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

Non-confidential

ECHA/RAC/RES-O-0000006790-71-01/F

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

Substance name	EC number	CAS number
Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17	-	-

9 June 2023

1. General comments and answers to specific information requests

1.1. Specific information requests

In addition to providing an opportunity for interested parties to submit general comments on the proposed restriction, the Dossier Submitter and RAC/SEAC Rapporteurs posed a series of specific information requests as part of the consultation. These requests were, as follows:

1. **Uses:**

The Dossier Submitter identified several uncertainties regarding the use (incl. tonnages) of substances potentially containing CA:C14-17. Because the current restriction proposal is based on the presence of CA:C14-17 and covers intended and unintended uses, the stakeholders are asked to provide additional information on:

a. possible intended uses (incl. tonnages) not mentioned in the restriction proposal and,

b. any unintended presence of CA:C14-17 in other substances not mentioned in the restriction proposal.

Please provide detailed information only on the additional uses that may be affected by the restriction proposal that are not mentioned in the restriction proposal, including information on the availability of alternatives for these uses, and on the socio-economic impacts of the proposed restriction. Please support your statements, and information, with quantified estimations and calculations.

2. **Manufacturing:**

The Dossier Submitter describes that the presence of CA:C14-17 in chloroalkanes depends on the carbon chain distribution of the starting material, and in particular on the quality and specification of the feedstock used. In addition, other process circumstances such as cross-contamination from one manufactured batch to another may also affect the presence of CA:C14-17. Therefore, stakeholders are requested to provide any additional information on the possible unintended presence of CA:C14-17 in substances, mixtures and articles taking into account the above, specifically the cross-contamination possibility, and measures that can or are implemented to limit it.

3. **Economic impact:**

Do you agree with the Dossier Submitter's assumptions and estimates of economic impacts per use in Section 2.3 of the Annex XV restriction proposal? If not, please provide well motivated additional information, arguments, or data. In particular:

a. Do you agree with the assumptions and calculations underpinning economic impacts for the PVC sector?

b. Do you agree with the assumptions and calculations underpinning economic impacts for the sealant sector?

4. **Metal working fluids:**

Based on the information gathered through the calls for evidence and a sector specific survey, the Dossier Submitter notes that some *'heavy duty'* metalworking processes such as '*deep drawing*', '*broaching*' and '*fine blanking'* appear to be the metalworking processes where the substitution of substances containing CA:C14-17 seems challenging. The Dossier Submitter also notes that the concentration of substances containing CA:C14-17 in the metalworking fluids used in these processes is in general high, e.g. >40-50%.

The Dossier Submitter however recognises that the derogation/7-year transition period for metalworking fluids, as currently proposed in the Annex XV, is not specific enough to set clear boundaries for this derogation (cf. Annex XV proposal Section 2.5.3 – Wording of paragraph 8). The Dossier Submitter may therefore consider removing this derogation/transition period unless sufficient and substantiated information – on the affected processes, respective metalworking fluids and socio-economic impacts - is received during the Annex XV consultation.

In case you consider that a derogation/transition period is justified for a specific metalworking fluid, please provide the information requested in the table below as well as provide an analysis of the expected socio-economic impacts that you would expect in the event of derogation/transition period not being granted. In the event that you consider that a transition period should be granted for the metalworking fluids, please justify what length would be necessary (e.g. 7-year, shorter or longer) to avoid disproportionate impact and provide the underlying justifications.

Please note that the information you provide needs to be sufficiently detailed and exhaustive so to allow an unambiguous identification of the affected processes and the related metalworking fluids.

Note that if metalworking fluids with lower concentration of substances containing CA:C14-17 (e.g. <40%) might still be used for less severe applications, where you consider that substitution by other technologies is possible, these products and the related metal forming processes are not relevant for this question.

Name of the metal working process where CA:C14-17 substitution is challenging	
Please provide a commonly agreed description or definition of this metal working process	
Please indicate for which metal (worked with this process) the substitution is challenging, e.g.: -carbon steel -stainless steel -aluminium -nickel alloy -titanium -titanium alloys -all metals	

-other (indicate which one)	
Please provide a description of the metal working fluid containing CA:C14-17 used for this process, e.g.: -fluid type (e.g. straight oils, soluble oils, semi-synthetic fluids, synthetic fluids) -concentration of substances containing CA:C14-17 -weblinks for the relevant products (if available)	
Please describe the downstream industry and specific article using this process/metal (e.g.: automotive industry to produce X, Y, Z)	
Other process information (if relevant): -pressure -temperature -machining speed -surface requirements -material thickness -other (indicate which one)	
Technical explanation on why the substitution of CA:C14-17 is challenging in the specific process/ metal	
Time needed for substituting CA:C14-17 and justification (impact in case shorter/longer transition period)	
Description of operational conditions and risk management measures implemented to minimise releases to the environment	
Quantitative information (e.g. measurements) on releases to the environment	
Any other relevant information that should be considered	

5. Leather fatliquor:

The Dossier Submitter assessed the economic impacts for the leather sector (producers of fatliquors) under two scenarios: a) the sector **IS NOT** affected by the restriction proposal because the sector is already using, or can shift within the transition period to substances containing CA:C14-17 with PBT and/or vPvB properties in concentration below 0.1 %, and b) the sector **IS** affected (i.e. in the scope of the restriction proposal).

The impacts under both scenarios have been described by the Dossier Submitter, as well as the assumptions and sources underpinning the analysis (cf. section 2.2.2.6 and 2.3.1.6 in the Restriction proposal and Appendix F.2.2.). Please provide a justification supporting your view as to which scenario is most plausible and indicate whether you agree with the economic assessment performed by the Dossier Submitter.

1.2. Overview of the comments received

46 comments were submitted during the Annex XV restriction report consultation. Figure 1 and Figure 2 give an overview of the comments received.

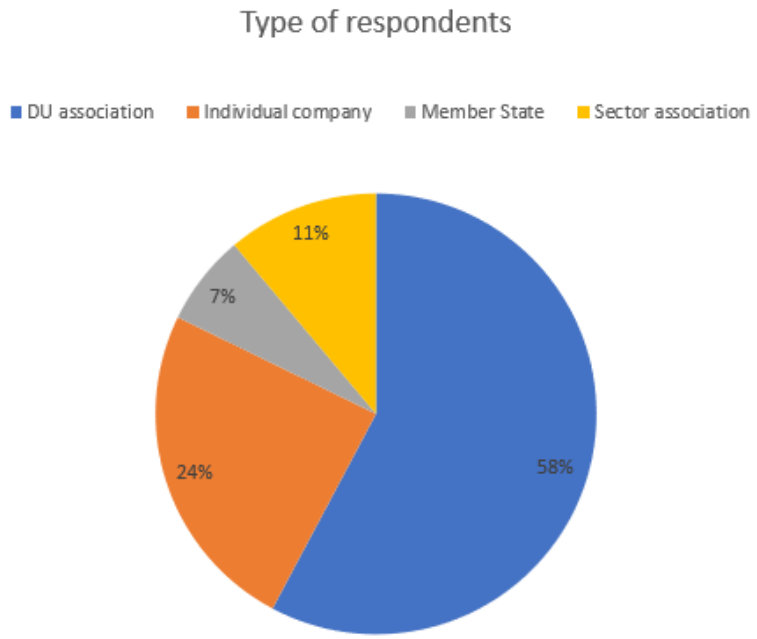

Figure 1:Type of respondents

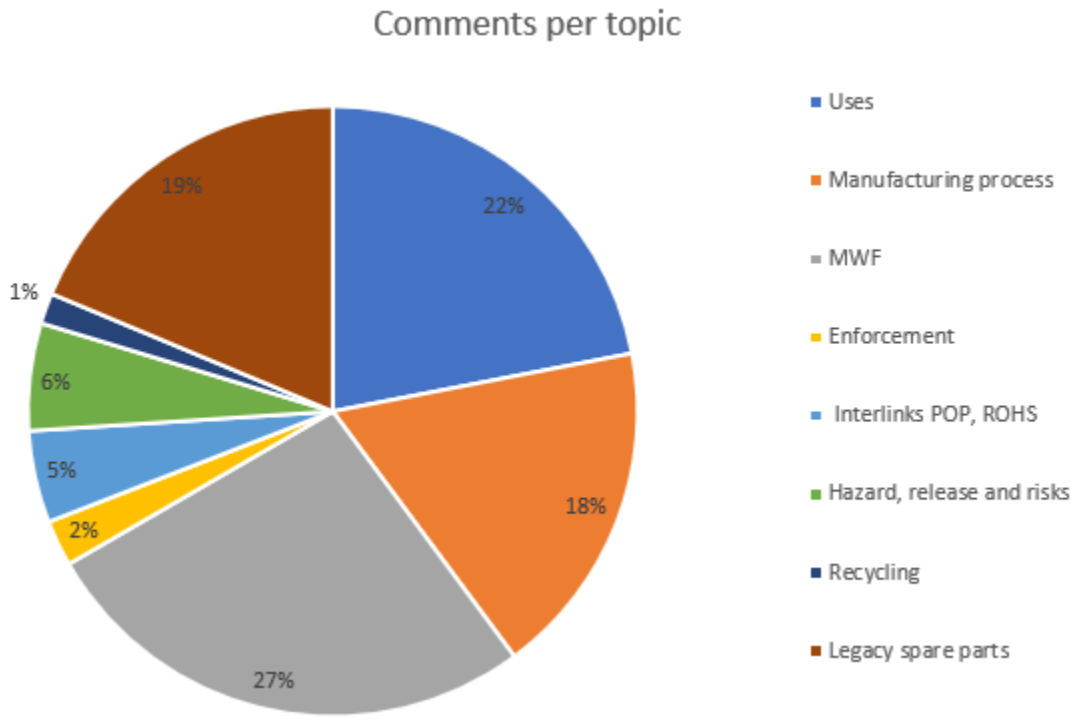

Figure 2: Type of comments received

2. Response to comments

The Dossier Submitter would like to thank the many interested parties that submitted comments and information to the Annex XV report consultation.

The Dossier Submitter notes that many of the comments received were similar in nature and concerned a limited number of common themes. Given the large number of comments received, and to improve the clarity of the Dossier Submitter's responses to them, the Dossier Submitter has prepared a set of general responses to common themes. These general responses summarise the nature of the comments received and how the Dossier Submitter has responded to them, typically by undertaking revisions to the Background Document. These general responses should be read alongside responses to specific comments below.

In some cases the Dossier Submitter has responded to comments by revising the wording of the 'conditions of the restriction'. Respondents should note that the wording of the conditions of the restriction in the Background Document is intended to express the intention of the Dossier Submitter. The European Commission would ultimately decide on the precise legal wording used to update REACH Annex XVII in the event that a restriction was adopted.

The comments received have been grouped into the following topics:

- Hazards, exposure and risks assessment
- Manufacturing process
- Uses and presence of CA:C14-17 in mixtures and articles
- Metalworking fluids (MWF)
- Socio-economic considerations for uses other than metalworking fluids
- Implementation and enforcement, including availability of analytical methods
- Interlink with other regulatory processes (e.g. POP and RoHS)

2.1. Hazards, exposure and risks assessment

2.1.1. Dossier Submitter response to comments

Some comments on the hazards, exposure and risks assessment were submitted by stakeholders. These include for example comments #3641, #3739, #3827, #3830, #3847, #3848.

2.1.1.1. PBT, vPvB properties and environmental releases

The Dossier Submitter takes note of the comments #3827 and #3847, on the persistence, bioaccumulation, and biodegradation of EC 287-477-0 and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17.

In response to these comments, the Dossier Submitter remarks that the PBT/vPvB status of MCCP and MCCP congeners was concluded by the ECHA Member State Committee (MSC) and is not under consideration during the opinion-making process for this restriction. In its assessment, the ECHA Member State Committee concluded that some *"congener groups of 'MCCP' have PBT and/or vPvB properties in accordance with the provisions of Annex XIII to the REACH Regulation"*, and that "substances other than 'MCCP' may contain these congener groups with PBT/PvB".

In addition, PBT/vPvB substances under REACH are non-threshold substances for which releases to all compartments shall be minimised. Indeed, according to REACH Guidance R11, the properties of PBT/vPvB substances lead to an increased uncertainty in the estimation of risk to human health and the environment when applying 'conventional' quantitative risk assessment methodologies e.g. by derivation of risk characterisation ratios (PEC-PNEC comparison). For PBT and vPvB substances a 'safe' concentration in the environment cannot be established using the methods currently available with sufficient reliability for an acceptable risk to be determined in a quantitative way.

Emissions and subsequent exposure, in the case of a PBT/vPvB substance, are therefore considered as a proxy for risk.

With regard to the comments on releases, the Dossier Submitter acknowledges the comments received on the release factor for PVC (#3748), and notes that the annual release factor of 8.03E-02 % (2.2E-04 %/day – 365 days) mentioned in the recent study from Haoran and al (in table S5 of the Background Document) is applicable to 'regular use of the cable' and not to recycling activities which implies shredding (and more dust generation to air). This release factor of 8.03E-02 % for 'regular use of the cable' is in fact within the same order of magnitude as the release factor of 5.00E—02 % (ERC-10a and 11a) considered by the Dossier Submitter for the service life of plastic articles (including cables).

Comments were also provided on the release estimates for waste life cycle stage (#3739, #3847, #3848). The releases were estimated based on information collected on the fate of the waste per use type, fraction of the tonnage going to each waste stream, and default release factors based on the available guidance. The Dossier Submitter takes note of the request for a 'robust revaluation' but also notes that no new information was provided in the comment #3739 for that purpose.

A respondent (#3847) provided the results of an OECD314B study on 'MCCP at 52% Cl

(wt). The results of this study were already provided during the dossier preparation (second call for evidence), and were not considered to be reliable by the Dossier Submitter (cf. Appendix F to the Background Document for more details). However, the Dossier Submitter used the outcome of this study in the sensitivity analysis to estimate an alternative input value for biodegradation that may occur in sewage treatment plants and what could be the consequences of such high degradation for release estimation.

Regarding the estimation of the emissions to air in the 'shredding' scenario (W1), the Dossier Submitter notes that the comments provided (#3739, and #3748) do not include any evidence supporting a lower release factor to air. For example, the release factor reported in the comment #3748 correspond to 'regular usage of material' (cf. Haoran and al study). It is expected that tearing down buildings is conducted at large scale in the open air with no risk management measures, producing a lot of dust, and that any adhesives/sealants attached to the building materials (minerals, wood etc) will therefore be released at the same time.

Regarding the emissions to soil in the 'landfill' scenario (W2), the Dossier Submitter took into account the source of information underlying the release factor to soil as indicated in the R.18 guidance, i.e. the default release factor of ERC 10a. The release factor to soil of ERC 10a (updated 2016) is 3.2%. Assuming 50% efficiency of risk management measures in landfills (by analogy with the release factor to water), the Dossier Submitter estimated a release factor to soil of 1.6%. The Dossier Submitter notes that the comment does not provide any evidence supporting a lower release factor to soil. The Background Document also highlights that the scenario W2 is meant to include backfilling as well (where no risk management measures are expected to be implemented), and that the estimated releases of W2 are likely to be underestimated because releases during the afterlife of landfills cannot be quantified.

The Dossier Submitter takes note of the explanations from the respondent that CA:C14-17 remain embedded within formulated polymers or in buildings for decades, but considers that a longer service life duration can rather postpone the releases during the waste stage to a later time, but does not mean that such releases do not occur.

A comment was made on the tonnages used as input in the release calculation and concern over double counting. Firstly, the Dossier Submitter has considered the tonnage of other substances, and not only substance EC 287-477-0, in the restriction proposal. Secondly, it is not relevant to add up the tonnages for W1 to the tonnages for W2 and W3. As explained in the Background Document, W1 occurs before W2 and W3 in the sequence of events leading to landfilling or incinerating waste (the same waste can undergo first shredding and then shredded pieces are landfilled or incinerated).

For the reasons mentioned above, the Dossier Submitter did not update the Background Document.

2.1.1.2. Other concerns

Two respondents (#3641, #3827) provided also information on potential adverse effects on health of EC 287-477-0. One respondent indicates that the potential human toxicity to workers, and consumers is not relevant, while the other respondent indicates that the Dossier Submitter should have considered the toxicity for workers in particular the ones handling metalworking fluids .

First, the Dossier Submitter would like to highlight that the risks for human health (e.g. due to occupational exposure) are not targeted with the restriction proposal, which focuses on PBT/vPvB properties.

With regard to comment (#3641) which was pointing out potential risks for workers handling metalworking fluids, the Dossier Submitter took note of the RMOA prepared by Germany for substance EC 287-477-0 (in 2020) when developing the restriction dossier but did not propose to set a maximal concentration limit of 3% of CA:C14-17 in oil-based metalworking fluids, in case a derogation/transition period for this application would be granted.

The Dossier Submitter noted that the RMOA conclusion indicates that the potential risk for workers would first require confirmation via generation of additional data on toxicity to reproduction and mutagenicity (standard data are missing in the registration dossier) to substantiate a restriction on the basis of risks for workers. It is also uncertain whether this RMOA assessment would apply to the other substances in the scope of the restriction proposal, i.e. the other substances containing CA:C14-17.

Furthermore, the Dossier Submitter notes that setting a concentration limit of 3% would actually equal to an indirect ban, because the technical functionality for extreme pressure additive (subject to the derogation/transition period) requires higher concentration, even up to 70%.

The Dossier Submitter also takes note of the comment #3830 which indicate an additional benefit (in term of CO2 reduction) of the manufacturing of EC 287-477-0 when considering a life cycle assessment approach.

For the reasons mentioned above, the Dossier Submitter did not update the Background Document.

2.1.2. RAC Rapporteurs comments

Overall, RAC agrees with the Dossier Submitter's responses.

RAC acknowledges the comments provided on the release estimates for waste life cycle stage and on the potential risks for workers handling metalworking fluids in the opinion but notes that the information did not warrant a re-evaluation by RAC.

2.1.3. SEAC Rapporteurs comments

SEAC rapporteurs acknowledge answers provided by Dossier Submitter to public comment and has nothing specific to add.

2.2. Manufacturing process

2.2.1. Dossier Submitter response to comments

Stakeholders were requested to respond to the specific question (Q2) on the manufacturing process, and in particular on the potential presence of CA:C14-17 in other substances (chloroalkanes).

With regard to the potential presence of CA:C14-17 in other substances (chloroalkanes), one respondent (#3824) indicated that cross-contamination during the manufacturing of

chloroalkanes is unlikely (without providing further details).

In addition, the Chloro Alkane Sector Group and MCCP REACH Consortium also confirmed in comment #3847 that the manufacturers of chloroalkanes do not intentionally make specific congener groups rather they chlorinate a paraffin feedstock of specific chain length.

The comments received (e.g. #3638, #3640, #3642, #3645, #3824, #3838, #3839, #3841, #3846) confirmed the Dossier Submitter assumptions that chloroalkanes, and EC 264-150-0 (chlorinated paraffin with chain length above C18) in particular may contain CA:C14-17 due to the starting material being a mixture of straight chains alkanes. Some respondents (e.g. #3827) indicated that chloroalkanes, other than EC 287-477-0, manufactured outside Europe are more likely to contain CA:C14-17 because the starting alkane feedstock has a broad carbon chain length distribution, often starting from the C10 fraction upwards.

Several comments, essentially submitted by automotive associations (e.g. #3638, #3639, #3640, #3642, #3645, #3646, #3743, #3841) pointed out in particular that for metalworking fluids application the target substitute for EC 287-477-0 is the long chain chlorinated paraffins LCCP (EC 264-150-0), and that the concentration limit of 0.1% for CA:C14-17 raises some concern on the possibility to use LCCP as alternative. Respondents indicate that a concentration limit of 0.1% is too low and request the concentration limit in the restriction proposal to be increased to between 1 and 2.5%.

The Dossier Submitter notes that in the comments it is not explained in detail why the concentration limit of 0.1% for CA:C14-17 in EC 264-150-0 is challenging for the metalworking sector. But, considering that the presence of CA:C14-17 in EC 264-150-0 is referred to as by-products or impurities, the Dossier Submitter assumes that the presence of CA:C14-17 in EC 264-150-0 is not intentional or needed for the technical function of LCCP in metalworking fluids. The Dossier Submitter assumes that the issue raised is related to technical challenges in producing EC 264-150-0 with only up to 0.1% of CA:C14-17 in its composition.

However, in a comment provided by the 'Chloro Alkane Sector Group and MCCP and LCCP REACH consortia' (#3739) – as also reported in section 2.4.1.2 - it is mentioned that there are no longer EC 264-150-0 substances on the EU market containing CA:C14-17 above 0.1% and that EC 264-150-0 (C18-20) containing CA:C14-17 in a concentration equal or above 0.1% have been removed voluntarily from the European market by the manufacturers of this consortium.

In addition, one of the respondents (# 3644) indicated that his supplier of EC 264-150-0 states that there is no EC 287-477-0 present in EC 264-150-0.

Based on these comments, the Dossier Submitter concludes – as also indicated in the Background Document - that the manufacturing of EC 264-150-0 with CA:C14-17 up to 0.1% is attainable.

To justify the 1% requested limit, the respondents also made an analogy to the 1% concentration limit for short chain chlorinated paraffins (SCCP) under the Stockholm Convention on persistent organic pollutants (POPs).

Regarding the analogy to the concentration limit defined for SCCP under POPs, the Dossier

Submitter notes that a different approach had been used at that time to set the limit compared to the current regulatory threshold for PBT/vPvB substances. Also no reason was provided in the comments justifying an alignment of the concentration limit between SCCP and substances containing CA:C14-17.

The Dossier Submitter would like to stress that the proposed 0.1 % limit is consistent with the conclusions of the Member State Committee on the SVHC identification of 'MCCP', which stated that substances containing CA:C14-17 could be considered to meet the REACH Annex XIII criteria for a PBT or vPvB substance if CA:C14-17 with PBT and/or vPvB properties are present in a concentration ≥ 0.1 % (w/w). It is also consistent with the ECHA PBT guidance (section R.11.4.1), which states that if registered substance contains constituents (in this case congeners) meeting the PBT and/or vPvB criteria in concentration above 0.1 % (w/w), then the relevant compositions meet the PBT and vPvB criteria .

For the reasons mentioned above, the Dossier Submitter did not update the proposed restriction entry in the Background Document.

However, to simulate the consequences of establishing a higher concentration limit, the Dossier Submitter calculated also the releases by considering a concentration limit of 1% of CA:C14-17 in EC 264-150-0. Assuming no change in the tonnage of EC 264-150-0 placed on the EU market, the difference is estimated to be an additional release of 115 to 254 tonnes in total over the next 20 years (see Appendix E.4 in the Background Document). This estimate takes into account only the new assumption that industry of the metalworking fluid sector would replace EC 287-477-0 with EC 264-150-0 alternatives containing ≤ 1% CA:C14-17.

In terms of economic impacts, this scenario would imply lower substitution costs for the metal working fluid sector, because the sector would have the possibility to shift to EC 264-150-0 with a concentration limit of ≤ 1 % (which is much cheaper compared to other alternatives, which appear to be up to 7 times more expensive). Specifically, the total substitution costs would be in the range of €97 million, so approximately €100 million less over 20 years compared to the costs estimated under RO4b.

2.2.2. RAC Rapporteurs comments

Overall, RAC agrees with the Dossier Submitter's responses.

RAC notes that several stakeholders requested the concentration limit to be increased. RAC however agrees with the response and the arguments provided by the Dossier Submitter and therefore considers that the concentration limit should be kept at 0.1%.

2.2.3. SEAC Rapporteurs comments

SEAC rapporteurs are grateful for the comments providing additional information on the manufacturing of chloroalkanes and possible unintended presence of CA:C14-17 in substances, mixtures and articles.

SEAC takes note that several respondents asked for a higher concentration limit (1%) but agrees with the arguments provide by the Dossier Submitter on why the concentration limit should be kept to 0.1%. Among other elements, SEAC notes that:

- 0.1 % limit is consistent with the conclusions of the Member State Committee on

the SVHC identification of 'MCCP',
- an increase in the limit concentration would lead to an important increase in the emissions,
- EC 264-150-0 (C18-20) containing CA:C14-17 in a concentration equal or above 0.1% are no longer placed on the EU market,
- respondents requesting for a concentration limit of 1% did not provide justifications on why 0.1% is difficult to achieve.

Therefore, SEAC rapporteurs have not identified a reason to update the opinion.

2.3. Presence of CA:C14-17 in mixtures and articles

2.3.1. Dossier Submitter response to comments

Stakeholders were requested to respond to the specific question (Q1) on uses, and in particular on the intended uses and intended/unintended presence of CA:C14-17 in mixtures and articles.

2.3.1.1. Presence of CA:C14-17 in mixtures and articles

The Dossier Submitter would like to thank the respondents for confirming in the submitted comments the presence of CA:C14-17 in mixtures and articles identified in the Annex XV Restriction proposal and its Appendix (e.g. #3641, #3739, #3816, #3817, #3827, #3832, #3833 #3840, #3846).

Norway (#3832) provided a link to a recent study where presence of CA:C14-17 was detected in various home furniture in concentration ranging from 0.08 to 9.85 % (w/w).

Respondents (e.g. #3827), confirmed the presence of CA:C14-17 in blends and PVC granules (considered as mixtures under REACH) produced in China and India and imported in Europe. The respondents indicate that the presence of CA:C14-17 in these mixtures is intentional as chloroalkanes producers outside Europe often use alkane feedstock with a broader carbon chain length (see also section 2.2 on the manufacturing process).

In addition, several comments were received (e.g. #3641, #3739, #3816, #3817), indicating that the Dossier Submitter may have omitted in the Background Document to mention some specific applications or articles containing CA:C14-17. The following examples were provided:

- sporting articles, leisure articles (e.g. gardening, swimming…), rubber track products, rubber toys, rubber flip-flops;
- rubber foam insulation for pipes, sheets and building materials;
- PVC hose and profile.

Respondents (e.g. #3827) also confirmed that CA:C14-17 may be present in articles imported from outside Europe, but there was no additional details on estimated imported quantity, nor estimated concentration of CA:C14-17 in these articles that would have allowed the Dossier Submitter to refine the release estimates from imported articles in the Background Document.

The Dossier Submitter notes that no new information has been identified in the submitted comments and that the information provided corroborates information already collected

by the Dossier Submitter and presented in Appendix A.2.2. (on uses, and presence of CA:C14-17 in mixtures and articles). Therefore, the Dossier Submitter did not update the Background Document, except for the new study referred to in comment #3832.

2.3.1.2. Unintended presence of CA:C14-17 in mixtures and articles

Several respondents (e.g. #3816, 3847 and #3848) indicated the unintended presence of CA:C14-17 in concentrations above 0.1% in (i) PVC recyclates (considered as mixtures under REACH Regulation) from PVC cables recycling for example, and in (ii) PVC articles made of these PVC recyclates (e.g. PVC hose, profile application, road traffic equipment, industrial applications and agriculture such as industrial coils, soft profiles, boots for professionals, etc.).

The respondents raised the concerns that certain PVC recyclers may not be able to meet the 0.1% required limit. They also provided justifications to support the need for a derogation to allow a higher concentration (between 1 and 4%) both in PVC recyclates and PVC articles produced with the PVC recyclates. One respondent (#3848) suggested also to limit such a derogation to specific end-use sectors such as *"industrial or agricultural use, or for use exclusively in the open air"*.

In the Background Document, the Dossier Submitter already acknowledges that a concentration limit below 10% may be difficult to achieve by PVC recyclers (see section 2.2.4), but did not propose to grant any derogation for PVC recyclates or articles made of recycled PVC considering various elements mentioned below.

The Dossier Submitter takes note of the comments received during the Annex XV Restriction consultation, and the elements provided to justify a request for derogation. Nevertheless, the Dossier Submitter would like to stress the following factors that play a role in the assessment of the potential impacts of such a derogation:

1. The benefits of recycling should be weighed against the risks derived from potential emissions of PBT and/or vPvB substances to the environment. The Dossier Submitter notes that most of the articles produced with PVC recyclates are intended for an outdoor use (such as road traffic management and agricultural articles) and pose an uncontrolled risk in terms of emissions of EC 287-477-0 and other substances containing CA:C14-C17 with PBT and/or vPvB properties. One respondent (#3848) cites as an example the restriction on DEHP for which a derogation is granted for articles exclusively for industrial or agricultural use, or for use exclusively in the open air (provided that there is no prolonged contact with human skin). Such a comparison is not relevant as DEHP is restricted due to its reproductive toxicity, while MCCP and other substances containing CA:C14-17 would be restricted because of environmental concerns.

2. In comment #3848, the respondent claims that monetized benefits of recycling are €255 million compared to incineration and €191 million compared to landfilling. In terms of economic impacts, the Dossier Submitter notes that each of the PVC waste treatment routes has its own costs, being recycling, incineration or landfilling. In case the derogation is not granted, the whole quantity of PVC from cable waste is expected to be incinerated or landfilled (meaning that the costs for recycling would be avoided). In case a derogation is granted, a share of PVC from cable waste is expected to be recycled (meaning that all three routes will account for share of the overall waste treatment costs). The Dossier Submitter however notes that the price

of the virgin PVC (which is of higher quality compared to recycled PVC) can be higher and that if a derogation is not granted the whole quantity of recycled PVC containing CA:C14-C17 above 0.1%, will have to be replaced by virgin PVC complying with the restriction conditions. In Dossier Submitter's view this could also translate into a price increase for the affected PVC articles, but the quality of these is expected to improve. For example, one respondent (#3816) indicated that if a derogation is not granted for PVC recyclate, they would have to use virgin PVC for the production of PVC hose and profile applications, with an expected price increase for the affected products in the range of 40%.

3. In terms of social impacts, the Dossier Submitter notes that the comment does not discuss the job losses that would be expected in case the derogation is not granted. The Dossier Submitter 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.

4. From an enforceability perspective, a derogation for PVC recyclates or articles made of PVC recyclates could create a potential loop-hole whereby producers and importers could claim that an article was made from recycled material and benefit from a higher concentration limit. It would be difficult indeed for downstream users and enforcement authorities to judge whether articles contain or are made of recycled or primary materials. Such a system would require the introduction of certification and/or labelling systems to ensure that the substances targeted by the restriction are not present in virgin PVC.

5. Finally, as already indicated in section 2.2.4 of the Background Document, some possibilities could exist to reduce the CA:C14-17 content in recycled PVC through dilution with virgin PVC or other materials (e.g. a filler). However, while economically questionable, and technically allowed, such a dilution would become impossible once the substances would be listed under the POPs Regulation. Indeed, Article 7(3) of the EU Regulation 2019/1021 on persistent organic pollutants prohibits the recycling or reuse of POP substances for substances listed in Annex IV to the POPs Regulation which sets limits for the recycling or re-use.

Considering the elements above, the Dossier Submitter did not update the Background Document. SEAC may still wish to request further information during the consultation of the SEAC draft opinion in order to consider a potential derogation or higher concentration limit for PVC recyclate.

2.3.2. RAC Rapporteurs comments

RAC takes note of the information provided by the respondents on the unintended presence of CA:C14-17 in PVC recyclates in a concentration above 0.1 % and in PVC articles made of these PVC recyclates, but agrees with the Dossier Submitter that the proposed derogation is not justified.

For more specific information please refer to the RAC opinion.

2.3.3. SEAC Rapporteurs comments

SEAC rapporteurs thank the respondents for providing information on some specific applications containing CA:C14-17 such as sport articles, leisure articles, rubber and PVC products.

SEAC also notes that the respondent submitting comment #3848 requested a higher concentration limit for PVC compounds from recycled PVC cables as well as for articles produced with these compounds. The Dossier Submitter did not find the request justified, by citing several relevant factors (including potential emissions from the articles for outdoor use which are produced with recycled PVC, enforceability aspects as well as the POP's Regulation ban to recycle or reuse of POP substances). SEAC concurs with the Dossier Submitter's reasoning and so concludes that the provided arguments in comment #3848 are not sufficient to justify a higher concentration limit.

For more specific information please refer to the SEAC opinion.

2.4. Metalworking fluids (MWF)

2.4.1. Dossier Submitter response to comments

Multiple comments on metalworking fluids and related metalworking operations were submitted by stakeholders in response to the specific information request (Q4). This includes for example comments #3638, #3639, #3640, #3641, #3642, #3643, #3644, #3645, #3646, #3647, #3648, #3649, #3650, #3651, #3657, #3739, #3743, #3804, #3811, #3828, #3829, #3831, #3833, #3837, #3838, #3839, #3840, #3841, #3842, #3842, #3844, #3845, #3846.

Some of the comments have been handled as confidential as per the respondent's request.

2.4.1.1. Identification of affected processes

The Dossier Submitter notes that many comments on the need for a derogation in metalworking fluids were already submitted by stakeholders to the three calls for evidence (organised during the restriction preparation). The same conclusion was also drawn from a sector specific survey that the Dossier Submitter conducted during the preparation of the restriction.

In the specific information request 4, the Dossier Submitter invited the stakeholders to provide an exhaustive list of the metalworking fluid products and processes (as well as materials) where the substitution of substances containing CA:C14-C17 appears to be particularly challenging on technical and/or economic grounds and for which a derogation would be needed. This information is needed to specify the text of the derogation under option B, paragraph 8.

Some of the mentioned processes in the comments are: extreme forming, massive forming, deep drawing, fine blanking, rod, bar and tube drawing, profile drawing (#3841), pilgering, cold heading.

One respondent (#3831) indicated that DIN 8584 is the relevant industry standard for the Deep Drawing process. However for most of the mentioned process the specific industry standard was not provided.

The respondents also indicate that different types of fluids would be affected by the restriction, with straight oils being mentioned with much higher frequency compared to any other type of metal working fluid. The respondents also reported that the maximum concentration of CA:C14-17 is 70%.

With regard to the materials being formed in the above processes, the following were mentioned with highest frequency by the respondents: stainless steel, carbon steel, titanium, copper and copper alloys.

The Dossier Submitter notes that – in line with the information collected from the three Calls for Evidence and the sector specific survey - the comments provided indicate that for a wide range of processes and materials, the substitution appears to be challenging. However, the information provided in the comments does not allow the Dossier Submitter to come up with an exhaustive list of specific processes that should be part of the wording of the text of the derogation under the restriction option B.

The additional information collected during the consultation on Annex XV report, did however confirm that the types of fluids where substitution appears technically challenging are oil-based fluids and that the substances containing CA:C14-17 are used as extreme pressure (EP) additive, as also described in the Background Document.

The Dossier Submitter has therefore refined in the Background Document the wording of the derogation for metal working fluids under restriction option B, only to specify the type of fluids that should be covered by the derogation, namely oil-based metal working fluids as defined under DIN 51385.

SEAC may wish to test the revised wording of the derogation during the 60-day consultation on the SEAC draft opinion.

2.4.1.2. Request for derogation or transition period

Several respondents – mainly trade associations representing non-EU industries - requested a longer transition period for metalworking fluids compared to the 7-year transition period proposed by the Dossier Submitter in the Background Document under the restriction option (RO) B. This request was also made by few European associations representing the automotive, motorcycle, marine and garden industries.

Some respondents requested a 15- year transition period, others 10 years and some a permanent derogation with a review clause, 7 years after the entrance into force.

In some comments, respondents requested a 15-year transition period for the metalworking fluids, deemed necessary to shift to EC 264-150-0 containing CA:C14-17 in a concentration between 1 and 2.5%. In the submitted comments it is also mentioned that if the concentration limit for CA:C14-17 is not changed from 0.1% to up to 2.5% for EC 264-150-0, an indefinite exemption for metalworking fluids would be necessary.

The Dossier Submitter acknowledges that the substitution of substances containing CA:C14-17 with PBT and/or vPvB properties appears to be challenging in several heavy-duty metalworking operations and that a transition period (longer than 2 years) appears to be needed, considering the technical and economic feasibility of the available alternatives as well as possible socio-economic implications of a 2-year transition period.

In the preparation of the restriction proposal the Dossier Submitter conducted a sector

specific survey to collect detailed information on the alternatives in metalworking fluids as well as assess the appropriate transition period for this use.

As reported in the Background Document, several respondents that participated in the survey indicated that a transition period between two and ten years would be needed to substitute the substances containing CA:C14-17 in the remaining metalworking applications. The request for a longer transition period was justified by the uniqueness of the remaining processes (essentially heavy-duty metalworking), and the necessity to test directly substitutes in those workshops where the substances containing CA:C14-17 are currently used.

The Dossier Submitter therefore proposed a 7-year transition period under restriction option B, also noting that a 7-year transition period 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 an SVHC substance.

Based on the respondents' comments, the Dossier Submitter notes that for metalworking fluids (used in heavy-duty metalworking operations), a transition period longer than 7-years might be needed. The Dossier Submitter notes that several respondents requesting this longer transition period stressed that 15 years are needed for implementing all the necessary substitution activities (development of alternative substances, development of alternative metalworking fluid mixtures, formulations adjustment, commercialisation, and validation by downstream sectors).

Based on all the available information collected through the ECHA market survey and the comments received from third parties, the Dossier Submitter considers plausible that a transition period longer than 7 years might be needed for metalworking fluids.

Additional scenarios considering longer transition period have been added in the Background Document (see Appendix E.4 in the Background Document).

In case a derogation will be granted for 12 years – which is akin to the long review period granted in the frame of authorisation applications or 15 years (as requested in the comments) instead of 7 years, there will be no implications in terms of the overall one-off costs and annual substitution following the completion of the substitution process. However, considering that the companies will start incurring higher variable costs later compared to a scenario with a 7-year transition period, the overall costs over 20 years will be lower (€152 million and €126 million with a transition period of 12 and 15 years respectively compared to €198 million, in case of a transition period for 7 years, as currently reported under the restriction option B).

The Dossier Submitter assessed also the implications of a 12 or 15-year transition period on releases and estimated that there would be additional emissions of approximately 170 to 1 250 tonnes of CA:C14-17 over 20 years with a transition period of 12 years instead of 7 years, and additional emissions of approximately 270 to 2 000 tonnes of CA:C14-17 over 20 years with a transition period of 15 years instead of 7 years (see Appendix E.4 in the Background Document).

Finally, in line with the information provided by producers of EC 264-150-0, the Dossier Submitter notes that EC 264-150-0 formulations with a concentration of CA:C14-C17

below 0.1% area already available on the market and therefore does not find the claim for a permanent derogation justified for this use.

More specifically, the Dossier Submitter notes that in comment #3739, the Chloro Alkane Sector Group indicated that "*there was a feedstock, described as C18-20 alkanes, that (once chlorinated) would have been subject to this restriction as it contained ≥ 0.1% C17; however, manufacturers of this particular product have voluntarily removed it from the European market"*. Also, in the same comment the consortium pointed out that *"based on a recent survey of the LCCP REACH registrants, there are no other LCCP products that contain C14-17 constituents above 0.1% w/w".*

For the reasons mentioned above, the Dossier Submitter does not find the request for a permanent derogation justified and did not update the proposed restriction entry in the Background Document.

However, based on the comments submitted by many respondents, the Dossier Submitter acknowledges that a transition period longer than 7-years may be justified for the metal working fluids. Therefore, SEAC may wish to request further information during the 60-day consultation on the SEAC draft opinion in order to consider a potential longer transition period (e.g 12 or 15 years) for metalworking fluids.

2.4.2. RAC Rapporteurs comments

RAC agrees with the Dossier Submitter's response.

RAC acknowledges the comments provided by the respondents requesting a derogation or a transition period longer than 7 years for metalworking fluids.

RAC however does not support a derogation for this use and notes the additional releases over the 7-year transition period.

For more specific information please refer to the RAC opinion.

2.4.3. SEAC Rapporteurs comments

SEAC rapporteurs thank the respondents for providing additional information on some specific metalworking fluid products containing CA:C14-C17 and the affected metal working processes.

The consultation confirmed that substances containing CA:C14-17, when used as extreme pressure additives in metal working fluids are challenging to replace with alternatives. SEAC also notes that oil-based metal working fluids appear to be the relevant product category where the substitution appears to be particularly difficult.

The Dossier Submitter has refined the wording of the derogation for metal working fluids under restriction option B in the Background Document to specify the type of fluids that should be covered by the derogation, namely oil-based metal working fluids as defined under DIN 51385.

SEAC agrees with the responses provided by the Dossier Submitter and also the changes and clarifications that were made as a consequence of the comments received during the Consultation.

SEAC however is concerned that it might be too restrictive to grant a longer transition period only to these specific fluids, as it is unclear whether the newly introduced wording is covering all the metal working fluid mixtures that should be included in this derogation.

Therefore, SEAC would like to request further information during the consultation of the SEAC opinion in order to conclude on the appropriateness of the revised wording for this derogation.

Regarding the requests for a transition period longer than 7 years, SEAC concurs with the Dossier Submitter that it cannot be excluded that a longer transition period might be needed for this use.

However, SEAC considers that the justifications (data and information) provided by the respondents are insufficiently detailed and exhaustive to justify a longer transition period. The insufficiencies stem from a lack of a robust assessment on, for example, substitution plans, technical limitations and an analysis of the expected socio-economic impacts. Moreover, SEAC notes that increasing the length of the transition period (e.g. to 12 or 15 years) would increase the emissions of CA:C14-C17 (and so decrease the benefits of this restriction). Considering the PBT and/or vPvB properties of CA:C14-17, any request for a longer transition period should be underpinned by a thorough justification.

SEAC would like however to request further information during the consultation of the SEAC opinion in order to conclude on the appropriateness on the length of the transition period, as proposed by the Dossier Submitter in the Background Document.

2.5. Socio-economic considerations for uses other than metalworking fluids

2.5.1. Dossier Submitter response to comments

Multiple comments on the transition period were submitted by respondents representing producers of complex articles (mainly Japanese associations representing producers of complex articles, such as Electric and Electronic Equipment (EEE), automotive applications, agricultural machinery, construction equipment, medical devices, industrial vehicles, analytical instruments manufacturers, electric control equipment), but also chloroalkanes manufacturers associations and few European associations. This includes for example comments #3638, #3640, #3642, #3643, #3645, #3646, #3647, #3648, #3649, #3650 #3653, #3833, #3837, #3839, #3840, #3842 #3845, #3846, #3847.

In the submitted comments the respondents request a transition period longer than two years to minimise the potential for regrettable substitution, and for the above listed articles and in general for: PVC, rubber, paints and coatings, adhesives, sealants and lubricants. Some of the comments have been handled as confidential as per the respondent's request.

In comment #3826, the respondent submitted a socio-economic analysis (SEA) describing the impacts of the restriction on the producers of test and measurements equipment –

category 9 under RoHS[1] – and requested a longer transition period of 10-11 years for this category of complex articles.

In comments #3638, #3639, #3640, #3642 and #3645, #3646, 3647,#3648, #3649, #3650, #3743, #3804, #3828, #3833, #3837, #3838, #3839, #3840, #3842, #3846 respondents request a longer or a permanent derogation for legacy spare parts (LSP).

2.5.1.1. Transition period or derogation for other uses

The Dossier Submitter notes that most of the comments provided by respondents refer to broad use categories without clearly defining the specific mixtures/articles being impacted by the restriction and without discussing the technical and economic feasibility of the alternatives.

During the preparation of the restriction proposal, the Dossier Submitter contacted more than 90 stakeholders (companies and industry associations) to collect additional information on the availability of alternatives in order to assess the time needed for the affected industries to shift to available alternatives. Moreover, the Dossier Submitter held calls and/or exchanged emails on aspects related to the alternatives with 40 of these companies.

The Dossier Submitter surveys were targeted at companies upstream in the supply chain, namely those that are expected to engage in substitution activities as a result of the restriction conditions.

Within each use category, the Dossier Submitter identified the specific applications being affected by the restriction and collected information on the substitution activities from the relevant stakeholders (e.g. producers of PVC compounds for PVC cables, producers of rubber conveyor belts, producers of one component foams (OCFs), producers of insulating glass sealants, producers of tapes, producers of paints and coatings, etc.)

Additional information on alternatives and the required transition period was collected through two sector specific surveys.

Based on the above findings, the Dossier Submitter concluded that a 2-year transition period (until 2026) will be sufficient for the affected industries to test and shift to the available alternatives.

The Dossier Submitter notes that most of the comments submitted by the respondents:

- do not specify the specific mixtures/articles for which a derogation would be needed based on the lack of alternatives
- do not discuss the availability of alternatives for each specific application within the mentioned use category
- do not include a detailed timeline justifying the requested transition period, and
- do not describe the socio-economic impacts expected for the EU market if the requested transition period is not granted.

Based on the above considerations, the Dossier Submitter considers that the comments submitted by respondents requesting a transition period longer than 2 years are too

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011L0065-20230301

generic and not underpinned by sufficient socio-economic data.

One company based in United-Sates submitted a comment (#3653) requesting a transition period of 10 years for aerospace and defence applications (A&D). The company in question indicated that the substance EC 287-477-0 is present in several products that the company source, such as: in aircraft carpet tapes, cargo liner tapes, tamper proof putties, pinhole fillers, adhesives, sealants and coatings as well as in electrical and electronic equipment (PVC cable insulation). The company in question indicates that even if viable alternatives were considered “available” for certain uses, due to the complexity of their supply chain and complex processes to test, qualify, gain customer acceptance, and certify potentially thousands of parts and assemblies, they will not be able to replace EC 287-477-0 for numerous years.

The Dossier Submitter notes that the sector specific survey on sealants and tapes – conducted during the preparation of the dossier – and the information provided by the European Adhesive Tape Association (Afera) and FEICA, the Association of the European Adhesive & Sealant did not reveal any need for a derogation for sealants, adhesives and tapes. Therefore, based on the information collected during the preparation of the restriction proposal, the Dossier Submitter concluded that technically and economically feasible alternatives are available in the EU for those applications and that a transition period of 2 years would be sufficient.

In two comments (#3839 and #3842), respondents ask for a longer transition period for vehicles, namely:

- 5 years for vehicles M1 according to Regulation EU 2018/858, motor vehicles category L within the scope of Regulation EU 168/2013 and
- 12 years for motor vehicles M2/3, N and O according to Regulation EU 2018/858.

In these two comments (#3839 and #3842), the respondents also provided a non-exhaustive list of the affected parts. The Dossier Submitter however notes that in the request for this derogation no information is provided on:

1. the available alternatives
2. the status of substitution activities by the manufacturers of materials and components, and
3. socio-economic impacts in case a e longer transition period is not granted.

The Dossier Submitter notes that, according to the respondents, when a chemical needs to be replaced, material testing is to be performed by the manufacturer of the material, to be followed by the component testing (which in series production is done in partnership with the supplier and car manufacturers). At the end of the process, the parts get fitted to test vehicles.

While the respondents do include a general overview of the testing regime, the contribution does not indicate that a longer transition period is required by the manufacturers of the materials and components. In particular, the Dossier Submitter would like to stress that the contribution does not include any information on whether the EU actors up in the supply chain (manufacturers of materials and components) have already transitioned or are transitioning to the available alternatives. The Dossier Submitter requires this information to have a clear understanding of the situation across

the whole supply chain.

The Dossier Submitter therefore does not find the requests from the vehicles manufacturers justified, considering that no requests for a longer transition period have been submitted by the manufacturers of materials and components during the 6-month consultation on the Annex XV report.

A comment (#3826) was submitted by Test and Measurement Coalition (representing the producers of test and measurement equipment) on the use of EC 287-477-0 in PVC cables, which are components of test and measurement equipment. The respondent indicated that a transition period of 10-11 years would be needed to ensure the transition to the alternatives across the whole supply chain, as well as provided a socio-economic analysis in support of the derogation request.

The Dossier Submitter notes that the socio-economic analysis provided by the respondent is in line with the ECHA practice in assessing the socio-economic analysis (SEA), submitted as part of the authorisation applications and therefore does not question the respondent's approach in assessing the impacts.

The respondent however assumes that in the restriction scenario, potentially all products manufactured by Test and Measurement Coalition companies would have to be removed from the EEA market (page 20 of the comment #3826). According to the Dossier Submitter's understanding, this assumption implicitly means that the producers of cables and components containing the cables will not be able to place on the market articles complying with the restriction conditions at the expiration of the two-year transition period.

The Dossier Submitter therefore asked for additional clarifications regarding the underlying assumptions from the respondent to understand:

1. what information the producers of test and measurement equipment received from the producers of cables regarding the alternatives and the possibility to transition to the alternatives within the 2-year TP
2. the status of the cable industry in terms of substitution activities
3. what alternatives were concretely assessed by the producers of cables and what technical requirements the cables need to meet to be suitable for the test and measurement applications (e.g. the relevant standards and regulations)
4. whether the alternatives assessed by producers of cables can meet the required technical requirements (e.g. results from the tests).

While the respondent provided detailed information on the technical requirements that need to be met by any technically feasible alternative, it was not in position to provide sufficient information on the other points listed above. The respondent only explained that the producers of test and measurement applications do not generally buy cables directly from the cables' producers and that they have not received any "*confirmation from the supply chain of the existence of technically suitable and economically viable alternatives".*

The Dossier Submitter appreciates the additional information submitted by the respondent. It would however like to stress that no requests for longer transition periods were submitted by the producers of cables and therefore cannot find the request for the 10–11-year transition period justified for the complex article containing the cables.

Based on the above considerations it is therefore unclear to the Dossier Submitter why

the producers of complex articles (users of 'articles' or "mixtures" to produce the complex articles) would still need a derogation, although the suppliers of the 'simple articles' (or mixtures) do not raise a concern with supplying them.

Also – with the exception of the comment #3826 - the respondents requesting for longer transition period or derogations did not quantify or describe the socio-economic impacts in case the requested derogations or longer transition periods are not granted. And none of the request gives any information on the substitution activities conducted by their suppliers of articles/mixtures.

The Dossier Submitter is therefore unable to support the request for longer transitional periods for aerospace and defence applications (A&D), motor vehicles, agricultural machinery, test and measurement equipment and the above listed complex articles, as insufficient evidence to justify it was supplied in the request. The Dossier Submitter did not therefore update the proposed restriction entry in the Background Document.

SEAC may wish to request further information during the consultation of the SEAC draft opinion in order to consider a potential derogation for aerospace and defence applications (A&D) and other complex articles.

2.5.1.2. Legacy spare parts

In the submitted comments, some respondents requested a permanent exemption for spare parts for products placed on the market before the restriction enters into force. Different sectors were mentioned such as EEE, medical devices, automotive industry, marine industry, etc.

In the justifications provided by respondents it is reported that the derogation for legacy spare parts is important in the context of the circular economy and for extending the useful life of the products.

In comment #3639, it is reported that "*even if some alternatives are proposed by chemical manufacturers in future, there is no guarantee that the same performance as before can be obtained".* And comment #3804 provides more information about the stages when the production of spare parts for the automotive industry takes place. Based on this comment, spare parts are produced:

1. in phase 1: at the time of mass production of vehicles

2. in phase 2: on order after mass production of vehicles is completed and

3. in phase 3, once the mass production of vehicles is completed. In this phase a certain quantity of legacy spare parts is produced to meet possible future requests from customers.

While the Dossier Submitter understands that the production of the legacy spare parts is expected to take place at different phases, the comments provided by respondents do not indicate that this production will be hampered if substances containing the chloroalkanes in a concentration equal to or greater than 0.1 % (w/w) cannot be used any longer. In particular, in the submitted comments it is not explained why substituting a substance in spare parts would result in a change of design of the spare parts, or their technical characteristics, that would be significant enough to render it unusable for the products placed on the market before the restriction enters into force.

In comments #3839 and #3840, respondents indicate that it is not possible to phase out substances containing C14-17 constituents above 0.1% w/w from Legacy Spare Parts (LSPs) because:

- The spare parts are produced in low volumes and that the testing cost would be prohibitive, and
- that it is not possible for the suppliers of Legacy Spare Parts (LSPs) – that produce parts based on OEMs (Original Manufacturer Equipment)' requirements – to perform the testing of vehicles.

While the Dossier Submitter understands the complexity of the automotive supply chain and the large number of actors involved at different levels, it still finds unclear:

1. whether spare parts produced with alternatives can meet the OEM's requirements (and so whether alternatives can be used to produce the spare parts) and
2. why the spare parts – produced with alternatives - cannot be validated by OEMs.

The Dossier Submitter would like also to stress that the comments provided by respondents do not include any information on the possible socio-economic impacts that may result in case no derogation for legacy spare parts is granted.

Also, based on information collected during the preparation of the restriction – which is documented in the Background Document and in the Appendix E, the Dossier Submitter's understanding is that technically and economically feasible alternatives are available for the upstream industries (e.g. PVC, rubber, adhesives, tapes, sealants.).

The Dossier Submitter also notes that none of the upstream industries listed above made a request for a derogation during the six-month consultation, confirming that a 2-year transition period is deemed sufficient to transition to the available alternatives. In Dossier Submitter's understanding this also means that these actors will be able to reformulate all the affected products by the end of transition period and so continue supplying their customers, without any interruption.

Based on the above the Dossier Submitter cannot find justified the request for a derogation for legacy spare parts.

Therefore the Dossier Submitter did not modify the proposed restriction entry in the Background Document.

SEAC may wish to request further information during the consultation of the SEAC draft opinion in order to consider a potential derogation for legacy spare parts.

2.5.2. RAC Rapporteurs comments

RAC agrees with the Dossier Submitter's response.

2.5.3. SEAC Rapporteurs comments

Multiple comments were received from respondents representing producers of complex articles (e.g. EEE, medical devices, analytical instrument manufacturers), and also motor vehicles requesting a longer transition period. SEAC notes that majority of the comments were submitted from trade associations representing non-EU industries. For the producers of complex articles, insufficient information (e.g., on availability of alternatives, socio

economic impacts) was provided by respondents and as a result, the Dossier Submitter was unable to effectively evaluate their request for a longer transition period. Notably the Test and Measurement Coalition submitted detailed information. However, upon the Dossier Submitter request for additional information related to the assumptions underpinning the submitted analysis, the subsequent information received was insufficient to enable the Dossier Submitter to effectively evaluate their request for a longer transition period. Moreover, the information retrieved from PVC cable producer and more simple goods do not corroborate the negative impacts of the restriction proposal on such complex articles. In absence of a detailed justification by the respondents, SEAC concurs that the Dossier Submitter is unable to justify the request for a longer transition period.

Another set of comments related to legacy spare parts. Similarly, to the information provided on complex articles, the information provided by respondents was insufficient to enable the Dossier Submitter to effectively evaluate their request for a longer transition period. In absence of a detailed justification by the respondents, SEAC concurs that the Dossier Submitter is unable to justify the request for a derogation for legacy spare parts.

Based on this information, SEAC rapporteurs have not identified a reason to update the opinion.

2.6. Implementation and enforcement, including availability of analytical methods

2.6.1. Dossier Submitter response to comments

Various respondents acknowledge (e.g. #3839, #3842, #3847) that a clear identification of the substances in the scope of the restriction cannot be made using numerical identifiers such as EC or CAS numbers. These respondents also welcome the proposal by the Dossier Submitter to publish an indicative list of substances containing CA:C14-17 with PBT and/or vPvB properties.

Some respondents (#3739, #3827) raised a concern on the lack of understanding of the supply chain on the congener approach (i.e. targeting of the restriction to congeners identified with their molecular formula) and on the lack of sufficient lab testing capacity.

As described in section 1.2 of the Background Document, the concern addressed in this restriction proposal stems from the properties of certain congeners that may be present in the composition of a substance. However, information on the composition is not available for all substances, mixtures or articles manufactured/imported in the EU. Therefore, it may not be possible to establish a list of all the substances relevant to the current restriction proposal.

In light of these considerations, the Dossier Submitter proposes to define the scope of this restriction using molecular formula descriptors that provide a clear characterisation of the congeners of concern, rather than establishing a list of numerical identifiers such as EC or CAS numbers.

Also, as summarised in Appendix B there is a wide range of analytical methods and techniques available to identify and quantify CA:C14-17 with PBT and/or vPvB properties on the basis of their molecular formula. These techniques range from ‘binary’ screening (yes/no response) to more advanced techniques which provide a more precise

quantification of the result.

Regarding the lack of sufficient lab testing, relevant in particular for enforcement, the Dossier Submitter notes that – as also described in the Background Document under section 2.3.4.2 - all the enforcement laboratories responding to the survey (conducted by the Dossier Submitter in March and April 2022) indicated that they have screening analytical methods in place and ~ 55 % of them have also advanced detection methods and instruments available. In addition, some enforcement laboratories indicate in the survey that they can sub-contract to private laboratories analysis in case of lack of capacity or technology in their own laboratories.

Comments #3839, and #3842 raised concerns on the fact that paragraph 6 of the restriction conditions is only applicable for substance manufacturers and does not apply to article manufacturers. In this comment it was also indicated that the relevant information on the presence of the relevant congeners cannot be provided through the whole supply chain (e.g. from producers of simple articles to the producers of complex articles). The Dossier Submitter however would like to stress that the concern raised in this specific comment is addressed by paragraph 7 of the restriction conditions – which by also targeting articles - aims to ensure a complete communication across the different actors in the relevant supply chains.

For the reasons mentioned above, the Dossier Submitter did not update the Background Document.

2.6.2. RAC Rapporteurs comments

RAC agrees with the Dossier Submitter's responses

2.6.3. SEAC Rapporteurs comments

SEAC rapporteurs concurs with the response provided by the Dossier Submitter.

SEAC also notes that the forum's view is that the restriction is monitorable and enforceable. No modification of the opinion was necessary following these comments.

2.7. Interlink with other regulatory processes (e.g. POP and RoHS)

Some comments on the links between the Restriction Process and POP were submitted by respondents. These included for example comments #3639, #3652, #3827, #3832, #3840.

2.7.1. Dossier Submitter response to comments

Some respondents (#3827) flag the potential for unfair competition (with non-EU manufacturer) if the restriction option A, which would ban the manufacturing in Europe, is adopted, and if a restriction under the POP framework is not applied simultaneously worldwide.

Comments #3639, #3652, #3837, #3840 request also more alignment between the proposed restriction and the usual duration of the transition period and definition of articles under the RoHS regulation.

In particular, in comment #3652 KEMI indicates that: in case of derogations to the restriction in REACH, it would be important to consider that the maximum period for an exemption in the RoHS Directive is five years, except for e.g., medical devices. KEMI also indicates that - for at least electric and electronic equipment (EEE) -, the restriction should apply to the homogeneous material.

In comment #3639, the Japan Electronics and Information Technology Industries Association (JEITA), indicates that a transition period of at least 36 months should be granted to complex articles, such as EEEs, also considering that "*based on the experience of compliance with the RoHS Directive, a period of at least three to four years for the substances contained in products is necessary to implement substitution in the article*".

The Dossier Submitter notes that any exemption under RoHS shall consider:

- the availability of substitutes and
- the socio-economic impacts of substitution.

Also, the Dossier Submitter notes that in comment #3639 no information is provided on:

- the current situation of the supply chain in terms of substitution
- the availability of alternatives and
- socio-economic impacts in case the requested transition period is not granted.

Regarding alternatives, the only point mentioned in comment #3639 is that: "*even if some alternatives are proposed by chemical manufacturers, there is no guarantee that the same performance as before can be obtained".*

The Dossier Submitter however notes that the comment does not provide any information on:

- what alternatives were offered by chemical manufacturers
- whether the alternatives are technically feasible
- whether the alternatives are economically feasible
- what economic and social impacts are expected if the requested 3-year transition period longer is not granted
- what is the situation on the EU market in terms of substitution.

The Dossier Submitter also takes note of the comment submitted by KEMI on the length of the derogations, but considers the comment not applicable taking into account that no derogation for EEE has been proposed by the Dossier Submitter.

Based on the above assessment, the Dossier Submitter is therefore unable to support the request for a derogation for EEE as insufficient evidence to justify it was supplied in the comment.

For the reasons mentioned above, the Dossier Submitter did not update the Background Document.

Further information can be submitted in the 60-day consultation on the SEAC draft opinion, which SEAC will consider before adopting their opinion.

2.7.2. RAC Rapporteurs comments

RAC agrees with the Dossier Submitter's responses and does not have any specific

remark.

2.7.3. SEAC Rapporteurs comments

SEAC agrees with the clarifications provided by the Dossier Submitter and does not have any specific comment.