

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-0000007283-75-01/F
**ECHA/SEAC/[reference code to be added after the
adoption of the SEAC opinion]**

Agreed

9 June 2023

8 June 2023

ECHA/RAC/RES-O-000007283-75-01/F

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

PROCESS FOR ADOPTION OF THE OPINIONS

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: Raili 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**.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

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

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

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: 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.]

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

Contents

1. OPINION OF RAC AND SEAC	1
1.1. THE OPINION OF RAC	5
1.2. THE OPINION OF SEAC	5
2. SUMMARY OF PROPOSAL AND OPINION.....	7
2.1. Summary of proposal	7
2.2. Summary of opinion	8
2.2.1. RAC opinion summary.....	8
2.2.2. SEAC opinion summary	8
3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC	10
3.1. RISK ASSESSMENT	10
3.1.1. Scope of the risk assessment.....	10
3.1.2. Hazard(s)	13
3.1.3. Emissions and exposures.....	13
3.1.4. Risk characterisation.....	14
3.1.5. Existing operational conditions and risk management measures	14
3.2. JUSTIFICATION THAT ACTION IS REQUIRED ON A UNION WIDE BASIS	15
3.3. ANALYSIS OF ALTERNATIVES	16
3.3.1. Approach to the analysis of alternatives	16
3.3.2. Availability and technical and economic feasibility of alternatives.....	18
3.3.3. Risk of alternatives.....	21
3.3.4. Conclusion on analysis of alternatives	21
3.4. JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE.....	23
3.4.1. Other regulatory risk management options.....	24
3.4.2. Effectiveness in reducing the identified risk(s).....	27
3.4.3. Socioeconomic analysis.....	29
3.4.3.1. Costs	29
3.4.3.2. Benefits.....	34
3.4.3.3. Other relevant impacts.....	36
3.4.3.4. Proportionality.....	36
3.4.4. Practicality, including enforceability	38
3.4.5. Monitorability.....	40
3.4.6. Conclusion whether the suggested restriction is the most appropriate EU-wide measure.....	41

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

3.5. SUMMARY OF UNCERTAINTIES	42
3.5.1. Uncertainties evaluated by RAC.....	42
3.5.2. Uncertainties evaluated by SEAC.....	43

Tables

Table 1: Proposed REACH Annex XVII entry (option A)	1
Table 2: Proposed REACH Annex XVII entry (option B).....	2
Table 3: Overview of uses.....	10
Table 4: Exposure scenarios identified for each use.....	11
Table 5: Economic impacts of RO1, RO3, RO4a and RO4b.....	29
Table 6: Cost-effectiveness of RO1, RO3, RO4a and RO4b	37

DRAFT

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	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.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

Designation	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	Conditions of restriction
<p>Linear chloroalkanes with the following molecular formulae:</p> <p>$C_{14}H_{30-y}Cl_y$ where $y = 3$ to 11</p> <p>$C_{15}H_{32-y}Cl_y$ where $y = 3$ to 8</p> <p>$C_{16}H_{34-y}Cl_y$ where $y = 3$ to 8</p> <p>$C_{17}H_{36-y}Cl_y$ where $y = 6$ to 9</p>	<p>1.</p> <p>a. REMOVED</p> <p>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>

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

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

Designation	Conditions of restriction
	<p>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 examples of identifiers describing substances that may contain the chloroalkanes listed in column 1.</p> <p>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.</p> <p>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.</p> <p>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.]</p> <p>9. 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].</p>

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

Guidance⁴

Rapporteurs to choose the appropriate option before agreement/adoption and complete any missing elements.

The summary will be added by ECHA-S at the start of the opinion-making process.

Headings throughout the document are not to be deleted under any circumstances.

DRAFT

⁴ Instructions to the Rapporteurs should be deleted only by ECHA secretariat when RAC and SEAC final opinions have been adopted/agreed.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

1.1. THE OPINION OF RAC

See SEAC opinion.

1.2. THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction **Option B** 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 risks, as concluded by RAC. This takes into account the proportionality of its socio-economic benefits to its socio-economic costs. This conclusion is provided that the scope or conditions are modified, as proposed by SEAC, as demonstrated in the justification supporting this opinion.

<p>Substance Identity (or group identity):</p> <p>Linear chloroalkanes with the following molecular formulae:</p> <p>$C_{14}H_{30-y}Cl_y$ where $y = 3$ to 14</p> <p>$C_{15}H_{32-y}Cl_y$ where $y = 3$ to 15</p> <p>$C_{16}H_{34-y}Cl_y$ where $y = 3$ to 16</p> <p>$C_{17}H_{36-y}Cl_y$ where $y = 3$ to 17</p>	<p>Entry identified as Option B as proposed by the Dossier Submitter, with the following modifications:</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 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.</p>
---	--

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

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).

SEAC agrees with RAC 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).

Based on the socio-economic considerations SEAC supports the longer transition period for the metal working fluids, as proposed by the Dossier Submitter under restriction option B.

However, SEAC agrees with RAC that should the decision maker consider that the derogation is appropriate, that the ban on manufacturing, formulation, and production of articles as defined in paragraphs 1a and 2 of Option A should enter into force also under option B, once the derogation for metal working fluids has ended.

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

DRAFT

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

The substances in the scope of the proposed restriction contain CA:C14-17⁵ with PBT and/or vPvB properties.

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:C14-17⁶ are used annually in the 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, professionals, and consumers. 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 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 over the 20-year assessment period. Uses in PVC and in adhesives and sealants are the largest contributors in term of releases.

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 some (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 congeners with PBT and/or vPvB properties. In addition, 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, 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 with CA:C14-17 with PBT and/or vPvB properties, the availability of alternatives and that the proposed restriction could also be useful for the ongoing discussions in relation to the POP listing of these substances under the Stockholm Convention, the Dossier Submitter assessed five different restriction options and proposes two options for the restriction entry:

- 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 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 either a longer

⁵ Throughout the proposed restriction, 'CA:C14-17' refers to 'the congeners/congener groups of chloroalkanes CA with carbon chain lengths within the range from C14 to C17'.

⁶ Equivalent to ~79 000 tonnes of substances containing CA:C14-17

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

transition period (7 years)⁷ or a derogation could be considered depending on the information submitted during the Annex XV 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/vPvB properties in other substances, mixtures and articles, the proposed restriction entries also include some compulsory complementary measures to promote the communication down the supply chain.

2.2. Summary of opinion

2.2.1. RAC opinion summary

See RAC opinion

2.2.2. SEAC opinion summary

SEAC agrees with the Dossier Submitter that a union-wide action is needed to address the risks associated with EU-manufactured, formulated, used or imported products (substances, mixture, and articles) containing CA:C14-17 with PBT and/or vPvB properties. SEAC however agrees with RAC that the substances identified as “other vP congeners” should also be included within the scope of the restriction proposal.

In SEAC’s view, this restriction proposal will ensure that a harmonised high level of protection can be established across the Union, while maintaining the free movement of goods within the EU.

SEAC also considers that the Dossier Submitter appropriately analysed all other regulatory risk management options and agrees with the Dossier Submitter’s conclusion that restriction is the most appropriate regulatory option to address the identified risk.

With regard to alternatives, SEAC considers that the Dossier Submitter’s assessment is comprehensive and supported by detailed evidence.

SEAC supports the Dossier Submitter’s evaluation of technical and economic feasibility of the identified alternatives and its conclusion regarding their ability to replace substances containing CA:C14-17 in the affected products (wide range of mixtures and articles).

SEAC notes that alternatives appear to be available for most of the uses and that substitution is expected to be achieved within the 2-year transition period. However, SEAC notes that generally there is no a drop-in alternative and that it is likely that a combination of different alternatives will be necessary to replace substances containing CA:C14-17 being subjected to this restriction proposal.

SEAC also notes that the Dossier Submitter identified some alternatives that cannot be considered suitable based on their current harmonised classification or their regulatory status.

SEAC agrees with the Dossier Submitter that it appears that in some applications it has not so far been possible to replace substances containing CA:C14-17. This appears to be the case of metalworking fluids used in ‘heavy-duty’ operations on hard materials, such as stainless steel and titanium. SEAC however notes that operations where substitution seems still to be challenging account for less than 5 % of the total metal working processes, meaning that for

⁷ “A 7-year TP is akin to the standard review period granted in the frame of authorisation applications where such a time span is considered as sufficient for industry to undertake the necessary research and development and substitute SVHC. In addition, during the ECHA market survey, several stakeholders from the metalworking sector indicated that a TP between two and ten years (on average six years) would be needed to substitute the substances containing CA:C14-17 in the remaining metalworking applications.” (Section 2.2.3 of the Background Document)

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

the metal working fluids used in these applications, a longer transition period (more than 2 years) appears to be needed.

In terms of costs, SEAC concludes that given the available evidence, the Dossier Submitter provided a reasonable estimate of the likely impacts on society of each of the examined restriction options. The Dossier Submitter estimated the costs for the five-uses accounting for more than 90% in terms of substances' volume used (PVC, adhesives and sealants, rubber, metalworking fluids, paints and coatings) and whenever possible, both one-off costs and ongoing increase in variable costs were quantified.

In terms of benefits SEAC notes that when compared to the baseline release, significant emission reductions (by ca. 90 %) are envisaged from each of the ROs.

SEAC concurs with the Dossier Submitter's assessment that the restriction can be considered implementable and manageable for the different actors in the supply chain, as well as monitorable. SEAC also notes that the Forum's advice on enforceability confirms the fact that the restriction is practicable and enforceable considering the variety of analytical techniques currently available and the ongoing development of new ones.

SEAC's conclusion is that the restriction option B with a transition period of 7 years is the preferred option, as it takes into account that alternative extreme pressure additives may not be readily available for all types of metal working fluids, and so recognises that for this use a transition period longer than 2 years is needed.

Finally, SEAC notes that a ban on manufacturing, formulation and production of articles could have been proposed under option B to further reduce the releases in the EU, in line with the overall restriction proposal's goal to minimise emissions of PBT and vPvB substances. SEAC therefore considers that a ban on manufacturing, formulation and production of articles under option B should be introduced once the transition period for the metal working fluids ends, to further minimise the releases.

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 Commission⁸, 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 hazard assessment of the Dossier Submitter refers to the ECHA Member State Committee⁹ (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 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 3).

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 3: Overview of uses

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 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	Plasticiser Flame retardant

⁸ 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

⁹ 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>.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

Use number and use name	End products and examples of applications	Main technical functions of
	flame retardancy properties (e.g. rubber conveyor belts and rubber tubes used in mining and underground activities).	
#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

The Dossier submitter then established a list of relevant exposure scenarios for each use (see Table 4) based on information from the CSR and gathered via the various calls for evidence.

Table 4: 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

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

#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 4. 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 tonnage, the Dossier Submitter concluded that EC 287-477-0 (Alkanes, C14-17, chloro) is the main driver of the risk assessment.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

3.1.2. Hazard(s)

Summary of Dossier Submitter's assessment:

The restriction proposal targets the presence of CA:C14-17¹⁰ with PBT and/or vPvB properties in substances, mixtures, and articles.

ECHA Member State Committee¹¹ (MSC) concluded that the following CA:C14-17 have PBT and/or vPvB properties, and are predicted to have long-range environmental transport potential (LRTP):

- 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 MSC concluded that CA:C14-17 with PBT and/or vPvB properties may be present in many substances.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

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 3 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 4 (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.

The release calculations include the releases from current uses and applications: i.e. historical

¹⁰ 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'.

¹¹ 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>.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

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 this Annex XV report. Uses in PVC and in adhesives and sealants are the largest contributors in term of release.

The lower bound corresponds to the releases estimated with the lowest release factors and lowest fraction of substances going to waste. On the contrary, the highest bound 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 is underpinned by studies and monitoring carried out in the EU, but also worldwide.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

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/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):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

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 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 nature of the uses themselves, which are essentially 'wide dispersive' such as metalworking fluid applications, lubricants, paints and coatings, adhesives and sealants (One

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

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 or vPvB properties.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

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

Summary of Dossier Submitter's assessment:

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

While few member states (e.g. Germany and Norway) have taken specific actions focused on one substance EC 287-477-0 (Alkanes, C14-17, chloro), 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):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

SEAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection of human health and the environment across the Union and of maintaining the free movement of goods within the Union, SEAC agrees that action is needed on an EU-wide basis to address the risks associated with CA:C14-17 with PBT and/or vPvB properties.

Key elements underpinning the SEAC conclusion(s):

The SEAC opinion is based on Section 1.5 of the Background Document, Appendix E and the information submitted in the consultation on the Annex XV report.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

SEAC agrees with the Dossier Submitter that substances containing CA:C14-17 with PBT and/or vPvB properties are used in a broad range of applications in the EU and that releases to the environment can occur throughout the life cycles of substances, mixtures and articles (manufacturing, formulation, use, waste disposal, and recycling). SEAC notes that releases to the environment occur mainly from wide dispersive uses (professional, consumer, service life and waste) which are essentially 'open'¹² such as metalworking fluid applications, lubricants, paints and coatings, adhesives and sealants in all EU Member States. It difficult to implement effective risk management measures for these uses that minimise releases.

SEAC agrees with the Dossier Submitter that union-wide action is needed to address the risks associated with EU-manufactured, formulated, used or imported products (substances, mixture, and articles) containing CA:C14-17 with PBT and/or vPvB properties. In SEAC's view, this restriction proposal will ensure that a harmonised high level of protection can be established across the Union, while maintaining the free movement of goods within the EU. The efficient functioning of the internal market for substances and articles containing these substances can only be achieved if regulatory measures do not differ significantly between Member States. SEAC also notes that, as indicated by the Dossier Submitter some EEA countries, i.e. Norway, and Germany have already some national measures in place to reduce the releases of CA:C14-17 and manage the resulting waste. In addition, SEAC notes that also The Netherlands have adopted some measures of similar nature.

SEAC also notes that part of the products (substances, mixture, and articles) containing CA:C14-17 imported, as well as produced in EU, need to circulate freely once on the EU market. Therefore, the need to support the internal market of substance stresses the importance of EU-wide action rather than action by individual Members.

3.3. ANALYSIS OF ALTERNATIVES

3.3.1. Approach to the analysis of alternatives

Summary of Dossier Submitter's assessment:

Approximately 70 different potential 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 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. While the Dossier

¹² Generally not using closed systems.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

Submitter acknowledges that alternatives are more expensive, the overall conclusion is that the shift to these is deemed economically feasible.

SEAC conclusion(s):

SEAC considers that the assessment of alternatives performed by the Dossier Submitter is comprehensive and supported by detailed evidence.

SEAC therefore considers that the approach is appropriate and sufficient to reach a conclusion on the availability and technical and economic feasibility of alternatives for the different uses.

SEAC also notes that some of the identified alternatives cannot be considered as safer, due to their hazard profile and regulatory status.

Finally, SEAC notes that the substitution appears to be more challenging in the metal working fluids used in 'heavy duty' metal working operations.

Key elements underpinning the SEAC conclusion(s):

The SEAC opinion is based on Section 2.2.2 of the Background Document, Appendix E and the information submitted in the consultation on Annex XV report.

SEAC considers that relevant information was taken into consideration by the Dossier Submitter in the analysis of alternatives.

SEAC notes that to search for information on alternatives, the Dossier Submitter reviewed the following documents: the Annex XV dossier for SVHC identification (ECHA, 2021b), UK RMOA (UK Environment Agency, 2019), German RMOA, Dechlorane Plus¹³ Annex XV restriction proposal¹⁴, RoHS Annex II Dossier for EC 287-477-0 (Alkanes, C14-17, chloro) (EU Commission, 2020b) based on the KEMI proposal (KEMI, 2018). Moreover, SEAC notes that three calls for evidence were organised by the Dossier Submitter. The first one (referred to as CfE1 in the Background Document) was targeted to EC 287-477-0 (Alkanes, C14-17, chloro). In addition, two calls for evidence to support the preparation of the restriction dossier were open on the ECHA website from 06/10/2021 to 28/11/2021 (CfE2), and then from 23/02/2022 to 25/03/2022 (CfE3). Additionally, multiple interviews and meetings with stakeholder associations and companies were conducted to collect additional information on alternatives. Information provided by stakeholders was mainly on metal working fluids (19%), adhesives and sealants (15%), PVC (15%) and other topics such as SEA data (7%), analytical technics (7%), paints and coatings (7%). SEAC also notes that the Dossier Submitter collected additional information on alternatives through discussions with the relevant industries and that use-specific investigations via consultants were performed between December 2021 and April 2022. The details on the performed consultations are reported in Appendix G.

SEAC notes that alternatives that seem to be providing the same functions (in terms of flame retardancy and plasticising properties) as substances containing CA:C14-17 were listed by the Dossier Submitter in Appendix E.

SEAC also notes that – within each use - the Dossier Submitter described the different functions provided by substances containing CA:C14-17 and reported in the Background Document (section 2.2.2) the alternatives that were reported with highest frequency by the

¹³ Considering that also Dechlorane Plus performs similar functions as MCCP and substances containing CA:C14-17. For example Dechlorane Plus is also used as Extreme Pressure additive.

¹⁴ Available at: <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e184a168c4>

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

interviewed stakeholders or by stakeholders that provided information to the calls for evidence and sector specific surveys.

SEAC also notes that the Dossier Submitter identified some alternatives that cannot be considered suitable based on their current harmonised classification or their regulatory status.

Finally, SEAC notes that the Dossier Submitter collected information on the indicative price of alternatives, noting however that this information was not available for all the identified alternative chemicals.

Overall SEAC considers that the approach adopted by the Dossier Submitter in identifying and assessing the alternatives is appropriate and allows to reach a conclusion on their feasibility.

3.3.2. 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, and technically and economically feasible.

There is no general drop-in one-for-one replacement 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 in some 'heavy-duty' metalworking operations.

SEAC conclusion(s):

SEAC supports the Dossier Submitter's assessment of technical and economic feasibility of the identified alternatives and its conclusion regarding their ability to replace substances containing CA:C14-17 in the affected products (wide range of mixtures and articles). SEAC agrees that there are no drop-in alternatives to substances containing CA:C14-17 for all the identified uses. Nevertheless, suitable alternatives (technically effective, economically sustainable, and quantitatively available) are already available for most of the uses and sometimes already implemented. For plasticiser and flame retardants formulations, 56 alternatives were identified in total and 19 alternatives performing the function as extreme pressure additives in metal working fluids.

However, SEAC notes that generally there is not a drop-in alternative and that it is likely that a combination of different alternatives will be necessary to replace substances containing CA:C14-17 being subjected to this restriction proposal.

SEAC notes that for some applications (as in case of one-component foam sealants), the implementation of alternatives will require the adaptation of the whole formulation to ensure that the reformulated products still meet the customer requirements. SEAC also notes that these adaptations may require time to implement but that, overall, these are expected to be marginal situations within the whole range of uses and implementable during the proposed transition period.

Finally, SEAC agrees with the Dossier Submitter that it appears that in some applications it has not so far been possible to replace substances containing CA:C14-17. This appears to be

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

the case for some types of metalworking fluids used in 'heavy-duty'¹⁵ operations on hard materials, such as stainless steel and titanium that are resistant to reaction with extreme pressure additives other than chloroalkanes. SEAC however notes that operations where substitution seems still to be challenging account for less than 5 % of the total metal working processes, meaning that for these specific applications, a longer transition period (more than 2 years) appears to be needed.

Key elements underpinning the SEAC conclusion(s):

The SEAC opinion is based on Section 2.2.2 of the Background Document, Appendix E and the information submitted in the consultation on the Annex XV report.

SEAC notes that the Dossier Submitter identified approximately 70 potential different alternatives from literature review, stakeholder consultations and the market survey. These alternatives are detailed in Appendix E. When feasible, a short list of alternatives was identified in the Background Document for each use (separated in 8 different use categories by the Dossier Submitter).

SEAC notes that (depending on the uses) the alternatives to substances containing CA:C14-17 need to be able to provide the following functionalities:

1. Plasticising and/or flame retardancy,
2. act as extreme pressure additives in metalworking fluid, or;
3. act as lubricants.

SEAC also notes that some functions can be more relevant than others, depending on the final (area of) applications of the products.

SEAC agrees with the Dossier Submitter that alternatives seem to be available and technically and economically feasible for all detailed uses except for metalworking fluids used in 'heavy-duty' operations on hard surface metals (e.g. titanium or stainless steel).

SEAC agrees with the Dossier Submitter that alternatives are available:

- in PVC applications, noting that in response to the restriction the affected industries are expected to select an alternative (or a combination of flame retardants and plasticisers) in view of the final cables' requirements
- for uses in one-component polyurethane foams (OCFs) and insulating glass (IG) sealants, noting however that the two sub-uses may require different alternatives and that alternatives do not always meet the required criteria in terms of viscosity, thermal performance, adhesion, or foam stability and that overall product reformulations are needed
- for paints and coatings, noting that possible alternatives in marine and protective coatings are non-chlorinated plasticisers and
- for paper, considering the use of substances containing CA:C14-17 appears to be obsolete
- for uses in rubber goods, noting that EC 264-150-0 (associated to a substance referred to as 'long chain chlorinated paraffins' and described by the acronym 'LCCP' in Europe) appears to be the closest alternative to EC 287-477-0 (Alkanes, C14-17, chloro) in articles (such as rubber conveyor belts used in underground mining activities), that have strict conditions for use in term of fire resistance and that other alternatives are

¹⁵ Metal forming operations (such as: deep drawing', 'broaching' and 'fine blanking') on hard metals such as titanium or steel under hard conditions of temperature and pressure. For example see also DIN 8584 for deep drawing operations ([link](#)).

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

available for other types of goods

SEAC notes that EC 264-150-0 (LCCP) was indicated as a potential alternative for several uses, other than rubber goods (e.g in PVC cables, sealants, etc).

The 'LCCP' chloroalkanes consist of carbon chain lengths in the range of C18 to C36. These substances may have different compositions, with carbon chain lengths ranging from C18-20 (with a chlorination level between 40 % and 52 %) to carbon chain lengths longer than C20 (with a chlorination level between 40 % and 54 %) and even carbon chain lengths longer than C20 (with a chlorination level above 70 %). Based on the manufacturing process, the predominant carbon chain lengths present in this substance are ≥ 18 ; nevertheless its composition may include as well shorter carbon chain lengths than C18 making composition analysis and certification of trace amount of CA:C14-17 below 0.1% a crucial parameter.

According to the information gathered by the Dossier Submitter, CA:C14-17 with PBT and/or vPvB properties may be present in 'LCCP' in various concentration levels up to ca.20 % . SEAC notes that concentration levels below 0.1 % are mostly expected when the feedstock to produce 'LCCP' predominantly consists of carbon chain lengths longer than C20 and that producers will be requested to adapt their feedstock or production to meet these criteria. Based on the information collected by the Dossier Submitter, SEAC notes that some suppliers of EC 264-150-0 (LCCP) may already fulfil the potential restriction conditions because their substances already contain <0.1 % of CA:C14-17 with PBT and/or vPvB and that others indicated that they could comply with the restriction concentration limit by changing the supply source and specifications of their feedstock.

SEAC takes note and concurs with the Dossier Submitter that as indicated in the Background Document and considering the restriction conditions, only EC 264-150-0 (LCCP) containing less than 0.1% of CA:C14-17 with PBT/vPvB properties can be considered as a possible alternative.

Regarding the use in fatliquor formulations (used to confer softness and waterproofing properties to leather as well as to strengthen its fibre structure), SEAC notes that, as described by the Dossier Submitter, it is unclear whether substitution will be required in this use because of this restriction. This is explained by the fact that it appears that CA:C14-17 with PBT/vPvB properties may be present in the two relevant substances ('*Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified*' and in '*Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified*'¹⁶) in concentration varying between below 0.1 % and up to ca. 10 %. SEAC therefore notes that companies currently using the substances containing <0.1 % of CA:C14-17 are expected to continue to do so under the restriction scenario, and that companies that may be currently using the substances containing more than 0.1 % of CA:C14-17 are expected to shift to compositions containing <0.1 % of CA:C14-17.

Regarding fire retardant paints and solvent-based intumescent coatings, SEAC notes that – as reported in section 2.2.2.5 of the Background Document – EC 264-150-0 (LCCP with chain lengths C22-30) is widely used in these types of products. Because the concentration of CA:C14-17 is expected to be below 0.1 % in EC 264-150-0 (with carbon chain lengths between C22 to C30), companies operating in this sector are not expected to be affected by this restriction. Also, in case some companies are currently using EC 264-150-0 with CA:C14-17 concentrations above 0.1 %, these are expected to shift to EC 264-150-0 (LCCP) , containing CA:C14-17 in a concentration below 0.1 % The Dossier Submitter also indicates

¹⁶ Of the 69 identified substances, only these two substances are used in fatliquors.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

that based on information collected from the CfEs and interviewed stakeholders, the price of EC 264-150-0 (LCCP) is 20-50% higher compared to EC 287-477-0 (Alkanes, C14-17, chloro).

Regarding metal working fluids, SEAC notes that several alternatives (such as phosphorus and sulphur-based additives) were identified by the Dossier Submitter and that substitution appears to have already occurred in more than 95% of the processes.

SEAC therefore notes that, based on the information provided in the Background Document, the metal working operations where the phasing out of substances containing CA:C14-17 appears to be still challenging (such as deep drawing', 'broaching' and 'fine blanking') represent less than 5% of all the metal working operations.

The Dossier Submitter therefore indicated that potentially a permanent derogation (under RO4a) or a time limited derogation of 7 years (under RO4b) may be appropriate for metalworking fluids to avoid disproportionate impacts of the two restriction options (RO1 and RO3) which do not include a specific derogation for this use. However, the need for this derogation will be reviewed by SEAC following the consultation on the Annex XV report.

SEAC also notes that the Dossier Submitter considers that a transition period of two years to transition to the identified alternatives is expected to be sufficient for all other uses.

3.3.3. Risk of alternatives

Summary of Dossier Submitter's assessment:

For most of the uses, there are already alternatives available on the market that are free from CA:C14-17.

In terms of hazards and risks associated with alternatives, 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):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

3.3.4. Conclusion on analysis of alternatives

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

SEAC conclusion(s):

SEAC considers that the assessment of alternatives performed by the Dossier Submitter is comprehensive and supported by detailed evidence. SEAC supports the Dossier Submitter's conclusion regarding the availability of alternatives and the expected time needed for the affected sectors to replace substances containing CA:C14-17 in the affected products (wide

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

range of mixtures and articles). SEAC also agrees that there are no drop-in alternatives to substances containing CA:C14-17 for all the identified uses but concurs with the Dossier Submitter's view that suitable alternatives (technically effective, economically feasible, and quantitatively available) are already available for most of the uses and sometimes already implemented. SEAC notes that for some applications (as in the case of one-component foam sealants, OCFs), the implementation of alternatives will require the adaptation of the whole formulation to ensure that the reformulated products still meet the customers' requirements. SEAC also notes that, despite most of the identified alternatives being safer than CA:C14-17, some of the identified alternatives cannot be considered as safer, due to their hazard profile and regulatory status.

Finally, SEAC agrees with the Dossier Submitter that it appears that in some applications it has not been so far possible to replace substances containing CA:C14-17. This appears to be the case for some of metalworking fluids used in 'heavy-duty' operations on hard materials, such as stainless steel and titanium that are resistant to reaction with extreme pressure additives other than chloroalkanes. SEAC however notes that operations where substitution seems still to be challenging account for less than 5 % of the total metal working processes.

Key elements underpinning the SEAC conclusion(s):

The SEAC opinion is based on Section 2.2.2 of the Background Document, Appendix E and the information submitted in the consultation on the Annex XV report.

SEAC considers that extensive information was taken into consideration by the Dossier Submitter in the analysis on alternatives.

SEAC notes that the Dossier Submitter reviewed a large amount of literature, made multiple surveys and consultations, and conducted specific interviews with many industrial sectors in the preparation of this restriction, to ensure that all relevant areas are covered and that all the necessary information is retrieved. All the information collected by the Dossier Submitter is reported in a detailed manner in the Background Document and in Appendix E, allowing a thorough assessment of the work performed and the data provided.

SEAC notes that the Dossier Submitter presented approximately 70 potential different alternatives, by also identifying which among those cannot be considered suitable on safety grounds based on their current harmonised classification or their regulatory status (see 3.3.2 for more details).

SEAC also notes that EC 264-150-0 (LCCP) was indicated as a potential alternative for several uses, other than rubber goods (e.g in PVC cables, sealants, etc). Nevertheless, SEAC notes that in line with restriction conditions only EC 264-150-0 (LCCP) with a concentration of CA:C14-17 with PBT and/or vPvB properties below 0.1% can be considered as a potential alternative. SEAC notes that the Forum's advice concurs with the DS that the threshold of 0.1% is sound and enforceable from a technical point of view.

SEAC also notes that a higher concentration limit of 1% was requested by some stakeholders providing inputs to the third-party consultation. SEAC notes that – from an analysis of alternatives perspective - a higher concentration limit of 1% would mean that more compositions of EC 264-150-0 (LCCP)¹⁷ would be allowed to be placed on the market. SEAC considers plausible that under this scenario demand for EC 264-150-0 (LCCP) with a concentration of CA:C14-17 with PBT and/or vPvB properties up to 1% might increase,

¹⁷ As well as of other substances.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

potentially leading to higher emissions.¹⁸ In general SEAC considers plausible that this scenario would be less costly to society (in terms of substitution costs), on the basis that EC 264-150-0 (LCCP) appears to be considered by many sectors as the closest alternative to EC 287-477-0 (Alkanes, C14-17, chloro) from both economic and technical perspective. So, under this scenario the overall reformulation costs as well as increase in variable costs, because of substitution, are likely to be lower compared to a 0.1% scenario.

SEAC also notes that, based on the information provided in the Background Document, the metal working operations where the phasing out of substances containing CA:C14-17 appears to be challenging (such as deep drawing', 'broaching' and 'fine blanking') represent less than 5% of all the metal working fluids operations.

Finally, SEAC notes that the Dossier Submitter collected information on the indicative price of alternatives, noting however that this information was not available for all of them.

Overall SEAC considers that the approach adopted by the Dossier Submitter in identifying and assessing the availability and feasibility of alternatives is appropriate and allows to reach clear conclusions on the alternatives for the different uses.

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 metal working fluid sector (RO4a includes an unconditional derogation, RO4b a transition period of 7 years and RO4C a conditional derogation)
- R05 – 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 longer transition period (7 years) is considered. Option B includes also some compulsory complementary measures to accompany the communication down the supply chain

¹⁸ In line with RAC's conclusions as reported in section (section 3.4.2).

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

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 (i) alternatives may not to be readily available for all Extreme Pressure metalworking fluids applications and (ii) a ban on manufacturing would de facto entail a ban on the manufacturing for the EU market

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. 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 constituent (here CA:C14-17 with PBT and/or vPvB properties).

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

SEAC conclusion(s):

SEAC agrees with the Dossier Submitter that compared to other risk management options, REACH restriction is better suited to address the risks related to the emissions of CA:C14-17 with PBT and/or vPvB properties.

SEAC notes that none of the other EU-wide risk management measures (voluntary nor legislative measures) would be sufficient to address the risks linked to the emissions of CA:C14-17 with PBT and/or vPvB properties, because they are harder to implement, slower, less effective or less appropriate in reducing emissions from CA:C14-17 compared to a REACH restriction.

SEAC also notes that the scope of the restriction proposal is unusual, as it is targeting multiple

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

substances and so provides multiples advantages such as:

- avoiding regrettable substitution
- increased efficiency by automatically covering any substance containing CA:C14-17 with PBT and/or vPvB properties in a concentration above 0.1%
- improving the overall efficiency of the risk management activities, by addressing group of substances (instead of focusing on one single substance)
- allowing the coverage of future and/or unknown substances, mixtures or articles;
- allowing to overcome administrative issues (naming, nomenclature uncertainties, incomplete listing).
- allowing to cover minor sectors where information is hardly available or where the quantities used are marginal (e.g. food packaging, recycling issues).

With regard to recycling, SEAC notes that a comment was submitted as part of the third-party consultation requesting a higher concentration limit for CA:C14-17 in PVC recycled compounds (from the PVC cables) as well as in articles manufactured with those compounds (comment#3848). SEAC agrees with the arguments provided by the Dossier Submitter on why a higher concentration limit for the above-mentioned mixtures and articles should not be granted. Among other things, the Dossier Submitter stressed that most of the articles produced with PVC recyclates are intended for an outdoor use (such as road traffic management and agricultural articles) and therefore pose an uncontrolled risk in terms of emissions. Moreover, the Dossier Submitter's understanding is that the profitability of the recycling activity in the cable sector is mainly driven by profits from metal recovery and to significantly less extent from the sales of recycled PVC. Additional arguments include the difficulty in enforcing such a derogation as well as the consideration of the EU Regulation 2019/1021 on persistent organic pollutants which prohibits the recycling or reuse of POP substances. In the absence of any other evidence SEAC considers that the Dossier Submitter's arguments reasonable.

SEAC considers that the Dossier Submitter appropriately analysed all other regulatory risk management options and agrees with the Dossier Submitter's conclusion that restriction is the most appropriate regulatory option to address the risks arising from releases of CA:C14-17 with PBT and/or vPvB properties.

Key elements underpinning the SEAC conclusion(s):

Other EU-wide legislative measures

SEAC's assessment is based on the information provided in Appendix E.

The Dossier Submitter provides an overview of possible EU wide legislative and non-legislative measures with the potential to control the releases from CA:C14-17, other than the proposed restriction. SEAC agrees with the line of argumentation presented by the Dossier Submitter with regards to voluntary measures, Eco Labels, biocidal products regulation (BPR), Waste Management, Authorisation, persistent organic pollutants (POPs) regulation, RoHS Directive, Industrial Emissions Directive (IED) and Ecodesign Directive, Environmental Liability Directive and overall consider them harder to implement, slower, less effective or less appropriate in reducing emissions of CA:C14-17 compared to a REACH restriction.

SEAC notes that the Dossier Submitter examined the following non-legislative and legislative measures as well as provided the reasons for discarding them:

- Non legislative measures, such as EU ecolabel or voluntary industry agreements
- Stockholm Convention on POPs
- RoHS Directive (2011/65/EU)
- Biocidal Products Regulation

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

- Waste management
- Industrial Emissions Directive (2010/75/EU) (IED)
- Environmental Liability Directive
- REACH Authorisation process

SEAC agrees with the Dossier Submitter that none of the above listed measures would be effective to address the identified risks. Also, some are sector specific and so would not be able to cover all the affected uses.

SEAC notes that:

- Non-legislative measures, such as voluntary industry agreements would be of limited impact in terms of reducing of CA:C14-17 with PBT and/or vPvB properties and while, some registrants have been engaged in activities to reduce the concentration of CA:C14-17 in the chloroalkanes placed on the market, no voluntary industry agreements or initiative at EU level have been identified by the Dossier Submitter
- Eco-labels are voluntary schemes awarded to the environmentally best products on the market and are limited in terms of uses, countries and substances covered
- Substances containing CA:C14-17 are currently not listed as restricted substances under RoHS. The RoHS Directive restricts (with exceptions) the use of listed hazardous substances in the manufacture of various types of electronic and electrical equipment (EEE). Additionally, although the Directive applies to some types of electric and electronic equipment that may contain CA:C14-17, it does not apply to all relevant sectors of applications where the congeners of concern are present.
- Some marginal uses may be covered by Biocidal Products Regulation (e.g. anti-fouling paints) but a derogation regime exists in the regulation even if the substances meet the criteria for PBT/vPvB and are present at concentration higher than 0.1%. Moreover, the regulation cover only a limited fraction of the substances identified in the scope of the proposed restriction.
- The Product Safety Directive, by focusing on risks to consumers of certain substances, would not cover all the substances falling in the scope of the restriction proposal and would not be able to cover all targeted applications and uses.
- Regarding the Waste Directive, the Dossier Submitter considers that a mandatory incineration scheme could be an appropriate risk management option for the waste life stage¹⁹. However, the lack of harmonisation of waste management practices across the EU and the difficulty to identify CA:C14-17 containing waste are relevant arguments to conclude that this option is not feasible. The lack of incineration capacity of some Member States, combined with large waste volumes, is also an issue.
- Regarding the Industrial Emission Directive, this legislation has no effect on the service life emissions or releases from the waste stage of CA:C14-17-containing articles, which is considered a key life cycle stage that could create a substantial part of the emissions.
- Regarding Environmental Liability Directive, the provisions of this legislations would have no effect in preventing the emissions of CA:C14-17 with PBT and/or vPvB
- Regarding the authorisation process, SEAC agrees that authorisation is not considered an appropriate risk management option, because only four substances out of 69, which are identified as SVHC, could be added to Annex XIV. Authorisation would also not apply to imported articles.

The UK proposed in 2019 to list 'chlorinated paraffins with carbon chain lengths within the range from C14 to C17 and chlorination levels ≥ 45 % for the Stockholm Convention proposal.

¹⁹ However the Directive would not be able to tackle emissions from other life cycle stages.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

SEAC notes, that in line with the EU Commission document on the interlinkage between REACH, the Stockholm Convention and the UNECE POP Protocol²⁰ it is good practice for the EU Member States or the Commission to initiate a restriction procedure under REACH if a substance is nominated to be listed under the POP Convention.

Also according to the document, the REACH restriction process will help to contribute to the scientific documents discussed in the POP Review Committee of the Stockholm Convention and will facilitate the development of the EU position for the Conference of Parties in which the listing of the substances will be decided. On the other hand, as the REACH restriction procedure could be quicker than the POP Convention, it may be desirable to introduce risk management measures in the EU in the form of a REACH restriction which would apply until superseded by the POP Convention and the POPs Regulation.

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 indeed targeted to the risks and issues identified:

- Risk posed by CA:C14-17 with PBT or vPvB properties which are present in many different substances
- Widespread uses and releases from all stage of the life-cycle including waste
- Lack of communication in the supply chain re. the presence (or absence) of the CA:C14-17 constituents with PBT/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 Dossier Submitter is proposing to restrict the presence of CA:C14-17 (congeners) having PBT and/or vPvB properties.

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

The Dossier Submitter therefore proposes to define the scope of the restriction using

²⁰ <https://ec.europa.eu/docsroom/documents/5805/attachments/1/translations/en/renditions/native>

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

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.

Uses and sector 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 such a ban is only partially covered by the ban on placing on the market considering that only the production of volumes for the EU market will no longer be possible. Indeed, in option B the manufacturing for export would remain possible (these represent max. 0.08 % of the total releases at the present time but this may evolve in the future if exports grow) .

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 longer transition period or derogation for metal working 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.

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.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

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 (PVC, adhesives and sealants, rubber, metalworking fluids, paints and coatings) 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, accounting for more than 65% of the total costs under each of the four examined restriction options (as reported in the table below).

One-off costs are expected to occur during the transition period, while the increase in variable costs is assumed to start at the end 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 5: Economic impacts of RO1, RO3, RO4a and RO4b

Restriction option (RO)	Total costs, NPV – 20-year analytical period) €	Annualised costs € over 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.

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.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

SEAC conclusion(s):

SEAC considers that the Dossier Submitter clearly described the efforts undertaken to gather evidence to support the analysis of the main restriction options (options: RO1; RO3; RO4a and RO4b). The Dossier Submitter drew on several sources of evidence (quantitative and qualitative) and where relevant used expert judgement and assumptions to estimate the economic costs associated with the main restriction options. The Dossier Submitter provided reasonable rationale for the selection of methods, assumptions made, and sensitivity analyses performed. The Dossier Submitter provided sufficient granularity to estimate possible behavioural responses of the affected industries.

The Dossier Submitter assessed impacts using compliance costs method (substitution costs) and where feasible, estimated consumer surplus losses using price elasticities.

SEAC considers that the assessment of costs is plausible, given that all the available evidence (collected through calls for evidence, market surveys and targeted interviews) was considered by the Dossier Submitter. Also, when certain data were not available (e.g. specific studies on price elasticities for sealants), the Dossier Submitter's calculations were tested by varying the elasticities, to assess how sensitive changes in consumer surplus were to this parameter.

Given some of the gaps in the availability of evidence, SEAC considers that the Dossier Submitter used the relevant methodologies to estimate economic costs associated with the restriction options, including the relevant guidance on the discount rates. SEAC considers that the Dossier Submitter's assumptions are reasonable, and that the sensitivity analysis was performed to account for the relevant uncertainties. SEAC agrees with the assessment of the costs of each of the four examined restriction options, while noting that some uncertainties persist, notably in relation to whether the leather sector is expected to be impacted. SEAC, however, notes that this was addressed by the Dossier Submitter as part of the uncertainty analysis.

SEAC also notes that the Dossier Submitter was unable to distinguish between small, medium, or large companies and as such this could conceal some distributional issues within the EU and between uses.

SEAC concludes that given the available evidence, the Dossier Submitter provided a reasonable estimate of the likely impacts on society.

Key elements underpinning the SEAC conclusion(s):

SEAC's opinion is based on section 2 of the Background Document and Appendix E.

SEAC takes notes that approximately 79 000 tonnes of substances containing CA:C14-C17 are used annually in EU, with EC 287-477-0 (Alkanes, C14-17, chloro) as the main contributor to this tonnage. This data was extrapolated to cover the whole tonnage of substances containing CA:C14-C17 in concentration above 0.1%.

Based on the analysis presented by the Dossier Submitter, SEAC concurs that the most likely response of the main users of substances containing CA:C14-C17 is to shift to the available alternatives within the 2-year transition period, indicating that for most of the uses, economically and technically feasible substitutes are available. However, for the metalworking fluids sector, the assumed most likely response for affected operations is to halt production or relocate. Fewer than 5% of the metalworking operations are assumed to be affected by the restriction, as in other metal working processes the use of non-chlorinated extreme pressure additives appears to be technically and economically feasible and the transition to the alternatives appears to have already occurred.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

SEAC's conclusion is based on the following:

- For **PVC applications**, substances containing CA:C14-C17 such as EC 287-477-0 (Alkanes, C14-17, chloro) appear to have been phased out or play a minor role. SEAC notes that this seems to be the case for PVC tubes, PVC pipes and PVC flooring and that the remaining relevant use appears to be in PVC cables. The Dossier Submitter estimates that approximately 400 companies will be affected by the proposed restriction. Compliance costs were estimated to capture both one-off costs and variable costs associated with the phasing out of substances containing CA:C14-C17 from PVC compounds used for the manufacturing of cables. The Dossier Submitter presented scenarios based on assumptions on how producers of PVC compounds could react (e.g. removal of substances containing CA:C14-C17, replacement of substances containing CA C14-C17 with a combination of flame retardants and plasticisers or shift to use EC 264-150-0, with less than 0.1% of CA:C14-C17). The Dossier Submitter calculated the substitution costs for replacing substances containing CA:C14-C17 in the PVC sector, noting that different alternatives options are available and that the producers of cables are very often also producers of PVC compounds. Due to the wide variety in the prices of cables and a lack of information on how any additional costs may affect the cost of the final products that contain the cables, it was not possible for the Dossier Submitter to estimate impacts on consumers. The Dossier Submitter's default assumption is that there will be no significant impacts on consumers. Total annual compliance costs for the PVC sector were presented as a combination of annualised one-off costs and annual increases in variable costs. The Dossier Submitter estimated that the total **compliance costs** for this use are €580 million (20 years NPV) under the four main ROs. To account for variations in one-off costs, the Dossier Submitter also performed sensitivity analysis, re-estimating the cost-effectiveness ratios after multiplying the estimated one-off costs by a factor of three.
- For **Sealants and Adhesives**, the impact assessment assumes that 80% of the substances' volumes are used in one-component polyurethane foams (OCFs) and 20% in insulating glass sealants (IG). This split is based on assumptions and data gathered in calls for evidence and a market survey. Also, there seem to be indications that substitution activities are on-going. Uses in tapes and adhesives were not assessed separately, as they are expected to account for a small comparative volume, and because there are indications from some of the major companies from the sector that substances containing CA:C14-C17 are not or no longer used in these products. However, to account for possible impacts on these remaining sub-uses in tapes and adhesives, the Dossier Submitter overestimated the costs for OCFs and IGs, by allocating the whole volumes to these sub-uses, which were then used as basis for the estimation of the substitution costs. In addition, the Dossier Submitter estimated consumer losses using different price elasticity scenarios. The assumption is that the sealants reformulated with alternatives are expected to be more expensive due to the higher price of alternative plasticisers and the need to adapt the overall sealant formulations. The Dossier Submitter assumed a price increase in the range of 10-13% and estimated potential losses using price elasticities of demand (0, 1, 0.5). As a basis for calculating the price increase, a price in the baseline scenario of €8 per can of OCF and €4 per kg of IG, were assumed by the Dossier Submitter. Consumer losses were estimated by the Dossier Submitter at € 3.2 billion, using central estimate, using 20 years NPV for each of the four main ROs.
- **Rubber:** Volumes of rubber products containing CA:C14-C17 are not available. The Dossier Submitter made the assumption that companies producing rubber conveyor belts are representative of this use and so estimated the costs for this sector, noting

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

that some cost transmission along the supply chain (e.g. to the mining companies) could be expected. Substances containing CA:C14-C17 are used in articles which require high fire resistance, such as rubber conveyor belts used in underground activities. The Dossier Submitter assumes that the demand for conveyor belts is not price sensitive and that producers would be able to pass on to some degree the compliance costs along the supply chain. The total costs for the rubber sector were estimated using present value and annualised costs. The Dossier Submitter estimated a total cost of €54 million over 20 years NPV under each of the four main ROs. As costs may differ between companies and there are uncertainties on the exact number of companies that would be affected by the restriction, the Dossier Submitter also performed sensitivity analysis on the cost-effectiveness ratios, multiplying one-off costs by a factor of 3.

- **Metal working fluids.** Within this use the Dossier Submitter assessed the impacts on additive suppliers, producers of metal working fluids and the metal working sector, using the affected products in heavy duty metal working operations. The Dossier Submitter analysed data from stakeholders, calls for evidence and results from a market survey. Based on the information collected, a 2-year transition period (TP) is concluded by the Dossier Submitter to be too short for the users to shift to alternatives, with the consequence that manufacturing for certain goods would be severely impacted. Therefore, under RO1 and RO3, the affected activities – production of extreme pressure additives and production of metal working fluids – are expected to cease in the EU. This scenario is also expected to impact all the companies from the metal working sector, relying on the use of CA:C14-C17-based metal working fluids (such as automotive or aerospace sectors). Under these two ROs, which do not include a specific derogation for this use nor a longer transitional period, total profit losses were estimated by the Dossier Submitter at €1 billion (NPV, 20 years). SEAC notes that the Dossier Submitter used the SEAC producer surplus loss paper²¹ and – because the availability of alternatives in this sector resembles a no-SAGA case - considered profit losses over a 4-year period to estimate the loss in producer surplus. Under restriction option RO4b (where a longer transition period is set for the metal working fluid sector, the Dossier Submitter estimated that compliance costs for the users to shift to non-chlorinated paraffin-based alternatives within a 7-year transition period (TP), are at €200 million (NPV, 20 years). For the estimation of the one-off costs, the Dossier Submitter used central estimates (based on lower and upper bound figures collected from the ECHA market survey) and for the estimation of the increase in variable costs, the Dossier Submitter applied three different methods to verify the consistency across the different pieces of information and data collected from stakeholders that participated in the calls for evidence and ECHA market survey (all three methods provided figures of similar magnitude). Finally, SEAC notes that no impacts for this sector are expected under RO4a, considering this restriction options includes a specific non-time limited derogation for this use.
- **For paints and coating.** For this use, the Dossier Submitter estimated the one-off costs (in terms of testing) that the producers of marine and protective coatings are expected to bear to shift to the available alternatives. SEAC notes that no variable costs were considered by the Dossier Submitter due to a lack of information. However, SEAC notes that the stakeholders interviewed by the Dossier Submitter reported that the variable costs are expected to play only a minor role, considering the overall low

²¹ See: https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

concentrations of substances containing CA:C14-C17 in these products. The total cost for this sector under each of the four examined ROs – was estimated at €10 million (NPV – 20-year period). The Dossier Submitter notes that overall costs may differ between companies and that there is uncertainty on the exact number of affected companies, so performed a sensitivity analysis, re-estimating the cost-effectiveness ratios after multiplying the one-off costs by a factor of three. For consumer surplus loss, the Dossier Submitter assumed that demand for these products is not sensitive to changes in price and that the companies will be able to pass on most of the substitution costs through price increases, while maintaining their sales volumes. The Dossier Submitter adopted this assumption considering the specialised nature of the products as well as the high value of the products being coated with the CA:C14-C17-based coatings.

- **For Leather:** SEAC notes that the Dossier Submitter's impact assessment is based on the assumption that none of the restriction options are expected to affect the leather sector and that companies will keep using the two substances ('Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified') with concentration of CA: C14-17 with PBT and/or vPvB properties below 0.1 % in the production of fatliquors. SEAC also notes that the Dossier Submitter assumes that in case companies are currently using the two substances but in concentrations of CA:C14-17 with PBT and/or vPvB properties >0.1 %, they will shift to substances with concentrations of CA:C14-17 with PBT and/or vPvB properties below 0.1 %, before the entrance into force of this restriction. Nevertheless, SEAC agrees with the Dossier Submitter that – given the uncertainties on the exact content of CA:C14-C17 with PBT and/or vPvB properties in the two substances - it cannot be concluded with certainty that this sector will not be affected by the restriction. SEAC therefore agrees with the Dossier Submitter's methodological choice to estimate the impacts of the restriction on this sector, as part of the uncertainty analysis.

SEAC notes that none of the stakeholders who contributed to the dossier preparation process considered the restriction as unaffordable. However, the Dossier Submitter acknowledges that, in practice, there may be a difference in terms of affordability between large versus small and medium companies. A 2-year transition period (TP) is, however, considered sufficient for all uses with the exception of the metal working fluid sector.

Based on the analysis presented by the Dossier Submitter, SEAC concurs that no major impacts on employment are expected under any of the RO, as substitution is technically and economically feasible across most of the uses.

SEAC also assessed the differences in terms of costs and benefits between the proposed option B (RO4b+RO5) and option A (RO3+RO5).

The conditions under option B do not include a ban on the manufacturing of substances containing more than 0.1% of CA:C14-17 with PBT and/or vPvB properties.

However, the Dossier Submitter assumes that the ban on the placing on the market of substances, mixtures and articles containing more than 0.1% of CA:C14-17 with PBT and/or vPvB properties, would de facto result in EU manufacturers ceasing the manufacturing of substances containing CA:C14-17 with PBT and/or vPvB properties for the EU market. SEAC concurs with this logic

SEAC therefore notes that the EU manufacturers of substances containing CA:C14-17 with PBT and/or vPvB will be allowed to continue producing for export from the EU. The quantity

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

of the substances produced for export is ~2600 tonnes per year and the corresponding releases are 4.2 tonnes per year (0.08% of the total releases). However SEAC notes that it cannot be excluded that production for exports could increase after the entrance into force of the restriction.

In SEAC's view, the proposed option B is very similar to Option A in terms of avoided releases (90% and 89-90% for A and B respectively) while noting that associated costs to society are €4.9 billion for Option A and €4.1 billion for Option B. SEAC notes that the difference is the profit losses for the metal working fluid sector, which would be expected under the option A and avoided under option B.

SEAC therefore notes that in absence of a longer transition period for the metal working fluids, important socio-economic impacts, including job losses in SMEs, may be expected. Here there may be also additional impacts along the supply chain, considering that the automotive and aerospace sectors will not be able to source the metal parts worked with the use of the affected metal working fluids. However, given the limited data available, the Dossier Submitter was not able to estimate possible job losses nor economic impacts on downstream sectors (e.g. automotive or aerospace).

Based on the above socio-economic considerations, SEAC supports the derogation for metal working fluids under option B.

SEAC however notes that a ban on the manufacturing could have been proposed under option B to further minimise releases in EU. Not proposing a ban on the manufacturing (under option B) would lead to the release of PBT, vPvB substances at the transboundary scale and to remote areas, even if considered minor in comparison to the total amount of releases estimated by the Dossier Submitter. SEAC also notes that the risks to the environment and to human health from PBT and/or vPvB substances cannot be adequately controlled and that emissions of these substances should be minimised throughout their lifecycle.

SEAC therefore supports RAC's view that should the decision maker consider the derogation for metal working fluids appropriate, the ban on manufacturing and formulation defined in paragraphs 1a and 2 of Option A should enter into force once the derogation for metal working fluids has ended.

SEAC also notes that – as assessed by the Dossier Submitter - a ban on manufacturing of substances would lead to marginal economic impacts (of approximately €300 000 euro per year, equivalent to approximately €4 M over 20 years).

Therefore, while SEAC supports a longer transition period for metal working fluids under Option B, it considers appropriate to include a ban on manufacturing and formulation as proposed by RAC once the derogation for metal working fluids has ended to further minimise the releases of CA:C14-17 in the scope of the proposal..

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 paper on its approach to evaluating restriction reports and applications for authorisation for PBT and vPvB

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

substances²². The Dossier Submitter has also followed the approach recommended in the paper by using emission reductions, in combination with factors of concern, including the level of persistence and bioaccumulation, long-range transport potential and uncertainty, as a proxy for potential future benefits.

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):

SEAC considers that the Dossier Submitter applied the relevant methodologies to estimate benefits (in terms of avoided releases) associated with the four main restriction options. The Dossier Submitter applied the standard social discount rate recommended in the Better Regulation toolbox 2001, i.e. 3% in real terms and tested the relevant uncertainties in the sensitivity analysis – including a lower discount rate (0%), which reflect the practice of assessing health impacts or environmental impacts which have long-term impacts (i.e. longer than the default 20 year period).

SEAC agrees with the Dossier Submitter that significant emission reductions (ca. 90 %) are estimated from each RO.

Key elements underpinning the SEAC conclusion(s):

SEAC's opinion is based on section 2.3.2 of the Background Document and Appendix E.

- SEAC notes that the restriction proposal is based on the PBT/vPvB properties of CA:C14-17, and so an assessment of human health impacts has not been performed. SEAC considers this reasonable.
- SEAC notes that the Dossier Submitter performed a specific analysis related to Metalworking Fluids (Use # Use 03), considering that RO4a includes a derogation for metalworking fluids and RO4b a longer transition period (7 years) for this use. The Dossier Submitter concluded that the remaining releases to the environment would be at a similar tonnage when compared with RO1 (i.e. ban on placing on the market) and RO3 (i.e. ban on manufacturing and on placing on the market). SEAC notes that this result reflects the fact that this use accounts for a relatively small share (5%) in terms of the overall substance volumes used. For comparison, the uses in PVC and Adhesives and Sealants combined account for 86% of substances' volumes.
- SEAC therefore concludes that the different ROs only marginally differ among them in terms of benefits.
- SEAC considers that for each of the four main ROs, the Dossier Submitter estimated the avoided emissions to the environment of CA:C14-C17 over 20 years compared to the baseline. The Net Present Values (NPV) of benefits were calculated by discounting (at 3% over 20 years) the avoided releases (using a central estimate).
- Based on the Dossier Submitter's analyses, SEAC concurs that the emission reductions

²² See: https://echa.europa.eu/documents/10162/17091/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3?t=1472819309457

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

(estimated at 90%) will result from the implementation of any of the above examined ROs. SEAC also notes that a 0% discount rate was applied by the Dossier Submitter, as part of the sensitivity analysis. The methodological implications of the discounting will be further analysed under section 3.4.3.4 on Proportionality.

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 impacts were only described qualitatively by the Dossier Submitter.

SEAC conclusion(s):

- Based on the analysis presented by the Dossier Submitter, SEAC concurs that no major impacts on employment are expected.

Key elements underpinning the SEAC conclusion(s):

SEAC's opinion is based on section 2.3.3 of the Background Document.

- Based on the analysis presented by the Dossier Submitter, SEAC concurs that no major impacts on employment are expected, as substitution is technically and economically feasible across most of the uses.
- SEAC notes that in absence of a derogation or a longer transition period for Use in metalworking fluids, job losses could be expected in SMEs. However, given limits in data availability, the Dossier Submitter was unable to estimate possible job losses. SEAC considers this reasonable.

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).

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
CHLOROALKANES C14-C17

Table 6: 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 ²³)	€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 RO4a, that this restriction option is equivalent to the baseline for this sector.

SEAC conclusion(s):

SEAC concurs with the Dossier Submitter that given the estimates from the cost effectiveness analysis across the main ROs, the restriction can be considered proportionate. For evaluating the proportionality of different restriction options based on cost-effectiveness analysis, the Dossier Submitter used a social discount rate of 3% for both costs and avoided emissions. SEAC notes that this approach deviates from previous restriction dossiers addressing PBT/vPvB substances, which used 0% for avoided emissions.

SEAC does not conclude on the appropriateness of the use of a positive social discount rate for emissions in the analysis. SEAC notes, however, as it is also referred to in the EU Better Regulation Guidelines and Toolbox, that it is common practise in many countries to choose a lower rate for health or environmental impacts. SEAC also notes that the choice of the discount rate for costs and emissions influences the results of the cost-effectiveness analysis.

SEAC however notes that – as part of the sensitivity analysis - the Dossier Submitter recalculated the cost-effectiveness ratios, using a discount rate of 0% for emissions. SEAC notes that the use of a 0% discount rate for emissions results in lower cost-effectiveness ratios for all combinations of restriction options. SEAC notes that the proportionality of the proposed ROs remain unaffected by the use of a different discount rate.

Key elements underpinning the SEAC conclusion(s):

SEAC's opinion is based on section 2.4 of the Background Document.

- SEAC supports the Dossier Submitter's assessment of costs and benefits of the restriction.

²³ 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.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

- SEAC also takes note that RAC has assessed the estimated avoided emissions.
- SEAC notes that the cost-effectiveness ratios range between 53 €/kg and 66 €/kg, and that the estimated cost effectiveness ratios are in line with that of previous restrictions for similar type of substances.
- The Dossier Submitter performed extensive analysis using different assumptions across key parameters to test the cost-effectiveness ratios and the outcome was that the cost-effectiveness ratios remained within the same range (50-72 €/kg), which indicates no substantial impact on the conclusions.
- SEAC also notes that RO1 and RO3 – with slightly higher emission reduction potential when compared to RO4a and RO4b - are less cost-effective. SEAC notes that this is explained by the higher costs on the metal working sector under RO1 and RO3, with a small reduction in terms of reduced releases when compared to RO4a and RO4b.
- In addition to calculating the cost effectiveness ratio of each restriction option, the Dossier Submitter calculated the marginal cost effectiveness ratios, indicating that RO1 (and RO3), which do not include a derogation nor a longer transition period for the metal working fluid sector, are more costly also in marginal terms compared to RO4a and RO4b, which include a derogation and a longer transition respectively (but are slightly less effective in terms of reducing the emissions of CA:C14-17 compared to RO1 and RO3).

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, 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):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

SEAC conclusion(s):

SEAC concurs with the Dossier Submitter's assessment that the restriction can be considered

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

implementable and manageable for the different actors in the supply chain: manufacturers, importers, downstream users, recyclers and waste operators. Moreover, SEAC concurs with the Dossier Submitter that the restriction can be considered practical and enforceable for the authorities.

Key elements underpinning the SEAC conclusion(s):

SEAC's opinion is based on section 2.3.4 of the Background Document.

SEAC agrees with the Dossier Submitter that the restriction is practicable, considering that alternatives are available for most of the uses and that the shift to alternatives is ongoing in several sectors. SEAC, however, notes that the available alternatives might not be technically feasible to replace the substances containing CA:C14-17 in certain 'heavy-duty' metal working operations.

SEAC also agrees with the Dossier Submitter that the restriction is enforceable, in view of the available detection techniques, ranging from screening analytical techniques to high resolution analytical methods. SEAC also agrees that reference standard samples for the analysis of chloroalkanes are more and more available and the specificity of each is well established despite the presence of different degrees of chlorination and interferences, ensuring a high level of confidence when performing analytical assessment. This specificity and technical adaptation in preparation and analysis of samples is particularly important for segregation and separation of different congeners during analysis allowing the precise and accurate analysis of complex samples and ensuring the enforceability of the restriction. The Dossier Submitter recognises that analysing and differentiating chloroalkane congeners can be challenging. However, the analytical methodology and technical equipment are reported to have made significant progress over recent years to overcome the majority of the issues encountered in the past.

The advanced techniques enabling a sufficient selectivity in the identification and quantification of groups of congeners having the same carbon chain length and chlorination level (i.e. CA:C14-17) are emerging and are nowadays available to detect and quantify CA:C14-17.

These techniques often combine enhanced chromatographic separation and high mass resolution, minimising interferences between chloroalkane congeners and other organo-halogen compounds.

SEAC notes that findings from a survey of EU enforcement laboratories, conducted by the Dossier Submitter, indicate that many laboratories have screening analytical methods in place and advanced detection methods and instruments allowing the detection and differentiation of chloroalkane congeners.

Moreover, standardised laboratory methods for measuring other types of chlorinated alkanes, such as short chain chloroalkanes (e.g. 287-476-5), have been developed or are in development in response to the POP restriction on short chain chlorinated paraffins.

SEAC notes that the Forum's draft advice²⁴ on enforceability confirms the fact that the restriction (both options A and B) is practicable and enforceable considering the variety of analytical techniques currently available and the ongoing development of new ones.

SEAC also notes that document-based inspection could be performed independently or in parallel or in complement to a laboratory testing inspection.

²⁴ The final Forum advice is not available at the time of agreement on the SEAC draft opinion.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

With regard to the paragraph 7 under restriction option A and B, SEAC notes that RAC supports the information requirements for suppliers 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. SEAC agrees with RAC's opinion, also in view that the classification as PBT and/or vPvB applies only if the concentration is above 0.1 %. Moreover, SEAC considers that a condition where no limit is defined, would be difficult to apply, notably when considering complex articles. However, SEAC considers that the requirements set under paragraph 7 (if a limit concentration is set to be equal to or greater than 0.1% w/w) could play an important role during the transition period in promoting communication across the relevant supply chains.

SEAC also agrees with the Dossier Submitter that information on the chlorination level in a substance is not relevant when it comes to the presence of CA:C14-17 in mixtures and articles. Therefore, SEAC considers that Dossier Submitter's approach - targeting the congeners of concern - is more effective, enforceable, and monitorable.

Finally, SEAC also concurs with the Dossier Submitter that authorities have at their disposal several tools (comprising classical inspections and analyses performed by authorities) to ensure the enforceability of the two proposed restrictions (A and B).

3.4.5. Monitorability

Summary of Dossier Submitter's assessment:

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

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:

- By checking substances' compositions in the registration dossiers;
- 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):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

SEAC conclusion(s):

SEAC concurs with the Dossier Submitter that the effectiveness of the restriction can be considered monitorable and that different tools are available, such as monitoring of the registration dossiers, market surveys and EU or national monitoring campaigns. SEAC agrees with the Dossier Submitter's observations that some difficulties may sometimes arise in laboratories' testing of chloroalkane congeners that need a proper up-to-date separative procedure and detection techniques to ensure an efficient and accurate identification of congeners.

Key elements underpinning the SEAC conclusion(s):

SEAC's opinion is based on section 2.3.4.3 of the Background Document.

SEAC concurs with the Dossier Submitter that the proposed Annex XVII entries Option A and B are considered monitorable.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

SEAC agrees with the Dossier Submitter that the effectiveness of the proposed restriction could indeed be monitored:

- By checking substances' compositions in the registration dossiers
- checking of the registration dossiers for some of the substances containing CA:C1417
- 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.
- Identification of possible CA:C14-17 constituent by EC or CAS number to facilitate identification of individual substance by industry or enforcers.

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

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

SEAC conclusion(s):

SEAC concludes that the suggested restriction options (both A and B) are the most appropriate EU risk management measures to address the releases of CA:C14-17 with PBT and/or vPvB properties, at an acceptable cost for the society.

In line with RAC's assessment, SEAC also notes that both the proposed restriction options will lead to a substantial reduction in emissions of CA:C14-17 with PBT and/or vPvB properties, within a reasonable period of time.

However – based on socio-economic considerations – SEAC's view is that the option B is the preferred one, as it includes a longer transition period for the metal working fluids, where the substitution of substances containing of CA:C14-17 with PBT and/or vPvB properties appears to be technically challenging and substitution cannot be expected to occur within the two-year transition period.

Key elements underpinning the SEAC conclusion(s):

SEAC's opinion is based on section 2.3, 2.3.4, 2.3.4.3 and 2.4 of the Background Document and Appendix E.

SEAC concurs with the Dossier Submitter that both the restriction options can be considered proportionate.

While SEAC recognises the advice from RAC that Option A is the most efficient measure to reduce emissions, it does however note that in terms of total avoided releases there is no significant difference between A and B (as the release reduction compared to the baseline is ~90% and ~ 89-90% under A and B respectively).

SEAC's view is that the restriction option B with a transition period of 7 years is the preferred option, as it takes into account that alternatives may not be readily available for all extreme pressure metal working fluid applications, and so recognises that for this use a transition period longer than 2 years is needed.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

SEAC also notes that the overall costs of restriction option B are €0.8 billion less compared to option A. And this is without considering possible economic impacts on the downstream sectors (automotive, aerospace, etc) relying on metal parts formed with the use of the metal working fluids being affected by this restriction. These impacts were only described qualitatively by the Dossier Submitter.

SEAC however acknowledges that RAC does not support any derogation for metal working fluids, considering emissions from these dispersive uses and the lack of information on RMMs and OCs to determine if releases are minimised or could be minimised.

SEAC also takes note that several respondents that have contributed to the third party consultation requested a transition period longer than 7 years. However, SEAC's view is that these requests were not sufficiently substantiated.

SEAC notes that a ban on manufacturing, formulation and production of articles could have been proposed under option B to further reduce the releases in the EU, in line with the overall restriction proposal's goal to minimise emissions of PBT and vPvB substances, which are transported at a transboundary scale. SEAC therefore considers that a ban on manufacturing, formulation and production of articles under option B should be introduced once the transition period for the metal working fluids ends, to further minimise the releases of CA:C14-17 with PBT and/or vPvB properties. SEAC also notes that – as assessed by the Dossier Submitter – a ban on manufacturing of substances would lead to marginal economic impacts (of approximately €300 000 euro per year, equivalent to approximately €4 M over 20 years).

SEAC also concurs with the Dossier Submitter that the two restriction options are implementable, enforceable, and monitorable in the EU, through different tools also in view of the communication obligations along the supply chain (RO5), included in both A and B options.

SEAC also concludes that alternatives to substances containing CA:C14-17 are available, technically and economically feasible for most of the uses. Other regulatory and voluntary measures are not considered effective enough to reach the goal of this restriction proposal.

3.5. SUMMARY OF 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, among the uncertainty relevant for the risk assessment, the Dossier Submitter

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

indicates that even though MSC was lacking data to assess the hazards of all CA:C14-17 congeners against the vPvB/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 because they may pose an intrinsic hazard similar to PBT and/or vPvB due to their structural similarities.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

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 versus 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):

SEAC agrees with the Dossier Submitter that the following are the most relevant sources of uncertainties of the proposed restriction:

- Number of substances, mixtures or articles covered by the restriction proposal and the related release estimates;
- Uncertainty related to the proportion of CA:C14-17 in the Chloroalkanes other than the one listed in the Candidate List.
- Real volumes of mixture and articles imported containing CA:C14-17 present in the EU;
- Uncertainties regarding the biodegradation of the substance and repartition between landfill and incineration.
- Impacts on the cost-effectiveness ratios when upper or lower estimates of avoided releases are considered.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

- Lack of information to quantify potential impacts of the restriction options (RO1, RO3 and RO4a) on some downstream sectors in the supply chain (e.g. the automotive, aerospace, and other sectors relying on the use of metal parts resulting from processes where substances containing CA:C14-17 are used);
- Lack of information to distinguish between small, medium, or large companies (this could conceal some distributional consequences within the EU and between uses).
- The implications for the cost effectiveness ratios when using 0% discount rate versus of the 3% discount rate.

Overall, SEAC considers that, the above uncertainties would have only marginal implications on SEAC assessment of costs and benefits.

The sensitivity analysis performed by the Dossier Submitter in Appendix F showed that none of the identified individual uncertainties have a significant effect on the cost effectiveness of the restriction options.

SEAC concurs with the Dossier Submitter that the level of such uncertainties is not of such a magnitude that they would affect SEAC's conclusions on the proposed restriction.

SEAC also considers that there are some additional uncertainties on costs and benefits in the baseline scenario (not directly related to this restriction proposal), which however were not evaluated by SEAC as they directly relate to general waste management and disposal practices.

Key elements underpinning the SEAC conclusion(s):

SEAC's opinion is based on section 3 of the Background Document and Appendix F.

The different uncertainties identified in the Annex XV report may influence the SEA conclusions.

The following are considered as the most relevant by SEAC:

1. Uncertainty on the list of substances potentially affected by the restriction proposal

The list of substances potentially affected by the restriction proposal is non-exhaustive and depends on the quality and specifications of the feedstock or on the manufacturing circumstances, meaning that the presence and concentration of CA:C14-17 with PBT and/or vPvB properties is specific to each supplier/manufacturer of the substances.

This may affect the baseline and release calculations, which are based on tonnage information for this list of substances (and therefore the cost effectiveness ratio). Secondly, this uncertainty may affect the availability of alternatives and the associated substitution costs especially for substances where CA:C14-17 are estimated as being a suitable alternative (< 0.1% of PBT, vPvB).

As the baseline and release estimates calculations are essentially driven by EC 287-477-0 (Alkanes, C14-17, chloro) tonnages, this uncertainty is estimated as being of low concern.

SEAC concurs with the Dossier Submitter that this uncertainty has a marginal effect based on the actual set of data but identification of new substance, mixture or product containing CA:C14-17 with PBT vPvB properties > 0.1% is possible and will possibly modify the estimation and reduce the global cost-effectiveness of the restriction proposal.

2. Potential underestimation of the tonnages released to the environment and uncertainty related to imported mixtures and articles

Related to the previous uncertainty, the increase in the list of substance covered by the

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

restriction proposal could automatically lead to an underestimation of the amount of CA: C14-17 available in the market and subjected to potential environmental release.

SEAC acknowledges the pragmatic approach taken by the Dossier Submitter and concludes that this uncertainty would probably not lead to substantial change in the release estimates.

In addition to the underestimation linked to the list of substance covered by the restriction proposal, the registered tonnages considered for the baseline calculation are high considering that substitution may be already ongoing following the SVHC identification of some chloroalkanes (not observed yet in tonnage used).

There is no precise information or data on the tonnages of CA: C14-17 in imported mixtures and articles. The Dossier Submitter highlighted that Asia is the main producer and consumer of substances containing CA: C14-17 and considering that Europe is a key importer of articles and mixtures produced in Asia, potential releases may be higher than estimated by the Dossier Submitter.

3. No information is available to quantify the potential impacts of the restriction options on specific industry sectors

The Dossier Submitter attempted to gather data for estimating the impact on downstream specific sectors, but no substantiated information was provided.

Considering the above uncertainties, the Dossier Submitter performed a sensitivity analysis considering:

- the upper estimates in terms of avoided releases
- lower estimates in terms of avoided releases
- the impacts of non-discounting the avoided releases and
- the potential additional costs under the assumption that the leather sector is impacted by the restriction.

The cost effectiveness ratios of each RO were recalculated to test their sensitivity to the above parameters. The remaining sources of analysis were described in a qualitative manner in Appendix F.

SEAC agrees with the Dossier Submitter that testing for the above parameters has only a minor impact on the C/E ratio (<10 % compared to the values used in the restriction proposal). The highest variation is observed with the use of non-discounted value for releases, leading to the restriction becoming 25% more cost effective, but this effectiveness is solely computational.

Regarding the leather sector, SEAC notes that the Dossier Submitter's impact assessment in the Background Document is based on the assumption that none of the restriction options are expected to affect the leather sector and that companies operating in this sector will keep using the two substances ('Paraffin waxes and Hydrocarbon waxes, chloro, sulfochlorinated, saponified' and 'Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified') with concentration of CA: C14-17 with PBT and/or vPvB properties below 0.1 % in the production of fatliquors. The Dossier Submitter assumes that companies that might be using the two substances with PBT and/or vPvB properties above 0.1 %, will shift to those where the concentration is below the critical threshold.

SEAC agrees with the Dossier Submitter that – given the uncertainties on the exact content of CA: C14-C17 with PBT and/or vPvB properties in the two substances - it cannot be concluded with certainty that this sector will not be affected by the restriction and so agrees with the Dossier Submitter's methodological choice to assess the economic impacts on this sector, as part of the sensitivity analysis.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CHLOROALKANES C14-C17

The inclusion of the leather sector also provides a minimal impact on the total C/E ratio, with a < 10% variation.

Overall, the Dossier Submitter estimates that when considering different assumptions the cost-effectiveness ratios remain within the same range – 50-72 €/kg – indicating that none of the changes in the considered parameters have a substantial impact on the overall conclusions on proportionality of the consideration restriction options.

SEAC concurs that no major impacts on employment are expected but uncertainties remain regarding some effects that can occur down the supply chain for the sector depending on the use of the metalworking fluids covered by the scope of the restriction such as automotive and aerospace sector.

Finally, SEAC reflected on the possible socio-economic implications of adding “other vP”²⁵ congeners in the scope of the restriction proposal and concluded that it is unlikely that this addition would have any socio-economic impact, on the basis that these congeners are likely to be present together with CA:C14-C17 with PBT and/or vPvB properties²⁶, which are already targeted by this restriction.

SEAC however notes that there is no certainty on whether substances could be produced only with “other vP” congeners and whether these could be considered as alternatives to substances containing CA:C14-C17 with PBT and/or vPvB properties in a concentration above 0.1 % or used in other uses which are not discussed in the restriction proposal. SEAC however concludes that this uncertainty does not affect SEAC’s overall conclusions on the restriction options proposed by the Dossier Submitter.

Overall SEAC notes that the methodologies used by the Dossier Submitter are in line with the relevant guidance and that thorough sensitivity analysis was performed by the Dossier Submitter to test the identified sources of uncertainties.

²⁵ ‘Other vP’ congeners are discussed by the Dossier Submitter in the Annex to the Background Document and in the RAC opinion (mainly section 3.1.2, 3.1.3 and 3.4.2)

²⁶ Please see also section 3.1.3 of the RAC opinion.