII entry (option B) ³

Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
Linear chloroalkanes with the following molecular formulae: C ₁₄ H _{30-y} Cl _y where y = 3 to 11 C ₁₅ H _{32-y} Cl _y where y = 3 to 8 C ₁₆ H _{34-y} Cl _y where y = 3 to 8 C ₁₇ H _{36-y} Cl _y where y = 6 to 9	<p>1.</p> <p style="padding-left: 20px;">a. REMOVED</p> <p style="padding-left: 20px;">b. Chloroalkanes listed in column 1 shall not be placed on the market in substances, in mixtures and in articles if their overall concentration in such substances, mixtures and articles is [equal to or greater than 0.1 % (w/w)].</p> <p>Paragraph 1 shall apply [2 years after entry into force of the restriction].</p> <p>2. REMOVED</p> <p>3. Paragraph 1 shall not apply to articles already in use and second-hand articles which were in end-use in the Union before [date of entry into force].</p> <p>4. Paragraph 1 shall not apply to reference materials and standards for analytical purpose.</p> <p>5. [Within three months after entry into force] of the restriction, the European Chemicals Agency shall</p>

³ As reported in the coming sections, option A is a combination of RO4b and RO5.

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Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
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publish and maintain on its website an indicative list of examples of identifiers describing substances that may contain the chloroalkanes listed in column 1.

6. [Within six months after entry into force] of the restriction, the suppliers of substances containing the chloroalkanes listed in column 1 or, of substances referred to in paragraph 5, shall conclude and identify the substances as PBT and/or vPvB unless they can demonstrate to the Competent Authorities that the overall upper concentration of the chloroalkanes listed in column 1 is [lower than 0.1 % (w/w)], by providing the following information (i) the overall upper concentration level of the chloroalkanes listed in column 1 in the composition(s). The upper concentration level should be determined using representative batches (typically five batches) manufactured according to the same technical specifications by the same manufacturer. The level should be determined using validated analytical methods and statistical calculations. (ii) a description of the analytical methods used and the results obtained to derive the overall upper concentration level mentioned above.
7. [Within 6 months after entry into force] of the restriction, the supplier placing on the market substances, mixtures, or articles containing [substances containing the chloroalkanes listed in column 1 or referred to in paragraph 5], irrespective of the concentration, shall inform their downstream users and customers of (i) the presence and overall concentration of the chloroalkanes listed in column 1, and (ii) the appropriate risk management measures and operating conditions to minimise the releases and exposure in case of presence of chloroalkanes listed in column 1.
8. [By way of derogation, paragraph 1 shall not apply to substances if placed on the market for use as Extreme Pressure Additives in oil-based metalworking fluids - as defined in DIN 51385 -] [for 7 years after into force.

By way of derogation, the concentration limit set under paragraph 1 shall not apply to mixtures placed on the market as oil-based metal working fluids referred to in paragraph 8 - [for 7 years after the EIF].

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 **Option A on Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17** 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 scope and conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are: **(changes from the Dossier Submitter’s proposal in red and strikeout):**

Table 3: Restriction proposed by RAC

Substance Identity (or group identity):	Conditions of the restriction
C ₁₄ H _{30-y} Cl _y where y = 3 to 14	Entry identified as Option A as proposed by the Dossier Submitter, with the following modifications: 7 [Within 6 months after entry into force] of the restriction, the supplier placing on the market substances, mixtures, or articles containing chloroalkanes listed in column 1 or referred to in paragraph 5 irrespective of the concentration in a concentration equal or greater than 0.1 % w/w shall inform their downstream users and customers of (i) the presence and overall concentration of the chloroalkanes listed in column 1, and (ii) the appropriate risk management measures and operating conditions to minimise the releases and exposure in case of presence of chloroalkanes listed in column 1.
C ₁₅ H _{32-y} Cl _y where y = 3 to 15	
C ₁₆ H _{34-y} Cl _y where y = 3 to 16	
C ₁₇ H _{36-y} Cl _y where y = 3 to 17	

RAC notes that the scope of the restriction as proposed by the Dossier Submitter covers those substances identified by the MSC as PBT and/vPvB (i.e. C₁₄Cl₃₋₁₁, C₁₅Cl₃₋₈, C₁₆Cl₃₋₈, C₁₇Cl₆₋₉ and C₁₇Cl₁₀₋₁₇). In addition, RAC proposes that the substances identified as “other vP congeners” should also be included within the scope of the restriction proposal (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇).

RAC does not support the derogation for metalworking fluids identified in option B by the

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Dossier Submitter. RAC highlights that, should the European Commission consider the derogation appropriate, the ban on manufacturing and formulation defined in paragraphs 1a and 2 of Option A should enter into force, once the derogation for metalworking fluids has ended.

Finally, RAC supports the information requirements for suppliers in paragraph 7 but notes that the requirements should be triggered when the concentration of chloroalkanes within the scope of the restriction is equal to or greater than 0.1 % w/w.

This information requirement will apply for 18 months (from six months after the entry into force of the restriction to two years) and would support the effective implementation of the restriction by ensuring that the presence of chloroalkanes is known along the supply chain before their manufacture and use is banned.

1.2. THE OPINION OF SEAC

See SEAC opinion

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

The substances in the scope of the proposed restriction contain 'CA:C14-17⁴ with PBT and/or vPvB properties', i.e. linear chloroalkanes with the following molecular formulae:

- C₁₄H_{30-y}Cl_y where y = 3 to 11
- C₁₅H_{32-y}Cl_y where y = 3 to 8
- C₁₆H_{34-y}Cl_y where y = 3 to 8
- C₁₇H_{36-y}Cl_y where y = 6 to 9.

These congeners may be present in many substances, mixtures and articles produced in the EU and/or imported and the Dossier Submitter estimates that ~55 000 tonnes of CA:C14-17⁵ are used annually in EU with EC 287-477-0 (Alkanes, C14-17, chloro) as the main contributor to this tonnage.

Substances containing CA:C14-17 are mainly used as plasticisers, flame-retardants or lubricants in mixtures and articles that are used by industry, consumers and professionals. Substances containing CA:C14-17 are used in various sectors, and in a broad range of applications, such as in PVC, adhesives and sealants, rubber, metalworking fluids, paints and coatings and leather fatliquor.

Releases may happen at all life-cycle stages including during the waste phase. The current releases of CA:C14-17 to the environment is estimated to be between 5 200 and 6 300 tonnes per year in the EU. This corresponds to a total of approximately 104 000 to 126 000 tonnes of CA:C14-17 released to the environment over the 20-year assessment period. Uses in PVC and in adhesives and sealants are the largest contributors in term of release.

CA:C14-17 have been detected in various environmental media (e.g., surface water and sludge, air, sediments and soils, other biota) in the EU but also in remote locations such as the Arctic, the Antarctic and the Tibetan Plateau at high altitude

While a limited number of substances containing CA:C14-17 are already on the Candidate List, this is not sufficient to address the risk posed by the whole group of substances containing congeners with PBT and/or vPvB properties. In addition, the operational conditions and risk management measures in place are not considered to be effective to address the risk associated with the broad, and wide-dispersive uses of the substances containing CA:C14-17. Thus, an action on a Union-wide basis, in the form of a REACH restriction, is warranted to effectively reduce the environmental exposure to PBT and/or vPvB substances in the EU.

Considering the risks associated to 'CA:C14-17 with PBT and/or vPvB properties', the availability of alternatives and that the proposed restriction could also be useful for the on-going discussions in relation to the POP listing of these substances under the Stockholm Convention, the Dossier Submitter proposes two options for the restriction entry:

- Option A: a ban on manufacturing and placing on the market of substances,

⁴ Throughout the proposed restriction, 'CA:C14-17' refers to 'the congeners/congener groups of chloroalkanes with carbon chain lengths within the range from C14 to C17'.

⁵ Equivalent to ~79 000 tonnes of substances containing CA:C14-17

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mixtures and articles containing more than 0.1 % of 'CA:C14-17 with PBT and/or vPvB properties'. The ban would apply after a two-year transition period.

- Option B: a ban on placing on the market substances, mixtures and articles containing more than 0.1 % of 'CA:C14-17 with PBT and/or vPvB properties'. The ban would apply after a two-year transition period, except for metalworking fluids where a time-limited derogation (7 years) could be considered depending on the information submitted during the Annex XV report consultation.

Due to the lack of transparency and communication in the supply chain regarding the presence (or absence) of CA:C14-17 constituents with PBT and/or vPvB properties in other substances, mixtures and articles, the proposed restriction entries also include compulsory measures to accompany the communication down the supply chain.

2.2. Summary of opinion

2.2.1. RAC opinion summary

The scope of the risk assessment and the risks to be addressed with the proposed restriction are well described and are based on a detailed assessment of the hazard, uses, exposure and risks.

The description of the identified hazard (PBT and/or vPvB properties) is adequate for C₁₄Cl₃₋₁₁, C₁₅Cl₃₋₈, C₁₆Cl₃₋₈, and C₁₇Cl₆₋₉ and for the substances covered by the proposed restriction. RAC fully agrees with the Dossier Submitter that the other congeners concluded by the MSC as vP only (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅, and C₁₇Cl₁₀₋₁₇), may also pose a hazard similar to substances with PBT and/or vPvB properties due to their structural similarities and the additional concern for their concentration in the environment. They may build-up to critical concentrations over time and induce toxic effects, thus justifying the application of the 'case-by-case' (Annex I 0.10) hazard and risk assessment.

The manufacture (and import), uses and end-of life of substances, mixtures and articles containing CA:C14-17 are clearly identified. The methodology and assumptions for the emissions assessment are well described and reasonable. The uses of CA:C14-17 are wide and dispersive in nature and the estimated emissions are plausible. The 'other vP congeners' are present as constituents in the same substances as CA:C14-17 and in effect are inseparable from those classed as PBT/vPvB. Thus, there is a risk that needs to be addressed for all congeners of concern.

A quantitative risk characterisation is not appropriate for 'CA:C14-17 with PBT and/or vPvB properties' as well as the 'other vP congeners' and they should all be treated as non-threshold substances for the purpose of risk assessment. The emissions of the 'CA:C14-C17 congeners with PBT and/or vPvB' or vP properties should be minimised and the releases are then used as a proxy for risk.

Based on the estimated releases during the whole life cycle (manufacture, use and waste stage) RAC concludes that the currently recommended and implemented operational conditions (OCs) and risk management measures (RMMs) are not sufficient and effective to control the risk. RAC agrees with the Dossier Submitter that a restriction under REACH is the most appropriate regulatory measure to minimise the identified risk in the EU.

From a human health and environmental perspective, the available alternatives seem to have a less hazardous profile than the substances to be restricted. The risks of alternatives, based on their human health and environmental concerns, poses no major

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shortcomings or uncertainties related to the methodology used.

The restriction is considered to be implementable and monitorable in the EU and also practical and manageable, in particular in terms of the proposed concentration limit of 0.1 % of CA:C14-17. The restriction option A with a general 2-year transition period is enforceable and deemed the most effective measure to minimise releases of 'CA:C14-17 with PBT and/or vPvB properties' to the environment and reduce the identified risks.

RAC does not support a derogation for the metalworking fluid uses and notes that, for this sector, future releases cannot be minimised as far as possible by implementing appropriate OCs and RMMs. RAC considers that given the diversity of metalworking operations, it is not possible to identify specific risk management measures that would be applicable to all uses of metalworking fluids containing 'CA:C14-17 with PBT and/or vPvB properties'.

RAC proposes a requirement to provide information down the supply chain regarding the content of chloroalkanes in substances, mixtures and articles to be triggered at a concentration level of 0.1 % w/w to ensure the implementability and enforceability of the requirement.

2.2.2. SEAC opinion summary

See SEAC Opinion

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. RISK ASSESSMENT

3.1.1. Scope of the risk assessment

Summary of Dossier Submitter's assessment:

As per the requests of the Commission⁶, the Annex XV report assesses *"the potential risks to human health or the environment arising from the manufacture, use or placing on the market of 'MCCP' (defined in the Candidate List as UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17) and other substances containing the same congener groups with PBT and/or vPvB properties as 'MCCP'"*.

The Dossier Submitter defines the proposed congeners by molecular formula:

- C₁₄H_{30-y}Cl_y where y = 3 to 11
- C₁₅H_{32-y}Cl_y where y = 3 to 8
- C₁₆H_{34-y}Cl_y where y = 3 to 8
- C₁₇H_{36-y}Cl_y where y = 6 to 9.

These congeners, which are a subgroup of CA:C14-17, are referred to as 'CA:C14-17' with PBT and/or vPvB properties' by the Dossier Submitter.

The hazard assessment of the Dossier Submitter refers to the ECHA Member State Committee⁸ (MSC) conclusion on the PBT and/or vPvB properties of some CA:C14-17. As a PBT and/or vPvB concern would be sufficient to justify a restriction for the hazard part the Dossier Submitter did not conduct an additional specific assessment of human health hazards.

In order to conduct the exposure and risk assessment, the Dossier Submitter identified all substances that could potentially contain 'CA:C14-17 with PBT and/or vPvB properties' (69 substances identified) and their relevant uses (cf. Table 4).

Considering the very broad range of applications and sectors, the Dossier Submitter grouped the uses in eight categories (use #00 to 07) according to the following similarities: technical requirements, operational conditions, substitution profiles and type of supply chain actors involved.

Table 4: Overview of uses

⁶ Request to the European Chemicals Agency to prepare an Annex XV restriction dossier on medium-chain chlorinated paraffins (MCCP) conforming to the requirements of Annex XV to REACH, and Request to the European Chemicals Agency to prepare an Annex XV restriction dossier on substances containing the same congener groups with PBT- or vPvB-properties as MCCPs received in July 2021 and March 2022

⁷ Throughout the proposed restriction, 'CA:C14-17' refers to 'the congeners/congener groups of chloroalkanes with carbon chain lengths within the range from C14 to C17'.

⁸ Agreement of the Member State Committee on the identification of medium-chain chlorinated paraffins (MCCP defined as 'UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17') as substances of very high concern. Adopted on 15 June 2021. Available at: <https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e185f78852>.

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Use number and use name	End products and examples of applications	Main technical functions of
#00 PVC	Predominantly in PVC compounds used for producing PVC cables and sheathing.	Flame retardant Secondary plasticiser
#01 Use in adhesive and sealants	Predominantly in polyurethane and polysulfide-based sealants to seal cracks or joints.	Plasticiser Flame-retardant
#02 Use in rubber	Substances containing CA:C14-17 are used in specific types of general rubber goods that require flame retardancy properties (e.g. rubber conveyor belts and rubber tubes used in mining and underground activities).	Plasticiser Flame retardant
#03 Use in metalworking fluids	Substances containing CA:C14-17 are added to certain types of metalworking fluids (e.g. neat oils) which are used in the processing of certain metals under extreme conditions.	Extreme pressure additive (EP)
#04 Use in paints and coatings	Specialised solvent-based coatings (e.g. protective coatings and marine coatings, intumescent coatings, flame retardant paints and anti-fouling paints and coating (as co-formulant in Biocidal product).	Flame retardant, plasticiser
#05 Use in leather	Products used in the processing of leather (re-greasing of leather).	Softening agent Leather resistance Waterproofness
#06 Use in paper	Not applicable (use mostly obsolete).	
#07 Other uses in mixtures (lubricants)	Other products where the presence of substances containing CA:C14-17 can be identified are in particular lubricants.	Lubricants

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The Dossier Submitter then established a list of relevant exposure scenarios for each use (cf. Table 5) based on information from the CSR of registered substances containing CA:C14-17 and information gathered via the various calls for evidence on any substances potentially containing CA:C14-17.

Table 5: Exposure scenarios identified for each use

Use name	Life cycle stages/sub-scenarios
Manufacturing	Manufacture
#00: Use in PVC	Formulation (compounding), industrial use (conversion – production of articles), service life
#01: Use in adhesive and sealants	Formulation, industrial use, professional and consumer use, service life
#02: Use in rubber	Formulation (compounding), industrial use (production of articles), service life
#03: Use in metalworking fluids	Formulation, industrial use oil-based metalworking fluids
#04: Use in paints and coatings	Formulation, industrial use, professional and consumer use, service life
#05: Use in leather	Formulation of mixtures, incorporation in leather, service life
#06: Use in paper manufacturing/recycling	Not assessed (obsolete use)
#07: Other uses	Formulation, professional and consumer use
Waste handling (for all uses)	Shredding, landfilling, incineration

The scope of the risk assessment includes manufacturing and all uses reported in Table 5. It includes releases from the waste stage (e.g. releases from disposal of waste to landfill).

The scope of the risk assessment excludes historical emissions and releases from landfills after their operating phase (i.e. during the after-care and after closure). This approach is consistent with other restriction proposals for PBT and/or vPvB substances.

Due to its high registered tonnage (cf. section 1.3 of the Background Document), the Dossier Submitter concluded that EC 287-477-0 is the main driver of the risk assessment.

RAC conclusion(s):

RAC concludes that the scope of the risk assessment and the risks to be addressed with the proposed restriction are well described and based on a detailed assessment of the hazard, uses, exposure and risks.

RAC notes that the scope covers (i) any substance containing 'CA:C14-17 with PBT and/or vPvB properties' and, (ii) all life-cycle stages, including the waste stage, in accordance with the request received from the Commission (EU Commission, 2022a). RAC notes that the Dossier Submitter also conducted a case-by-case hazard and risk assessment for some CA:C14-17 which, according to MSC, fulfil the vP criterion, whereas the MSC was not able to conclude on the B and T properties due to lack of data.

Key elements underpinning the RAC conclusion(s):

The RAC opinion is based on Section 1 of the Background Document supported by information in Appendix A, B.1, B.4, B.5, B.6 and B.7.⁹

1. The scope of the hazard assessment is justified.

RAC considers that risks of PBT and/or vPvB substances cannot be adequately controlled and any CA:C14-17 identified as PBT and/or vPvB may cause severe and irreversible adverse effects if released to the environment.

RAC takes note of the assessment and conclusions of MSC regarding the PBT and/or vPvB properties of some CA:C14-17 (namely C₁₄Cl₃₋₁₁, C₁₅Cl₃₋₈, C₁₆Cl₃₋₈, C₁₇Cl₆₋₉), which do not warrant further assessment by RAC. Additionally, a risk assessment based on PBT and/or vPvB properties is enough to justify a restriction and therefore an assessment of potential human health hazards is not deemed necessary for the purpose of this restriction.

RAC notes that the Dossier Submitter also undertook a case-by-case risk assessment (cf. Appendix B.7 to the Background document) of some additional CA:C14-17 (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇) for which the MSC concluded that they fulfil the vP criterion but could not conclude on PBT and/or vPvB properties due to the lack of information available during the SVHC identification of 'MCCP'. RAC has considered the implications of this case-by-case assessment under the further elements of the evaluation (see sections 3.4).

2. The substances within the scope of the risk assessment are clearly described by the Dossier Submitter, and there is a clear justification to target a group of substances.

The substances containing 'CA:C14-17 with PBT and/or vPvB properties' in the scope of the risk assessment belong to the chloroalkane family. Additionally, the risk assessment performed by the Dossier Submitter includes some additional CA:C14-17 (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇) with vP properties as described above.

RAC underlines the rationale and appropriateness of the approach applied by the Dossier Submitter to group, describe and identify the substances in the scope of the risk assessment. This is clearly explained in the Background Document and a list of substances potentially containing CA:C14-17 (69 substances identified) is available in Appendix B.1.2.

RAC considers that the methods applied for identifying the substances in the scope of the risk assessment are well justified by an adequate description of the manufacturing process of chloroalkanes.

RAC notes that the group of substances within the risk assessment is wider than those currently on the Candidate List for the 'MCCP'¹⁰ entry and agrees that the grouping of substances proposed by the Dossier Submitter is consistent with the approach to regulating substances where regrettable substitution could occur. Similarly, RAC also

⁹ 'Annex XV report consultation' in this document refers to the 'Annex XV restriction proposal consultation' that run between 21 October 2022 and 22 March 2023.

¹⁰ 'MCCP' (defined in the Candidate List as UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17)

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points out that the group of substances targeted in the risk assessment is in accordance with the Commission request to "assess the risks of MCCP' (defined in the Candidate List as UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain lengths within the range from C14 to C17) and other substances containing the same congener groups with PBT and/or vPvB properties as 'MCCP'". In addition, the Dossier Submitter targeted additional congeners with the same carbon chain lengths and for which the MSC concluded on their vP properties.

Overall RAC agrees on the scope of the risk assessment performed by the Dossier Submitter based on the presence of structurally similar congeners with PBT and/or vPvB or vP properties.

RAC notes that this scope is similar but wider than the scope of the risk assessment of the UK proposal for listing 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥ 45 %' in the Annexes to the Stockholm Convention on Persistent Organic Pollutants (for example C₁₄Cl₃₋₄, C₁₅Cl₃₋₄, C₁₆Cl₃₋₅ would be excluded from the proposed POP scope).

3. The uses, life cycle stage, and exposure within the scope of the risk assessment are clearly described and justified for release calculation.

The Dossier Submitter identified eight different categories of uses in the scope of the risk assessment and a list of relevant exposure scenarios for each use and life cycle stage.

RAC considers that the information provided on uses, and associated exposure scenarios, is underpinned by plausible and relevant data provided by industry and stakeholders as part of registration dossiers, the conducted market surveys and from other relevant sources of information.

RAC notes that the risk assessment covers all intended and unintended uses resulting from the presence of CA:C14-17 in substances, mixtures and articles in a broad range of applications. Articles already in use and second-hand articles are outside of the scope of the risk assessment and RAC will consider the implications of excluding these applications under the further elements of the restriction proposal evaluation (see sections 3.4).

RAC notes that the risk assessment covers the whole life cycle of substances containing CA:C14-17. It includes manufacturing, all exposure scenarios for the identified industrial, professional and consumer uses. Releases from the waste stage, including releases from landfills, are also covered.

3.1.2. Hazard(s)

Summary of Dossier Submitter's assessment:

The restriction proposal targets the presence of CA:C14-17¹¹ with PBT and/or vPvB properties in substances, mixtures, and articles.

ECHA Member State Committee¹² (MSC) concluded that the following CA:C14-17 have PBT

¹¹ Throughout the proposed restriction, 'CA:C14-17' refers to 'the congeners/congener groups of chloroalkanes with carbon chain lengths within the range from C14 to C17'.

¹² Agreement of the member state committee on the identification of medium-chain chlorinated paraffins (MCCP defined as 'UVCB substances consisting of more than or equal to 80 % linear chloroalkanes with carbon chain

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and/or vPvB properties:

- C₁₄H_{30-y}Cl_y where y = 3 to 11
- C₁₅H_{32-y}Cl_y where y = 3 to 8
- C₁₆H_{34-y}Cl_y where y = 3 to 8
- C₁₇H_{36-y}Cl_y where y = 6 to 9.

In addition, the Dossier Submitter provided in the Appendix to the Background Document a supplementary hazard assessment of other CA:C14-17 (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅, and C₁₇Cl₁₀₋₁₇).

RAC conclusion(s):

RAC concludes that the above description of the identified hazard (PBT and/or vPvB properties) is adequate.

RAC takes note of the MSC conclusion that the CA:C14-17 listed above have PBT and/or vPvB properties and any substances containing these CA:C14-17 at a concentration ≥ 0.1 % (w/w) fulfil the criteria for a PBT and/or vPvB substance in accordance with Annex XIII to REACH.

Consequently, RAC agrees with the identified hazard (PBT and/or vPvB properties) for C₁₄Cl₃₋₁₁, C₁₅Cl₃₋₈, C₁₆Cl₃₋₈, and C₁₇Cl₆₋₉ and for the substances covered by the proposed restriction and considers it well justified.

The MSC could not conclude on the PBT and/or vPvB properties of all CA:C14-17 due to a lack of data for some of the congeners to assess the hazards against the vPvB/PBT criteria. The Dossier Submitter has conducted a case-by-case hazard and risk assessment of the other congeners (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅, and C₁₇Cl₁₀₋₁₇) concluded by the MSC as very persistent (vP).

RAC fully agrees with the Dossier Submitter that these other congeners concluded by the MSC as vP (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅, and C₁₇Cl₁₀₋₁₇) may pose an hazard similar to PBT and/or vPvB due to their structural similarities. Although only the very persistent criterion of REACH Annex XIII is met, RAC considers that the additional concern for their concentration in the environment to build-up to critical concentrations over time and induce toxic effects justifies the Dossier Submitter's proposal to apply the 'case-by-case' approach to hazard and risk assessment as described in paragraph 0.10. of REACH Annex I, i.e. where a standard risk assessment is not considered to be practicable.

Finally RAC also takes note that "*some (CA:C14-17) are predicted to have long-range environmental transport potential (LRTP)*" according to the MSC.

RAC's conclusions regarding the hazard assessment of CA:C14-17 are summarised in Table 6.

Key elements underpinning the RAC conclusion(s):

'CA:C14-17 with PBT and/or vPvB properties' (i.e. C₁₄Cl₃₋₁₁, C₁₅Cl₃₋₈, C₁₆Cl₃₋₈, and C₁₇Cl₆₋₉):

The RAC opinion is based on Sections 1.2.1, 1.4.2 of the Background Document, Appendix

lengths within the range from C14 to C17') as substances of very high concern. Adopted on 15 June 2021. Available at: <https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e185f78852>.

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B.4.

The PBT and/or vPvB properties of CA:C14-17 have been evaluated and concluded by the MSC¹² and were therefore not evaluated by RAC.

'Other vP congeners' (i.e. C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅, and C₁₇Cl₁₀₋₁₇):

RAC notes that the Dossier Submitter also reported in Appendix B.7 of the Background Document a case-by-case hazard and risk assessment of some CA:C14-17 (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇) for which the MSC concluded that they are very persistent but could not conclude on PBT and/or vPvB properties due to the absence of data.

For clarity, these are referred to as CA:C14-17 (i.e. C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇) as 'other vP congeners' in this document.

The Dossier Submitter's case-by-case assessment is based on 1) confirmation by the MSC of the vP properties of C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇, 2) predictions of toxicity using QSAR and 3) grouping and read-across which is supported by experimental and monitoring data comparing bioavailability across the congener groups.

The Dossier Submitter justifies the need for a case-by-case assessment because in the MSC conclusions, there is no information available to conclude on the absence of hazards but rather a lack of data for some of the congeners to fully assess the hazards against the PBT and/or vPvB criteria.

The elements to support RAC evaluation and conclusions of the potential hazard of these 'other vP congeners' are elaborated below.

1. C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇ are very persistent:

RAC takes note of the MSC assessment and conclusion that the CA:C14-17 (congeners) with three or more Chlorine atoms have vP properties. In particular, MSC assessed and concluded that C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇ are all very persistent.

The MSC assessment and conclusion with regard to the Persistency (P), Bioaccumulation (B) and Toxicity (T) properties are reported in Table 6.

2. Structural similarity forms a solid basis to group the 'other vP congeners' (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇):

The MSC already assessed and concluded that the CA:C14-17 (congeners) are all structurally very similar by differing only in carbon chain length and number of chlorine substituents. None has additional functional groups attached to the chlorinated alkane structure.

Due to structural similarity, the MSC concludes as well that these congeners can be expected to exert toxic effects by the same mode(s) of action.

3. The 'other vP congeners' can be expected to build-up to critical concentrations over time and induce therefore toxic effects. Higher trophic levels may be affected:

The 'other vP congeners' display limited biodegradation, low metabolic potential, high log K_{ow}, low solubility in water and high log K_{oc}, relatively high K_{oa} and low to moderate K_{aw}.

They are highly bioavailable for biota (daphnids, fish, plants, and terrestrial species) and the increasing level of chlorination does not seem to limit the bioavailability, based on biomagnification and bioconcentration studies. Despite an expected faster

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biotransformation of lower chlorinated congeners than higher chlorinated congeners, C₁₇Cl₃₋₅ congeners do not appear to have fast disappearance from organisms based on experimental data.

As described in Appendix B.7 of the Background Document):

- The data on the technical mixtures corroborates a high bioconcentration potential and indicates that the degree of chlorination would not limit bioaccumulation potential in *Daphnia magna*. Data on other species supports that bioavailability is not significantly prevented by an increasing level of chlorination or that immediate excretion of C₁₇Cl₃₋₅ congeners takes place due to rapid metabolism. Even though higher metabolism of the lower chlorinated congeners is expected, it is not assumed to significantly decrease the tendency of C₁₇Cl₃₋₅ congeners to accumulate in an organism. Data on the C14 to C16 congeners with chlorination levels from 3 to 5 shows high bioaccumulation and therefore they cannot be expected to be metabolised/eliminated to a large extent.
- This indicates the potential to reach the sites of toxic action (receptors, cell membranes, etc) showing the potential for inducing effects if they build-up to a critical concentration.
- All congeners of CA:C14-17 are potentially bioaccumulative (log Kow >4.5). The range of the predicted log Kow for C₁₄Cl₁₋₁₄ is 6.2-8.25, C₁₅Cl₁₋₁₅, is 6.63 – 8.76, C₁₆Cl₁₋₁₆ is 7.07-9.28 and C₁₇Cl₁₋₁₇ is 7.33 - 9.8. While QSAR models predict BCFs below 2 000 L/kg wet weight for the hydrophobic CA:C14-17 congeners with a chlorine content > 65 % , it was recognised that, in contrast, experimental data on CA:C14-17 indicates high uptake of these highly chlorinated congeners. Evidence is presented that not only the small molecular size congeners accumulate to *Daphnia magna*, but equally the large chloroalkanes contribute to the high log BCF and log BAF values indicating that the increasing chlorine content does not limit bioavailability of the chloroalkane congeners. Similar results have been observed in plants in a wetland ecosystem: there is a positive correlation between the log Kow of the congeners and BCF. This means that the congeners with high log Kow (such as highly chlorinated congeners) are expected to be bioavailable and accumulate in wetland plants even more than the less lipophilic congeners. A significant positive correlation between BMFs and the number of Cl atoms has been demonstrated also in the fish–watersnake food chain and fish–waterbird egg food chain (5-10 chlorine atom). Additionally both congeners C₁₆Cl₃ and C₁₆Cl₁₃ have a BCF above 5 000 L/kg indicating that these congeners are taken up and have a tendency to accumulate in fish exposed via food.

Very hydrophobic substances can also pass the gastro-intestinal tract as lack of size or hydrophobicity cut-off has been indicated by experimental studies on chloroalkanes. This is confirmed by monitoring data on e.g. a fish-watersnake food chain as explained above. As 'other vP congeners' are very persistent and potentially magnify in food chains, the concern in higher trophic levels arises directly from the exposure to the chemicals via food.

Furthermore, because high bioconcentration potential to *Daphnia magna* has been indicated also for 'other vP congeners', continued exposures to invertebrates can lead to effects in lower trophic levels (mortality, reduced reproduction). Considering that aquatic invertebrates are an important part of aquatic food chains, reduced population size of *Daphnia magna* (or other aquatic invertebrates) may reduce food availability at higher levels of the food chain. Thus, populations at higher trophic levels can be affected also

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indirectly, with potential community- and ecosystem level effects.

4. Effects on Daphnia

In terms of effects, immobilisation/mortality and reduced reproductive output is observed in *Daphnia magna*. The predicted NOEC for daphnids (0.4 – 2.2 µg/L) for the 'other vP congeners' is considered relatively consistent with the experimental NOEC (reproduction) value for *Daphnia magna* (21-day 8.7 µg/L) indicating on the reliability of the modelling to predict chronic daphnia toxicity.

5. Effects on mammals

The effects in higher trophic levels may be observed in liver, thyroid, kidney, internal haemorrhaging and deaths of newborn animals based on the mammalian toxicity studies mostly performed on CA:C14-17. Effects in mammals have been reviewed in several documents (e.g. CEPA, 2008, Joint Research Centre, 2011b, SCHER, 2008, Danish EPA, 2013 as referred to in the Background document).

6. Increase of environmental concentrations

Considering that 'other vP congeners' are very persistent, their environmental concentrations will increase over time as a result from ongoing releases. The increasing concentrations have been confirmed by limited monitoring data. CA:C14-17 congeners with chlorination levels of 4-10 have been also detected in remote regions.

7. Uncertainties related to the monitoring data on 'other vP congeners'

RAC notes that monitoring data on environmental fate of 'other vP congeners' is limited:

- The presence of the 'other vP congeners' in the environment is not systematically addressed in existing monitoring programmes and therefore current monitoring results are expected to provide only a partial picture and possibly an underestimation of the overall exposures to the 'other vP congeners'.
- The analytical methods used in several previous studies did not allow in the past to assess accurately the concentrations of different CA:C14-17 with varying level of chlorination in the environment. Nevertheless, recent studies where more advanced analytical methods were used, indicate a wide spectrum of congeners in environmental samples from chlorination level 3, up to 17.

8. Summary of justification of RAC conclusions on 'other vP congeners':

RAC agrees that structural similarity forms a solid basis to group all 'other vP congeners' and discuss the toxicity of these congeners. RAC concludes that, considering that toxic effects have been observed in several studies, these congeners are structurally similar with the PBT and/or vPvB congeners and that bioaccumulation potential may be expected to be at similar level with the PBT and/or vPvB congeners. RAC agrees with the Dossier Submitter that 'other vP congeners' have the potential to induce toxic effects.

Considering their vP properties, their potential to induce toxicity, their long-range transport potential, and their presence in the environment, RAC concludes that the 'other vP congeners' may pose an intrinsic hazard. Due to the persistence and toxic potential of these substances, continued emissions will result in an environmental stockpile that in the longer term will lead to adverse effects that are likely to be irreversible for the environment and human health.

RAC concludes that for the 'other vP congeners' (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇), a case-by-case approach according to REACH Annex I is suitable and that these

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congeners may pose an intrinsic hazard similar to PBT/vPvB .

Finally, RAC notes that the case-by-case assessment approach is in line with the approach taken in several previous restrictions (e.g. PFHxA, microplastics) where it was agreed that high persistency, in combination with other properties pose an intrinsic hazard.

Overview of RAC conclusions:

Table 6: Overview of RAC's hazard assessment

Cl	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
14	-	-	vPv B	vPvB , PBT	vPvB , PBT	vPvB , PBT	vPvB , PBT	vPv B	vPvB	vPv B	vPv B	P/v P	P/v P	P/v P			
15	-	-	vPv B	vPvB	vPvB , PBT	vP, PBT	vP, PBT	vP, PBT	P/vP , B	P/vP	P/vP	P/v P	P/v P	P/v P	P/v P		
16	-	B/v B	vPv B	vPvB	vPvB , PBT	vP, PBT	vP, PBT	vP, PBT	P/vP , B	P/vP	P/vP	P/v P	P/v P	P/v P	P/v P	P/v P	
17	-	-	P/vP	P/vP	P/vP, B	vP, PBT	vP, PBT	vP, PBT	vP, PBT	P/vP	P/vP	P/v P	P/v P	P/v P	P/v P	P/v P	P/v P
	RAC takes note of the MSC assessment and conclusion that these CA:C14-17 (congeners) have PBT and/or vPvB properties. RAC agrees with the identified hazard.																
	RAC agrees with the Dossier Submitter that these congeners concluded by the MSC as vP may pose an intrinsic hazard similar to congeners having PBT and/or vPvB properties.																
	No conclusion from Dossier Submitter and RAC. MSC could not conclude on P properties due to lack of experimental data.																
	Congener much less likely to exist in manufactured substances																

3.1.3. Emissions and exposures

Summary of Dossier Submitter's assessment:

Among the substances that may contain CA:C14-17, six of them are registered by 46 active registrants.

Substances containing CA:C14-17 are used in a broad range of applications to confer several properties to the final products. Table 4 gives an overview of the uses.

The Dossier Submitter estimates that ~79 000 tonnes of substances containing CA:C14-17 are used yearly in the EU, which corresponds to ~ 55 000 tonnes of CA:C14-17.

The releases were estimated for all life cycle stages and exposure scenarios identified in Table 5 (from manufacturing till waste management), using a static model. A thorough review of available release factors per environment compartment and uses (from ECHA guidance R16, R18, SpERC, OECD emission scenario documents, CSRs) was performed in order to select the most relevant ones.

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The release calculations include the releases from current uses and applications: i.e. historical emissions and releases from landfills after their operating phase (i.e. during the after-care and after closure) are not estimated. This approach is consistent with the release estimates for other restriction proposals on PBT and/or vPvB substances and follows the ECHA guidance R16 on environmental exposure assessment.

The current releases of CA:C14-17 to the environment are estimated to be between 5 200 and 6 300 tonnes per year in the EU. This corresponds to a total of approximately 104 000 to 126 000 tonnes of CA:C14-17 released to the environment during the 20-year assessment period used in the Annex XV report. Uses in PVC and in adhesives and sealants are the largest contributors of releases. (See Table 9 from the Background Document below)

Table 7. Tonnage of CA:C14:17 released per use scenario (all life cycle stages included)

Use	Lower bound (tonnes of CA:C14-17 per year)				Higher bound (tonnes of CA:C14-17 per year)			
	release from manufacture for that use	release from use	release from waste from that use	Total (% of total)	release from manufacture for that use	release from use	release from waste from that use	Total (% of total)
#00 - PVC	14	16	410	440 (8.5 %)	14	720	410	1 100 (18 %)
#01 - Adhesives/sealants	32	390	3 900	4 300 (82 %)	32	390	3 900	4 300 (69 %)
#02 - Rubber	3	180	47	230 (4.3 %)	3	190	47	230 (3.7 %)
#03 - Metalworking fluids	3	31	0.5	34 (0.7 %)	3	250	0.5	250 (4 %)
#04 - Paints/coatings	0.6	14	71	85 (1.6 %)	0.6	88	71	160 (2.5 %)
#05 - Leather	0.2	0.6	2	2.6 (0.05 %)	0.2	22	2	24 (0.4 %)
#07 - Other	1	130	4	140 (2.6 %)	1	130	8	140 (2.3 %)
Manufacture for export – not allocated to a use	4.1	-	0.04	4.2 (0.08 %)	4.1	-	0.04	4.2 (0.07 %)
Total				~5 200				~6 300

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The lower bound estimation of releases corresponds to the releases estimated with the lowest release factors and lowest fraction of substances going to waste. On the contrary, the highest bound estimation of releases is calculated using the highest release factors and highest fraction of substances going to waste.

Releases to the environment, and presence of CA:C14-17 in all environmental compartments are underpinned by studies and monitoring carried out in the EU, but also worldwide.

RAC conclusion(s):

RAC concludes that the manufacture (and import), uses and end-of life of substances, mixtures and articles containing CA:C14-17 are clearly identified and described in the Background Document and give a robust basis for emissions assessment.

The methodology and assumptions for the emissions assessment are well described and reasonable.

RAC notes that uses of CA:C14-17 are wide dispersive in nature.

The monitoring studies for different environmental matrices and biota at various locations are discussed in sufficient detail. The measured concentrations provide robust evidence of ongoing releases and large-scale exposures.

RAC considers the estimated emissions to be plausible.

Key elements underpinning the RAC conclusion(s):

The RAC opinion is based on Sections 1.3 and 1.4.3 of the Background Document and Appendix B.5..

RAC considers that the emission estimates have been derived applying relevant use data, for the whole life cycle of CA:C14-17 and using a plausible set of corresponding release factors. Main waste categories (recycling, landfilling, incineration) relevant for materials and articles containing CA:C14-17 have been taken into account. The emission estimates are corroborated by the monitoring studies that indicate global distribution and detection of emissions of CA:C14-17 in different environmental matrices, sewage sludge and biota at all trophic levels at different types of locations, from industrial sites to urban and remote areas as well as from the article service life stage in indoor dust.

RAC notes that the assumptions on emissions rely on the registration data of six substances containing CA:C14-17¹³, i.e. information on their tonnages and their uses. The Dossier Submitter assumed that substances containing CA:C14-17 contain 'CA:C14-17 (congeners) with PBT and/or vPvB properties' and the 'other vP congeners' due to the manufacturing process (random chlorination of the carbon chain of the paraffin feedstock). However, the exact composition of the different congeners in each substance is not known or consistently provided. Some of the substances contain also other constituents which are not in the scope of the risk assessment and the restriction. Therefore, the Dossier Submitter made assumptions on the composition of congeners in each of these substances based on available data, to estimate the related tonnage of congeners and calculate their releases to the environment. For this reason, releases are estimated for CA:C14-17 in general, and there is

¹³ Alkanes, C14-17, chloro (EC 287-477-0); Di-, tri- and tetrachlorotetradecane (EC: -); Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated, saponified (EC: -); Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified (EC: -); Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated (EC 269-145-7); Paraffin waxes and Hydrocarbon waxes, chloro (also known as 'LCCP') (EC 264-150-0).

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an uncertainty related to the releases of CA:C14-17 belonging to the different subgroups ('CA:C14-17 with PBT and/or vPvB properties', 'other vP congeners', other congeners in the C14-17 range).

The 63 other substances potentially containing CA:C14-17 are not registered. For the non-registered substances, the tonnage limit triggering registration (1 tonne per year) is used as a worst-case assumption of the tonnage manufactured and used in the EU and that 100 % of the tonnage corresponds to CA:C14-17. Also, due to its high registered tonnage (between 10 000 and 100 000 tonnes per year) Alkanes, C14-17, chloro (EC 287-477-0) is the main driver, in terms of tonnage, for the risk assessment. Use in PVC and adhesives/sealants are considered to contribute most to the total emission based on the high tonnage placed on the market for these uses.

There is no information available specifically on the import and placing on the market of substances containing CA:C14-17 in articles. This may lead to an underestimation of emissions resulting from the use of imported articles as the volumes are assumed to be zero in the calculations. RAC agrees that the imported tonnage may be much higher in reality, as there is no obligation to register substances imported below the registration threshold of one tonne/year, and no obligation to register substances imported in articles above one tonne/year per company when there is no intended release from the articles. These tonnages are not known and are therefore not taken into account in the release estimates.

RAC notes the possible unintended presence of CA:C14-17 in other substances than the 69 substances mentioned above, in mixtures and articles. This may be expected taking into account the feedstock used, the manufacturing process of chloroalkanes describing and the possible cross-contamination from one manufactured batch to another. CA:C14-17 have also been found as impurities in food/feed packaging. Thus, there may be unaccounted volumes of CA:C14-17 which should be considered as an uncertainty in the emission assessment.

As CA:C14-17 do not degrade naturally and are expected to remain in the final product or article, it is expected that the main source for emission to the environment will be from service life and from waste, the waste phase corresponding to 84-71% of the estimated annual releases for CA:C14-17. RAC notes that no degradation is expected in municipal WWTP, a large fraction of CA:C14-17 is expected to be transferred from waste water to sludges, which are assumed to be either applied on land, incinerated or landfilled. A connection rate from waste stage to municipal WWTP of 100 % is assumed: meaning that emission to water from operating landfill (via leachate) and incineration (via scrubbing) will be treated and not go directly to surface water. It is further assumed that the sludges from WWTP connected to landfill and incinerating plant would be incinerated. Only emission to the first receiving environmental compartment have been considered, further treatment steps are not accounted and the estimations are considered indicative.

RAC acknowledges the comments provided during the Annex XV report consultation on the release estimates for waste life cycle stage (#3739, #3847, #3848) and notes that the information did not warrant a re-evaluation by RAC.

RAC notes that landfills may constitute a long-term reservoir of CA:C14-17. Even if it is expected that the relative tonnage landfilled instead of incinerated or recycled will decrease over time and no degradation of CA:C14-17 takes place, RAC agrees that it can be assumed that the emission from the after-care does not exceed emission to the environment during the actual operating phase of the landfill. RAC also notes that the conditions for after-care and closure may also affect the potential and magnitude of ongoing emission. In the landfill scenario, tonnage that remains sunk in after-care and in 'abandoned' landfills after their closure provides an overestimation as no degradation is assumed and no mass balance in the

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life cycle stages before landfilling is taken into account. Emissions from incineration residues (ash) disposed of to landfill are assumed to be negligible compared to releases from other sources.

3.1.4. Risk characterisation

Summary of Dossier Submitter's assessment:

According to REACH Annex I para 6.5, the risk to the environment and to human health for PBT and/or vPvB substances cannot be adequately controlled. No safe concentration, thus no threshold, can be determined for PBT or vPvB substances.

It is therefore concluded that any CA:C14-17 identified as PBT and/or vPvB may cause severe and irreversible adverse effects if released, and that emissions and release should be minimised throughout the lifecycle of these substances.

Releases of CA:C14-17 are therefore used as proxy for risk (and risk reduction).

RAC conclusion(s):

RAC agrees that a quantitative risk characterisation is not appropriate for 'CA:C14-17 with PBT and/or vPvB properties'. RAC agrees that the 'CA:C14-17 with PBT and/or vPvB properties' should be treated as non-threshold substances for the purpose of risk assessment.

In addition, supported by the case-by-case approach assessed in section 3.1.2, RAC concludes that the congeners concluded by the MSC as vP (aka 'other vP congeners' in this document) should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT and/or vPvB substances.

RAC consequently agrees that emissions of the 'CA:C14-C17 congeners with PBT and/or vPvB' or vP properties should be minimised and the releases should be used as a proxy for risk. As provided in section 3.1.3, the current uses of substances containing CA:C14-C17 cause releases and exposures of 'CA:C14-C17 with PBT and/or vPvB' or vP properties. RAC therefore concludes that there is a risk that needs to be addressed.

Key elements underpinning the RAC conclusion(s):

The RAC opinion is based on Section 1.4.4 of the Background Document, Appendix B.6.

PBT and vPvB substances are of specific concern due to their potential to remain and accumulate in the environment over long periods of time. The effects of such accumulation are unpredictable in the long-term and very difficult to reverse because a cessation of emissions will not result in an immediate reduction of concentrations in the environment. Furthermore, PBT and/or vPvB substances may have the potential to contaminate remote areas that should be protected from contamination by hazardous substances resulting from human activity.

Considering their vP properties, their potential to induce toxicity, their long-range transport potential, their presence in the environment, RAC concludes in section 3.1.2 that the 'other vP congeners' may pose an intrinsic hazard similar to congeners with PBT and/or vPvB properties due to their structural similarities. The 'other vP congeners' should therefore be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT and/or vPvB substances.

RAC considered that releases, estimated at approximately 104 000 to 126 000 tonnes of CA:C14-17 for the near 20-year period, are a suitable proxy for assessing the risks of CA:C14-17. This is consistent with the Restriction Task Force guidance (2020) and previous restrictions on PBT and/or vPvB substances.

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RAC notes that releases are estimated for CA:C14-C17, which contain both the congeners with PBT/vPvB properties and the 'other vP congeners'.

Based on the assessment presented in sections 3.1.2 and 3.1.3, the current uses cause releases and exposures which justifies that there is a risk that needs to be addressed.

The approach taken by the Dossier Submitter for the calculation of emissions leads to an overestimation of the risks since the estimates are essentially based on the volumes in use of the highest tonnage substance in the EU (EC 287-477-0) which contains CA:C14-17 with PBT and/or vPvB properties. However, no specific tonnage data regarding the content of CA:C14-17 in the substance itself was made available to the Dossier Submitter. Additionally, the estimates are based on the tonnage information from the registration dossiers but the use of some chloroalkanes may be already limited due to their SVHC identification.

3.1.5. Existing operational conditions and risk management measures

Summary of Dossier Submitter's assessment:

Releases to the environment occur mainly from wide dispersive uses (professional, consumer and service life) and from waste handling. However, since the identification of 'MCCP' as SVHC by the MSC due to their PBT and/or vPvB properties, no emission minimisation efforts have been documented by the REACH registrants of the four substances explicitly indicated on the ECHA Candidate List (e.g. no changes in recommended operational conditions (OCs) and risk management measures (RMMs) to downstream users and waste operators and no uses advised against targeting these life cycle stages).

The broad nature of the uses themselves, including 'open'¹⁴ and 'wide dispersive'¹⁵ uses such as metalworking fluid applications, lubricants, paints and coatings, adhesives and sealants (One Component Foam - OCF cans), additives in consumers mixtures and/or articles, makes it difficult to implement effective risk management measures to limit the releases and exposures.

The existing operating conditions and risk management in place are therefore not sufficient to address the risks of 'CA:C14-17 with PBT and/or vPvB properties'.

RAC conclusion(s):

RAC concludes based on the estimated releases during the whole life cycle (manufacture, use and waste stage) that the currently recommended and implemented operational conditions (OCs) and risk management measures (RMMs) are not sufficient and effective to control the risk.

Key elements underpinning the RAC conclusion(s):

The RAC opinion is based on Section 1.5 of the Background Document and Appendix C.

The Dossier Submitter conducted specific surveys toward registrants and downstream users to get an overview of the measures in place to minimise the releases to the environment (cf.

¹⁴ Industrial uses are described by the Dossier Submitter as mainly "open" uses, i.e. taking place in non-enclosed systems.

¹⁵ Wide dispersive uses are defined as uses that take place at many sites and/or by many users and have potential for releases/exposure, Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description, available at: [R_12_CARACAL_cross_check_TC \(europa.eu\)](https://echa.europa.eu/r12)

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Appendix G). RAC agrees that, taking into account:

- the open and wide dispersive nature of the uses,
- the lack of information on the effectiveness of the risk management measures to minimise the releases implemented and communicated by the registrants and suppliers of substances containing CA:C14-17 down the supply chain (cf. registration dossiers and surveys) and
- the estimated releases (corroborated by the monitoring data)

The existing operating conditions and risk management in place, are not sufficient to address the risks of CA:C14-17 with PBT and/or vPvB, or vP properties.

RAC notes that since the identification of 'MCCP' as SVHC by the MSC due to their PBT and vPvB properties, no emission minimisation efforts have been documented by the REACH registrants of the four substances included in the ECHA Candidate List (e.g. no changes in recommended operational conditions (OCs) and risk management measures (RMMs) to downstream users and no uses advised against targeting these life cycle stages).

The Dossier Submitter has indicated that it is not known to which extent companies using CA:C14-17 implement suitable RMMs (especially in downstream uses), and what their effectiveness is in reducing the emissions. Additionally, there is no information in the registration dossiers and no use advised against targeting the service life and waste handling, which account for the largest part of the emissions. Despite the described RMMs, for all registered substances, releases still occur to the environment.

3.2. JUSTIFICATION THAT ACTION IS REQUIRED ON A UNION WIDE BASIS

Summary of Dossier Submitter's assessment:

Substances containing CA:C14-17 are manufactured, formulated and used in a broad range of substances, mixtures and articles in the EU.

While two member states (Germany and Norway) have taken specific actions focused on one substance (EC 287-477-0), and a limited number of substances containing CA:C14-17 are already on the Candidate List, these measures are not sufficient to address the risk posed by the congeners with PBT and/or vPvB properties at the EU level.

Releases can occur throughout the life cycles of substances, mixtures and articles containing CA:C14-17: the operating conditions and risk management measures in place are not effective to address the risk associated with the broad, and wide-dispersive uses of the substances containing CA:C14-17.

Thus, an action on a Union-wide basis is needed to:

- effectively reduce the environmental exposure to these substances
- limit the potential for trans-boundary exposure to these substances from EU sources, and
- 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.

RAC conclusion(s):

Based on the key principle of ensuring a high level of protection across the Union, RAC concludes that any necessary action to address the risk(s) associated with medium-chain

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chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17 should be implemented in all Member States.

Key elements underpinning the RAC conclusion(s):

The RAC opinion is based on Section 1.5 of the Background Document and Appendix C.

RAC agrees that EU-wide measures are needed to minimise the releases of CA:C14-17 into the environment from their manufacturing, placing on the market and use. Professional and consumer uses of products (substances, mixture, and articles) containing CA:C14-17 are wide dispersive in nature; articles containing CA:C14-17 are imported into the EU and are placed on the market in all EU member states.

Releases to the environment occur during the whole life cycle from wide range of uses (industrial, professional, consumer and service life) and from waste handling. The monitoring studies for different environmental matrices and biota in several places in the EU corroborate the release information.

Some CA:C14-17 have PBT and/or vPvB properties and some CA:C14-17 are predicted to have LRTP. RAC notes that the 'other vP congeners' may carry similar hazards as the congeners having PBT and/or vPvB properties (see section 3.1.2 above). Due to these properties, the human health and environmental impacts may not be limited to the countries where the uses initially occur.

Currently recommended and implemented operational conditions (OCs) and risk management measures (RMMs) as well as national measures are not sufficient and effective to control the risk. Risk management action on an EU wide level is needed to minimise exposures and emissions of CA:C14-17 with PBT and/or vPvB and/or vP properties.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.3. ANALYSIS OF ALTERNATIVES

Summary of Dossier Submitter's assessment:

~ 70 potential different alternatives are identified from a literature review, stakeholders' consultations (three calls for evidence and sector targeted surveys) and the ECHA market survey. Bilateral exchanges with relevant trade associations and companies were also organised.

The aim of this investigation was to:

- gain a better understanding of the technical and economic profiles of the identified alternatives
- identify (when possible) the most promising alternatives in each of the above-described uses
- understand the state of technology of the different sectors regarding substitution, as well as the time that different sectors may require to shift to the alternatives.

A short-list of alternatives - technically feasible and available on the market - was subsequently identified for each use category. Moreover, price information for the alternatives

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was collected as part of the assessment of the overall economic feasibility of the alternatives, as well as hazard and risk reduction potential of these alternatives.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.3.1. Availability and technical and economic feasibility of alternatives

Summary of Dossier Submitter's assessment:

The Dossier Submitter concludes that alternatives to substances containing CA:C14-17 are available, technically and economically feasible.

There is no general drop-in one-for-one replacements for substances containing CA:C14-17 in all identified uses, but multiple potential alternatives were identified for each use and technical function.

However, the Dossier Submitter notes that, it is not certain whether the available alternatives are technically able to replace the substances containing CA:C14-17 for some heavy-duty metalworking operations.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.3.2. Risk of alternatives

Summary of Dossier Submitter's assessment:

The analysis of alternatives looked at both human health and environmental hazard and risks. The identified alternatives varied in regard to their relative environmental and human health risks: for some there are concerns about ED, PBT/vPvB properties. Nevertheless, overall, alternatives appeared less hazardous and to pose less risk than substances containing CA:C14-17.

RAC conclusion(s):

RAC agrees with the Dossier Submitter that from a human health and environmental perspective, the available alternatives seem to have a less hazardous profile than the substances to be restricted.

RAC concludes that the Dossier Submitter's assessment of risks of alternatives, based on their human health and environmental concerns, poses no major shortcomings or uncertainties related to the methodology used.

Key elements underpinning the RAC conclusion(s):

The RAC opinion is based on information on hazards and regulatory status of the identified alternatives, as provided in Sections 2.2.2 and 2.3.2 of the Background Document and Appendix E.

A list of technically feasible and available alternatives on the market has been identified for each use category. Several technically and economically suitable alternatives – both alternative substances and technologies (e.g. compounds based on alternative polymers) –

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appear to be available on the market (see section 3.3.1).

The Dossier Submitter listed the regulatory status of the identified alternatives with regards their classification, SVHC identification, prioritisation for further action or ongoing evaluation. Some of them are under investigation for PBT properties, endocrine disruption (ED) properties, carcinogenic, mutagenic, reprotoxic (CMR) properties, or other hazards. The Dossier Submitter did not provide a risk assessment due to lack of detailed information on the conditions of uses of the alternatives. However, RAC did not find out any shortcomings or uncertainties related to the methodology used for presenting the information on the hazards and regulatory status of alternative substances.

The analysis of alternatives looked at both human health and environmental hazard and risks. The identified alternatives varied in regard to their relative environmental and human health hazards:

- There are alternatives that are already in Annex XIV or Candidate List as SVHC, e.g. terphenyl, hydrogenated (EC 262-967-7), trixylyl phosphate (EC 246-677-8), 1,1'-[ethane-1,2-diylbis(oxy)]bis[2,4,6-tribromobenzene] (EC 253-692-3), 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (EC 201-236-9). These alternatives would lead to regrettable substitution.
- Alternatives under scrutiny for environmental or human health concerns (e.g. included in the restriction roadmap or under evaluation), such as Tris(2-chloro-1-methylethyl) phosphate (TCPP) (EC 237-158-7), TDCP (EC 237-159-2), antimony trioxide (ATO) (EC 215-175-0), triphenyl phosphate (EC 204-112-2).
- Alternatives with more favourable hazard profile, i.e. with harmonised classification (non CMR) such as Phosphorus (EC 231-768-7), TEP (EC 201-114-5), no harmonised classification, or no potential hazards for human health and the environment.

Regarding the alternatives covered by the last two bullet points, RAC has not enough information on their conditions of use to conclude on whether they would present a lower risk to CA: C14-C17. However, the substances could be considered in terms of risk as safer alternatives.

For the metalworking fluids sector, RAC points out that paraffin waxes and Hydrocarbon waxes, chloro (LCCPs, EC 264-150-0) and phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts (EC 283-392-8) are under assessment for their PBT and/or vPvB properties either by ECHA or in the UK. Phenol, isopropylated, phosphate (3:1)¹⁶ is undergoing PBT assessment and Substance Evaluation for suspected ED properties. Sulphurised olefins and fatty acid esters appear technically/economically feasible to replace substances containing CA:C14-17 in some applications using oil-based fluids. Phosphate esters were also indicated as potential alternatives that could be used in combination with other extreme pressure additives, but some of them are already under investigation for PBT properties. Overall, there are alternative substances with no identified concerns, such as phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts (EC 270-608-0), in the list of alternatives provided by the Dossier Submitter.

3.3.3. Conclusion on analysis of alternatives

RAC conclusion(s):

¹⁶ EC 273-066-3; Repr. 2, STOT RE 2, Aquatic Chronic 1, Skin Sens. 1, Aquatic Chronic 2, Aquatic Chronic 4

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See section 3.3.3 above.

Key elements underpinning the RAC conclusion(s):

See section 3.3.3 above.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.4. JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Summary of the proposed restriction

The Dossier Submitter examined the following restriction options (ROs):

- RO1 – Ban on placing on the market.
- RO2 – Ban on placing on the market and use.
- RO3 – Ban on manufacturing and placing on the market.
- RO4a, RO4b and RO4c – Ban on placing on the market with derogations for the metalworking fluid sector (RO4a includes an unconditional derogation, RO4b a time limited-derogation of seven years and RO4C a conditional derogation).
- RO5 – Complementary measures to accompany the communication down the supply chain.

Following the analysis of the above options, the Dossier Submitter proposes two Annex XVII restriction entries to be assessed by RAC and SEAC:

- Option A: a ban on manufacturing and placing on the market substances, mixtures and articles containing more than 0.1 % of 'CA:C14-17 with PBT and/or vPvB properties'. The ban would apply after a two-year transition period. Option A includes also some compulsory complementary measures to accompany the communication down the supply chain.
- Option B: a ban on solely placing on the market substances, mixtures and articles containing more than 0.1 % of 'CA:C14-17 with PBT and/or vPvB properties'. The ban would apply after a two-year transition period, except for metalworking fluids where a 7 year-derogation could be considered depending on the information submitted during the Annex XV consultation. Option B includes also some compulsory complementary measures to accompany the communication down the supply chain.

On one hand Option A, which is a combination of RO3 (ban on manufacturing and placing on the market) with RO5 (complementary measures), is the restriction entry that would minimise the most the releases in the EU and that would support the preparation of the EU position in the frame of the on-going discussions for the POP listing of the substances containing CA:C14-17.

On the other hand, Option B, which is a combination of RO4b (i.e. RO1 ban on placing on the market with a longer transition period for metalworking fluids) with RO5 (complementary measures), takes into account that alternatives may not to be readily available for all Extreme Pressure metalworking fluids applications.

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The Dossier Submitter discarded RO2 and RO4c. RO2, which also includes a ban on the “use” is considered extremely costly by the Dossier Submitter and non-proportionate to implement in practice. On the other hand, RO4c was discarded, on the basis that it has not been possible for the Dossier Submitter to establish and prescribe specific risk management measures that would fit all uses of metalworking fluids containing ‘CA:C14-17 with PBT and/or vPvB properties’, nor to assess the related compliance costs. So, for RO4c practicality, enforceability and proportionality could not be fully assessed by the Dossier Submitter.

3.4.1. Other regulatory risk management options

Summary of Dossier Submitter’s assessment:

Possible Union-wide risk management measures range from voluntary measures (e.g. Ecolabelling, voluntary industry commitment or action) to legislative ones (e.g. Industrial Emission Directive, RoHS, Biocidal Products Regulation, Product Safety Directive, Waste Directive, REACH authorisation).

However, none of the considered measures on their own are practical, or effective means of addressing all the risks and issues posed by ‘CA:C14-17 with PBT and/or vPvB properties’. In addition, some measures are too sector-specific to address the overall risks.

The Dossier Submitter concludes that REACH restriction is better suited to address multiple substances where the concern is related to the presence of the same hazardous constituents (here ‘CA:C14-17 with PBT and/or vPvB properties’).

RAC conclusion(s):

RAC agrees that other regulatory risk management options are not sufficient to address the risks and that a restriction under REACH is the most appropriate option to reduce the identified risk in the EU.

RAC notes that the restriction under REACH is interlinked to and expected to support a global restriction under the Stockholm Convention.

Key elements underpinning the RAC conclusion(s):

The RAC opinion is based on Section 2.1.2 of the Background Document and Appendix E.

A description of other EU-wide risk management measures other than a REACH restriction has been provided. The possible limitations of other measures are clearly justified and none of the listed measures on their own are considered practical, or effective means of addressing the risks identified in section 3.1.

RAC notes that the proposed REACH restriction and the proposed POP listing of chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels $\geq 45\%$ in the Annexes under the Stockholm Convention¹⁷ are interlinked and lead to a ban or a severe restriction of the production and use of multiple chloroalkanes under the Convention. However, it is assumed that the inclusion of chlorinated paraffins (i.e. chloroalkanes) containing some CA:C14-17 (of concern) in the scope of a global restriction under the Stockholm Convention would not be concluded prior to the conclusion on the need for a REACH restriction. The restriction under REACH is expected to support the global restriction under the Stockholm Convention. RAC notes however that the proposed restriction

¹⁷ The substances are also proposed for listing in the Annexes to the Stockholm Convention on Persistent Organic Pollutants (UNEP, 2021) by the POP Review Committee.

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targets 'CA:C14-17 with PBT and/or vPvB properties' and that this designation does not include all the congeners in the scope of the POP restriction. Indeed, the proposal under the POP regulation targets C14-17 congeners with chlorination levels $\geq 45\%$, i.e. 'other vP congeners' with the molecular formula: $C_xH_{(2x-y+2)}Cl_y$, where $x = 14$ to 17 and $y = \geq 9$ to 17 are also included. On the other hand, congeners with 3 or 4 chlorides covered by the REACH restriction proposal are not included in the POP listing proposal.

The Dossier Submitter also took into account the interlinkage between REACH and the RoSH Directive (Directive 2011/65/EU) as the inclusion of substance EC 287-477-0 in Annex II to the RoHS Directive is still on-going and the request from the Commission for a REACH restriction did not exclude the uses covered under the RoHS Directive. RAC notes that the restriction proposal under REACH is broader both in terms of uses and substances covered than a restriction under the RoSH Directive.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.4.2. Effectiveness in reducing the identified risk(s)

Summary of Dossier Submitter's assessment:

The Dossier Submitter concludes that both proposed restriction entries (A and B) are effective in reducing the identified risks. The proposed restriction entries are targeted to the risks and issues identified:

- Risk posed by 'CA:C14-17 with PBT and/or vPvB properties' which are present in many different substances
- Widespread uses and releases from all stages of the life-cycle including waste
- Lack of communication in the supply chain regarding the presence (or absence) of the CA:C14-17 constituents with PBT and/or vPvB properties in other substances, mixtures and articles.

In addition, both proposed restriction entries (A and B) are capable in reducing the risks within a reasonable amount of time.

Group of substances targeted

The proposed restriction entries (A and B) therefore target the presence of 'CA:C14-17 with PBT and/or vPvB properties', on they own, in other substances, mixtures or articles.

The grouping based on congeners for the purposes of this restriction is primarily justified as the relevant congeners have a similar chemical structure and hazard profile (vPvB and/or PBT properties). The grouping is also justified by the desire to avoid regrettable substitution and prevent future release of congeners of concern. In particular:

- the scope of the two proposed entries corresponds to those CA:C14-17 (i.e. constituents/congeners of 'MCCP') that have PBT and/or vPvB properties.
- 'CA:C14-17 with PBT and/or vPvB properties' may be present in many substances
- 'CA:C14-17 with PBT and/or vPvB properties' may be used as markers or indicators of PBT and/or vPvB concerns in other substances when their concentration is $> 0.1\%$ (i.e. in the 69 substances of the non-exhaustive list provided in the Background Document, and any other substance potentially not yet identified)

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- it may not be possible to establish a list of all the substances relevant to the current restriction proposal.

As presented in Table 1 and Table 2 (section 1 of this opinion), and section 3.1.1, the Dossier Submitter therefore proposes to define the substance scope of the restriction using molecular formula descriptors that provide a clear characterisation of the congeners of concern, rather than establishing a list of numerical identifiers such as EC or CAS numbers.

The restriction proposal affects more substances than those listed in the Candidate List.

Uses and sectors targeted

Considering the PBT and vPvB properties of the substances to be restricted, and the risks arising from the releases of CA:C14-17 to the environment, the proposed Annex XVII restriction entries (option A and B) are broad and do not target specific uses or applications. The main difference between the two proposed Annex XVII restriction entry options is that option A mentions explicitly a ban on manufacturing, while in option B manufacturing is only indirectly affected by the ban on placing on the market which should reduce the demand; in addition, option B foresees a 7 year derogation for metalworking fluids. Indeed, in option B the manufacturing for export (which represents max. 0.08 % of the total releases) would remain possible.

Targeted to the lack of communication in the supply chain

Both Annex XVII proposed restriction entries (A and B) include in paragraphs 6 and 7 (i) substances supplier duties and, (ii) supply chain communication duties.

These measures aim at avoiding regrettable substitution by making available information on the presence of 'CA:C14-17 with PBT and/or vPvB properties' in substances, mixtures and articles placed on the market.

Derogation

In both proposed Annex XVII restriction entries (option A and B), derogations are proposed for reference materials and standards for analytical purposes, as well as for articles already in use and second-hand articles.

In addition option B includes a 7 year derogation for metalworking fluid (to be confirmed after the Annex XV consultation).

Capability of the restriction proposal to reduce the risks within a reasonable amount of time

Considering that risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way (e.g. by derivation of risk characterisation ratios), the Dossier Submitter assessed the effectiveness of each restriction option (RO) by looking at its release reduction potential, i.e. it calculated the total avoided emissions of CA:C14-17 in the environment over 20 years in comparison with the baseline.

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

RO1 (and RO3), RO4b and RO4a are anticipated to reduce CA:C14-17 releases to the environment by about 103 000 tonnes, 102 700 tonnes and 101 000 tonnes, respectively (nominal values, central estimates, values rounded to the nearest thousand) over the 20-year period used for the impact assessment.

Table 8. CA:C14-17 release reduction over the 20-year period used for the impact assessment

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	Remaining CA:C14-17 releases to the environment (lower and upper estimate) ^[1]	CA:C14-17 releases reduction compared to the baseline (lower and upper estimate ^[2], and central estimate ^[3])	% reduction compared to the baseline
Baseline (i.e. no EU action)	104 000- 126 000 tonnes	-	-
Option A		~ 103 000 tonnes	~90 %
Option B		~ 102 700 tonnes	~89-90 %
RO1 (i.e. ban on placing on the market)	11 000 - 13 000 tonnes	94 000 - 113 000 tonnes Central estimate: 103 000	90 %
RO3 (i.e. ban on manufacturing and on placing on the market)	10 000 - 13 000 tonnes	94 000 -113 000 Central estimate: 103 000	90 %
RO4a (i.e. RO1 with a derogation for the metalworking fluid uses)	11 000 - 17 000 tonnes	93 000 -108 000 tonnes Central estimate: 101 000	89 – 86 %
RO4b (i.e RO1 with a longer transition period for the metalworking fluid uses)	11 000 - 14 000 tonnes	94 000 – 112 000 tonnes Central estimate: 102 700	90 – 89 %

Note: [1] values rounded to the nearest thousand

[2] values rounded to the nearest thousand

[3] for RO1, RO3 and RO4a, values are rounded to the nearest thousand and for RO4b value has been rounded to the nearest hundredth

When compared to the baseline release, significant emission reductions (by ca. 90 %) are envisaged from each of the above examined ROs, and so the same emission reductions are expected from the two proposed Annex XVII restriction entries (A and B).

In addition, the effectiveness of the proposed restriction was assessed by the Dossier Submitter by looking at the risk reduction potential of the alternatives to substances containing CA:C14-17, and its capacity in limiting the potential for 'regrettable' substitution.

RAC conclusion(s):

RAC agrees to define the scope of the restriction using molecular formula descriptors.

RAC agrees that the proposed restriction entries (A and B) are targeted and take into account all uses, sectors and risk posed by the 'CA:C14-17 with PBT and/or vPvB properties' on their own as well their presence in substances, mixtures and articles as the main concern.

RAC agrees that the proposed concentration limit of 0.1 % w/w is effective.

RAC notes that the RO5 specifically addresses the concern on lack of communication in the supply chain regarding the presence (or absence) of the CA:C14-17 constituents with PBT and/or vPvB properties in substances, mixtures and articles and aims at avoiding regrettable substitution. However, RAC proposes to define a concentration limit of 0.1 % to trigger the information requirements down the supply chain regarding the presence of chloroalkanes with PBT and/or vPvB properties. This information requirement will apply for 18 months (from six months after the entry into force of the restriction to two years) and would support the effective implementation of the restriction by ensuring that the presence of chloroalkanes is known along the supply chain before their manufacture and use is banned.

RAC concludes that the releases calculated over a period of 20 years for the four different risk management options are considered as plausible.

RAC concludes that the estimation of the annual reduction potential (by ca. 90 %) of each restriction option (A and B) is plausible.

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RAC concludes that the restriction option A with a general 2-year transition period is the most effective measure to minimise releases of 'CA:C14-17 with PBT and/or vPvB properties' to the environment and reduce the identified risks. RAC notes that RO3 (included in option A) is the most effective risk management option to reduce the identified risks as it includes a ban on manufacturing, formulation and production of articles.

RAC concludes that a transition period of six months for RO5 is justified.

RAC does not support a derogation for the metalworking fluid uses and also notes that, for this sector, future releases cannot be minimised as far as possible by implementing appropriate OCs and RMMs. It is deemed not possible to identify specific risk management measures that would be applicable to all uses of metalworking fluids containing 'CA:C14-17 with PBT and/or vPvB properties'. RAC strongly recommends considering the 'other vP congeners' under the scope of the restriction. The Dossier Submitter has covered 'other vP congeners' in the risk assessment and implicitly also in the analysis of the emission reduction capacity of the restriction proposal.

Key elements underpinning the RAC conclusion(s):

The RAC opinion is based on Sections 2.1, 2.2 (justification of the proposed transition periods and concentration limit) and 2.3 of the Background Document, Appendix E and the information submitted during the Annex XV report consultation.

Grouping analysis and designation

The grouping of substances within the scope of the restriction proposal is based on structural similarity and PBT and/or vPvB properties, and aims to avoid regrettable substitution. The proposed grouping and the designation using molecular formula is underpinned by:

- the impossibility to draw a list of all the identifiers (e.g. EC and CAS numbers) describing the substances containing 'CA:C14-17 with PBT and/or vPvB properties';
- congeners having PBT and/or vPvB properties may be present in other substances which may be used in high tonnages in a wide range of uses, and can possibly lead to significant overall exposure and releases to the environment;
- the technical properties of the substances are broadly similar.

The key justification for recommending 'other vP congeners' (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇) under the scope of the restriction is that these congeners have been fully covered in the risk assessment as provided in section 3.1. Furthermore, the 'other vP congeners' are in majority in the scope of the UK POP proposal as indicated in section 3.4.1.

Targeted scope

The proposed restriction options A and B are targeted to the identified risk, i.e. the presence of congeners with PBT and/or vPvB properties and the risks arising from their releases to the environment. RAC considers that the environmental stock of 'CA:C14-17 with PBT and/or vPvB properties' as well as the "other vP congeners" will increase over time if emissions are not minimised. According to the Dossier Submitter the impact of targeting the 'other vP congeners' on the effectiveness of the restriction is expected to be low. The Dossier Submitter assumed that substances containing CA:C14-17 contain congeners with PBT and/or vPvB properties and 'other vP congeners' due to the manufacturing process (random chlorination of the carbon chain of the paraffin feedstock), and therefore it is sufficient to target the CA:C14-17 with PBT/vPvB properties in the restriction proposal (in line with the mandate from the Commission), as it would indirectly also affect the 'other vP congeners'. In consequence, the Dossier Submitter considers that the proposed restriction will be effective in reducing the

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releases and risks from CA:C14-17 in general. Nevertheless, RAC considers that taking into account the 'other vP congeners' in the scope of the restriction adds to the clarity and effectiveness of the restriction by avoiding any potential substitution of substances containing 'CA:C14-17 with PBT and/or vPvB properties' with substances containing 'other vP congeners'.

Concentration limit justification

A concentration limit of 0.1 % (w/w) is proposed by the Dossier Submitter for restricting the presence of 'CA:C14-17 with PBT and/or vPvB properties' in substances, mixtures and articles. As indicated in section 2.5.3 of the Background Document, it applies to restricted congeners individually, or to the sum of some or all of them. It is based on the MSC conclusions, PBT guidance and several REACH provisions as well as Waste Framework Directive 2008/98/EC. The proposed 0.1 % limit is consistent with the conclusions of the MSC on the SVHC identification of 'MCCP' (cf. section 1.4.2 of the Background Document), the REACH Annex XIII criteria for a PBT or vPvB substance, with the ECHA PBT guidance (section R.11.4.1). Furthermore, the 0.1 % concentration limit proposed by the Dossier Submitter is consistent with the current provisions on PBT and vPvB substances in REACH. REACH Articles 14(2)(f), 31(3)(b) and 56(6)(a) apply the same concentration limit for PBT and vPvB substances in mixtures to trigger various obligations under REACH. The 0.1 % limit is also the limit triggering obligations for PBT and vPvB substances in articles under REACH Article 7(2)(b), and under Article 9(1)(i) of the Waste Framework Directive. In case of complex object, the concentration limit applies to each of the individual articles composing the complex object.

RAC notes that the proposed concentration limit of 0.1 % for the CA:C14-17 congeners is already restrictive taking into account the low average concentration of substance containing CA:C14-17 in end products (approx. 5 – 10 %) across the use sectors.

The concentration limit in articles applies to each of the individual articles in the complex object, in line with the ECHA Guidance on requirements for substances in articles¹⁸.

The concentration limit of 0.1 % is considered to be effective in reducing the risk (release reduction by *ca* 90 %).

RAC notes that the Dossier Submitter investigated the possibility to set a lower concentration limit than 0.1 % for mixtures and articles (see Appendix E) and concluded that a concentration limit of 0.005 % might be set in mixtures and articles. Nevertheless, due to uncertainties (lack of data on imported articles, diversity of the use...) appropriateness and proportionality of a concentration limit lower than 0.1 % cannot be concluded. Then, setting a lower concentration limit than 0.1 % for mixtures and articles is considered not appropriate and proportionate by the Dossier Submitter.

RAC notes that the 0.1 % is also justified by the available analytical methods that allow to achieve lower limit of detection. The proposed 0.1 % limit value for detecting CA:C14-17 is a general limit based on which the suppliers need to conclude that the composition does not meet PBT or vPvB criteria (REACH article 31). See further discussion on the practicality of the restriction proposal when considering 'other vP congeners' under the scope in section 3.4.4.A higher concentration limit between 1 % and 2.5 % has been proposed by several stakeholders in the consultation of the Annex XV restriction report (#3638, #3639, #3640, #3642, #3645, #3646, #3743, #3841) due to the unintentional presence of CA:C14-17 in CA:C18-(LCCP) (EC 264-150-0). No detailed information on the specific challenges to reach the proposed 0.1 % limit is provided. The estimated release calculation show increase under each RO considering the releases with a concentration limit of 1 % of CA:C14-17 in EC 264-150-0 and

¹⁸ Version 4.0, June 2017. Available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

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is therefore not supported by RAC. Furthermore, RAC agrees with the Dossier Submitter, considering it plausible for chloroalkanes and other paraffin waxes to be manufactured and placed on the market with CA:C14-17 in concentration below 0.1 %, taking also into account that the presence of CA:C14-17 in EC 264-150-0 is not intentional or needed for the technical function of LCCP in metalworking fluids.

Several respondents (e.g. #3816, 3847 and #3848) in the Annex XV report consultation indicated the unintended presence of CA:C14-17 in concentrations above 0.1 % in (i) PVC recyclates, and in (ii) PVC articles made of these PVC recyclates and requested a derogation to allow a higher concentration level (between 1 and 4 %) in both. RAC notes that the information provided in the consultation is not robust enough to support the proposal and the benefits of recycling should be weighed against the risks derived from potential emissions of PBT and/or vPvB substances to the environment. See section 3.4.4 for enforcement issues with regards to the proposal.

Analysis of the Restriction Options

The Dossier Submitter proposes two restriction options: Option A and Option B.

RAC notes that **option A** introduces a combination of a ban on manufacturing, formulation and production of articles and on placing on the market (RO3) with complementary measures (RO5) supporting the Stockholm Convention framework. The restriction option A with a general 2-year transition period presents the highest risk reduction potential and is considered thus the most effective measure to minimise releases of CA:C14-17 to the environment and reduce the identified risks.

The **option B** is a restriction on the placing on the market of chloroalkanes with carbon chain lengths within the range from C14 to C17, on their own, in other substances, in mixtures or in articles with derogation for the metalworking sector (i.e a combination of a ban on placing on the market (RO1) with a longer transition period for metalworking fluids (RO4b) and complementary measures (RO5)).

According to the Dossier Submitter, both **RO3** (ban on manufacturing, formulation, and production of articles, included in option A) and **RO1** (ban on placing on the market, included in option B) result in a 90 % emission reduction over a 20 year-period. RAC agrees with the emission reduction as estimated by the Dossier Submitter but notes that in RO1, export of substances, mixtures and articles containing chloroalkanes within the scope of the restriction proposal will still be allowed without any time limit. RAC considers that, although annual releases resulting from manufacturing for export represents only 0.08 % of the total releases (ca 4.2 tonnes/year), the export of PBT, vPvB and/or vP substances with LRT potential contributes to the global contamination of the environment and should be banned. Taking into account the resulting emissions and the hazard profile of the substances, RAC does not support RO1, which is the basis for restriction option B.

The Dossier Submitter proposes a transition period of two years for the entry into force of RO3 (ban on manufacturing, formulation and production of articles). This transition period takes into account the time needed by the laboratories to prepare and for the industry to investigate the substitution possibilities with new alternatives, also taking into account that no 'one fits-all solution' is available for all the different applications (see section 3.3.2 above). Two years is considered long enough by RAC to allow the entire use/consumption of stocks of the substances and mixtures. The transition period should be short enough to avoid future manufacture, import or use of the concerned substances in the EU such that release reduction can be achieved without unnecessary delay.

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In addition, the Dossier Submitter proposes complementary measures to address the lack of transparency and communication in the supply chain in particular on the presence (or absence) of CA:C14-17 constituents with PBT and/or vPvB properties in other substances, mixtures and articles. This concern is addressed by **RO5** which would also support and enhance their enforceability by making the complementary measures explicit and mandatory in the restriction entry, which is expected to improve compliance with the proposed restriction throughout the supply chain. RO5 also aims to avoid regrettable substitution by making available information on the presence of CA:C14-17 in the supply chain.

The baseline for RO5 is to assume that all chloroalkanes may contain 'CA:C14-17 with PBT and/or vPvB properties' unless demonstrated otherwise by the suppliers whichever the tonnage they place on the market. This measure is proposed to avoid regrettable substitution, and to allow a level playing field among all registrants and suppliers of substances containing CA:C14-17.

However, RAC notes that the Dossier Submitter proposes no concentration level for the triggering of the information requirements, i.e. the supplier should inform of the content of chloroalkanes in substances, mixtures or articles irrespective of its concentration. RAC proposes that the information requirements are triggered when the concentration levels are equal or greater than 0.1 %, in line with the limit defined for the identification of the substances as PBT, vPvB and vP and with the duty to communicate information for suppliers of articles containing substances in the Candidate List. In the view of RAC, the information on the presence of chloroalkanes below this concentration limit does not provide additional effectiveness to the restriction since the substances and/or mixtures are not considered hazardous when the concentration of chloroalkanes is below 0.1 % w/w. In addition, RAC considers that the requirement is not practical and enforceable if no concentration limit is defined (see section 3.4.4 for discussion of the practicality and enforceability of RO5).

A transition period of six months proposed for implementing RO5 requirements is considered achievable within the proposed timeframe as the requirements are purely administrative (update of the registration dossier, transfer of information in the supply chain), and should already be in place for the substances in the Candidate List which represent the biggest share (in term of tonnage) of substances containing CA:C14-17. The proposed transition period of six months is consistent with the Commission implementing Regulation EU 2020/1435, which clarifies that Registrants shall update their registration dossier within six months once new information on hazard and risk are identified, and within 3 months when reporting a change in the composition of the substances registered.

RAC notes that, by setting the concentration limit for the information requirements at 0.1 %, the obligation to report the presence of chloroalkanes along the supply chain ceases to apply once the ban on the manufacture and use enters into force, i.e. after two years. RAC considers that the requirement to provide information regarding the presence of chloroalkanes in substances, mixtures and articles during the transition period until the ban enters into force will improve the information flow along the supply chain and support the effective implementation of the restriction.

Metal working fluid sector derogation (RO4)

The proposal for a 7 year (**RO4b**) or a permanent derogation (**RO4a**) for the metalworking fluid sector under option B is justified by the uniqueness of the process which requires special technical features to stand the extreme pressure conditions and the time required to test alternative substances in those workshops where the substances containing CA:C14-17 are currently used (see section 3.3.1 and 3.4.3).

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RAC acknowledges the trade association's comments (# 3638, #3639, # 3640, # 3642, # 3643, #3645, # 3646, # 3647, # 3648, # 3649, # 3650, # 3651, # 3743) submitted in the consultation of the Annex XV restriction report referring to the need for a derogation for metalworking fluids. According to the comments provided, there are no alternatives for extreme pressure additive in metalworking fluids. Additionally, as the metal working fluids are not intended to remain in the articles, the industry sector notes that there are no releases of metal working fluids from articles. Furthermore, the trade association remarks that the sector complies with the applicable regulations regarding emissions and occupational safety and requires compliance in the supply chain. Releases are considered controllable in the life cycle. RAC notes that it is not possible to draw conclusions from the generic comments made in the consultation and the available data is too vague to evaluate the requirements for release minimisation during the whole life cycle. In addition, despite of the calls for evidence to collect information conducted by the Dossier Submitter, the information provided in the Background Document does not allow to conclude on the level of implementation of risk management measures across the sector and their effectiveness in reducing the risk. Therefore, RAC concurs with the Dossier Submitter that given the diversity of metalworking operations, it is not possible to define risk management measures that would be applicable to all uses of metalworking fluids containing CA:C14-17.

According to the Background Document, there are less than 5 % of niche applications (e.g. very heavy-duty applications and hard materials) of the overall metalworking processes where alternatives appear not to be yet fully available. For these applications, CA:C14-17 up to 70% in concentration are used as Extreme Pressure Additives in oil-based metalworking fluids - as defined in DIN 51385.

RAC notes that a longer transition period for metalworking fluids would most likely enable the sector to come to terms of the proposed restriction by targeting actions towards finding alternatives for the most critical use categories. However, it needs to be emphasised that the use of metalworking fluids does not take place generally in closed systems and the congeners of concern in metalworking fluids are used in high number of industrial sites in the EU. RAC notes that the information on the exact number of companies producing and using metalworking fluids with substances containing CA:C14-17 is missing, so several assumptions have been made by the Dossier Submitter to estimate the number of companies expected to be impacted as well as volumes used. The Dossier Submitter estimates that the total releases to the environment from the full life cycle of metalworking fluids represents 0.7 - 4 % .

The risk reduction potential calculated for RO4a (permanent derogation) is slightly lower (86 - 89 %) than the preferred option by the Dossier Submitter RO4b (7 year derogation) (89 - 90 %). However, RAC notes that even if RO4b presents a similar effectiveness as RO1 and RO3 (90 %) in the long term, the derogation for metalworking fluids results in the release of 34 - 250 additional tonnes of CA:C14-C17 annually which corresponds to an additional release of 238-1750 tonnes in total during 7 years. RAC considers that, taking into account the hazards arising from the PBT and/or vPvB properties of the substances and the identified risk, a derogation for metalworking fluids cannot be supported unless risk management measures are in place to minimise the emissions during the whole life cycle (i.e. at manufacturing, formulation, use, and waste disposal). However, RAC recognises that it is difficult to identify measures for risk reduction in this sector due to the large diversity of metalworking activities covered by the restriction proposal (see section 3.1.5 for further information).

In addition, RAC notes the proposal presented in comment # 3641 from the consultation of the Annex XV report to limit the concentration of MCCP in oil-based metalworking fluids to concentrations of ≤ 3 %, considering that the risks may not be controlled for workers using oil-based metalworking fluids containing MCCP above 3 % w/w. However, RAC notes that the

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current restriction proposal concentrates on the concerns of possible PBT and/or vPvB properties of the substances under scope, which requires the minimisation of emissions and exposures, and does not consider that a concentration limit of 3 % is appropriate to control the risks for the environment.

Other potential derogations

Several respondents to the consultation of the Annex XV dossier – that represent the producers of complex articles - requested derogations for their specific sector of use. In addition, a higher concentration limit of CA: C14-C15 (up to 4%) in PVC recyclates was requested to allow for the recycling of PVC cables containing chloroalkanes. RAC notes that the comments submitted did not specify the specific mixtures/articles for which a derogation would be needed or did not discuss the availability of alternatives for each specific application within the mentioned use category. Furthermore, the information provided did not include a detailed description of the risk management measures in place to minimise the risks during the transition period. Therefore, RAC does not support the proposals based on the lack of robust data for their evaluation.

3.4.3. Socioeconomic analysis

3.4.3.1. Costs

Summary of Dossier Submitter's assessment:

In the impact assessment the Dossier Submitter estimated the substitution costs that the affected industries are expected to bear because of the restriction.

These costs were estimated for the five-uses accounting for more than 90 % in terms of substances' volume used and whenever possible, both one-off costs and ongoing increase in variable costs were quantified. Overall, the increase in variable costs for the sealant sector is the main driver of the economic impacts of the examined restrictions.

One-off costs are expected to occur during the transition period, while the increase in variable costs is assumed to start at the of the transition period.

For the remaining uses (accounting for less than 10 % in terms of used volumes), qualitative considerations were made by the Dossier Submitter. Given information on the availability of alternatives, no relevant impacts are expected on these.

Table 9: Economic impacts of RO1, RO3, RO4a and RO4b

Restriction option (RO)	Total costs, NPV – 20-year analytical period) €	Annualised costs Cover 20 years
RO1	€4.9 billion	€330 million
RO3	€4.9 billion	€330.3 million
RO4a	€3.9 billion	€260 million
RO4b	€4.1 billion	€270 million

The Dossier Submitter performed a qualitative assessment of RO2, RO4C and RO5.

Regarding RO4C, due to the diversity and broadness of metalworking activities covered by the restriction proposal, it has not been possible for the Dossier Submitter to establish and prescribe specific risk management measures that would fit all uses of metalworking fluids containing 'CA:C14-17 with PBT and/or vPvB properties', nor to assess the related compliance costs.

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Likewise, no cost estimation was made for RO2. However, this option is considered extremely costly and non-proportionate to implement in practice,

While costs were not quantified for RO5, these are expected to be only marginal considering that obligations under this complementary restriction option are purely of administrative nature and easily implementable.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.4.3.2. Benefits

Summary of Dossier Submitter's assessment:

As risks of PBT and/or vPvB substances cannot be quantified, benefits of the proposed restriction are delivered through emission reductions and avoided increase in environmental stocks.

The Dossier Submitter has taken a cost-effectiveness analysis approach, whereby emission reductions are used as a proxy for benefits, in line with SEAC's PBT/vPvB approach.

RO1 (and RO3), RO4b and RO4a are anticipated to reduce CA:C14-17 releases to the environment by about 103 000 tonnes, 102 700 tonnes and 101 000 tonnes, respectively (nominal values, central estimates, values rounded to the nearest thousands) over the 20-year period used for the impact assessment. This is equivalent to 74 500 tonnes, 73 900 tonnes and 73 000 tonnes (when discounted at 3 %).

When compared to the baseline release, significant emission reductions (by ca. 90 %) are envisaged from each of the ROs.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.4.3.3. Other relevant impacts

Summary of Dossier Submitter's assessment:

With regard to other impacts, such as social impacts, the Dossier Submitter foresees no major effects on employment in view of the available information on alternatives.

This said, some job losses could occur among the producers of substances containing CA:C14-17, considering that, because of the restriction, the output produced would be lower and so some employees could be made redundant. However, considering that technically and economically feasible alternatives are available, it is likely that the producers of alternatives might need to hire new employees to meet the growing demand and increase their production capacity.

One sector where job losses may be expected is the metalworking fluid sector under RO1 (and RO3), considering that the economic activities relying on the use of substances containing CA:C14-17 might have to be halted because of the restriction. The Dossier Submitter also notes that potential job losses under RO1 (and RO3) would be mainly incurred by small and medium companies in the metalworking sector. Given data constraints, these

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impacts were only described qualitatively by the Dossier Submitter.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.4.3.4. Proportionality

Summary of Dossier Submitter’s assessment:

The Dossier Submitter performed an indicative abatement cost approach (cost effectiveness) as suggested by SEAC for the evaluation of restriction proposals and applications for authorisation for PBT and vPvB substances.

The average cost-effectiveness ratio ranges between 53 €/kg and 66 €/kg for the restriction options considered.

The incremental cost-effectiveness ratio, which measures the marginal abatement costs for the releases, is 53 €/kg for RO4a, 222 €/kg for RO4b and 1 333 €/kg for RO1 (and RO3).

Table 10: Cost-effectiveness of RO1, RO3, RO4a and RO4b

Restriction option	Total costs (NPV over 20 year)	Total emission Reduction (NPV over 20-year, central estimates)	C/E-ratio €/kg	Incremental change in costs € (NPV over 20 year)	Incremental reduction of kg (NPV over 20 year)	Incremental C/E-ratio €/kg
RO4a	€3.9 billion	73 million kg	53	€3.9 billion	73 million kg	53
RO4b	€4.1 billion	73.9 million kg	55	€200 million	0.9 million kg	222
RO1(and RO3 ¹⁹)	€4.9 billion	74.5 million kg	66	€800 million	0.6 million kg	1 333

RO1, RO3, RO4a and RO4b are all as cost-effective as previously adopted restrictions on environmental pollutants. Therefore, the Dossier Submitter concludes that the proposed restriction options can be seen as proportionate to the risks associated with CA:C14-17 with PBT and vPvB properties.

The Dossier Submitter also calculated the sectorial cost-effectiveness ratios for the metalworking fluid sector. These were estimated at 170 €/kg, and 580 €/kg for RO4b and RO1(and RO3) respectively. No cost-effectiveness was calculated for RO4g, that this restriction option is equivalent to the baseline for this sector.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

¹⁹ Given the marginal differences between RO1 and RO3 (in terms of costs and avoided release), the costs effectiveness ratios are almost the same. More precisely, CE ratio of RO1 is 65.91 €/kg, while CE ratio of RO3 is 65.96 €/kg.

3.4.4. Practicality, including enforceability

Summary of Dossier Submitter's assessment:

The proposed Annex XVII entries Option A and B are considered implementable and manageable.

Indeed the restriction options RO1, RO3, RO4a, RO4b and RO5 are all considered implementable and manageable for the different actors in the supply chain: manufacturers, importers, downstream users, recyclers and waste operators.

The proposed concentration limit of 0.1 % of CA:C14-17 is an achievable limit of detection in terms of analysis of unintentional trace contaminants in substances, mixtures and articles.

The restriction options are also considered practical and enforceable for the authorities. The enforcement of the proposed restriction could be done through inspections at manufacturer sites, retailers, customs, or websites, either by paper or document-based inspection, or laboratory testing acknowledging that a lot of progress has been made in recent years regarding the analytical detection and quantification of CA:C14-17. Additionally, the implementation of RO5, i.e. the supplier documentation and supply chain communication obligations, would support and enable the enforcement of the restriction proposal.

Finally, the provision of a non-exhaustive list of substances that may contain CA:C14-C17 either as a separate list (e.g. published on ECHA website) or as an Appendix to the Annex XVII restriction entry would also support the enforceability of the restriction proposal.

RAC conclusion(s):

RAC concludes that the proposed restriction option A is practical and enforceable. However, RAC proposes that the requirement to provide information down the supply chain regarding the content of chloroalkanes in substances, mixtures and articles is triggered at a concentration level of 0.1 % w/w to ensure the implementability and enforceability of the requirement. Option B is not considered to be practical and would deserve further clarifications and description regarding the proposed derogation for metalworking fluids.

RAC proposes that considering the 'other vP congeners' under the scope of the restriction proposal is also practical (to prevent regrettable substitution) and enforceable.

Key elements underpinning the RAC conclusion(s):

The RAC opinion is based on Section 2.3.4 of the Background Document, Appendix E and the draft Forum advice²⁰.

The scope of the proposed restriction option A is unambiguous. RAC notes that with regards to the enforceability and practicality the ban on placing on the market intends to cover:

- the substances containing CA:C14-17 in their composition,
- the presence of CA:C14-17 in the final mixture and not the content of the substance (containing CA:C14-17 of concern) used in the formulation
- and the presence of CA:C14-17 in the final article and not the content of the substance (containing CA:C14-17) used to produce the article.

From an enforcement point of view the Forum supports option A of the restriction which includes also a restriction of the manufacturing, as having manufacturing and placing on the

²⁰ At the time of adoption of the RAC opinion, only the draft Forum advice is available; incorporation of the final Forum advice may make a targeted revision of the RAC opinion necessary before SEAC adopts its opinion.

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market regulated is more consistent and clear and therefore more straightforward to enforce at different duty holders irrespective of their role(s) (i.e. downstream users, suppliers).

RAC also assumes that with regards to the enforceability of option B, the issues with regards to continued possibility to placing on the market from stock as well as EU manufacture for export should have consequences.

For Option B, RAC notes the definition of the derogation for metalworking fluid (encompassed in RO4a and RO4b) would deserve further clarifications and description given that metalworking sector may include a broad range of metals and metalworking techniques. The Forum agrees with this but does not have any further suggestions on the specific wording. Furthermore, the Forum concludes that the suggested exemption for metalworking fluids would complicate enforcement since it is a very broad definition with the current proposed wording. RAC notes that based on the information provided in the consultation it was possible to specify the wording of the derogation for metalworking fluids under restriction option B, to add the type of fluids that should be covered by the derogation, namely oil-based metalworking fluids. Moreover, the Dossier Submitter updated the wording of the derogation to include a reference to the DIN 51385.

The Dossier Submitter introduced a tiered approach for enforcement purposes where screening and high resolution methods could be used to confirm the presence of CA:C14-17 and quantify the individual congeners to achieve the proposed limit value of 0.1 % in substances, mixtures and articles. This proposed tiered approach for enforcement is considered practical by RAC and further supported by the fact that appropriate analytical methods and standards seem to be available for variety of laboratories in the EU.

By identifying the carbon-chain lengths of the feedstock used to manufacture chloroalkanes, REACH registrants and manufacturer/importers of chloroalkanes (whatever the tonnage) can identify the substances and compositions that would fall under the scope of the restriction proposal and modify the specifications of the feedstock accordingly.

RAC notes that the Dossier Submitter has not assessed the applicability of the available analytical methods to the 'other vP congeners'. However, based on the description of the methods in the restriction dossier, the applicability seems plausible. Information on the available (standardised and non-standardised) analytical methods or standards (as well as the obligations for communication in the supply chain) do not indicate that adding the 'other vP congeners' in the entry affects negatively the practicality or enforceability of the proposed restriction.

At present, reference standards for the analysis of chloroalkanes exists or are under development for all CA:C14-17 intended to be restricted. RAC notes the increase of the incentive for industry sector to develop the analytical methods further after the entry into force of the restriction proposal. The most recent scientific research has increased the understanding of analytical processes and obtained results, providing the opportunity to better control the accuracy of the determination despite the presence of different degree of chlorination and of interferences, in particular for environmental samples, supporting the need to consider the applicability of scope also for the 'other vP congeners' in addition to 'CA:C14-17 with PBT and/or vPvB properties'. This further supports the conclusions that considering the 'other vP congeners' within the scope, may not have a significant impact on the practicality (incl. enforceability) of the restriction.

RAC notes from the enforcement perspective the importance of the indicative list to be published on the ECHA website of identifiers describing substances that may contain the chloroalkanes under the scope of the restriction proposal and also having two different descriptor systems (molecular formula and chlorination level) supporting each other.

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The Dossier Submitter highlighted a lack of transparency and communication in the supply chain regarding the presence (or absence) of CA:C14-17 with PBT/vPvB properties in other substances, mixtures and articles. As complementary measures under both restriction options A and B, under RO5, the restriction proposal describes obligations to conclude on and indicate the PBT and/or vPvB status of the composition of the substances, mixtures and articles to be placed on the market, as well as obligations to make available or provide information and justify that a composition contains less than 0.1 % of 'CA:C14-17 with PBT and/or vPvB properties' as specified in paragraph 6 and 7 of the restriction proposal. These provisions would allow for enforcement authorities to verify the consistency and compliance between the composition and the PBT and/or vPvB properties reported by the suppliers, and the information available in the supply chain. RAC notes that the Dossier Submitter does not impose nor prescribe any specific format to transfer the PBT and/or vPvB information down the supply chain. Then, the implementation of RO5, and in particular the suppliers' obligations and supply chain communication obligations, could be facilitated and substantiated by the voluntary implementation of certification schemes in the affected sectors of use (voluntary action from the relevant sectors).

RAC notes that paragraph 7 implies that the downstream users and customers shall be informed on the presence and overall concentration of the contained chloroalkanes irrespective of the concentration. However, the classification as PBT and/or vPvB applies only if the concentration is above 0.1 %. The Dossier Submitter implies that the proposed requirements are similar to a conditional derogation; meaning that a supplier of chloroalkane substances does not need to identify/conclude its substance as PBT and/or vPvB properties if it can prove to the Authorities (i.e. either ECHA, Member States Competent Authorities, or enforcement authorities) that its substance does not contain the CA:C14-17 with PBT and/or vPvB properties in concentration ≥ 0.1 %. RAC finds it doubtful that these provisions are in practice enforceable without a specified limit and does not think the Dossier Submitter has justified the proposal in sufficient detail. RAC is lacking a robust analysis over the proposal and notes that it would be particularly difficult to apply the requirement for identifying PBT or vPvB substances in (complex) articles. The proposal is as valid and serves the same purpose with specifying a concentration limit of 0.1 % as it would require the supplier to inform their downstream users and customers in case the substances, mixtures and articles contain the CA:C14-17 with PBT and/or vPvB properties in concentration ≥ 0.1 %.'On-line' analysis already exists to detect the presence of chlorine and therefore the presence of chloroalkanes in different types of waste streams. Thus, these waste streams can be separated and sent for specific treatment. The ED-XRF (X-ray fluorescence or X-ray fluorimeter analysis), and hand-held XRF are capable of separating chlorine-containing plastics from other types of plastics/polymers enabling to detect and separate the restricted substances from the recycle stream. The XRF online analysis are commonly applied as a screening step in recycling facilities. As the chlorine content in the relevant waste detected with XRF cannot be automatically attributed to substances containing CA:C14-17, this would lead to an over rejection of material from the potential recycling. The Dossier Submitter notes that this is already the case for the detection of 'SCCP' in recycling facilities. The ED-XRF analysis and the different available standards are already applied in the waste treatment of other chloroalkanes such as SCCP which are very similar in term of structure (and in used applications) to substances containing CA:C14-17. Therefore, RAC considers that the proposed restriction is also practical for substances, mixtures and articles made from recycled material. The Forum does not see any specific issues with sampling and preparation, especially the experience with SCCP. The ISO standards seem to cover standard procedures for sampling and sample preparations for the example matrices leather and textiles. In order to ensure comparability, the Forum recommends to provide further clarification (guidance) on

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how to proceed with other matrices.

The Forum noted the need to clarify the difference between “articles already in use” and “second-hand articles which were in end-use in the Union before XX” recommends to improve the wording for the “re-use” of “second-hand article” for better enforceability.

RAC notes that the derogation proposal for a higher concentration limit provided in the Annex XV report consultation for PVC recyclates or articles made of PVC recyclates could create a potential loophole whereby producers and importers could claim that an article was made from recycled material and benefit from a higher concentration limit. It would be difficult for downstream users and enforcement authorities to judge whether articles contain or are made of recycled or primary materials.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.4.5. Monitorability

Summary of Dossier Submitter’s assessment:

The proposed Annex XVII entries Option A and B are considered monitorable.

The restriction options RO1, RO3, RO4a, RO4b and RO5 are all considered to be monitorable by the Dossier Submitter.

The effectiveness of the proposed restriction could indeed be monitored:

- Via the monitoring and checking of the content of the registration dossiers (registered compositions, tonnages and uses) for some of the substances containing CA:C14-17
- Via a market survey similar to the one undertaken by the Dossier Submitter for the preparation of this restriction proposal
- Via EU or national monitoring campaign of CA:C14-17 in the environment.

RAC conclusion(s):

RAC agrees that the restriction options RO1, RO3, RO4a, RO4b and RO5 are all considered monitorable. Consequently, option A (RO3+RO5) and option B (RO4b+RO5) are also considered monitorable.

Key elements underpinning the RAC conclusion(s):

The RAC opinion is based on Section 2.3.4 of the Background Document and Appendix B.

RAC considers that monitoring of the effectiveness of the restriction proposal is possible by monitoring and checking the content of the registration dossiers for some of the substances containing CA:C14-17, and by a market survey similar to the one undertaken by the Dossier Submitter for the preparation of this restriction proposal.

Furthermore, monitoring of CA:C14-17 in the environment is considered possible. However, the effect of the restriction may be difficult to measure solely via monitoring campaigns after the entry into force of the restriction proposal due to the PBT, vPvB, and LRT properties of the substances restricted. The concentrations of CA:C14-17 measured in the environment may indeed come from previous sources of releases and uses (e.g. landfill disposal prior to the restriction), as well as from uses and releases outside the EU.

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RAC notes the presence of the 'other vP congeners' in the environment is not systematically addressed in existing monitoring programmes which shall be targeted once considered under the scope.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

3.4.6. Conclusion whether the suggested restriction is the most appropriate EU-wide measure

RAC conclusion(s):

RAC concludes that the proposed restriction is the most appropriate risk management measure for 'CA:C14-17 with PBT and/or vPvB properties'.

RAC notes that the 'other vP congeners' may present similar risks as the congeners having PBT and/or vPvB properties (see section 3.1.4 above) and are present as constituents in the same substances as 'CA:C14-17 with PBT and/or vPvB properties' (see section 3.4.2 for specifics), thus the restriction measures should consider all congeners of concern.

RAC concludes that the restriction is targeted to the effects or exposures that cause the risks identified, capable of reducing these risks within a reasonable period of time and proportional to the risk posed by the CA:C14-17 on their own and CA:C14-17 contained in substances, mixtures and articles.

RAC concludes that the restriction is in general implementable and monitorable in the EU and also that the restriction is practical and manageable, in particular in terms of the proposed concentration limit of 0.1 % of CA:C14-17.

RAC concludes that the provisions for the supply chain communication allow to achieve sufficient level of enforceability. However, RAC notes that it could be difficult to enforce the identification requirement of CA:C14-17 in the composition of substances, mixtures and (complex) articles irrespective of the concentration and proposes to set a concentration limit of 0.1 % w/w to ensure the practicality of the requirement.

Key elements underpinning the RAC conclusion(s):

Other measures than a restriction on their own are not considered practical, or effective mean of addressing risks as well that would affect the uses and emissions of CA:C14-17 (see section 3.4.1).

Safer alternatives to substances containing CA:C14-17 are available.

Please see section 3.4.2 for justifications on considering the 'other vP congeners' under the scope of the restriction proposal.

Please see section 3.4.4 for justifications on the practicality, including enforceability and section 3.4.5 on the monitorability of the proposed restriction.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

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See SEAC opinion.

3.5. UNCERTAINTIES

3.5.1. Uncertainties evaluated by RAC

Summary of Dossier Submitter's assessment:

The Dossier Submitter identifies several uncertainties that may affect the release estimates (baseline and release per RO), such as:

- Tonnage estimates (e.g. substances potentially affected by the restriction proposal, proportion of CA:C14-17 in chloroalkanes, tonnages imported in mixtures or articles, etc.)
- Proportion of waste treated in landfill vs incineration
- Effectiveness of the WWTP
- Estimated tonnage split between industrial and consumer/professional uses

To assess the impact of these uncertainties, the Dossier Submitter performed a sensitivity analysis and concluded that the identified uncertainties – both individually and jointly – have only a minor impact on the total releases (<10 % compared to the values used in the restriction proposal), and would only affect in a negligible way the baseline release, and release reduction potential associated to each RO.

Finally, regarding the risk assessment, the Dossier Submitter indicates that even though MSC was lacking data to assess the hazards of all CA:C14-17 congeners against the vPvB and/or PBT criteria, other CA:C14-17 congener groups (C₁₄Cl₁₂₋₁₄, C₁₅Cl₉₋₁₅, C₁₆Cl₉₋₁₆, C₁₇Cl₃₋₅ and C₁₇Cl₁₀₋₁₇) may warrant a need for minimisation of the release.

RAC conclusion(s):

- RAC agrees with the uncertainties identified with the Dossier Submitter related to the tonnage in use and emissions resulting from the life cycle stages of the substances in use including the waste stage.
- There are also uncertainties regarding the risk management measures in place and their effectiveness in minimising the risks in industrial uses and specifically in the formulation and use of metal working fluids.
- In addition, RAC considers that there are some uncertainties related to the hazards of the congeners identified with vP properties.
- RAC concludes that the uncertainties identified do not have a significant impact on the conclusions of the risk assessment. RAC also considers that the conclusions related to the emission reduction of the restriction proposal and the additional restriction options presented by the Dossier Submitter are not substantially affected by the uncertainties

Key elements underpinning the RAC conclusion(s):

RAC finds it justified to recommend considering the 'other vP congeners' under the scope of the restriction despite the remaining uncertainties in the overall and in the specific considerations in the provided data. See section 3.1.2 for further information on the uncertainties related to the hazard assessment.

The case-by-case approach for hazard and risk assessment of the "other vP congeners" is robust and well justified. RAC notes that the outcome of the assessment give basis for

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considering similar hazard properties for these congeners and warrant a need for minimisation of the releases of all congener groups of concern to ensure sufficient reduction of the risk arising from the manufacture and use of CA:C14-17.

Section 3.1.2 refers to details on the uncertainties related to the monitoring data on 'other vP congeners'.

Section 3.1.3 refers to the uncertainties regarding the unaccounted volumes and the calculated releases of different congener subgroups (the 'CA:C14-17 with PBT and/or vPvB properties' and 'other vP congeners') as well as the imported articles.

Section 3.1.4 refers to the uncertainties on possible overestimation of releases as a result of estimating releases of substances containing CA:C14-C17 as a proxy for risk.

3.5.2. Uncertainties evaluated by SEAC

Summary of Dossier Submitter's assessment:

The Dossier Submitter identifies several uncertainties that may affect the impact assessment of each RO and in particular its cost effectiveness, such as:

- Baseline release and avoided release assumptions to calculate the cost effectiveness of each RO
- Data constraints for the estimation of one-off substitution costs
- Lack of clarity on whether the leather sector would be affected by the entry into force of the restriction
- Methodological choice to use a 3 % rate vs the 0 % rate for discounting the benefits
- Lack of information on the impacts of the restriction on sectors down the supply chain (e.g. automotive and aerospace)

To assess the impact of these uncertainties, the Dossier Submitter performed a sensitivity analysis and concluded that the identified uncertainties – both individually and jointly – have only a minor impact on the cost effectiveness of the restriction options (<10 % compared to the values used in the restriction proposal).

The last source of uncertainty was only considered qualitatively, given lack of data.

SEAC conclusion(s):

See SEAC opinion.

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion.

4. REFERENCES

N/A