EUROPEAN CHEMICALS AGENCY

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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For alkanes, C_{14-17}, chloro (MCCP, Medium-chain chlorinated paraffins), CAS No 85535-85-9 (EC No 287-477-0)

Addressees: Registrant(s)[1] of alkanes, C_{14-17}, chloro (MCCPs, Medium-chain chlorinated paraffins) (Registrant(s))

This decision is addressed to all Registrant(s) of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrant(s) meeting the following criteria are *not* addressees of this decision: i) Registrant(s) who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrant(s) who have ceased manufacture/import of the above substance in accordance with Article 50(3)of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by the Environment Agency as the Competent Authority of the United Kingdom (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision does not take into account any updates of the registrations of the concerned registrant(s) after 1 December 2012.

This decision does not imply that the information provided by the concerned registrant(s) in the registrations is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossiers of the concerned registrant(s) at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of the United Kingdom has initiated substance evaluation for alkanes, C_{14-17}, chloro (MCCPs, Medium-chain chlorinated paraffins), CAS No 85535-85-9 (EC No 287-477-0) based on registration dossiers submitted by the concerned registrant(s) in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

for concern relating to the need to check current exposure scenarios for the environment to ensure that the risk characterization ratios are all below one, and to review the registrants' persistence, bioaccumulation and toxicity (PBT) assessment, alkanes, C_{14-17}, chloro (MCCPs, Medium-chain chlorinated paraffins) was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012. The Competent Authority of the United Kingdom was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the above mentioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 27 February 2013.

On 4 April 2013 ECHA sent the draft decision to the concerned registrants and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

The concerned registrants provided comments to ECHA on the draft decision by the deadline of the 6 May 2013.

On the 10 May 2013 ECHA notified the evaluating MSCA of the comments received. The evaluating MSCA considered the comments received from the concerned registrants. The information contained therein was reflected in the Statement of Reasons (section III) and an amendment to the Information Required (Section II) was made.

In accordance with Article 52(1) of the REACH Regulation, on 5 September 2013 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

Subsequently, ECHA submitted proposals for amendment to the draft decision.

On 11 October 2013 ECHA notified the concerned registrants of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA has reviewed the ECHA's proposals for amendment and amended the draft decision accordingly.

On 21 October 2013 ECHA referred the draft decision to the Member State Committee.

By 11 November 2013 the Registrant provided comments on the proposed amendments and on the amended draft decision. The Member State Committee took into account the comments the Registrant made on the proposals for amendment. However, the Member State Committee did not consider the Registrant's comments that were not related to the proposals for amendment.

After discussion in the Member State Committee meeting on 10-13 December 2013, a unanimous agreement of the Member State Committee on the draft decision was reached on 12 December 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit the following information in the technical dossier and chemical safety report:

1. Information on the the amounts of carbon chain lengths shorter than C_{14} that are present at or above 0.1% w/w for all of the MCCP product types supplied by the registrant (noting where content may vary between different product types). This information can be based on the composition of the *n*-alkane starting materials used to make the MCCP products, and shall be expressed in terms of a mean and range if appropriate. This information can be provided separately by each registrant if it is commercially sensitive.

2. Information on the chlorine contents of all MCCP product types supplied by the registrant, as well as a description of chlorine content for each registered use. This information can be provided separately by each registrant if it is commercially sensitive. Information on chlorine content for registered uses can be provided as aggregated data representative of all registrants.

3. Robust study summaries for all available fish feeding study bioaccumulation data, including consideration of the effects of growth correction and lipid normalisation on the results obtained. This should include at least the following studies:

    - Fisk AT, Cymbalisty CD, Bergman A and Muir DCG (1996). Dietary accumulation of C12- and C16-chlorinated alkanes by juvenile rainbow trout (*Oncorhynchus mykiss*). Environ. Toxicol. Chem., **15**, 1775-1782.
    - Fisk AT, Cymbalisty CD, Tomy GT and Muir DCG (1998). Dietary accumulation and depuration of individual C10-, C11- and C14-polychlorinated alkanes by juvenile rainbow trout (*Oncorhynchus mykiss*). Aquat. Toxicol., **43**, 209-221.
    - Fisk AT, Tomy GT, Cymbalisty CD and Muir CG (2000). Dietary accumulation and quantitative structure-activity relationships for depuration and biotransformation of short (C10), medium (C14) and long (C18) carbon-chain polychlorinated alkanes by juvenile rainbow trout (*Oncorhynchus mykiss*). Environ. Toxicol. Chem., **19**, 1508-1516.
    - Cooley HM, Fisk AT, Weins SC, Tomy GT, Evans RE and Muir DCG (2001). Examination of the behaviour and liver and thyroid histology of juvenile rainbow trout (*Oncorhynchus mykiss*) exposed to high dietary concentrations of C10-, C11-, C12- and C14- polychlorinated n-alkanes. Aquat. Toxicol., **54**, 81-99.

4. The exposure scenarios in Section 9 of the Chemical Safety Report for the following applications and lifecycle stages need to be updated to identify the appropriate operational conditions and risk management measures:

    - Manufacture of MCCPs.
    - Formulation and use of MCCPs in PVC and rubber.
    - Formulation, use and service life of MCCPs in textiles.
    - Formulation and use of MCCPs in leather fat liquors.
    - 'Other' reported uses of MCCPs, including use in the denaturing of fuels and use in the manufacturing of absorbent formulations.
    - Waste lifecycle stage.

Pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit the following information using the indicated test methods/instructions and the registered substance with composition as specified, subject to the present decision:

5. Bioaccumulation in fish: Aqueous and Dietary Exposure test (test method OECD TG 305). Exposure can be either via aqueous or dietary exposure, and the test substance shall be a C_{14} chlorinated n-alkane with a chlorine content of 50-52% by weight. Radiolabelled test substance may be used along with parent substance analysis, to allow an assessment of the relevant contribution of metabolites to any observed accumulation. If aqueous exposure is used, the organic carbon content of the test water (e.g. from fish excreta and food residues) should be kept as low as possible, and efforts shall be made to establish the truly dissolved concentration, for example by taking measurements of particulate and dissolved organic carbon concentrations at appropriate time points and using an appropriate technique to enable the estimation of the bioavailable fraction if feasible (e.g. solid-phase microextraction). Excessive fish growth and lipid increases should also be avoided, since these might confound the results. The results should in any case be corrected for growth and normalized to a 5% lipid content.

6. Bioaccumulation in fish: Aqueous and Dietary Exposure test (test method OECD TG 305). Exposure can be either via aqueous or dietary exposure, and the test substance shall be a C_{14} chlorinated n-alkane with a chlorine content of around 55-60% by weight. Radiolabelled test substance may be used along with parent substance analysis, to allow an assessment of the relevant contribution of metabolites to any observed accumulation. If aqueous exposure is used, the organic carbon content of the test water (e.g. from fish excreta and food residues) should be kept as low as possible, and efforts shall be made to establish the truly dissolved concentration, for example by taking measurements of particulate and dissolved organic carbon concentrations at appropriate time points and using an appropriate technique to enable the estimation of the bioavailable fraction if feasible (e.g. solid-phase microextraction). Excessive fish growth and lipid increases should also be avoided, since these might confound the results. The results should in any case be corrected for growth and normalized to a 5% lipid content.

7. Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24/OECD TG 308). The test substance shall be a C_{14} chlorinated n-alkane with a chlorine content of 50-52% by weight. Should only partial mineralization occur in the test it will be necessary to identify any potentially persistent metabolites that are formed – if this is not possible (for example due to analytical difficulties) then other approaches to profile the persistent, bioaccumulative and toxic properties of the metabolites may be considered.

8. Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24/OECD TG 308). The test substance shall be a C_{14} chlorinated *n*-alkane with a chlorine content of 55-60% by weight. Should only partial mineralization occur in the test it will be necessary to identify any potentially persistent metabolites that are formed – if this is not possible (for example due to analytical difficulties) then other approaches to profile the persistent, bioaccumulative and toxic properties of the metabolites may be considered.

9. Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24/OECD TG 308). The test substance shall be a C_{15} chlorinated *n*-alkane with a chlorine content of around 51% by weight. Should only partial mineralization occur in the test it will be necessary to identify any potentially persistent metabolites that are formed – if this is not possible (for example due to analytical difficulties) then other

approaches to profile the persistent, bioaccumulative and toxic properties of the metabolites may be considered.

A tiered approach to testing is possible. This would involve persistence and bioaccumulation testing for the lower chlorine content C_{14} substance first:

- If it is found to meet the P criterion, the registrants may choose to read across this conclusion to the higher chlorine content C_{14} substance as well as the C_{15} substance, without the need for further sediment simulation testing.
- Should the lower chlorine content C_{14} substance also be confirmed as meeting the B/vB criteria then the registrant may choose to conclude that the C_{14} substance with a higher chlorine content also meets the PBT criteria without carrying out the further bioaccumulation testing necessary to show this.

The registrants will need to provide a justification for any read-across. If conclusions cannot be read across from the lower chlorine content C_{14} substance, the testing for the other two substances (sediment simulation and fish bioaccumulation for the C_{14} 55-60% w/w *n*-alkane; sediment simulation for the C_{15} ~51% Cl w/w *n*-alkane) shall be carried out in parallel.

Furthermore, pursuant to Article 46(1) of the REACH Regulation the concerned registrants, once the information required under points 1-4 & 6-10 of this section II is available, shall submit the following;

10. A PBT assessment for all relevant constituents of the substance and any transformation product found to be formed in a relevant environmental compartment at any time point, at a concentration of ≥ 0.1 % w/w (grouped as appropriate).

Pursuant to Article 46(2) of the REACH Regulation, the concerned registrants shall submit to ECHA by 25 February 2017 an update of the registration dossiers containing the information required by this decision.

At any time, the concerned registrants shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

Based on the evaluation of all relevant information submitted on MCCPs and other relevant and available information and taking into account the comments of the concerned registrants, proposals for amendment submitted by ECHA and the deliberations of the Member State Committee, ECHA concludes that further information is required in order to enable the evaluating MSCA to complete the evaluation of whether the substance constitutes a risk to human health or the environment.

MCCPs is a poorly water soluble substance with a complex and variable composition. It is made from an *n*-alkane ([redacted]) feedstock of specified carbon chain length range (from C_{14} to C_{17}), but the actual chain length distribution (including minor constituents outside of this range) can vary. The extent of chlorination can also be controlled to produce distinct MCCP product types with different physical properties. This is expressed as an average percentage chlorination level (generally within the range 40% to around 63% by weight), but in reality there will be a distribution of the number of chlorine atoms present in constituents of specific chain length. Therefore although the substance is identified with a single CAS number, it contains many hundreds of constituents with a range of chlorine content and

carbon chain lengths. It is not feasible (nor justifiable) to determine the PBT properties of every constituent based on experimental information, and it is inappropriate to cite a single value for MCCPs for comparison with each PBT criterion (such an approach *is* acceptable for generic risk assessment purposes under REACH, to avoid recommended risk management measures becoming unnecessarily complicated). A read-across/modelling approach has therefore been used to estimate the persistence and bioaccumulation properties of representative constituent structures.

Constituents with lower chlorine contents are readily biodegradable and so do not meet the Annex XIII persistence criteria, but persistence is predicted to increase with increasing chlorine content. Substances with chlorine contents above 50% by weight are generally not readily biodegradable (although still undergo some degradation in ready biodegradation tests), but it is not clear if this increased persistence means that such substances would meet the Annex XIII persistence criteria in terms of an environmental half-life in sediment (or soil).

The available bioaccumulation data suggest that fish bioconcentration factors (BCFs) may exceed 2,000 L/kg for C_{14} constituents with chlorine contents between ~15 and 56% by weight. Some C_{15} constituents with ~14 to 41% chlorine contents and C_{16} constituents with ~14% chlorine contents are also predicted to have BCFs above 2,000 L/kg. The REACH Guidance[2] indicates that, where possible, growth-corrected BCF data should be taken into account. When this is done for MCCPs, the range of constituents with BCFs predicted to be above 2,000 L/kg is increased with, notably, the C_{15}, 51% wt. Cl constituent becoming borderline B, and the C_{14}, 45% wt. Cl chlorinated paraffin becoming vB.

When persistence and bioaccumulation are considered together, it appears that C_{14} constituents with chlorine contents around 50% to 56% by weight, and C_{15} constituents with a ~51% chlorine content, are potentially persistent and bioaccumulative. The same constituents are considered to meet the T criterion. For clarity, the tentative P and B designations are indicated in the table below.

Estimated P & B properties of potential constituents of MCCPs

Carbon no.	Chlorine content (w/w)			
	~40-50%	~50-55%	~55%-65%	>65%
Constituents that may be present at >1% w/w				
14	Not P vB	P? B	P? Borderline B?	P Not B?
15	P? Not B	P? Borderline B	P Not B	P Not B
16	P? Not B	P? Not B	P Not B	P Not B
17	P? Not B	P? Not B	P Not B	P Not B
Constituents that may be present at 0.1% w/w but ≤1% w/w				
10	Not P B	P? B	P? vB	P B or vB

[2] ECHA (2012). Guidance on information requirements and chemical safety assessment. Chapter R.11: PBT Assessment. ECHA-12-G-24-EN. November 2012. European Chemicals Agency.

11	Not P vB	P? vB	P? vB	P B or vB
12	Not P vB	P? vB	P? vB	P B or vB
13	Not P B or vB	P? B	P? B	P B

Note: The shaded box represents constituent groups potentially meeting both the P and B/vB criteria.

Categorisation for some of the constituents is uncertain because of inherent limitations in the underlying data sets, so a final conclusion cannot yet be drawn. Therefore it is important to obtain definitive information for these constituents.
The registrants commented that the proposed approach of testing "representative" individual carbon length chloroalkanes for the assessment of MCCPs is fundamentally inappropriate because:

- one cannot determine what is a representative chloroalkane of MCCP,
- there is no means of selectively making a single representative test chemical of MCCP (any such test material would also be a mixture), and
- the proposed approach would require the testing of (non-commercial) UVCB substances to represent the actual (commercial) UVCB substance.

Instead, the registrants believe that a whole product testing approach would be preferable.

ECHA accepts that MCCPs is a complex UVCB substance, and that there are difficulties in selecting substances to be tested as well as chemical analysis. However, the evaluation has identified several carbon chain length and chlorine content combinations present in commercial products that meet the PBT screening criteria, as indicated above. It is therefore important to generate further information on these constituents to clarify this concern. Since they cannot be isolated from the commercial products, ECHA believes that it is appropriate to request testing on surrogate test material that is broadly representative of these constituents on the basis of likely physico-chemical properties, recognising that the test material itself is not a commercial product. This is not a novel aspect of the assessment of this type of substance (similar 'representative' test substances were tested under the Existing Substances Regulation for both this substance and an analogue (short-chain length chlorinated paraffins, EC No: 287-476-5, CAS no. 85535-84-8)). The registrants themselves cite data in their registrations for substances with specific chain lengths and chlorination levels (e.g. extended ready biodegradation tests, fish bioconcentration tests and terrestrial bioaccumulation tests). ECHA does not consider that testing the whole substance will generate useful information for direct comparison with the Annex XIII criteria, since a single product type does not exist (due to the range of chlorination) and this approach cannot distinguish different levels of hazard (in terms of the combinations of properties) between relevant constituents.

So, in response to the registrant's comments, ECHA modified the original draft decision slightly to remove the word 'representative' from the naming of the test substance, to avoid unintentional ambiguity about the meaning of this term. The test material for the persistence and bioaccumulation testing is simply a practical surrogate for relevant MCCP constituents (not a constituent as such).

The information outlined in points 1-11 of section II are needed to provide more detailed information on composition, use, operational conditions and risk management measures, and properties related to the PBT assessment of different MCCP product types.

1. Information on $C_{<14}$ content

One of the initial grounds for concern related to PBT assessment. The registration dossiers indicate that commercial MCCP product types can contain up to around 1% $C_{<14}$ constituents, related to the feedstock that is used. These are predicted to have BCF values above 2,000 L/kg over a wide chlorine range, and some with higher chlorine contents (e.g. a C_{10}, 65% wt. Cl substance and a C_{13}, 65% wt. Cl substance) are known to meet the persistence criteria based on a measured half-life in sediment. They are considered to meet the T criterion, so it is possible that they could meet the PBT criteria. This has not been considered by the registrants and little detail is available about actual $C_{<14}$ constituent levels in most registrations. A conclusion therefore cannot be drawn about the relevance of these constituents. It is important to establish the actual amounts of these constituents that are present in all registered substances.

In their comments on the original draft decision, the registrants highlighted that it was not possible to analytically identify individual constituents of the commercial products, and that some generic information was already included in the registration dossiers. ECHA therefore modified the decision to indicate that the requirement is for the mean concentration (and range) for each carbon chain length present in the actual products supplied by each registrant, and this could be based on the composition of the starting *n*-alkane feedstocks.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the registrants are required to provide the following: Information on the amounts of carbon chain lengths shorter than C_{14} that are present at or above 0.1% w/w for all of the MCCP product types supplied by the registrant (noting where content may vary between different product types). This information can be based on the composition of the *n*-alkane starting materials used to make the MCCP products, and shall be expressed in terms of a mean and range if appropriate. This information can be provided separately by each registrant if it is commercially sensitive.

2. Information on chlorine content

One of the initial grounds for concern related to PBT assessment. The registration dossiers indicate that commercial MCCP product types can vary in their degree of chlorination, which affects the persistence and hydrophobicity of their constituents. This has not been considered by the registrants and little detail is available about actual chlorine contents of supplied products in most registrations. They do not all indicate which commercial MCCP product types are used in different applications. A conclusion therefore cannot be drawn about the relevance of the PBT assessment for the whole life cycle of the substance made or imported by individual registrants. It is therefore important to know what types of products are supplied to the European market by each registrant, and the uses of specific MCCP product types. This will help guide possible future risk management decisions by individual registrants (if necessary).

In their comments on the original draft decision, the registrants highlighted that it was not possible to provide information on the chlorine contents of individual constituents of each commercial product. In response, ECHA clarified that the intention of the request was to gather information on the overall level of chlorination for the actual commercial products supplied by each registrant, together with details of the recommended use(s) of each of the different product types (for example, product names could be recorded along with their chain length distribution below C_{14}, chlorine contents and uses in a single table for each registrant). ECHA therefore modified the decision to refer to 'MCCP product types'.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the registrants are required to provide the following: Information on the chlorine contents of all MCCP product types supplied by the registrant, as well as a description of chlorine content for each registered use. This information can be provided separately by each registrant if it is commercially sensitive. Information on chlorine content for registered uses can be provided as aggregated data representative of all registrants.

3. Robust Study Summaries for available fish feeding study bioaccumulation data

One of the initial grounds for concern related to PBT assessment. The registrants discuss dietary fish bioaccumulation data, which are relevant for the B assessment. However, this information is given in a text annex only, and no robust study summaries have been prepared for the available information. The registrants do not consider the effects of growth correction and lipid normalization on the results. Their assessment is therefore insufficiently robust, and more information is required.

In their comments on the original draft decision, the registrants asked which specific data need to be added to the registration dossiers, pointing out that robust study summaries had not been included because the test materials were different from the chloroalkanes likely to be found in commercial products. In response, ECHA pointed out that these studies have been used in the registrant's weight of evidence analysis for the PBT assessment, so they should be properly summarised for transparency, and amended the decision to specify which studies require robust study summaries.

Therefore, pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit the following information: Robust study summaries for all available fish feeding study bioaccumulation data, including consideration of the effects of growth correction and lipid normalisation on the results obtained. This should include at least the following studies:

- Fisk AT, Cymbalisty CD, Bergman A and Muir DCG (1996). Dietary accumulation of C12- and C16-chlorinated alkanes by juvenile rainbow trout (*Oncorhynchus mykiss*). Environ. Toxicol. Chem., **15**, 1775-1782.
- Fisk AT, Cymbalisty CD, Tomy GT and Muir DCG (1998). Dietary accumulation and depuration of individual C10-, C11- and C14-polychlorinated alkanes by juvenile rainbow trout (*Oncorhynchus mykiss*). Aquat. Toxicol., **43**, 209-221.
- Fisk AT, Tomy GT, Cymbalisty CD and Muir CG (2000). Dietary accumulation and quantitative structure-activity relationships for depuration and biotransformation of short (C10), medium (C14) and long (C18) carbon-chain polychlorinated alkanes by juvenile rainbow trout (*Oncorhynchus mykiss*). Environ. Toxicol. Chem., **19**, 1508-1516.
- Cooley HM, Fisk AT, Weins SC, Tomy GT, Evans RE and Muir DCG (2001). Examination of the behaviour and liver and thyroid histology of juvenile rainbow trout (*Oncorhynchus mykiss*) exposed to high dietary concentrations of C10-, C11-, C12- and C14- polychlorinated n-alkanes. Aquat. Toxicol., **54**, 81-99.

4. Update of exposure scenarios

One of the initial grounds for concern related to the need to check current exposure scenarios for the environment to ensure that the risk characterization ratios are all below one. The assumptions that form the basis of the exposure scenarios in the registration dossiers have been reviewed by the UK Competent Authority, particularly with regard to the previous risk assessments performed under the Existing Substances Regulation[3,4]. Following this review, the reliability of a number of the exposure scenarios is unclear (as indicated in the following paragraphs) and so further information is needed to ensure that the recommended risk management measures are adequate, and cover all identified uses. This applies to:

- Manufacture of MCCPs. A previous EU risk assessment[4] suggests that the releases from some sites after waste treatment could be higher than the critical release value of [redacted] after treatment. The tonnage assumed in the generic exposure scenario may also be too low for some production sites. These details should be checked and the exposure scenario and/or recommended risk management measures updated if necessary.

- Formulation and use of MCCPs in PVC and rubber. Further justification for the selected emission factors is necessary, in particular relating to the use of the emission factor for [redacted] without adjustment for the increased volatility of MCCPs compared with [redacted] ([redacted] is used as an example of a 'medium volatility' plasticiser in the OECD Emission Scenario Document[5] on plastics additives that forms the basis of the exposure scenario). It is not clear how applicable the assumed risk management measures (use of closed sinks and basins to prevent discharge to wastewater and surface water and exhaust recovery and treatment by thermal or catalytic oxidation) are to all downstream user sites using MCCPs in the formulation of PVC and rubber. Further information is required to indicate that the required risk management technologies are actually in place in downstream user sites. The exposure scenario for PVC and rubber processing also needs to indicate more clearly the risk management measures necessary to demonstrate that the releases are lower than assumed in the previous EU risk assessment, particularly for the more volatile MCCP product types in open processes. In addition, the exposure scenario should also be updated to include the possibility of formulation and use occurring on the same site.

- Formulation, use and service life of MCCPs in textiles. Either further information shall be obtained to demonstrate that the local tonnage of [redacted] represents a realistic worst case for a generic site or the exposure scenario shall be refined to consider a higher local tonnage and any further risk management measures necessary to demonstrate safe use. Further information that may be useful to refine the exposure scenario includes the actual amounts of MCCPs used at textile treatment sites, information on the rates of application of coatings containing MCCPs and information on the emissions to the environment from the process. There is no information in the registration dossiers as to the types of textiles treated with MCCPs which can be considered to be indoor or outdoor applications, nor whether any of the treated textiles are subject to regular washing which could lead to a different release pattern than presented by the registrants. Further information shall be provided on

[3] ECHA (2009). Annex XV Transitional Dossier for Medium chain chlorinated paraffins (MCCPs). European Chemicals Agency.
[4] EU (2005). European Union Risk Assessment Report: Alkanes, C_{14-17}, chloro-. 3rd Priority List, Volume 58. European Commission Joint Research Centre, EUR 21640 EN.
[5] OECD (2009). Emission Scenario Document on Plastics Additives. OECD Series on Emission Scenario Documents Number 3, ENV/JM/MONO(2004)8/Rev1, 9th July 2009. Organisation for Economic Co-operation and Development.

the actual uses of the textiles treated with MCCPs and, if appropriate, further consideration given to the potential for releases to waste water from regular washing of such textiles.

- Formulation and use of MCCPs in leather fat liquors. This was identified as an application leading to a potential risk to the environment in a previous EU risk assessment[3,4], and the conditions of safe use are not presented in the registration dossiers.
- 'Other' reported uses of MCCPs in most of the registration dossiers include use in the denaturing of fuels and use in the manufacturing of absorbent formulations. No exposure scenario is provided. If these are genuine uses, an appropriate exposure scenario should be developed along with recommended risk management measures.
- Waste lifecycle stage. The assumptions in the registration dossiers do not necessarily reflect a worst case. For example, although most MCCPs are used in industrial and professional applications, they may be present in articles that are used by the consumer (e.g. PVC flooring, shoe soles, etc.) and so may be disposed of by consumers. Further consideration shall be given to the methods outlined in Chapter R18 of the REACH Guidance[6], specific information on waste handling at manufacturing sites, information in relevant OECD emission scenario documents (for example on coatings[7]) and any specific information on the waste management practice in the particular industry area concerned for each reported use.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the registrants are required to provide the following: The exposure scenarios in Section 9 of the Chemical Safety Report for the following applications and lifecycle stages need to be updated to identify the appropriate operational conditions and risk management measures:

- Manufacture of MCCPs.
- Formulation and use of MCCPs in PVC and rubber.
- Formulation, use and service life of MCCPs in textiles.
- Formulation and use of MCCPs in leather fat liquors.
- 'Other' reported uses of MCCPs, including use in the denaturing of fuels and use in the manufacturing of absorbent formulations.
- Waste lifecycle stage.

5-6. Bioaccumulation in aquatic species

One of the initial grounds for concern related to PBT assessment. Although some fish BCF (and other) data are available in the registration dossiers, they do not provide sufficient information on the range of possible values for different MCCP constituents, which depends on chain length and degree of chlorination. Read across from the available data performed by the UK Competent Authority suggests that fish BCFs may exceed 2,000 L/kg for C_{14} chlorinated paraffins with chlorine contents up to around 56% by weight (these constituents

[6] ECHA (2012). Guidance on information requirements and chemical safety assessment. Chapter R.18: Exposure scenario building and environmental release estimation for the waste life stage. ECHA-2010-G-20-EN. October 2012. European Chemicals Agency.
[7] OECD (2009). Emission Scenario Document on Coating Industry (Paints, Lacquers and Varnishes). OECD Series on Emission Scenario Documents Number 22. ENV/JM/MONO(2009)24, 8th July 2009. Organisation for Economic Co-operation and Development.

might also be persistent – see the next requirement). [redacted]. Tests are necessary to provide definitive information to allow a decision about the B status of these constituents to be made, as well as providing additional data to read across to other constituents. Testing of two substances that may be considered to be broadly representative surrogates of constituents of different commercial MCCP products is recommended.

Existing studies indicate that fish might be able to metabolise the substance to some extent, and this will need to be taken into account in the testing. If aqueous exposure is used, care will be needed to avoid interpretation problems due to the effects of organic carbon on the truly dissolved fraction. The organic carbon content of the test water should be minimised, and it will be important to express the aqueous concentration on an appropriate basis, taking account of the effect of particulate and dissolved organic carbon concentrations on bioavailability. Excessive fish growth and lipid increases have also been found to complicate interpretation of the existing studies, so should be minimised. To allow comparability, the studies should be corrected for growth and normalized to a 5% lipid content.

As explained in their comments, the registrants believe that additional studies are not necessary because, in their view, food-chain information should take precedence over fish BCF data (which represent a 'lower tier' in bioaccumulation assessment), and so the overall weight of evidence indicates that MCCPs is not bioaccumulative within the meaning of Annex XIII based on BMF, TMF and field data. Rather than spending further resources on 'parent compounds' the registrants think that it would be more environmentally relevant to assess the bioaccumulation potential of possible metabolites.

ECHA disagrees with this conclusion since:

- The field biomagnification studies generally have significant experimental limitations, and in any case, lack of biomagnification in one food chain does not automatically mean that it can be excluded for all others. Several factors could be important, such as the metabolic potential of the species examined, and whether the food chain is dominated by benthic or pelagic organisms.

- A significant level of accumulation arising from biconcentration processes is still a legitimate concern, since it may lead to effects at one level of a food chain that could have consequences for predators. Substances have already been added to the Candidate List because of their PBT identification based on BCF data.

- Although a weight of evidence approach should be used when comparing the available data with the Annex XIII criteria, the only numerical criteria are based on BCF. The ECHA Guidance for PBT assessment (Chapter R11) says that "because food chain transfer and secondary poisoning are basic concerns in relation to PBT and vPvB substance, an indication of biomagnification potential can on its own right be considered to conclude that a substance meets the B or vB criteria but ***absence of such a biomagnification potential cannot be used to conclude that these criteria are not fulfilled.***" (Emphasis added.)

- The contribution of metabolites to observed bioaccumulation in the existing studies is unclear (there are only very limited data on this aspect).

Although lack of biomagnification potential is clearly an important consideration, ECHA does not think it is sufficient to outweigh the fact that a substance may meet the B or vB criteria based on BCF alone. Given the uncertainties in the modelling approach both presented by the registrants and carried out in the substance evaluation, ECHA remains convinced that

testing is needed to confirm the BCF for those chain lengths and chlorine contents suspected to meet the B/vB criteria.

In response to the registrant's comments, ECHA modified the original draft decision to indicate that radiolabelled test substance may be used along with parent substance analysis, to allow an assessment of the relevant contribution of metabolites to any observed accumulation, and to highlight precautions to avoid confounding factors if aqueous exposure is used (relating to organic carbon content, dissolved concentrations, fish growth and lipid content). In addition, as mentioned at the beginning of this section, the word 'representative' was removed from the naming of the test substance, to avoid unintentional ambiguity about the meaning of this term. The test material for the bioaccumulation testing is simply a practical surrogate for relevant MCCP constituents (not a constituent as such).

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are required to carry out the following study using two different C_{14} chlorinated *n*-alkane test substances, with chlorine contents of 50-52% and around 55-60% by weight, respectively: Bioaccumulation in fish: Aqueous and Dietary Exposure test (test method OECD TG 305). Either aqueous or dietary exposure would be acceptable (the choice is left to the registrant). Radiolabelled test substance may be used along with parent substance analysis, to allow an assessment of the relevant contribution of metabolites to any observed accumulation. If aqueous exposure is used, the organic carbon content of the test water (e.g. from fish excreta and food residues) should be kept as low as possible, and efforts shall be made to establish the truly dissolved concentration, for example by taking measurements of particulate and dissolved organic carbon concentrations at appropriate time points and using an appropriate technique to enable the estimation of the bioavailable fraction if feasible (e.g. solid-phase microextraction). Excessive fish growth and lipid increases should also be avoided, since these might confound the results. The results should in any case be corrected for growth and normalized to a 5% lipid content.

7-9. Sediment simulation testing

One of the initial grounds for concern related to PBT assessment. The registrants summarise a range of information on ready biodegradation, but do not report any sediment biodegradation half-lives. Constituents with lower chlorine contents are readily biodegradable and so do not meet the Annex XIII persistence criteria, but persistence is predicted to increase with increasing chlorine content. Substances with chlorine contents above 50% are generally not readily biodegradable (although still undergo some degradation in ready biodegradation tests), but it is not clear if this increased persistence means that such substances would meet the Annex XIII persistence criteria in terms of an environmental half-life in sediment (or soil). Since MCCPs are released to waste water and are highly adsorbing, it is appropriate to investigate fate in sediment. A reliable sediment biodegradation half-life is required to determine whether constituents of the registered substance meet the Annex XIII P/vP criteria under the conditions of the test, and also to identify any transformation products. This information is needed for three substances that may be considered to be broadly representative surrogates of constituents of different commercial MCCP products:

- A C_{14} chlorinated *n*-alkane with a chlorine content of 50-52% by weight. Such constituents of the registered substance are potentially persistent, predicted to meet the B criterion and are assumed to meet the T criterion based on the available evidence.
- A C_{14} chlorinated *n*-alkane with a chlorine content of 55-60% by weight. Such constituents of the registered substance are potentially persistent, predicted to meet

the B criterion and are assumed to meet the T criterion based on the available evidence.

- A C_{15} chlorinated *n*-alkane with a chlorine content of around 51% by weight. This constituent is potentially persistent and the fish BCF is around 1,833-2,072 L/kg. It is assumed to meet the T criterion based on the available evidence.

In their comments on the original draft decision, the registrants claim that the existing enhanced ready test results in combination with Sequential Batch Reactors (SBR) and mass balance results are much more informative than an OECD 308 test. They consider that the OECD 308 test is unsuitable for the study of low water solubility substances like chlorinated alkanes, pointing out that it has not been evaluated for its ability to simulate real environmental conditions, and that it has not been ring-tested. They believe that the number of variables in the test design (including aerobic/anaerobic phases, sorption/desorption and complicated bioavailability) means that the results will be inconclusive for determining the actual sediment half-life for MCCPs. They also suggest that based on the available information there is no reason to expect that the carbon chain length is of any relevance for the persistence of MCCPs (rather, chlorination appears to be the determining factor in biodegradation rate). Moreover, the C_{15} component with 51% chlorination has a lower carbon to chlorine ratio than a C_{14}-50% ww chlorinated component which already meets the 'readily biodegradable' criterion. As such, there appears to be no justification for testing such a component. Finally, the registrants suggest that rather than spending further resources on testing 'parent compounds' it would be more environmentally relevant to assess the fate of possible metabolites, which could be done on actual mixtures from SBR reactors and using whole effluent testing techniques.

In response, ECHA has already taken full account of the available enhanced ready tests in the substance evaluation, including carrying out an extensive read-across. Whilst further enhanced ready biodegradation and SBR studies may provide useful supplementary information for the assessment of persistence, they do not allow any conclusion to be drawn about degradation **half-life in sediment**, which is required for comparison with the Annex XIII criteria. Based on its analysis of the available data, ECHA thinks that it is not proven that chlorination alone is the determining factor in the rate of biodegradation; carbon chain length may also be important. In addition, ECHA notes that the OECD 308 test method uses natural sediment and is the standard approach adopted for all substances when degradation in sediment is investigated. In particular, ***it has already been used to test the analogue short-chain chlorinated paraffins***. The technical arguments against its use are therefore not accepted. ECHA notes that even if a substance degrades relatively quickly in the dissolved phase following desorption (and the kinetics of this are uncertain for MCCPs in natural sediments), a long residence time in sediment is still a relevant consideration since organisms that feed on sediment will potentially be exposed to high concentrations. ECHA therefore believes that the OECD 308 test is still relevant in this case.

ECHA recognises that although the OECD 308 studies should be able to measure mineralisation and loss of parent substance, the complexity of the test substances may make identification and quantification of metabolites difficult (if any are formed). ECHA agrees that it might be useful to clarify the bioaccumulation potential of persistent metabolites, and so has modified the original draft decision to indicate that if it is not possible to identify metabolites in the OECD 308 studies (for example due to analytical difficulties) then other approaches to profile the persistent, bioaccumulative and toxic properties of the metabolites may be considered.

In addition, as mentioned at the beginning of this section, the words 'representative' and 'constituent' were removed from the naming of the test substance, to avoid unintentional ambiguity about the meaning of these terms. The test material for the bioaccumulation

testing is simply a practical surrogate for relevant MCCP constituents (not a constituent as such).

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are required to carry out the following study using three different test substances (a C_{14} chlorinated *n*-alkane with a chlorine content of 50-52% by weight; a C_{14} chlorinated *n*-alkane with a chlorine content of 55-60% by weight; and a C_{15} chlorinated *n*-alkane with a chlorine content of around 51% by weight): Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24/OECD TG 308).

Should only partial mineralization occur in the test it will be necessary to identify any potentially persistent metabolites that are formed – if this is not possible (for example due to analytical difficulties) then other approaches to profile the persistent, bioaccumulative and toxic properties of the metabolites may be considered.

A tiered approach to testing is possible. This would involve persistence and bioaccumulation testing for the lower chlorine content C_{14} substance first:

- If it is found to meet the P criterion, the registrant may choose to read across this conclusion to the higher chlorine content C_{14} substance as well as the C_{15} substance, without the need for further sediment simulation testing.
- Should the lower chlorine content C_{14} substance also be confirmed as meeting the B/vB criteria then the registrant may choose to conclude that the C_{14} substance with a higher chlorine content also meets the PBT criteria without carrying out the further bioaccumulation testing necessary to show this.

The registrants will need to provide a justification for any read-across. If conclusions cannot be read across from the lower chlorine content C_{14} substance, the testing for the other two substances (sediment simulation and fish bioaccumulation for the C_{14} 55-60% w/w *n*-alkane; sediment simulation for the C_{15} ~51% Cl w/w *n*-alkane) shall be carried out in parallel.

10. PBT assessment

The registrants are reminded of their obligation to revise the PBT assessment once new information is available. In particular, the registrants shall take account of the variation in PBT properties of all relevant constituent groups present at 0.1% w/w or above in the commercial MCCP product types, as described in this decision, as well as any relevant transformation products observed in the sediment simulation tests.

In their comments on the original draft decision, the registrants objected to the grouping approach that has been adopted by ECHA for this UVCB substance for the purposes of PBT assessment, preferring instead to consider the properties of the whole substance. As described above, ECHA believes that such an approach would be misleading for such a highly variable substance. Instead, it is considered appropriate to identify groups of relevant constituents that potentially meet the PBT criteria, and to perform testing on relevant test materials accordingly, even if they are not themselves commercial products. The decision has therefore been modified to emphasise that the results of the requested testing must be applied to groups of relevant constituents (not the whole substance) for the purposes of PBT assessment.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are required to provide the following information subject to this decision: PBT assessments for

all relevant constituents of the substance and any transformation product found to be formed in a relevant environmental compartment at any time point, at a concentration of ≥ 0.1 % w/w (grouped as appropriate).

IV. Adequate identification of the composition of the tested material

The substance identity information submitted in the registration dossiers has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. In relation to the required tests, the sample of substance used for the new studies shall have a composition that is within the specifications of the substance composition that are given by all concerned registrants. It is the responsibility of all the concerned registrants to agree on the tested materials to be subjected to the tests subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the studies must be shared by the concerned registrants.

V. Avoidance of unnecessary testing by data- and cost- sharing

Avoidance of unnecessary testing and the duplication of tests is a general aim of the REACH Regulation (Article 25). The legal text foresees the sharing of information between registrants. Since several registrants of the same substance are required to provide the same information, they are obliged to make every effort to reach an agreement for every endpoint as to who is to carry out the test on behalf of the other registrants and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation.

If ECHA is not informed of such agreement within 90 days, it shall designate one of the registrants to perform the tests on behalf of all of them. If a registrant performs a test on behalf of other registrants, they shall share the cost of that study equally and the registrant performing the test shall provide each of the others with copies of the full study reports.

This information should be submitted to ECHA using the following form stating the decision number above at:

https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/datasharing_en.asp.

VI. General requirements regarding Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

VII. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Jukka Malm
Deputy Executive Director

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.