

ECHA PROPOSES RESTRICTION ON MEDIUM-CHAIN CHLORINATED PARAFFINS (MCCP) AND OTHER SUBSTANCES THAT CONTAIN CHLOROALKANES WITH CARBON CHAIN LENGTHS WITHIN THE RANGE FROM C14 TO C17¹

Summary

The proposed restriction aims at "assessing and addressing 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 'MCCP' constituents having PBT and/or vPvB properties"².

The substances in the scope of the proposed restriction are UVCB containing CA:C14-17 constituents³ (congeners) with PBT and/or vPvB properties: 69 substances are identified that may fall within the scope of the proposed restriction (a non- exhaustive list is available in Appendix B.1.2. to the Annex XV restriction proposal, and at the end of this info note).

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

- 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 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 either a longer transition period (7 years) 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 re. the presence (or absence) of CA:C14-17 constituents with PBT/vPvB properties in other substances, mixtures and articles, the proposed restriction entries includes as well some compulsory complementary measures to accompany the communication down the supply chain.

The consultation on this proposed restriction will start on 21/09/2022 and ends on 22/03/2023 at 23H59 (Helsinki Time zone).

When responding to the consultation, stakeholders should ensure that they are referring to the most recent version of the Annex XV report and any appendices (i.e. those published

¹ The information note has been prepared based on the Annex XV report prepared by ECHA.

² Requests received from the Commission (June 2021 and March 2022)

³ 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'. The acronym 'MCCP' is only used to refer to the Candidate List definition.

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alongside the consultation).

Respondents are also encouraged to take into account when certain aspects of the proposal are planned to be discussed in the committee's plenary meetings (see table below) and time their submissions accordingly (multiple submissions are possible throughout the consultation).

In addition, **initial reactions to the proposed restriction may be submitted by the early comments deadline of 21/10/2022**. In early comments respondents may outline when they plan to submit subsequent comments and on which topics. This information can assist the Rapporteurs of the committees to plan their evaluation.

	Committee		
Plenary meeting of the Committee (timing)	Risk Assessment Committee (RAC)	Socio-Economic Assessment Committee (SEAC)	
1 (2.5 months after the start of the Annex XV consultation)	Verify the proposed scope. Conclude on hazard and hold preliminary discussion on exposure/risk.	Verify the proposed scope. Conclude on costs of the proposed restriction and hold preliminary discussions on its benefits.	
2 (5.5 months)	Conclude on exposure/risk and hold preliminary discussion derogations.	Conclude on benefits and hold preliminary discussions on proportionality and derogations.	
3 (8.5 months)	Finalise the derogations. Finalise the opinion plus justification text and adopt the final opinion.	Conclude on proportionality and derogations. Finalise the opinion plus justification text and agree the draft opinion.	
4 (11.5 months)	Not relevant.	Conclude on issues raised during the SEAC draft opinion consultation. Adopt the final opinion.	

Information on the hazards of the substance(s) and the costs of the proposal would make the most impact if submitted by month two and exposure/risk, beneifts and derogations by month four of the consultation. This early submission would also allow the information to be considered at the appropriate time. This timing takes into account that stakeholders have access to the dossier much earlier than in the past, as it is published two weeks after submission or more than six weeks in advance of the start of the consultation.

It is possible to submit more than one consultation response during the six month period so please take this into account when deciding when to submit information.

How to submit a comment in the Consultation on the proposed restriction

Firstly please read the consultation guidance that describes the relevant information that should be submitted. It is available here:

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https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c.

When you are ready to make your comments, click on the appropriate link on the ECHA website. Please be aware that it is not possible to save your submission and come back to it, so you should already have your comments prepared in an attachment or saved in some other format in advance.

The web form contains five main parts:

- Introduction: containing some general information on the restriction and a link to this note and the PC guidance.
- Section 1: Personal information
- Section 2: Organisational information
- Section 3: Non-confidential comments on the proposal both general comments and information on specific issues (see below). Your responses can be entered directly into the form or through section 4 as an attachment. However, please do not submit the same comments via both means. General comments can be on any aspect of the Annex XV restriction proposal, including on issues related to socioeconomic analysis.
- Section 4: Non-confidential attachments can be added here.
- Section 5: Confidential attachments can be added here. Confidential information
 will only be available to the ECHA Secretariat, the Committees and Member State
 Competent Authorities. However, if ECHA receives an Access to Documents
 request, we may come back to you for justifications why the information is
 confidential. You can also add this information already in the relevant part of the
 webform.

Once you have finished your submission press the submit button and your comments will be submitted. You will receive a submission number via e-mail and you should refer to this in any communication with ECHA on this issue.

It is not possible for you to retrieve your submission so you may want to take a screen shot, or printed copy for your future reference.

Specific information requests

In addition to the general comments, outlined above, the consultation includes several specific questions to gather information that is considered to be particularly relevant to the evaluation of the proposal, 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) <u>not mentioned</u> in the restriction proposal and,

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

Please provide detailed information only on the additional uses that may be affected by the restriction proposal that <u>are not mentioned</u> 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 metal working 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 metal working 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 metal working 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 metal working 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 metal working 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

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that a transition period should be granted for the metal working 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 metal working fluids.

Note that if metal working 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	

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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.

The final opinions of both Committees are scheduled to be available in September 2023. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in Annex XVII to the REACH Regulation.

The Dossier Submitter and the Rapporteurs will all respond to the issues raised in the consultation and these responses will be published with the launch of the consultation on the SEAC draft opinion in month nine of the process.

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Annex – Non-exhaustive list of substances potentially falling within the scope of the proposed restriction

Entry	EC#	CAS#	Name
1	287-477-0	85535-85-9	Alkanes, C ₁₄₋₁₇ , chloro (aka 'MCCP' in Europe)
2	-	-	Di-, tri- and tetrachlorotetradecane
3	-	1372804-76-6	Alkanes, C ₁₄₋₁₆ , chloro
4	-	198840-65-2	Tetradecane, chloro derivs.
5	264-150-0	63449-39-8	Paraffin waxes and Hydrocarbon waxes, chloro (aka 'LCCP' in Europe)
6	281-985-6	84082-38-2	Alkanes, C ₁₀₋₂₁ , chloro (aka CP52 in Asia)
7	272-924-4	68920-70-7	Alkanes, C ₆₋₁₈ , chloro
8	283-930-1	84776-06-7	Alkanes, C ₁₀₋₃₂ , chloro
9	283-931-7	84776-07-8	Alkanes, C ₁₆₋₂₇ , chloro
10	285-195-2	85049-26-9	Alkanes, C ₁₆₋₃₅ , chloro
11	287-504-6	85536-22-7	Alkanes, C ₁₂₋₁₄ , chloro
12	307-451-5	97659-46-6	Alkanes, C ₁₀₋₂₆ , chloro
13	307-202-0	97553-43-0	Paraffins (petroleum), normal C _{>10} , chloro
14	288-211-6	85681-73-8	Alkanes, C10-14, chloro
15	-	104948-36-9	Alkanes, C10-22, chloro
16	-	126207-70-3	Heptadecane, chloro-
17	-	129521-61-5	Alkanes, C14-32, chloro
18	-	159715-72-7	Pentadecane, 3,5,7,9,11,13-hexachloro-
19	-	221174-08-9	Tetradecane, 1,2,13,14,?-pentachloro-
20	-	221174-09-0	Tetradecane, 1,2,13,14,?,?-hexachloro-
21	-	2233595-19-0	Pentadecane, 2,5,6,11,14-pentachloro-
22	-	276673-41-7	Octachloropentadecane
23	-	276673-44-0	Hexachlorohexadecane
24	-	276673-45-1	Octachlorohexadecane
25	-	28085-66-7	Heptachloroheptadecane
26	-	308061-49-6	Chloroalkanes, C14-18
27	-	360790-74-5	Chloroalkanes, C17-20
28	-	3922-32-5	1,1,1,15-Tetrachloropentadecane
29	-	57437-53-3	Tetradecane, tetrachloro-
30	-	57437-56-6	Pentachloropentadecane
31	-	57437-57-7	Hexadecane, pentachloro-
32	-	57437-58-8	Heptachlorohexadecane
33	-	57437-60-2	Hexachloropentadecane

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Entry	EC#	CAS#	Name
34	-	57437-61-3	Heptachloropentadecane
35	-	62108-59-2	1,1,1-Trichloropentadecane
36	-	67095-51-6	1,1,1,3-Tetrachloropentadecane
37	-	700864-25-1	Hexadecane, tetrachloro-
38	-	700864-27-3	Hexachloroheptadecane
39	-	700864-28-4	Octachloroheptadecane
40	-	700864-29-5	Nonachloroheptadecane
41	-	865306-25-8	Tetradecane, 1,1,1,3-tetrachloro-
42	-	866758-65-8	Chloroalkanes, C12-16
43	-	97262-09-4	Pentadecane, tetrachloro-
44	263-004-3	61788-76-9	Alkanes, chloro
45	287-196-3	85422-92-0	Paraffin oils, chloro
46	-	2097144-44-8	Slack Wax (petroleum), chloro
47	-	39443-51-1	WK 30 (chloroparaffin)
48	-	52737-80-1	KhP 1100
49	-	68410-99-1	Alkenes, polymd., chlorinated
50	-	68477-12-3	Alkanesulfonic acids, chloro
51	-	106232-85-3	Alkanes, C18-20, chloro
52	-	108171-27-3	Chloroalkanes, C22-26
53	-	2097144-45-9	Alkanes, C20-24, chloro
54	-	308061-50-9	Chloroalkanes, C18-26
55	-	308061-51-0	Chloroalkanes, C22-24
56	287-478-6	85535-86-0	Alkanes, C18-28, chloro
57	-	106232-86-4	Alkanes, C22-40, chloro
58	-	127133-59-9	Alkanes, C21-38, chloro
59	-	1392825-28-3	Alkanes, C19-28-branched and linear, chloro
60	-	1401974-24-0	Alkanes, C22-30-branched and linear, chloro
61	-	1402738-52-6	Alkanes, C24-28, chloro
62	-	1417900-96-9	Alkanes, C21-34-branched and linear, chloro
63	-	1632986-67-4	Alkanes, C22-32, chloro
64	-	2097144-43-7	Alkanes, C20-28, chloro
65	-	288260-42-4	Alkanes, C22-30, chloro
66	-	-	Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated, saponified
67	269-145-7	68188-19-2	Paraffin waxes and hydrocarbon waxes, chloro, sulfochlorinated
68	273-276-5	68955-41-9	Alkanes, C10-18, bromo chloro
69	_	-	Paraffin waxes and Hydrocarbon waxes C14-17, chloro,

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Entry	EC#	CAS#	Name
			sulfochlorinated, low sulphonated, saponified

Source: Appendix B.1.2 to the Annex XV proposal