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Item 5 (b) (ii) of the provisional agenda*

Technical work: consideration of draft risk profiles: chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight

Comments and responses relating to the draft risk profile for chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight

Note by the Secretariat

As is mentioned in the note by the Secretariat on the draft risk profile: chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight (UNEP/POPS/POPRC.18/5), the annex to the present note sets out a compilation of comments and responses relating to the draft risk profile for chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight, submitted by the chair of the intersessional working group on those chemicals. The present note, including its annex, has not been formally edited.

* UNEP/POPS/POPRC.18/1.

Annex

Comments and responses relating to the draft risk profile for chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight

Minor grammatical or spelling changes have been made without acknowledgment. Only substantial comments are listed. Parts of the text with comments are indicated in bold. Suggested insertions and deletions are indicated in red text and strikethrough, respectively.

Source of comments	Page	Para	Comments on the 2nd draft risk profile for chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight	Response
Canada	1	2	Please explain the abbreviation UVCB.	Text updated to include full name.
Canada	1	2	"**For clarify, a CP constituent is an individual structural isomer…**" To clarify or for clarification ?	Amended to "clarity".
Canada	4	Table 3	Consider adding the octanol-air partition coefficient values, provided in table 17, to this table.	Included in table 3 as a range for each carbon length
Canada	7	19	Recommended revision to better reflect the group of substances covered by the Canadian assessment- Environment Canada and Health Canada have reviewed the CPs group in 2008 (Canada, 2008). The review concluded that "chlorinated alkanes that have the molecular formula CnHxCl(2n+2-x) in which $10 \leq n \leq$ 20MCCPs" are "toxic" as defined in paragraphs 64 (a) and (c) of the Canadian Environmental Protection Act, 1999. This includes CPs of the chain lengths for MCCPs covered in this proposal.	Amended as proposed.
Canada	8	26	Consider clarifiying if this means "production".	This is specific to Australia. Nevertheless, this section has now been significantly updated.
Canada	8	28	Consider adding global production estimates from Chen et al. (2022). https://doi.org/10.1021/acs.est.2c00264	These have been included.
Canada	10	41	Chen et al (2022) is missing from the references list.	Added to reference list.
Canada	11	44	**...predicted biodegradation data** The information provided here may seem less relevant as these are MCCPs with <45% chlorination. Consider amending this paragraph to present and elaborate on this information in a way as to inform trends for MCCPs with > 45% chlorination.	This text was added in response to comments received in the previous round from other Parties. As there are differing views, we think the data should be reflected in the document.
Canada	16	66	Suggested addition since modelled data suggest otherwise.	Amendment accepted.
Canada	22	95	For your consideration. Please see a suggested addition based on new data from a recent Canadian study (Fernie *et al.* 2022), which will be submitted for publication later this year. These findings were presented at the SETAC Europe/Copenhagen meeting in May 2022 (see	As these data have not yet been published nor submitted for publication, we do not think that it would be appropriate to add this to the RP at present.

Source of comments	Page	Para	Comments on the 2nd draft risk profile for chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight	Response
			presentation attached to our submission). "Concentrations of MCCPs (summed congeners) were measured in the blood of 90% of Peregrine Falcon nestlings (N = 38 of 42; Mean ± SEM: 483 ± 53 ng/g lw; Range: 130-1400 ng/g lw) in Central Canada (i.e., across Ontario), with urban nestlings having higher MCCP concentrations than rural Peregrine Falcon nestlings. The CP blood profile of these Central Canadian Peregrine Falcon nestlings (Fernie *et al.* 2022) was similar to the CP muscle profile of adult Peregrine Falcons in Sweden (Yuan *et al.* 2019) : MCCP concentrations were higher than those of vSCCPs or SCCPs, but lower than LCCP concentrations. Concentrations of MCCPs were similar in the Peregrine Falcon nestlings from Central Canada (blood: 483 ± 53 ng/g lw) (Fernie *et al.* 2022) and the adult Peregrine Falcons from Sweden (muscle : 410 ng/g lw) (Yuan *et al.* 2019)." Fernie KJ, de Wit CA, Yuan A. 2022. Chlorinated paraffins, diet and endocrine measures in nestling peregrine falcons in the Canadian Great Lakes Basin. SETAC Europe 32nd Annual Meeting, 15-19 May 2022. Copenhagen, Denmark.	
Canada	24	104	Referring to De Witt et al., 2020, this publication is missing from the reference list.	Added to reference list.
Canada	28	2.2.4.3	For your consideration. Nipen et al. (2022) have measured <0.4–35 ng/m^3 of MCCPs in air samples collected in Tanzania. https://doi.org/10.1016/j.envpol.2021.118298	This has been noted in the RP and added to the air monitoring table in the INF document.
Canada	39	205	For your consideration. Please see below a suggested addition based on new data from a recent Canadian study (Fernie *et al.* 2022), which will be submitted for publication later this year. These findings were presented at the SETAC Europe/Copenhagen meeting in May 2022 (see presentation attached to our submission). "Nevertheless, preliminary findings suggest that collectively, circulating concentrations of vSCCPs, MCCPs, and LCCPs, may modestly influence circulating free thyroxine (FT4) (P = 0.07) in wild Peregrine Falcon nestlings in Central Canada, but not circulating SCCPs, dietary trophic position (delta-15N), nor body condition of the nestlings (Fernie et al. 2022)." Fernie KJ, de Wit CA, Yuan A. 2022. Chlorinated paraffins, diet and endocrine measures in nestling peregrine falcons in the Canadian Great Lakes Basin. SETAC Europe 32nd Annual Meeting, 15-19 May 2022. Copenhagen, Denmark.	See previous response above.
Canada	41	217	Suggest replacing the NOEC with a LOEC/EC_x value, if available, or replacing by another example where an effect value can be provided.	Text updated with LOEC value.
Canada	N/A		Monitoring data for INF document – Fernie data	See previous response.
China	17	69	**Overall, the log Kow is greater than 5 for all constituents of CPs with C14-17 chain lengths**	Each of the studies (Hilger *et al*. (2011a), Fisk *et al*. (1998a) and Renberg *et al*. (1980)) have been

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			with chlorination >45% using predicted and measured data. It is suggested to provide supportive information for this sentence. Reason: Unreliable evidence. The data provided about the log Kow of C15-17 CPs (table 3) are from the early research papers by Hilger et al (2011a), Fisk et al (1998a) and Renberg et al (1980), and as mentioned in this draft, the conclusions from the abovementioned papers do NOT meet the OECD guideline nor the GLP guideline or lack enough information like the internal standard. The analysis method of MCCPs adopted in the early research papers are semiquantitative or inaccurate, therefore the log Kow is only for indication, but not reliable enough for Annex D and not convincing for the conclusion that the log Kow of C15-17 CPs is greater than 5.	previously evaluated against contemporary OECD test guidelines and guidance (ECHA R7a and R.11). Hilger *et al*. (2011) followed the test method of the OECD TG 117. Both the OECD GD 23 and the ECHA R7a guidance identify the OECD 117 as suitable for determining Log Kow of homologous UVCBs. It is clear from the paper that the authors understood how to use the HPLC method to measure log K_{OW}, for example they state "Determination of the log K_{OW} using RP-HPLC is an accepted method [12]. [12: Klein W., Keordel W., Weiss M. and Poremski H. J. (1988). Updating the OECD Test Guideline 107 "Partition Coefficient n-Octanol/Water": OECD Laboratory Intercomparison Test on the HPLC Method. Chemosphere, 17, 361–386.]" The method is therefore suitable and robust. Internal standards are not required for this type of study that relies on external standards with known log Kow values that are used to build a linear regression curve based on retention times and HPLC capacity factors. The HPLC test does not need quantitative analysis of the test substance or reference substances. For all external standards and samples, the requirement for each is a well resolved peak in the chromatogram that can be used to determine retention times. By analysing single congeners and a number of products it is possible to determine the range of log K_{ow} values that are associated with these complex products. Overall, the Hilger study is very similar to a recognised OECD test guideline, and the validity criteria specified in the test guideline have been met in the study. The individual CPs of relevance to this RP were synthesized specifically for this study (e.g., chain lengths of C_{14}, C_{15}, C_{16}, C_{18} and a C_{14-17} product). The Hilger paper is therefore considered to be "reliable with restrictions", and so reliable data are available for the C_{15-17} CPs

Source of comments	Page	Para	Comments on the 2nd draft risk profile for chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight	Response
				demonstrating the log K_{OW} exceeds 5. We also note that the log K_{OW} of 6.58 measured in the recent GLP slow stir study (OECD TG 123) for C_{14} 50% Cl wt. is comparable to the result reported in Hilger *et al.* (2011) of 6.30 for C_{14} 47% Cl wt. The studies of Fisk *et al.* (1998a) and Renberg *et al.* (1980) are already noted as indicative only in the text of the RP. Nevertheless, these data support the findings of the OECD TG 123 and Hilger *et al.* (2011) studies as the results are consistent with those data. "Reliable with restriction" does not mean "unreliable". The term is taken from a well-recognised paper (Klimisch H.J., Andreae M. and Tillmann U. (1997). A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data. Regulatory Toxicology and Pharmacology. 25(1), 1-5). Klimisch scoring has been used to assess data validity in various regulatory programmes such as EU REACH and the OECD Co-operative Chemicals Assessment Programme. The POPs assessment is made by an evaluation of the available data with a weight given to the reliability and relevance of each study. As an example, conclusions about persistence and bioaccumulation for Dechlorane Plus were drawn by POPRC in the absence of any studies performed to GLP or to OECD test guidelines. A lot of those studies would be "reliable with restriction", so the RP here is consistent with previous cases. No changes to the main RP document have been made. Additional information on the Hilger *et al.* (2011) paper has been included in the INF document.
China	19	83	**In summary, laboratory bioaccumulation studies using fish indicate high levels of bioaccumulation for different constituents of CPs with C14-17 chain lengths.** It is suggested to provide supportive information for this sentence. Reason: Unreliable evidence.	Fisk *et al.* (1996, 1998b, and 2000) We agree that these studies were not performed to GLP. As noted in our reply to your comment on log K_{OW} above, the absence of GLP does not in itself invalidate a study (it simply provides

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			The research that support the BCF of C15-17 CPs are not reliable, similar as above. The high concentration adopted in the experiments of Tompson et al (2000) exceeds the solubility of MCCPs. And the BCF is deducted from its half-life period by experience, which does not fit in with the review of Annex D. The research conducted by Fisk el at (1996, 1998b, and 2000) do not meet GLP standards, and the analysis method is semiquantitative. Therefore, the only convincing conclusion is the BCF of C14 is above 5000. We need more solid, supportive evidence for "C15-17 CPs are bioaccumulative" and even more for "BCF of C15-17 CPs are greater than 5000".	reassurance that data have been carefully recorded and reported). We have advised caution regarding exact results. This is due to the absence of certified reference standards that would be used to validate aspects of analysis of the individual congeners. Nevertheless the studies assess individual in-house synthesised radio-labelled CP congeners of relevance to this RP (e.g. C_{14}, C_{16}, C_{18}). Radio chemical analysis is a fully quantitative method allowing for a mass balance to be derived. Uptake and depuration kinetics for each of the congeners of interest were derived from the radio analyses, which allowed for BMFs to be calculated. The example radio-chromatograms provided in the publications confirmed the complexity of the components and the associated range of physicochemical variation dictated by chain length, chlorination degree and positional variation. These will look more variable than data from contemporary mass spectrometric methods, that target the most abundant congeners. Thompson *et al.* (2000) This study (which was performed to GLP) was conducted using two test concentrations (1 µg/L and 5 µg/L). We disagree that these concentrations were especially high (for example the lower concentration of 1 µg/L is not significantly higher than the 0.34 µg/L concentration used in the C_{14} study). Instead, it seems more likely that the levels were around the water solubility limit of the test substance. As indicated in the RP, the higher test concentration gave a lower BCF value, which suggested that the water solubility was exceeded in that part of the experiment. We highlight that if the solubility limit in the test medium was exceeded, the resulting BCF values would be under-estimated (because the fish are assumed to take up dissolved substance only, so the reported concentrations in the test media would be over-estimates of that). This is demonstrated by the two different

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				BCF values in the Thompson *et al.* (2000) study. The kinetic BCF values reported in the RP for the Thompson *et al.* (2000) study were calculated in the usual way (k_1/k_2). The point made in the RP is that the k_2 value by itself would suggest a high BCF value (above 5 000). The approach of considering k_2 or depuration half-life is included in the OECD guidance for bioaccumulation. We also highlight that this approach was used by POPRC to draw conclusions about bioaccumulation in the assessment of Dechlorane Plus. Finally, (and as discussed in a later comment response) the data for bioaccumulation in the Risk Profile are not limited to these 4 studies.
China	32	143	**Sampling locations include China, Hong Kong, Japan, Sweden, Norway, UK, Germany, the Netherlands, Canada, Australia, Switzerland, Czech Republic, Irish Sea and the Baltic Sea.** Remove "Hong Kong" Reason: Hong Kong is part of China.	Text updated as requested.
Columbia	General		For both documents, it is suggested that chapters "Production and trade" or "Uses", include an indicative list of the more relevant commercial products that include the substances, as it is very focused on the production, trade and use of the Chlorinated paraffins as they are, but for many countries, these pollutants are present in products, usually as a mix, whose MSDS usually do not declare their presence and amount.	The RP (and INF document) does include some discussion of concentrations in products, but this is limited because the focus of the RP is on demonstrating why the substance meets the criteria to be listed as a POP. The Risk Management Evaluation will include a more detailed discussion of products containing the substance.
Denmark	General		<u>Additional literature:</u> I have focused on new literature from the Arctic and find the current draft rather comprehensive in this respect, with few additions and comments. The monitoring data from Zeppelin have been updated with a new report (Bohlin-Nizzetto *et al*., 2021) covering measurements from 2020 and showing higher concentrations of MCCPs than in the previous year, however, with uncertainties. The median concentration is 280 pg/m^3. The discussion of temporal trends might also want to consider the time trends of MCCPs emerging from the Norwegian monitoring in the coastal marine environment, as discussed by Vorkamp *et al*. (2019).	Data from Bohlin-Nizzetto *et al.* (2021) has been added, including information about the apparent increasing trend. The data reviewed by Vorkamp *et al.* (2019) are generally already described in the same section of the RP, but we have added the mussel data which was not previously captured.
Denmark	23	104	The reference to De Witt et al. (2020) in paragraph no. 104 should be de Wit et al. (2020), as correctly stated in paragraph no. 87.	Updated.

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Denmark	28	126	The draft risk profile includes conclusions on the reliability of measurements, based on information in the respective papers and expert judgement. Paragraph no. 126 includes a reference to Schlabach et al. (2022) on data for pine needles. Schlabach et al. (2022) provide a detailed discussion of methodological issues related to sample homogeneity and representativeness of pine needle samples, including MCCP data from parallel analyses. These data and discussions could be included, as they appear very useful information to assess data quality.	Text added to acknowledge the uncertainty.
Denmark	32	152	Paragraph no. 152 referring to the review article by Vorkamp et al. (2019): It would be more correct to describe these locations as "Northern Norway" than "Arctic". It could be worth noting that all MCCP concentrations exceeded SCCP concentrations in the same samples. The temporal development was discussed by Vorkamp et al. (2019) as well, with increasing concentrations at Lofoten, but no trend at Bodø. The same reference also included data on MCCP concentrations in Atlantic cod liver from Northern Norway, preceding the data that are currently included in the draft risk profile.	Text updated to consider these points.
Denmark	32 & 33	151 & 156	The reference to Green et al. (2020) seems to be missing from the reference list. It might in fact be Green et al. (2022) as the report was revised with corrections.	Updated using the later reference.
Denmark	General		Medium-chain chlorinated paraffins (CAS 85535-85-9) - CAS number is not specific to the compounds assessed in the draft risk profile, as explained there.	The CPs proposed for listing do not have a single CAS number. In part this reflects the different commercial forms of the substance supplied in various parts of the world, but also that the concern is specific to a certain level of chlorination (and above). The majority of the laboratory studies discussed in the RP are for "MCCPs" as defined in Europe, since this is the form that has been investigated most thoroughly.
Denmark	28	123 & 125	Paragraph 125 describes similar concentrations of SCCPs and MCCPs in source regions, while data from the Arctic show lower MCCP than SCCP concentrations. This is interpreted with a lower long-range environmental transport of MCCPs (compared to SCCPs). However, these conclusions might not be consistent with Schlabach et al. (2022) who showed MCCP > SCCP in air at remote regions, but SCCP > MCCP at urban stations. It should also be noted that MCCP concentrations in Arctic air, as measured at Zeppelin, have decreased relatively to SCCP concentration, as is described in paragraph no. 123.	We are cautious in drawing firm conclusions when comparing urban and remote air concentration from Schlabach *et al*. (2022), as there were only 3 urban samples, and these were taken from a single location (Reykjavik) in the same year. While there is a lower detection frequency for MCCPs, the concentrations are increasing relative to SCCPs.
Denmark	Reference		References:	Noted.

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			Bohlin-Nizzetto, P.; Aas, W.; Halvorsen, H.L.; Nikiforov, V.; Pfaffhuber, K.A. (2021) Monitoring of environmental contaminants in air and precipitation. Annual report 2020. NILU report 12/2021: Norwegian Environment Agency M-2060 De Wit, C.A.; Bossi, R.; Dietz, R.; Dreyer, A.; Faxneld, S.; Garbus, S.E.; Hellström, P.; Koschorreck, J.; Lohmann, N.; Roos, A.; Sellström, U.; Sonne, C.; Treu, G., Vorkamp, K.; Yuan, B.; Eulaers, I. (2020) Organohalogen compounds of emerging concern in Baltic Sea biota: levels, biomagnification potential and comparisons with legacy contaminants. Environ. Int. 144, 106037 Green, N.W.; Schøyen, M.; Hjermann, D.Ø.; Øxnevad, S.; Ruus, A.; Grung, M.; Beylich, B.; Lund, E.; Tveiten, L.; Jenssen, M.T.S.; Håvardstun, J.; Ribeiro, A.L.; Doyer, I.; Bæk, K. (2022) Contaminants in coastal waters of Norway 2019. NIVA – Norwegian Report for Water Research. Report 7741-2022, revised version of report 7565-2020. Schlabach, M.; Borgen, A.; Bæk, K.; Kringstad, A. (2022) Screening of chlorinated paraffins, dechloranes and UV-filters in Nordic Countries. https://pub.norden.org/temanord2022-519. ISBN: 978-92-893-7291-6 Vorkamp, K.; Balmer, J.; Hung, H.; Letcher, R.; Rigét, F.F. (2019) A review of chlorinated paraffin contamination in Arctic ecosystems. Emerging Contaminants 5, 219-231	
Equatorial Guinea	General		La Convención de Estocolmo, recientemente firmado 26/06/2019 y ratificado, todavía no dispone de mecanismos de control, evaluación y cumplimiento de ciertas acciones del Articulo 10, inciso 3 del Convenio. Concerniente a las revisiones de propuestas de enmiendas realizadas en el Comité sobre los riesgos que conlleva los productos químicos del Anexo A, B o C del Convenio: Dechlorane Plus; UV-328, Chlorpiryfos, Chlorinates parafines de cadena C14-17 y chlorination del nivel que excede 45% de nchlorine de peso y Long-chain perfluorocarboxylic acids(LC-PFCAs). Debido al desarrollo de su aplicabilidad en diversos campos en la agricultura, en los hospitales y su eco toxicidad no ha sido todavía estudiada en nuestro País en los mares y en los ríos como contaminantes orgánicos persistentes, por lo que, se caben evitar todos los posibles vertidos al medio ambiente dichas sustancias químicas. Tampoco Guinea Ecuatorial, no tiene elaborado un listando nacional que identifica los productos químicos en cuestión para un plan de acción de consentimiento fundamentado previo. En conclusión, el esfuerzo de nuestra Parte para utilizar, cuando es necesario, establecer los medios para incorporar dichas sustancias en los planes nacionales de aplicación relativo a los	Noted. The Risk Management Evaluation will provide more information on the use of the substance, which may inform your planned survey.

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			contaminantes orgánicos persistentes en sus documentos estratégicos de desarrollo sostenible; necesita realizar una encuesta nacional sobre el uso e importación de referidos productos químicos en el País, luego la aprobación de un proyecto de directrices técnico para la gestión ambiental en los tres Convenios sobre el uso de sus residuos tóxicos,	
European Union (EU)	General		Extract from draft risk profile - UK's response to EU comment: 'there is little to no available evidence indicating LRET of the lower chlorinated congeners. LRET modelling of <45% Cl wt. constituents indicates that their atmospheric half-life is significantly shorter, and very few monitoring studies are able to analytically detect <Cl5. Bioaccumulation data below 45% are also limited' EU comments- Modelling data should be considered carefully as it is possible that the association of chemicals with particles may substantially extend their lifetimes over those expected for the same substances in the gas phase (Bidleman et al., 1990 as cited in the POP LRTP 'guidance' (version May 2022)). The draft risk profile for CPs points out the uncertainties around the predictions for the LRET (likely underestimated). The sorption potential of MCCP congener groups to particulates in air reduces the potential for photodegradation during atmospheric transport relative to the gaseous phase. Regarding monitoring data, please note that absence of detection/quantification of congener groups with a chlorination level $<Cl_5$ due to analytical methods should not be interpreted as absence of these congeners in the environment/biota. Indeed, you cannot exclude their presence in the environment/biota based on the information available and in particular as most of the monitoring studies available in remote areas are referring to concentration levels for ΣMCCP. We have monitoring data which indicate that following congener groups are found in remote areas (away from point sources) and thus supporting the evidence of their LRTP (congener groups having an average chlorination level <45% Cl wt. are highlighted in bold red).: Gawor and Wania (2013) predicted that MCCP with ~5–6 and ~6–7 chlorines, respectively, were identified to have the highest combined potential for LRT and bioaccumulation in humans (the so called Arctic contamination and bioaccumulation potential (AC-BAP)) and thus to have the potential to be persistent organic pollutants. Monitoring data tend to confirm this prediction as it has been found that MCCP congener groups with C_{14-15} and Cl_{4-9} were found in the Arctic (biota; Reth *et al.*, 2006) and in the Antarctic (air; Ma *et al.*, 2014 and Jiang *et al.*, 2021). We are of the opinion that the above information should be taken into account in the LRTP	<u>LRET</u> The under-estimation of predicted LRET due to adsorption to particulate matter is discussed in Section 2.2.4.1 of the RP, including the observed trends within different chain lengths and levels of chlorination. No further changes have been made. The monitoring data and definitive detection of congener groups with fewer than 5 Cl atoms is discussed in detail in the analytical challenges section of the document. We agree that absence of data cannot be used to reach a firm conclusion one way or the other. Nevertheless, a conclusion needs be drawn from the *available* data, and the predicted data clearly indicates lower LRET potential for lower levels of chlorination. This is consistent with the comparison of SCCPs and MCCPs, involving both modelled and measured data. We acknowledge that there are uncertainties, but we believe that the current conclusions drawn are reasonable based on the data available. With regard to the Gawor & Wania (2013) paper, $C_{14}Cl_5$ and $C_{15}Cl_5$ are within the scope of the proposed listing. Ma *et al.* (2014) detected $C_{15}Cl_4$ and $C_{16}Cl_4$, but not $C_{14}Cl_4$. Reth *et al.* (2006) only detected $C_{14-15}Cl_{5-9}$. No detection of Cl_4 is reported. The analysis performed by Jiang *et al.* (2021) did not include congeners with <5 chlorine atoms. <u>Bioaccumulation</u> While the Unpublished (2010h) dietary study is valid, the non-detects for some of the congener level chemical analysis means it is not possible to draw reliable conclusions on congener-specific bioaccumulation.

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			assessment of congener groups of MCCP having an average chlorination level <45% Cl wt. As regards bioaccumulation data, following data are available in the EU SVHC dossier for congener groups having an average chlorination level <45% Cl wt. and for which it was possible to conclude on their bioaccumulation potential (the EU vB criteria is equivalent to the bioaccumulation criteria under the POPs): <u>C14 chlorinated n-alkane with 3 chlorine atoms (equivalent to 35.3% Cl wt):</u> A lipid-normalised and growth-corrected kinetic fish aquatic BCF value of ca. 11 530 L/kg was measured for C14 chlorinated n-alkane, 45% Cl wt. (a high weight is given to this study in the WoE approach; Unpublished, 2010h). Lipid normalised BMFs >1 were measured in the muscles and livers of a snake-frog predator-prey relationship for the congeners C14Cl3 (a low weight is given to this study in the WoE approach; Du et al., 2020). The BCF Baseline model of CATALOGIC yields a BCF prediction for C14Cl3 which is over the threshold of log BCF 3.69 (BCF ~ 5000 L/kg) and therefore indicating bioaccumulation potential (a low weight is given to QSAR predictions in the WoE approach). These predictions are supported by the outcome of the BCF predictions for C14Cl2 and C14Cl4 which indicate bioaccumulation potential. For the C14Cl3 group of congeners, there is one reliable fish aquatic BCF available which indicates vB for a testing material which contains C14Cl3 group of congeners. There is one supporting study with a BMF study which indicates B for C14Cl3 congeners. As supporting information, BCF predictions indicate vB for C14Cl3 congeners. Based on the weight of the evidence available, the C14Cl3 group of congeners is concluded to meet the bioaccumulation criterion (B) and the very bioaccumulative criterion (vB) of Annex XIII of the REACH Regulation. <u>C14 chlorinated n-alkane with 4 chlorine atoms (equivalent to 42.3% Cl wt):</u> A lipid-normalised and growth-corrected kinetic fish aquatic BCF value of ca. 11 530 L/kg was measured for C14 chlorinated n-alkane, 45% Cl wt. (a high weight is given to this study in the WoE approach; Unpublished, 2010h). A growth-corrected depuration rate constant of 0.018 day-1 for C14H26Cl4 (42.3% Cl wt.; Fisk et al., 1998b) indicates a BCF above 5 000 L/kg as calculated for the purpose of this report (a medium weight is given to this study in the WoE approach). For Daphnia magna, lipid-normalised steady-state BCF of 10 000 000 L/kg lipid and steady-state wet weight BCF of ca. 50 119 L/kg ww were measured for a C13- C18 45% Cl wt. product (Cereclor S45); (a medium weight is	At a broad level, the Du *et al.* (2020) study is of limited reliability, and so drawing conclusions at a congener level is even more uncertain. While we now agree that the Castro *et al.* study is 'reliable with restriction' thanks to the additional information you provided, the analytical data are still noted to be semi-quantitative, and we do not consider this to provide sufficiently reliable data at a congener level. The aquatic fish BCF >5 000 L/kg result measured using a 45% Cl wt. substance does not provide congener specific data. CATALOGIC modelling – which is given a "low reliability" weighting by the EU – was excluded from our evaluation due to the lack of information about the training set and validity of the model for this type of substance. We therefore question whether it is appropriate to derive information on specific congeners using this model. This information has not been added to the RP. Overall, your summary of the available measured data for the lower congeners is similar to ours, and we think our comment that the "BCF data for <45% Cl wt. substances are limited" is reasonable. No change has been made to the RP.

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			given to this study in the WoE approach; Castro et al., 2019 and Castro, 2020). Lipid normalised BMFs >1 were measured in the muscles and livers of a snake-frog predator-prey relationship for the congeners C14Cl4 (a low weight is given to this study in the WoE approach; Du et al., 2020). The BCF Baseline model of CATALOGIC yields BCF predictions for C14Cl4 which are over the threshold of log BCF 3.69 (BCF ~ 5000 L/kg) and therefore indicating bioaccumulation potential (a low weight is given to QSAR predictions in the WoE approach). For the C14Cl4 group of congeners, there is one reliable fish aquatic BCF available which indicates vB for a testing material which contains C14Cl4 group of congeners. There are three supporting studies: one which indicates vB in fish for C14Cl4 congeners, one which indicates vB in Daphnia magna for a testing material which contains C14Cl4 group of congeners (including detection of the C14Cl4 group of congeners in the Daphnia thus suggesting accumulation) and one BMF study which indicates B for C14Cl4 congeners. As supporting information, BCF predictions indicate vB for C14Cl4 congeners. Based on the weight of the evidence available, the C14Cl4 group of congeners is concluded to meet the bioaccumulation criterion (B) and the very bioaccumulative criterion (vB) of Annex XIII of the REACH Regulation. <u>C15 chlorinated n-alkane with 3 chlorine atoms (equivalent to 33.8% Cl wt):</u> For Daphnia magna, lipid-normalised steady-state BCF of 10 000 000 L/kg lipid and steady-state wet weight BCF of ca. 50 119 L/kg ww were measured for a C13- C18 45% Cl wt. product (Cereclor S45); (a medium weight is given to this study in the WoE approach; Castro et al., 2019 and Castro, 2020). Lipid normalised BMFs >1 were measured in the muscles and livers of a snake-frog predator-prey relationship for the congeners C15Cl3 (a low weight is given to this study in the WoE approach; Du et al., 2020). The BCF Baseline model of CATALOGIC yields BCF predictions for C15Cl3 which are over the threshold of log BCF 3.3 (BCF ~ 2000 L/kg) and therefore indicating bioaccumulation potential (a low weight is given to QSAR predictions in the WoE approach). For the C15Cl3 group of congeners, there are two supporting studies: one Daphnia magna study which indicates vB for a testing material which contains C15Cl3 group of congeners (including detection of the C15Cl3 group of congeners in the Daphnia thus suggesting accumulation) and one BMF study which indicates B for C15Cl3 congeners. As supporting information, BCF predictions indicate B for	

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			C15Cl3 congeners. In addition, as the weight of available evidence is sufficient for the C14Cl3 and C16Cl3 groups of congeners to conclude that these are B/vB, it can be reasonably inferred that C15Cl3 also must be B/vB. Based on the weight of the evidence available, the C15Cl3 group of congeners is concluded to meet the bioaccumulation criterion (B) and the very bioaccumulative criterion (vB) of Annex XIII of the REACH Regulation. <u>C15 chlorinated n-alkane with 4 chlorine atoms (equivalent to 40.6% Cl wt):</u> For Daphnia magna, lipid-normalised steady-state BCF of 10 000 000 L/kg lipid and steady-state wet weight BCF of ca. 50 119 L/kg ww were measured for a C13- C18 45% Cl wt. product (Cereclor S45); (a medium weight is given to this study in the WoE approach; Castro et al., 2019 and Castro, 2020). Lipid normalised BMFs >1 were measured in the muscles and livers of a snake-frog predator-prey relationship for the congeners C15Cl4 (a low weight is given to this study in the WoE approach; Du et al., 2020). The BCF Baseline model of CATALOGIC yields BCF predictions for C15Cl4 which are over the threshold of log BCF 3.3 (BCF ~ 2000 L/kg) and therefore indicating bioaccumulation potential (a low weight is given to QSAR predictions in the WoE approach). For the C15Cl4 group of congeners, there are two supporting studies: one Daphnia magna study which indicates vB for a testing material which contains C15Cl4 group of congeners (including detection of the C15Cl4 group of congeners in the Daphnia thus suggesting accumulation) and one BMF study which indicates B for C15Cl4 congeners. As supporting information, BCF predictions indicate B for C15Cl4 congeners. In addition, as the weight of available evidence is sufficient for the C14Cl4 and C16Cl4 groups of congeners to conclude that these are B/vB, it can be reasonably inferred that C15Cl4 also must be B/vB. Based on the weight of the evidence available, the C15Cl4 group of congeners is concluded to meet the bioaccumulation criterion (B) and the very bioaccumulative criterion (vB) of Annex XIII of the REACH Regulation. <u>C16 chlorinated n-alkane with 2 chlorine atoms (equivalent to 24.1% Cl wt.):</u> A growth-corrected depuration rate constant in the range of 0.014─0.019 day-1 for C16H31Cl3 (34.1% Cl wt.; Fisk et al., 1996) indicates a BCF above 5 000 L/kg as calculated for the purpose of this report (a medium weight is given to this study in the WoE approach). For Daphnia magna, lipid-normalised steady-state BCF of 10 000 000 L/kg lipid and steady-state wet weight BCF of ca. 50 119 L/kg ww were measured for a C13- C18 45% Cl wt.	

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			product (Cereclor S45); (a medium weight is given to this study in the WoE approach; Castro et al., 2019 and Castro, 2020). For Mytilus edulis, a lipid-normalised BAF value of 7 031 L/kg (steady-state value) and 7 204 L/kg (statistically determined) with confidence limits of 4 694─9 723 L/kg was measured for C16H30.7Cl3.3 (34.1% Cl wt.; a medium weight is given to this study in the WoE approach; Renberg et al., 1986). The BCF Baseline model of CATALOGIC yields BCF predictions for C16Cl2 which are below the threshold of log BCF 3.3 (BCF ~ 2000 L/kg) and therefore indicating a lack of bioaccumulation potential (a low weight is given to QSAR predictions in the WoE approach). For the C16Cl2 group of congeners, there are three supporting studies: one which indicates vB in fish for a testing material which contains C16Cl2 group of congeners; one which indicates vB in Daphnia magna for Cereclor S45 and detection of the C16Cl2 group of congeners in the Daphnia thus suggesting accumulation and one which indicates vB in Mytilus edulis for a testing material which contains C16Cl2 group of congeners. However, the BCF predictions indicate not B for C16Cl2 congeners. As the three supporting studies all indicate B and/or vB, all together they are considered to have a higher weight than the QSAR predictions. Based on the weight of the evidence available, the C16Cl2 group of congeners is concluded to meet the bioaccumulation criterion (B) and the very bioaccumulative criterion (vB) of Annex XIII of the REACH Regulation. <u>C16 chlorinated n-alkane with 3 chlorine atoms (equivalent to 32.3% Cl wt.):</u> A growth-corrected depuration rate constant in the range of 0.014─0.019 day-1 for C16H31Cl3 (34.1% Cl wt. Fisk et al., 1996) indicates a BCF above 5 000 L/kg as calculated for the purpose of this report (a medium weight is given to this study in the WoE approach). For Daphnia magna, lipid-normalised steady-state BCF of 10 000 000 L/kg lipid and steady-state wet weight BCF of ca. 50 119 L/kg ww were measured for a C13- C18 45% Cl wt. product (Cereclor S45); (a medium weight is given to this study in the WoE approach; Castro et al., 2019 and Castro, 2020). For Mytilus edulis, a lipid-normalised BAF value of 7 031 L/kg (steady-state value) and 7 204 L/kg (statistically determined) with confidence limits of 4 694─9 723 L/kg was measured for C16H30.7Cl3.3 (34.1% Cl wt.; a medium weight is given to this study in the WoE approach; Renberg et al., 1986). Lipid normalised BMFs >1 were measured in the muscles and livers of a snake-frog predator-prey relationship for the congeners C16Cl3 (a low weight is given to this study in the WoE	

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			approach; Du et al., 2020). o The BCF Baseline model of CATALOGIC yields BCF predictions for C16Cl3 which are below the threshold of log BCF 3.3 (BCF ~ 2000 L/kg) and therefore indicating a lack of bioaccumulation potential (a low weight is given to QSAR predictions in the WoE approach). For the C16Cl3 group of congeners, there are four supporting studies: one which indicates vB in fish for a testing material which contains C16Cl3 group of congeners; one which indicates vB in Daphnia magna for a testing material which contains C16Cl3 group of congeners (including detection of the C16Cl3 group of congeners in the Daphnia thus suggesting accumulation); one which indicates vB in Mytilus edulis for a testing material which contains C16Cl3 group of congeners and one which indicates B based on a BMF study for C16Cl3 congeners. However, the BCF predictions indicate not B for C16Cl3 congeners. As the four supporting studies all indicate B and/or vB, all together they are considered to have a higher weight than the QSAR predictions. Based on the weight of the evidence available, the C16Cl3 group of congeners is concluded to meet the bioaccumulation criterion (B) and the very bioaccumulative criterion (vB) of Annex XIII of the REACH Regulation. <u>C16 chlorinated n-alkane with 4 chlorine atoms (equivalent to 39% Cl wt.):</u> A growth-corrected depuration rate constant in the range of 0.014─0.019 day-1 for C16H31Cl3 (34.1% Cl wt.; Fisk et al., 1996) indicates a BCF above 5 000 L/kg as calculated for the purpose of this report (a medium weight is given to this study in the WoE approach). For Daphnia magna, lipid-normalised steady-state BCF of 10 000 000 L/kg lipid and steady-state wet weight BCF of ca. 50 119 L/kg ww were measured for a C13- C18 45% Cl wt. product (Cereclor S45); (a medium weight is given to this study in the WoE approach; Castro et al., 2019 and Castro, 2020). For Mytilus edulis, a lipid-normalised BAF value of 7 031 L/kg (steady-state value) and 7 204 L/kg (statistically determined) with confidence limits of 4 694─9 723 L/kg was measured for C16H30.7Cl3.3 (34.1% Cl wt.; a medium weight is given to this study in the WoE approach; Renberg et al., 1986). Lipid normalised BMFs >1 were measured in the muscles and livers of a snake-frog predator-prey relationship for the congeners C16Cl4 (a low weight is given to this study in the WoE approach; Du et al., 2020). The BCF Baseline model of CATALOGIC yields BCF predictions for C16Cl4 which are below the threshold of log BCF 3.3 (BCF ~ 2000 L/kg) and therefore indicating a lack of bioaccumulation	

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			potential (a low weight is given to QSAR predictions in the WoE approach). For the C16Cl4 group of congeners, there are four supporting studies: one which indicates vB in fish for a testing material which contains C16Cl4 group of congeners; one which indicates vB in Daphnia magna for a testing material which contains C16Cl4 group of congeners (including detection of the C16Cl4 group of congeners in the Daphnia thus suggesting accumulation); one which indicates vB in Mytilus edulis for a testing material which contains C16Cl4 group of congeners and one which indicates B based on a BMF study for C16Cl4 congeners. However, the BCF predictions indicate not B for C16Cl4 congeners. As the four supporting studies all indicate B and/or vB, all together they are considered to have a higher weight than the QSAR predictions. Based on the weight of the evidence available, the C16Cl4 group of congeners is concluded to meet the bioaccumulation criterion (B) and the very bioaccumulative criterion (vB) of Annex XIII of the REACH Regulation. <u>C16 chlorinated n-alkane with 5 chlorine atoms (equivalent to 44.5% Cl wt.):</u> A growth-corrected depuration rate constant in the range of 0.014─0.019 day-1 for C16H31Cl3 (34.1% Cl wt.; Fisk et al., 1996) indicates a BCF above 5 000 L/kg as calculated for the purpose of this report (a medium weight is given to this study in the WoE approach). For Daphnia magna, lipid-normalised steady-state BCF of 10 000 000 L/kg lipid and steady-state wet weight BCF of ca. 50 119 L/kg ww were measured for a C13- C18 45% Cl wt. product (Cereclor S45); (a medium weight is given to this study in the WoE approach; Castro et al., 2019 and Castro, 2020). For Mytilus edulis, a lipid-normalised BAF value of 7 031 L/kg (steady-state value) and 7 204 L/kg (statistically determined) with confidence limits of 4 694─9 723 L/kg was measured for C16H30.7Cl3.3 (34.1% Cl wt.; a medium weight is given to this study in the WoE approach; Renberg et al., 1986). Lipid normalised BMFs >1 were measured in the muscles and livers of a snake-frog predator-prey relationship for the congeners C16Cl5 (a low weight is given to this study in the WoE approach; Du et al., 2020). The BCF Baseline model of CATALOGIC yields BCF predictions for C16Cl5 which are over the threshold of log BCF 3.3 (BCF ~ 2000 L/kg) and therefore indicating bioaccumulation potential (a low weight is given to QSAR predictions in the WoE approach). For the C16Cl5 group of congeners, there are four supporting studies: one which indicates vB in fish for a testing material which contains C16Cl5 group of congeners; one which indicates	

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			vB in Daphnia magna for a testing material which contains C16Cl5 group of congeners (including detection of the C16Cl5 group of congeners in the Daphnia thus suggesting accumulation); one which indicates vB in Mytilus edulis for a testing material which contains C16Cl5 group of congeners and one which indicates B based on a BMF study for C16Cl5 congeners. As supporting information, BCF predictions indicate B for C16Cl5 congeners. Based on the weight of the evidence available, the C16Cl5 group of congeners is concluded to meet the bioaccumulation criterion (B) and the very bioaccumulative criterion (vB) of Annex XIII of the REACH Regulation. For the C17 congener groups insufficient information is available for C17cl2-4 to conclude on their B property. It was only possible to conclude on the bioaccumulation potential of C17Cl5 congener groups. For this group of congeners, there are two supporting studies which indicate vB in Daphnia magna for a testing material which contains C17Cl5 group of congeners (including detection of the C17Cl5 group of congeners in the Daphnia thus suggesting accumulation) and B based on a BMF study for C17Cl5 congeners. However, the BCF predictions indicate not B for C17Cl5 congeners. As the two supporting studies indicate B and/or vB, all together they are considered to have a higher weight than the QSAR predictions. Based on the weight of the evidence available, the C17Cl5 group of congeners is concluded to meet (at least) the bioaccumulation criterion (B) of Annex XIII of the REACH Regulation. The available information on C18 chain lengths suggests that LCCP would have a BCF above 5 000 L/kg. As a consequence, a similar result would have been seen if C17 congener groups had been tested. We are of the opinion that enough information is available on congener groups of MCCP having an average chlorination level <45% Cl wt. to conclude them as bioaccumulative according to the Stockholm Convention and based on a weight-of-evidence approach. The references mentioned above can be found in the EU SVHC dossier for MCCP which is available at the following link: Annex XV report (europa.eu).	
EU	2	7	The reference made to skewed and non-gaussian distributions derives from the conclusions of the writers by observing, in the article mentioned, Figure S4 (NMR compared to MS formulae for top 100 isomers) where the specific results of NMR analyses are reported. However, the authors explains that 2D HSQC experiments are not quantitative as the peak search algorithm matches on the basis of patterns in the 2D data rather than intensity. The author in the article	We consider that the data do not reflect absolutely normal distributions for the congeners associated with the C_{14-15} chain lengths (e.g. congener level). The use of the normal distribution is for simplicity and does not reflect the level of complexity in determining the isomeric

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			underlines that it should be noted that these NMR results are not quantitative and explains that, differently from MS, results are not reported as molar distribution of the congeners but only of the specifically 100 identifies isomers. The NMR pattern matching approach followed in this study can identify isomeric structures, however this approach cannot quantitatively resolve the relative abundance of each isomer. Instead, the MS patterns shown in the cited article are quantitative and show the molar distributions of CxCly congeners in the tested substances. The MS patterns observed show that, the chlorination level on the various alkyl chains in a chlorinated paraffin follows a normal distribution. Also, it should be noted that the chlorination degrees calculated based on the MS patterns match the manufacturers' specifications. Therefore, it can be concluded that the MS and NMR figures reported in the article are not comparable in relation to the quantitative distribution of the congeners. Reference to the skewed NMR figures is not appropriate for defining the quantitative distribution of the chlorine atoms on the alkyl chains. Therefore, we are of the opinion that stating that the analytical results reported in the mentioned article show "non-gaussian distributions of chlorination for the top 100 isomers of each homologue" is not correct. On the contrary the results show a gaussian distribution of the chlorination.	distribution or the full diversity of components involved. The authors note that the peak search algorithm of NMR is not fully quantitative, because the matches to fragments are performed on the basis of pattern rather than intensity. They then go on to explain it was carried out computationally and 'by eye' biasing the most intense and well-defined peaks in the spectra. The top 100 matches in the NMR data are expected to represent the most likely abundant compounds in the mixtures. We have interpreted this as a semi-quantitative method. All data were grouped based on molecular formulas, to present a molar distribution in Fig 1 e and f and Figure S4, for both MS and NMR detection, respectively. Therefore we have interpreted this semi-quantitatively for both detection methods and considered them as complementary to one another. Our interpretation accounts for limitations in the list of isomers selected in the NMR data for $C_{14}Cl_{1-10}$ and $C_{15}Cl_{1-7}$, which was not applied to the MS data. The consequences of this have not been explicitly addressed by the authors, but are acknowledged for the least comparable congener group distributions (e.g. the NMR data for C_{15} 54.75% Cl wt. excluded approximately 33% of the data in comparison to that of the MS due to the cut off at $C_{15}Cl_{>7}$). Therefore, there are congener level NMR data missing from the distributions for the most highly chlorinated isomers. We have been cautious around the use of the MS data at the lower and higher chlorination degrees due to analytical uncertainties and those of the MS data processing method, based on the observations of Yuan *et al*. (2017) and Gao *et al*. (2016). Both publications acknowledge the assumptions made when they developed the non-linear algorithm, where a major point of ambiguity in the quantification is that the proportions of some congener groups might deviate considerably from values estimated on the tails of the

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				Gaussian distributions. This method was developed using SCCPs and is considered fit for purpose with MCCPs and was employed in the Yuan *et al.* (2019) evaluation. MS data are still mathematically refined and therefore are considered as indicative of the components but not absolutely representative. We have therefore concluded that the congener level distribution may not be normal (as noted in the figures) and is likely to be far more complex, especially for the most highly chlorinated congeners. The RP has been updated to include the following sentence for clarification '*Molar plots of the detected congeners using both detection methods generated pseudo-normal and non-normal distributions for the top 100 isomers of each homologue, respectively*'.
EU	3	8	**For laboratory studies this requires an assumption about which congeners were present in the test, and at what concentration, as in many cases congener-specific analysis is not available. Applying such an approach then requires an assumption of equality, rather than trends, across the different congeners to interpret each test for a specific property.** When carrying out an assessment of these substances on the basis of the number of chlorine atoms per chain length, i.e. considering the congeners distributions, it is necessary to assume equality between the chlorination degrees of each carbon chain length in the composition and the overall chlorination degree of the substance. However, a trend following a normal distribution can be reasonably assumed across the different congeners having the same carbon number and different chlorine atoms on the alkyl chains. Such assumptions are analytically confirmed by the MS results reported in the supporting information of the reference Yuan et al. (2020) provided in the report. We are of the opinion that the sentence "**Applying such an approach then requires an assumption of equality, rather than trends, across the different congeners to interpret each test for a specific property**" should be amended as it seems to refer to paragraph 7 where data from NMR were misunderstood.	Please see the previous response above for clarification. No changes have been made to the RP.
EU	7	16	**The EU SVHC listing for "MCCPs" applied to carbon chain lengths C14-17 and with 3 or more chlorine atoms (which is ≥32% Cl wt.).** This statement is not fully correct as in the EU Candidate list we specify "Medium-chain	Text amended as suggested. The original text focussed on the scientific conclusions drawn in the ECHA SVHC dossier.

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			chlorinated paraffins (MCCP) [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C_{14} to C_{17}]" as substances identified as SVHC. Please refer to ECHA decision on inclusion in Candidate List (europa.eu).	
EU	10 & 11	42	Please consider amending this paragraph based on the following suggestions: Paragraph 42 should be amended as it mixes information referring to low resolution with information referring to high resolution. Could you please add a reference to the following statement as it is unclear where this statement comes from: 'In addition, direct injection into HRMS instruments has been shown to provide a relatively large amount of data for 'clean' samples" it is unclear from where it is taken. Regarding the following sentence: '**No chromatographic method is currently available that allows for the separation of congeners into their different isomers**'. Please note that we do not see the need for this statement as the differentiation of thousands of isomers in respect to the approach taken is not required and not even useful bringing to confusion in quantification of the "members" of the congeners. Regarding the sentence '**NMR analysis is required for this level of detail (Sprengel et al., 2019) and can only confirm the structure of single isomers (van Mourik et al. 2021)**'. Please note that this statement is not fully correct as it refers to special standards to enable such characterisation not a real sample.	Reference to Krätschmer K. & Schächtele A. (2019). Interlaboratory studies on chlorinated paraffins: evaluation of different methods for food matrices. Chemosphere, 234, 252–259. https://doi.org/10.1016/j.chemosphere.2019.06.022 added to the text. The sentence about separation of congeners into isomeric components has been retained to demonstrate the complexity of the substance and the assumptions made in the interpretation of data at a congener level. We agree that the studies of Sprengel *et al.* (2019) and van Mourik *et al.* (2021) used specialised standards and not products – however, NMR is the only techniques that would allow this differentiation and the reference is correct. No change to the text of the RP.
EU	11	44	**The predictions for the Cl3 and Cl4 congeners are given a low weight in this assessment as these data are at odds with the observed high levels of degradation seen in the measured screening studies covering the relevant chlorination range described in paragraph 46.** BIOWIN 2, 3 and 6 predictions for the Cl_3 and Cl_4 congeners (screened as 'potentially persistent or very persistent') are confirmed by the outcome of the OECD TG 308 study which shows that all congener groups of MCCP with C_{14} carbon chain length and chlorine substitution numbers from 3 to 14 (i.e. $C_{14}Cl_{3-14}$) have P/vP properties. Based on the predicted and observed trends in physico-chemical properties of structures of the different MCCP congeners, which are in line with the general scientific knowledge on the expected partitioning behaviour and environmental fate of hydrophobic aliphatic chloroalkanes, it can be reasonably estimated that the C_{15-17} congeners with the same or higher chlorine contents than the congeners of C_{14} chlorinated n-alkane, 50% Cl. wt. (which contains $C_{14}Cl_{3-14}$ congeners that all are P/vP) will be equally or more adsorptive to sediment, have lower water solubilities and	We acknowledge that there is a difference of opinion about the persistence of CPs with a small number of chlorine atoms (we note that the decision to identify SCCPs as a POP was heavily reliant on half-life data for 65% Cl wt. substances, with an average of more than 5 chlorine atoms per molecule). As noted there is a clear trend in degradation based on the degree of chlorination. The predictions confirm that a trend exists but suggest that substances with a lower level of chlorination might still be persistent. However, we consider that the measured OECD TG 301 data provide a better guide to the trend than the predicted data. We note that ECHA does not give a high weighting to the outputs of the BIOWIN model (and as pointed out in the RP, other models within

Source of comments	Page	Para	Comments on the 2nd draft risk profile for chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight	Response
			partition stronger to octanol. They therefore will at least be equally if not more persistent in sediments.	EPI Suite™ give differing outputs compared to other types of model for MCCPs). We remain of the view that the OECD TG 308 study should be interpreted at a whole substance level (as a sum of all components) - principally that the whole substance chromatograms at 0 and 120 days in the test are the same. We think interpretation of the data at an individual congener level particularly at the lower chlorination levels goes beyond what the chemical analysis used in the study is able to provide. We've not changed the RP.
EU	12	46 & 49	**Under the conditions of these studies, C14 chlorinated n-alkanes with a chlorine content of 41.3% and 45.5% were readily biodegradable within 28 days (>60% mineralisation). C14 chlorinated n-alkane, 50% Cl wt. failed to meet the 60% pass threshold within 28 days but did meet it after 56 days.** As regards your response to our comment on the outcome of the screening tests where it is concluded that some testing materials are readily biodegradable within 28 days (>60% mineralisation). Please note that for an UVCB substance, observed biodegradation may indeed represent the biodegradation of only some of its constituents. Furthermore, the PBT guidance (REACH Chapter R.11, ECHA, 2017b), indicates that if the test item composition does not consist of similar structures or is not well characterised, it may still contain a certain amount of constituents that are persistent although the amount of easily degradable constituents is high enough to lead to an overall degradation percentage sufficient to meet the criteria for ready biodegradation. For UVCB substances, there are uncertainties related to the screening tests where the contribution of the different congeners of MCCP to the overall degradation is unknown. That is why screening tests without further supplementary information enabling the possibility to verify the claims made with regard to the composition of the test substance, i.e. the identity of the individual congener groups and their concentration in the substance as well as on the degree of degradation of the individual congener groups in a test, are considered not sufficient to draw conclusions on the persistence of MCCP as a substance and in particular on the persistence of its different congener groups and individual constituents.	We acknowledge that the usefulness of screening biodegradation tests for UVCBs depends on the similarity of the structures involved. At the same time, ready biodegradation tests are stringent and difficult to pass, so failure to meet the criterion does not mean that a substance is definitely persistent within the meaning of the Annex D criteria. By extension, although some constituents of a UVCB might resist degradation in a ready test, this does not mean they will be persistent in the environment – it is screening level information only. Further discussion can be found in the original EU REACH Substance Evaluation (ECHA, 2019) which reflects on many of the points raised in this comment, as well as the response in the previous commenting round. Overall, there is a clear trend in the degradation data and we think that this should be reflected in the listing. No change has been made to the RP.
EU	15 & 16	66	We do not agree with the statements made in this paragraph. Please refer to our previous comment on the screening tests in paragraph 46 and 49.	We acknowledge that there are differences of opinion about the persistence of CPs with a small number of chlorine atoms.

Source of comments	Page	Para	Comments on the 2nd draft risk profile for chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight	Response
			Overall, these screening studies are not considered to be the appropriate type of test for concluding on the persistence potential of UVCB substances such as MCCP and this is confirmed by the outcome of the OECD TG 308 study. The OECD "Guidelines for the Testing of Chemicals, Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3 Part I: Principles and Strategies Related to the Testing of Degradation of Organic Chemicals" (OECD, 2006) indicate that ready biodegradability tests are intended for pure substances and are generally not applicable for complex compositions containing different types of congeners, like UVCB. For an UVCB substance, observed biodegradation may indeed represent the biodegradation of only some of its constituents. In the EU dossier, it is demonstrated that congener groups having three or more chlorine atoms are expected to be persistent or very persistent while congener groups having two chlorine atoms or less are not expected to be persistent or more information is needed to conclude. As a consequence, congener groups having three or more chlorine atoms should not be excluded from this proposal. Even if the concentration of any potentially persistent constituents present in the <45% Cl wt. fraction used in the screening studies is 'likely to be low', it has been demonstrated in the EU SVHC dossier (Annex XV report (europa.eu) that these constituents were present at a relevant concentration (≥0.1% (w/w)) for the P assessment. As a consequence, chain lengths <45% Cl wt. and in particular those having three and four chlorine atoms should not be excluded from this proposal as they contain congener groups having P/vP properties.	We refer to our response on this point in the previous commenting round. Whilst a 0.1% w/w threshold is a consideration for PBT assessment under EU REACH, there appears to be no precedent for this in previous POP cases. Indeed, the POPs listing for SCCPs used a 1% threshold. We think this needs further discussion at POPRC. No change has been made to the RP.
EU	19	79	Please note that in the EU SVHC dossier for MCCP: The BCF was back calculated based on a daphnia water content of 90% and the BCF derived was ca. 50119 L/kg ww thus well above 5000. Furthermore, please find hereafter our comments to UK's responses to EU previous comments on the Castro *et al.* studies: *UK: 'There is no standard test guideline for bioaccumulation in Daphnia, so the reliability and reproducibility of the method is not known'.* EU: Correct, but non-standard tests can be used in a weight-of-evidence assessment if reliable and relevant. *UK: 'The very short uptake period used in the study makes it uncertain whether steady state was reached'.* EU: The authors claim that steady-state in the organisms was achieved after 48 hours. The duration of the uptake and depuration phase was based on a pilot screening study using test material CP-52 that lasted 72 h. In a previous study (Castro et al., 2018), chlorinated paraffins	We have updated the RP to conclude that the study is of higher reliability than previously assessed and also included some additional supporting text.

Source of comments	Page	Para	Comments on the 2nd draft risk profile for chlorinated paraffins with carbon chain lengths in the range $C_{14–17}$ and chlorination levels at or exceeding 45 per cent chlorine by weight	Response
			were observed to equilibrate within 24 h in a passive dosing system. The authors also noted that studies with polychlorobiphenyls (PCBs) have also used 2−4 day uptake and depuration phases for this species. In any case, if steady-state had not been reached, the final concentration may have been higher. *UK: 'Bioaccumulation studies should be conducted at concentrations that do not cause adverse effects. The test concentration was only 5-fold below the 48h-EC50 and mortality did occur in the study, but the numbers were not recorded'.* EU: Mortality did not exceed 10% in any of the controls or treatment groups (Castro M, Personal Communication, 2020). *UK: 'The method of dosing used means it is not certain if the CPs were evenly distributed in the test system (which was also using static exposure)'.* EU: Correct, but Figure S6 in the Supplementary information to Castro et al., 2019 reports a 90% similarity between the congener patterns found in the test material and in the Daphnia, which suggests that there was sufficient time at least for a majority of congeners to dissolve and distribute in the test system. *UK: 'There was no measure of the effectiveness or efficiency of extraction for the chemical analysis of the animals'.* EU: An internal standard was used to measure the extraction efficiency but its recovery is not reported in the publication. *UK: 'The small size of Daphnia complicates the measurement of uptake (but the amount of sample collected was not stated). Limited sampling points in the test also result in uncertainty for the kinetics'.* EU: Agree, we reported this in the SVHC dossier. In the EU SVHC dossier, we concluded that the daphnia study is considered to be reliable with restrictions.	
Germany	1	2	Please explain the abbreviation UVCB.	Abbreviation defined as suggested
Germany	8	24	Please explain what you mean with a "grandfathered" REACH registration.	This has been added.
Germany	19	84	**Muir et al. (2002) found no indication of biomagnification of "MCCPs" in three Lake Trout – fish food chains but did suggest BMFs above 1 for "MCCPs" in a fish – invertebrate food chain.** Fish-invertebrate food chain or invertebrate-fish food chain?	Text amended (now in the INF document)
Madagascar	General		Monsieur Le Ministre, Suite à la lettre en référence et relative à l'objet sus visé, et après lecture des documents, le Ministère de l'Enseignement Supérieur et de la Recherche Scientifique n'a pas de commentaire ni d'observation par rapport à ces projets. Vous souhaitant bonne réception, recevez Monsieur Le Ministre, mes salutations cordiales.	Noted.

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Nigeria	General		Chlorinated Paraffins with carbon chain lengths in the range C14 – 17 and chlorination levels at or exceeding 45 percent chlorine by weight having fulfilled the screening criteria for listing into Annexes A, B and/or C, however until sufficient information on bioaccumulation is obtained, in accordance to Annex D to Stockholm Convention the decision of the committee to prepare the draft risk profile for the chemical should be suspended until more detailed data on bioaccumulation is provided.	Noted. The updated RP for the substance will be presented to POPRC 18, and it will be for the Committee to decide the next steps.
Norway	General		We appreciate the level of detail provided in this risk profile, but it is currently to long considering the 20-page limitation for risk profiles. We therefore suggest shortening the text and to move more detailed explanations as well as Appendixes to a separate information document.	We note the preferred length for POPRC documents. More recent RPs have been longer than this, and we highlight that the current substance is significantly more complex than single component chemicals, and there is a large dataset to summarise in a fair and transparent way. We are also mindful that clear views were expressed at POPRC 17 regarding the need for more detail for some of the endpoints. Overall, we have moved some of the main text to an INF document, but the document will exceed 20 pages.
Norway	1	2	"For clarify, a CP constituent is an individual structural isomer…" To clarify or for clarification?	Corrected.
Norway	1	3	"This is based on the substance identity for "MCCPs" from the REACH Substance Evaluation (Environment Agency, 2019a) ~~and applying the suggested ≥ 45% Cl wt. scope~~." Suggested text amendment.	Updated as suggested.
Norway	1	3	Talking about appendix 3- We would prefer to follow the established practices of POPRC and to have a separate information document instead of Appendices. This is given the 20-page limitation for risk profiles, high translation costs and considering that the ordinary approach of the POPRC is to open the whole text of a risk profile for discussion. A longer text with appendices will make it more difficult to conclude the work at POPRC-18.	There is now an INF document containing the appendices, and a further INF document covering the monitoring data.
Norway	4 & 5	Table 3	References for "unpublished 2019a and b". Please only refer to openly available information.	Please refer to the comprehensive reply made to comments regarding unpublished data made in the previous commenting round. A note has been added to indicate that a review of the study is provided in Environment Agency (2019).
Norway	15	2.2.2.3	Please add references to this section.	Updated as suggested.
Norway	15	64	Please indicate here which substances this is i.e. is it MCCP or something else?	Text amended – the paragraph is discussing the individual substances used in tests and how

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				the data can be used to conclude for the longer homologues.
Norway	16	2.2.3	We would suggest shortening the text on bioaccumulation considerably and that you present the main lines of evidence i.e. more like a scientific review paper. Detailed information can be provided in an information document.	We have made some changes but given the remit from POPRC 17 to provide more details of bioaccumulation of the C_{15-17} chain lengths, we are reluctant to reduce the text further. We also think it is important that the description of the study in the main report is sufficiently detailed so that the reader can understand its relevance.
Norway	16	70	Please see earlier comments on citing unpublished data. Same as above. This comment also applies to the rest of this document where "unpublished" data are cited.	Please refer to the comprehensive reply made to comments regarding unpublished data in the previous commenting round. CPIA have now made this bioaccumulation study (and a further bioaccumulation study and the sediment simulation study available to the POPRC) available to the POPRC secretariat. However, we note that many previous POPRC assessments have referenced industry-sponsored studies (as reviewed in regulatory assessments) which were not challenged, and so not made available to previous meetings. A consistent approach is needed.
Norway	17	71	We would suggest deleting “The study is assessed to be reliable without restrictions”.	These studies have been formally evaluated to determine their reliability, and we think this is important when assessing the weight of evidence. We believe that an assessment of data quality is crucial to the integrity and transparency of POPRC evaluations.
Norway	17	71	It is s not entirely clear what you intend to say with this text - it seems contradictory – can you be more concise and to the point – in few words what is the main message?	The highlighted text explains why a BMF value below 1 (not the calculated BCF value) in a laboratory dietary study is of concern. It is not possible to make the explanation briefer, as the two points described refer to the key information (OECD guidance, and the Inoue *et al*. study). However as a conclusion has been drawn based on the calculated BCF values, we have moved the data to the INF document for brevity.
Norway	17	Table 6	This table is very useful and gives the reader a good overview.	Noted.
Norway	17	Table 6 heading	Please delete – it is not clear what the assessment of reliability is based upon.	Re-phrased to “supporting studies” to be consistent with conclusions drawn in the text.

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				The comparison of reliability is discussed in the main text and is intentional to differentiate these studies from the recent OECD TG 305 studies performed according to GLP. The reliability assessment is explained in the text.
Norway	18	74	Please consider shortening to around one sentence. Additional information that you consider relevant can be included in an information document if necessary.	Text has been shortened.
Norway	18	75	POPRC is not able to assess the reliability of unpublished studies and therefore such studies should not be cited. However, if these studies have already been described/ assessed in any national or regional assessment it is possible to refer to this information instead. See suggestions for how this can be done.	See response in previous commenting round regarding the use of industry-sponsored studies submitted for regulatory purposes. The earlier description of each unpublished regulatory study has been updated to note where the study has been reviewed. The CPIA have made the two bioaccumulation studies and the sediment simulation study available to the POPRC.
Norway	18	77	Please indicate what the findings were and if they are in line with the findings presented above or not.	Text updated.
Norway	19	78	Same comment as above. What were the findings?	Text updated.
Norway	25	108 & 109	Considering the length of this risk profile could this text (Li et al) perhaps be shortened to 1-2 sentences?	Text amended as suggested, with remainder in INF document.
Norway	35	2.3.2	Please also consider including information from Xu et al. 2022. Xu S, Hansen S, Rautio A, Järvelin MR, Abass K, Rysä J, Palaniswamy S, Huber S, Grimalt JO, Dumas P, Odland JØ. Monitoring temporal trends of dioxins, organochlorine pesticides and chlorinated paraffins in pooled serum samples collected from Northern Norwegian women: The MISA cohort study. Environ Res. 2022 Mar;204(Pt A):111980. doi: 10.1016/j.envres.2021.111980. Epub 2021 Aug 30. PMID: 34474033.	Added to RP and INF monitoring table.
Norway	38	2.4.1	This section should include a brief review/ synthesis of all available ecotoxicity data to give the reader an introduction to and overview of the available data. Similar to what has been done below for the EU human health risk assessments, we would also suggest referring to the EU REACH assessment and its conclusions regarding toxicity.	We have added an introduction as suggested. The (harmonised) classification provided a clear indication of recognised toxicity (and relevant at a UN level), but we have also added the “T” conclusion.
Norway	41	217	This is the adverse effects synthesis, please add further information to indicate overall weight of evidence in the dataset more clearly.	Amendments made to the highlighted section.

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Norway	41	217	We would suggest deleting "from reliable laboratory studies". See similar comments above and below.	For the synthesis section, we have removed reference to "reliable", as it would be expected that data discussed in this section would be reliable.
Norway	41	219	Suggestion for minor text edit.	Text amended as proposed.
Norway	41	220	Consider rephrasing – it is not entirely clear what you intend to say with this sentence.	Text amended for clarity. [this was a consequence of a change made in the previous commenting round]
Norway	41	221	We suggest deleting as this reliable" comes across as subjective as it is not explained how reliability has been assessed. Furthermore, laboratory studies have low environmentally relevance and may therefore see from another perspective be considered less reliable/ relevant.	For the synthesis section, we have removed reference to "reliable", as it would be expected that data discussed in this section would be reliable. To respond to the second point, laboratory data are the standard type of data that regulators require and request to assess whether substances are of concern or present a risk. Several of the Stockholm Convention criteria directly relate to results that can only be obtained from recognised laboratory tests. We agree that all data need to be evaluated for their reliability and relevance and weighted accordingly in POPRC assessments.
Norway	42	221	Please indicate if BMFs or TMFs>1 have been reported in the available literature.	Data added.
Norway	42	222	We suggest rephrasing.	Text amended for clarity.
Norway	42	222	Please delete as multiple detections have also been made in other matrixes including Arctic air.	Text amended as proposed.
Norway	43	229	We would suggest moving this information to the synthesis of information above and rephrase the information here to indicate whether these criteria are fulfilled under the Convention.	Text moved as suggested.
Norway	44	App 1	If this is to be included we would suggest putting this at the beginning of the document e.g. after the outline.	Noted. For document readability we prefer the abbreviation list to be after the main text.
Norway	45	App 2	We would suggest not to call this an appendix.	This is now titled "References".
Norway	61	App 3	Please move the information in this and the below Appendices to a separate information document.	Appendices 3 onwards have now been moved to the main INF document.
Norway	65 & 66	Table 11	Please explain "pass/fail" .	Explanation added.
United States of America (USA)	General		We suggest taking a more expansive look at human dietary uptake as a route for exposure, if possible. The following studies may be useful in this regard: Y Liu - 2022 Exposure to Chlorinated Paraffins in the Sixth Total Diet Study — China, 2016–	Several of the studies are already included in the current RP. We have added a brief summary of the Chinese data.

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			2019 *(Note – the risk profile references the Liu 2020 paper but not this 2022 publication).* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8930411/ K Krätschmer - 2021 Chlorinated Paraffin Levels in Relation to Other Persistent Organic Pollutants Found in Pooled Human Milk Samples from Primiparous Mothers in 53 Countries https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8371996/ EFSA 2020 - Risk assessment of chlorinated paraffins in feed and food https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.5991 L Cui 2020 - Short- and Medium-Chain Chlorinated Paraffins in Foods from the Sixth Chinese Total Diet Study: Occurrences and Estimates of Dietary Intakes in South China https://pubs.acs.org/doi/abs/10.1021/acs.jafc.0c03491	
Alaska Community Action on Toxics and International Pollutants Elimination Network (ACAT/IPEN)	General		SPG alterations throughout the document.	Noted.
ACAT/IPEN	2	4	"**in small amounts**" This is relative and subjective, therefore unnecessary unless quantified.	The actual amounts are confidential. It is necessary to indicate that the substances are not exclusively C_{14-17} chain lengths.
ACAT/IPEN	2	6	Is the chlorination process truly random or would a better term be "variable?"	We prefer "random" as this better indicates the chemical reaction process in this instance.
ACAT/IPEN	9	36	MCCPs are not used "in" dishcloths, but have been found on dishcloths because of their prevalence in kitchen environments. This should be included in Section 2.3.3.	This has been amended.
ACAT/IPEN	11	43	Reference is needed here.	The full sentence states '*Due to their structure, CPs are not expected to hydrolyse significantly*' – this explains the basis for the conclusion drawn, and a reference is not necessary.
ACAT/IPEN	15	60	Please indicate the date ranges represented in the sediment core samples.	These have now been included.
ACAT/IPEN	15	63	The key data include evidence of the absence of transformation of a C_{14} chlorinated n-alkane, 50% Cl wt. substance after 120 days at 12 °C in a reliable OECD TG 308 study involving two different sediment types, performed to GLP under aerobic conditions.	Text unchanged. The emphasis was intentional in this sentence.
ACAT/IPEN	17 & 18	70 & 71	This unpublished study should be made available for peer review, otherwise it has been the	Please refer to earlier response above.

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			practice to exclude non-published data.	
ACAT/IPEN	18	72	Please summarize why these studies are considered to be of lower reliability.	A detailed review of the Fisk *et al.* studies is included in the text below the table and in the INF document.
ACAT/IPEN	19	75	Again, unpublishes studies should be made available for review so the results and comparisons can be verified. In general, unpublished studies are not optimal, as peer-reviewed studies are more credible.	See earlier response.
ACAT/IPEN	24	103	As stated above, these unpublished studies should be made available for review so that they can be independently evaluated for reliability. Studies published in peer-reviewed journals are preferable.	See earlier response in this commenting round, and previous commenting round. In general, we disagree that academic articles in the literature should be preferred to studies performed to internationally recognised test guidelines and GLP that have been requested and reviewed by regulatory authorities. We have contacted the CPIA, and they have made the two bioaccumulation tests and the sediment persistence study available to the POPRC secretariat. Nevertheless, we think this approach is inconsistent with previous reviews and decision making at POPRC, as many assessments have relied upon regulatory tests that by their nature are unpublished.
ACAT/IPEN	30 & 31	127 & 130	Is this meant to be "higher" rather than "similar?" Otherwise, it would be best to use one or the other modifier.	Text modified to be clearer regarding meaning.
ACAT/IPEN	35	157	It would be helpful to include the range of concentrations and comparison between the urban and remote locations.	Text updated.
ACAT/IPEN	35	160	It would be helpful to include the range of concentrations for the other species as well.	Text updated.
ACAT/IPEN	37	175	Please include the genus and species names. Comment refers to “seal” and “terrestrial mammals”.	For brevity the monitoring section does not include genus and species names. Details of these can be found in the monitoring tables of the INF document.
ACAT/IPEN	38	182	It would be useful to distinguish the concentration ranges for the blood and placental tissues.	We have re-checked the publication and it appears that only placental samples were analysed in this study. We apologise for the error and will revise the paragraph accordingly.
ACAT/IPEN			Commentator changed paragraph numbering for the remainder of the report after paragraph 183.	Noted, it is not clear who the commentator was.
ACAT/IPEN	39	184/185	Add: Darnerud and Bergman (2022) summarize studies from numerous regions on CP absorption	We have included a summary of the toxicokinetic aspects of the paper earlier in the RP. The data

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			in humans and levels in specified tissues and in blood. Darnerud O and A Bergman. 2022. Critical review on disposition of chlorinated paraffins in animals and humans. Environment International 163, 107195 https://doi.org/10.1016/j.envint.2022.107195.	that the paper uses are already sufficiently covered in the current text.
ACAT/IPEN	39	Section 2.3.3	There are additional studies that should be cited in this section because of the importance of direct and indirect exposure pathways through food and household products, with special concern for babies, infants, and children. We have included some of them here and note that several of these were cited in our previous comments.	We think it is appropriate to refer to the review by EFSA, which is an internationally recognised authority on chemicals in food. We also recognise the limitations that the review identifies for the conclusions that can be drawn. We have included references to some of the specific studies both here, and in the use section earlier in the document. Whilst there are specific detections, the number of studies are limited, and we are cautious about including text that suggests otherwise.
ACAT/IPEN	39	187	This is not a complete summary, thus additional original scientific literature should be cited in this section.	See previous response.
ACAT/IPEN	39	187	The summary gives a skewed view of detections of CPs in foods by highlighting China and not including significant findings of CPs in foods measured in other countries.	No change. This text was based on the summary section of the EFSA report, and we feel is a fair reflection of the available data. China was highlighted in the EFSA report as it had higher levels of contamination.
ACAT/IPEN	39	188	**Perkons *et al.* (2022)** This appears to be a sentence fragment.	Text amended.
ACAT/IPEN			Respondent appears to have added in completely new paragraphs 189 to 195,198, 200, 204, 216	Noted, we are not sure who "respondent" is.
ACAT/IPEN	39	189	Add: Yuan *et al*. (2017) found that hand blenders leak chlorinated paraffins into prepared foods, including MCCPs. Of the hand blenders tested (n=16), CPs were found in samples (blended cooking oil/water) at concentrations exceeding the limit of quantification in 12 of the 16 blenders and ranging from 0.10-120 µg. MCCPs were predominant in samples from 8 of the 12 blenders, accounting for 67-91% of the total CP content, with C_{14} the most abundant chain length of MCCPs. The authors determined that "the median intake of ΣMCCPs from one-time hand blender use per day contributes 19-160% of additional exposure for Swedish infants and adults. However, the P95 intake from one-time use of the hand blender is significantly higher (43 µg). This would increase exposure for Swedish infants and adults by a factor of 120 and 14 compared to their median/mean dietary intakes, respectively. For China and the UK, the increase in exposure of infants to ΣMCCPs would be respectively 253 and 69 times higher than the median dietary intake." CP intake via hand blender use exceeded the tolerable daily intake	Please refer to our response in the previous RCOM. We have included this study in the food/consumer exposure section.

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			for infants with a body weight < 7.2 kg. Exposures may continue after many uses of the hand blender. Because of leakage of CPs into prepared foods from hand blenders, consumption of these foods may pose a health risk to infants. Yuan B et al. 2017. Chlorinated paraffins leaking from hand blenders can lead to significant human exposures. Environment International 109: 73-80.	
ACAT/IPEN	39	190	Add: Sprengel *et al*. (2019) investigated levels of CPs in dietary supplements (DS) with an emphasis on Vitamin E supplements with the goal of evaluating the possible threat for the consumers. The authors indicate that this is the first study to investigate levels of CPs in dietary supplements. The study analysed 25 dietary supplements on the German market that are made from plant or fish oils. The authors state: "Six vitamin E preparations containing palm oil showed alarmingly high CP concentrations of > 35 µg/g fat. Six other DS contained much lower CP amounts (< 4 µg/g fat). If consumed as recommended, the mean daily intake of CPs (5.5 µg SCCPs + 38 µg MCCPs) via palm oil-based DS surpassed that of the regular diet by a factor of 4 for SCCPs and 13 for MCCPs, exceeding the PCB intake via food by up to two orders of magnitude. Samples reached up to 26% of the TDI of MCCPs for an average European adult. Consequently, the P95 intake of those samples would amount to ~43 mg CPs per year. The CP contamination probably originated from raw material, as CPs were also found in palm oils and vitamin E concentrates made from palm oil. Our findings suggest that DS can contain high amounts of contaminants that compromise the purpose of the product and should be considered for regular CP monitoring." Sprengel J, Wieselmann S, Kröpfl A, Vetter W. High amounts of chlorinated paraffins in oil-based vitamin E dietary supplements on the German market. Environ Int. 2019 Jul;128:438-445. doi: 10.1016/j.envint.2019.04.065. Epub 2019 May 10. PMID: 31082722.	Please refer to our response in the previous RCOM. We have included this study in the food/consumer exposure section.
ACAT/IPEN	40	191	Add: Tomasko *et al*. (2022) determined CPs in fish oil-based omega-3 dietary supplements (DS). "The CPs were isolated from DS (n = 85) by solid phase extraction. The SCCPs and MCCPs were determined by gas chromatography coupled with high-resolution mass spectrometry operated in a negative chemical ionisation mode. The LCCPs (up to C_{21}) were screened using supercritical fluid chromatography coupled with high-resolution mass spectrometry with electrospray ionisation operated in negative mode. The CP concentrations varied from <0.01 to 56.48 µg/g fat for SCCPs (median 0.12 µg/g fat; limit of quantification, LOQ, for SCCPs was exceeded in 51 out of 85 samples) and from <0.03–89.08 µg/g fat for MCCPs (median 0.26 µg/g fat; LOQ for MCCPs was exceeded in 66 out of 85 samples), respectively. The LCCPs	Please refer to our response in the previous RCOM. We have included this study in the food/consumer exposure section.

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			were not quantified in this study, nevertheless their limit of detection (0.5 µg/g fat) was exceeded in 7 out of 85 samples. Due to high levels of CPs, DS might pose as a significant source of CPs exposure to some population groups." Tomasko, J et al. 2022. Are fish oil-based dietary supplements a significant source of exposure to chlorinated paraffins? Science of The Total Environment. 833, 55137. https://doi.org/10.1016/j.scitotenv.2022.155137.	
ACAT/IPEN	40	193	Add: Gallistl *et al.* (2018) measured high levels of MCCPs in fat samples obtained by wipe tests on the inner surface of 21 baking ovens from Germany. The samples were analysed for a number of halogenated flame retardants (HFRs), including SCCPs and MCCPs. The study measured very high levels of MCCPs in 10 of the 21 samples and ranging up to 100,000 mg/g. "When detected, CPs (sum of MCCPs and SCCPs) generally represented the highest proportion (on average of all other HFRs were also exclusively in the range of "high levels" (range: 2200–93,200 µg/g). Noteworthy, the highest four reported MCCP levels were above the calibration range and were calculated by extrapolation. The fact, that these compounds were either detected in exceedingly high concentrations in ~ 50% of the samples or otherwise were not detected, strongly pointed towards their origination from the baking oven itself. In these ten samples, CPs typically represented the highest proportion of all HFRs, whereas the sum concentration of all other target compounds was three to four orders of magnitude lower abundant and therefore in the same range as those of the CP-negative samples MCCPs were predominant in ~50% of the samples with levels in the mg/g fat range." The authors concluded that "the release of substantial amounts of HFRs from the oven casing during its use may contribute to human exposure to these compounds, especially MCCPs and SCCPs." Add: In a study (Gallistl *et al.*, 2017) that analysed dishcloths (n=19) for levels of polyhalogenated compounds after 14 days of use in household kitchens, researchers detected 29 polyhalogenated contaminants with total mean/median concentrations of 6,900/3,600 ng/dishcloth, respectively. The researchers found levels of MCCPs up to 55,400 ng/dishcloth and MCCPs were by far the most prominent compound class, present. Levels (with the exception of one sample) and the detection frequency of MCCPs were significantly higher ($p<0.05$) than for SCCPs, with mean levels of MCCPs at 4,600 ng/dishcloth and SCCPs at 290 ng/dishcloth. The authors noted that contaminated dishcloths are a potential source of exposure to polyhalogenated compounds, including MCCPs, through dermal uptake, with possible disproportionate occupational exposures	Please refer to our response in the previous RCOM. We have included these studies in the food/consumer exposure section.

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			for professional kitchen workers. Kitchen professionals and laypersons are advised to wear protective gloves when handling dishcloths during cleaning. Gallistl C, Lok B, Schlienz A, Vetter W. 2017. Polyhalogenated compounds (chlorinated paraffins, novel and classic flame retardants, POPs) in dishcloths after their regular use in households. Sci. Total Environ. 595:303–314, PMID: 28384585, 10.1016/j.scitotenv.2017.03.217.	
ACAT/IPEN	40	194	Add: Sprengel *et al*. (2021) conducted wipe tests on lubricants of 29 hinges used on different types of kitchen appliances, including refrigerators, baking ovens, dishwashers, freezers, microwave oven, pasta machine, food processor, and steam cooker. The wipes were analysed for both SCCPs and MCCPs. The overall detection frequency (DF) for CPs was high (72%) with the DF only slightly lower for MCCPs (62%) compared with SCCPs (66%). MCCPs levels ranged from 0.09 to 750 µg, with the highest MCCP levels (380 and 750 µg per wipe, respectively) found in new and unused appliances. The authors indicated concern that volatilisation, abrasion, and cleaning processes could release CPs into the home environment and result in exposures to persons living in the households. Sprengel J, Vetter W. Chlorinated paraffins in hinges of kitchen appliances. Environ Monit Assess. 2021 Apr 7;193(5):250. doi: 10.1007/s10661-021-09023-z. PMID: 33829339; PMCID: PMC8026443.	Please refer to our response in the previous RCOM. We have included this study in the food/consumer exposure section.
ACAT/IPEN	40	195	Add: Zeng *et al*. (2018) reported levels of SCCPs and MCCPs in home-produced eggs in the vicinity of a former e-waste recycling site, with levels of SCCPs, and MCCPs ranging from 477 to 111,000 ng/g lw, and 125 to 91,100 ng/g lw, respectively. EDIs of SCCPs and MCCPs for adults and children ranged between 12 and 11,900 ng kg-1 bw day-1 and 4 and 11,400 ng kg-1 bw day-1, respectively. Zeng Y. C. Huang, X. Luo, Y. Liu, Z. Ren, B. Mai. 2018. Polychlorinated biphenyls and chlorinated paraffins in home-produced eggs from an e-waste polluted area in South China: occurrence and human dietary exposure. Environ. Int. 116:52-59. https://doi.org/10.1016/j.envint.2018.04.006.	Please refer to our response in the previous RCOM. We have included this study in the food/consumer exposure section.
ACAT/IPEN	41	198	Add: Wang *et al*. (2018) investigated CPs in domestic polymeric products, including plastics, rubber and food packaging in China and found that “the average concentrations of SCCPs in polyethylene terephthalate (PET), polypropylene (PP), polyeth ylene (PE) and food packaging were 234, 3968, 150 and 188 ng/g, respectively and the corresponding average concentrations of MCCPs in these samples were 37.4, 2537, 208 and 644 ng/g, respectively. The concentrations of CPs in rubber and polyvinylchloride (PVC) were	Please refer to our response in the previous RCOM. We have included this study in the food/consumer exposure section.

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			significantly higher than in other matrices. The highest concentrations of SCCPs and MCCPs were found in a PVC cable sheath with 191 mg/g and 145 mg/g, respectively. Congener group profiles analysis indicated C_{11}- and C_{13}-congener groups were predominant in carbon homologues of SCCPs, and C_{14}-congener groups were predominant in MCCPs. High levels of SCCPs and MCCPs in domestic polymeric products implied that they might be a significant source to the environment and human exposure." Wang C, Gao W, Liang Y, Wang Y and Jiang G. 2018. Concentrations and congener profiles of chlorinated paraffins in domestic polymeric products in China. Environmental Pollution, 238, 326 – 335.	
ACAT/IPEN	41	199	These studies should be referenced directly rather than just referring to EFSA, as they represent important routes of exposure to humans.	We refer to the EFSA report as this provides a good authoritative overview of the data and an expert regulatory consideration of the consequences.
ACAT/IPEN	41	199	However, because of the limited available information exposure levels cannot be estimated, <u>although they may be significant.</u>	Text unchanged to remain factual and based on the EFSA report.
ACAT/IPEN	41	200	Exposures through household dust are particularly relevant for infants and children because of their physiological characteristics, hand-mouth behaviours, and time spent on or near the floor where they may inhale or ingest the dust. Hazards of household dust for example in: Zota AR, Singla V, Adamkiewicz G, Mitro SD, Dodson RE. Reducing chemical exposures at home: opportunities for action. *J Epidemiol Community Health*. 2017;71(9):937-940. doi:10.1136/jech-2016-208676	Text has been included based on the EFSA report regarding dust exposure.
ACAT/IPEN	41	200	Darnerud and Bergman (2022) note that in humans, "the dietary route is dominating, and could constitute more than 90% of total estimated CP exposure (citing e.g. Environment Canada, 1993; Gao et al., 2018), but in toddlers dust ingestion may be more important and in certain cases estimated to make up more than half of the total exposure (citing Fridén et al., 2011)." Darnerud O and A Bergman. 2022. Critical review on disposition of chlorinated paraffins in animals and humans. Environment International 163, 107195 https://doi.org/10.1016/j.envint.2022.107195	Text has been included based on the EFSA report regarding dust exposure.
ACAT/IPEN	41	202	It would be helpful to use consistent units for comparison.	We have tried to do this where the data permit, but studies do not always report comparable data.
ACAT/IPEN	42	204	Add: "MCCPs" are also present in market foods, household dust, household products and appliances, playing fields and other sources that represent important exposure pathways to humans	Text included with amendment as EFSA have identified uncertainties and limitations with the available data.

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ACAT/IPEN	43	216	Add: Ali et al (2010) summarized the environmental and mammalian toxicity for chlorinated paraffins: "For the MCCPs, rodent toxicity studies have revealed similar or even lower LOEL levels than SCCPs. The lowest reported LOEL is 25 mg/kg/day in Wistar rats given C14–17, 52% Cl in the diet for 90 days."	Not included. See response in previous commenting round to this study.
ACAT/IPEN	44	224	Were low-dose effects measured such that might be linked with reproductive endocrine effects? What were the lower end exposures and did the researchers consider a non-linear dose-response curve?	These were regulatory toxicology studies, conducted in 1985 and designed to meet particular regulatory requirements of the time. They were not intended to investigate potential non-monotonic effects. We do not consider any additional text in the RP to be necessary. It should also be noted that standard OECD TG compliant studies conducted at this time did not routinely investigate ED-related parameters. The lowest doses employed were: 1-generation study: 20-25 mg/kg bw/day Screening study: 6 mg/kg bw/day Rat developmental toxicity study: 500 mg/kg bw/day Rabbit developmental toxicity study: 10 mg/kg bw/day
ACAT/IPEN	45	227	It is quite different to say MCCPs do not meet the criteria rather than they have not yet been studied or classified. It is more accurate to say the latter.	We have looked back into our records, and the human health classification for MCCPs was considered by the relevant EU experts (to provide the harmonised EU classification), and we can say that they do not meet the criteria. Please note for carcinogenicity the RP indicates that 'no classification' is based on no data.
ACAT/IPEN	46	232	Text edit: Each has limitations, but the data ~~indicate that the possibility of~~ provide evidence of biomagnification ~~of "MCCPs" cannot be excluded~~.	Text unchanged: the proposed amendment changes the conclusion drawn from the available weight of evidence.
ACAT/IPEN	46	235	Add: MCCPs are also found in a range of market foods, household dust, household products and appliances, playing fields and other sources that represent important exposure pathways to humans.	Text included with amendment as EFSA have identified uncertainties and limitations with the available data.
ACAT/IPEN	47	238/240	Text edit: international regulation ~~risk management~~	No change. We prefer the term risk management as this is specific about what action is being taken; it is also the term used for the next steps in the POPRC process (i.e., RME).
ACAT/IPEN	47	241	Consistently use the plural when referring to MCCPs throughout the document.	"MCCPs" is a single substance, and therefore referred to in the singular in general. In some

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				places, “MCCP” has been used for readability.
ACAT/IPEN	47	241	Text change: [...] global action is required to ~~manage~~ prevent risks to human health and the environment from carbon chain lengths in the range C_{14-17} and chlorination levels ≥45% chlorine by	We have retained “manage” in the present document for consistency with the RME point above.
China Chlor-Alkali Industry Association (CCAIA)	2	6	Regarding the 6th term in Section 1.1.1.CAS number, chain length and chlorination on page 2, we have a different opinion on the chlorine content of CP-52. Specifically, according to the industry standard HG/T 2092, China defines CP-52 as a product with a chlorine content between “50%-54%”by weight, rather than "45%-52%".	We have updated the text with this information. We highlight that academic studies detailed in the RP show that CP-52 can be more variable than this specification.
CCAIA	8	22	"(2018) Based on information from Chen et al. (2021) and Li et al. (2018b) there are around 100 to 150 CP producers in China." which is obviously inconsistent with the industry situation in China, and it is suggested to delete it.	This is information from two different Chinese publications. Please note that the number of producers is likely to reflect both large- and small-scale manufacture. We would be grateful for more specific information about the Chinese market. Without further information, the current text is retained as it is publicly available.
CCAIA	9	37	Regarding the 37th term in Section 2.1.3, we have a different view here. (Chlorinated paraffins can potentially be released to the environment throughout their life cycle from production, use in industrial processes, from consumer products, and disposal.) It is believed that chlorinated paraffins will not be released to the environment during the production process in principle because they are produced in a fully enclosed device. It is suggested to delete “production”.	Several monitoring studies detected CPs at CP production sites in China, for example Niu *et al*. (2021) and Guida *et al.* (2020). These indicate that release has occured during production. Text unchanged.
CCAIA	15 to 16	63- 66	The terms from 63 to 66 in Section 2.2.2.3 indicate that biodegradation is not likely to occur in C14 chlorinated n-alkane, 50% Cl wt while C14 chlorinated n-alkanes with low chlorine content (≤45% Cl wt.) are readily biodegradable.However, there is a lack of enough reliable experimental data to explain its non-degradability for C14 chlorinated n-alkanes with chlorine content (45%-50% Cl wt.). Therefore, the argument presented in the 67th term that “the half-life for sediment is assessed to exceed 180 days for C14-17 all chain lengths with chlorination levels ≥45% Cl wt.” does not hold water. It is necessary to supplement the specific research data on the degradation of C14 chlorinated n-alkanes with chlorine content (45%-50% Cl wt.) In addition, SCCPs is considered to be a product with chlorine content (>48% Cl wt.) according to the Convention. Is it more appropriate to define MCCPs as C14 chlorinated n-alkanes with chlorine content (>50% Cl wt.)?	The proposal is for a listing covering C_{14-17} chain lengths, not just C_{14}. As detailed in the RP, a ready biodegradation test on a C_{14-17} 45.5% Cl wt. substance indicated that it was not readily biodegradable. If that is benchmarked against the C_{14} 50% Cl wt. results, this indicates that the C_{14-17} substance is persistent. Your commentary also omits the information from the sediment core data included in the RP. In those studies where congener level information is available, $C_{14}Cl_5$ can clearly be detected. Such detection would not be anticipated if the 45 and 50% Cl wt. congners were as degradable as you suggest. SCCPs is listed as >48% Cl wt. based on the available data for that substance. The conclusion for *Chlorinated paraffins with carbon chain*

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				lengths in the range C14-17 and chlorination levels at or exceeding 45% chlorine by weight, should similarly be based on the available data for this substance. As detailed in the RP, this shows that the threshold should be set at ≥45%.
CCAIA	15 & 16	63-67	In the content of 2.2.2.3, there is a serious lack of experimental data on the bioaccumulation of c15-c17 chlorinated paraffin at 63-66 and 70-78. Please supplement them fully.	As you note above, para 63-66 refers to the persistence summary. We disagree that there is a serious lack of experimental data. The bioaccumulation data set is significantly more extensive than the information provided in paragraphs 70-78. The data are covered in paragraphs 70-107: • Screening information • Aquatic (fish) • Aquatic (other taxa) • Field biomagnification and monitoring studies • Terrestrial organisms • Mammalian data relevant to bioaccumulation • Other data relevant to bioaccumulation (which cross-references to data in paragraphs 142-173 (biota and human monitoring section) as the Stockholm Convention criteria for bioaccumulation include: *Monitoring data in biota indicating that the bio-accumulation potential of the chemical is sufficient to justify its consideration within the scope of this Convention*) The RP text explains why the extensive available data set is sufficient to conclude that all four chain lengths meet the criteria.
CCAIA	38, 39, 43 and 86-95	199-205, 230& Appendix 7	Neither Section 2.4.1. Ecotoxicity nor Appendix 7 Human Health Toxicity Assessment Prepared by HSE April 2021 indicates that MCCP has obvious toxicity to human beings and animals. The Profile includes contents as follows: 1) "MCCPs" has no apparent effect upon fertility in rats up to approximately 400 mg/kg/day in the diet. 2) MCCPs (40-60% chlorination; with or without 0.2-1% epoxy stabiliser) administered orally to rats had low acute toxicity, with reportedly no deaths or other severe adverse effects at doses up to 15 g/kg bw reported. 3) Seven days after a single oral dose (dose not clear to the CONTAM panel) to 10-day-old mice, there were no changes between treated and	In Appendix 7 of the RP titled "Effects on or via Lactation" we state: "*CLP Appendix 7 contains an entry for alkanes, C14-17, chloro (chlorinated paraffins, C14-17), CAS number 85535-85-9 that includes Lact. H362: May cause harm to breast-fed children. No new information is available and EFSA (2020) reaffirmed the assumption that MCCPs perturb the clotting system in lactating pups of exposed mothers, leading*

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			control mice, and the panel concluded that MCCPs was not neurotoxic in this test. 4) No studies that investigated the immunotoxicity of MCCPs were identified. 5) The REACH registrants concluded that MCCPs do not meet the criteria for classification for mutagenicity. 6) MCCPs do not meet the criteria for classification for carcinogenicity (no data available). 7) This would support there not being a direct effect of MCCPs on the foetus via in utero exposure. The above points of view all prove that MCCP has no significant impact on the health and safety of human beings and animals. Therefore, the argument presented in Section 4 Concluding statement that "it is concluded that carbon chain lengths in the range C14-17 and chlorination levels ≥45% chlorine by weight are likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects" is not rigorous. Since the harm of toxicity is the premise of scientific research, does it meet the definition of toxicity in POPs Convention if the research only covers the significant toxicity to aquatic invertebrates? It is suggested to specifically analyze at what level, in what aspects and to what extent it will cause harm to animals and human beings, point out the gap between the environmental concentration of existing MCCP and the warning value of harmful concentration to human body and then analyze the risk degree of toxicity of MCCP.	*to internal haemorrhaging and deaths. The likely explanation is that the foetus in utero receives enough vitamin K via the placenta, but after birth it becomes deficient in vitamin K and related clotting factors when reliant on these via the mother's milk. Exposure to pups of MCCPs via the milk might also contribute to the reduction of vitamin K. Haemorrhaging appears to be a consequence of the vitamin K deficiency. This effect is potentially relevant to humans*." It can be seen that Appendix 7 clearly states MCCPs pose a human health hazard; specifically on or via lactation. This is reflected in our concluding statement in Section 4 of the RP. As stated in the ecotoxicity section of the RP, MCCPs meets the UN GHS classification criteria for Aquatic Chronic 1 and Aquatic Acute 1 – both are the most stringent classification categories for the environment for acute and chronic classification respectively. This is therefore clear evidence of significant toxicity to organisms in the environment. Invertebrates are a significant component of food chains, so they are relevant to POPs listing in our opinion. The synthesis section clearly explains the rationale for drawing conclusions: *'This indicates significant toxicity to aquatic invertebrates which are an important part of aquatic food chains. Effects on organisms at this trophic level may reduce food availability at higher levels of the food chain with potential population-level effects. Regulatory testing is designed to protect all organisms living in the environment, and is limited in scope for practical and ethical reasons. Therefore high toxicity observed in one organism within a trophic level means that it cannot be excluded that others are equally or more affected (a general principal of regulatory ecotoxicology). For chemicals that are also shown to be persistent and bioaccumulative, the concern is also for unpredictable effects within the food chain.'*

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				The request in your final paragraph goes significantly beyond the requirements of Annex E of the Convention.
La Grande Puissance de Dieu	General		Typographical comments raised.	Addressed.
World Chlorine Council (received via ECHA public consultation)	General		As the World Chlorine Council, we thank the European Chemicals Agency for enabling our comments to this process. Building on our previous notes, we believe that there is a need to have a clear substance identity in this proposal that uses using specific chemical nomenclature when reviewing and regulating complex or Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) substances, such as chlorinated paraffins (CP). The following are several general considerations for how this could be applied to the nomination process: • Complex/ UVCB substances should be defined as narrowly and precisely as possible for POPs consideration. In practice this may mean defining substances based on specific CAS numbers and/or other specific definitions that allow for the easy differentiation of the listed UVCB substance from other substances. This would be consistent with existing Convention nominations. • UVCB substances are typically defined based on how they are manufactured. Common characteristics used to define UVCBs are starting materials (feedstocks), chemical reactions used in the manufacturing process, conditions of the manufacturing process, etc. • Data (endpoint, exposure, uses, etc.) on the UVCB substance as manufactured and used in commerce should receive greater priority in assessments than data on related substances or constituents (especially if those constituents are UVCBs themselves). Read-across of concerns/ hazards from one UVCB substance to another should be done on a case-by-case basis for each endpoint and must include a clear justification for each endpoint. We encourage the application of these considerations for this and future evaluations of complex substances. We would also encourage consideration of some specific items from the proposal as detailed below: Paragraphs 2 and 3 – This proposal is built upon the assessment of a specific CP substance (CAS 85535-85-9; EC 287-477-0) as registered under the EU REACH regulation and noted in Table 1. The application of this evaluation to other CP substances should be done with great care as the broader the scope of the substances attempted to be covered under this assessment, the less clear it may become to some as to the exact substances covered under the proposed listing. We believe this is a particular concern for broader CP substances that are not typically defined by their	Nearly all of these comments were submitted by WCC in the first intercessional commenting round, and are addressed there. In relation to the comment regarding Table 5: *Table 5 – The predicted total releases are not necessarily consistent with those predicted by the ECHA-recognised Chesar tool. Chesar uses calculations based on established phys/ chem properties of MCCP so it remains unclear why such a large proportion released into air is attributed when considering the low vapour pressure of MCCP. In addition, any releases that go through sewage treatment sludge, and subsequently to incineration, should not count as a release into the environment.* The data in this table are taken from the Regulatory Management Options Analysis performed in the EU (https://echa.europa.eu/assessment-regulatory-needs/-/dislist/details/0b0236e1811f547f). As that document explains, the values used are based on the emission estimates provided in the lead EU REACH Registrant's Chemical Safety Report, using the total EU supply volume. The RP is transparent regarding the possible fate of sewage sludge. The proportion of sewage sludge incinerated at a global level is not known. The approach under REACH has been to assume land-spreading of sludge (a common practice within the UK) unless data are available to contrary. We think it is reasonable to apply the same approach here. Refined emission estimates, if available, can be taken into account in the RME.

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			carbon-chain length (e.g. those from outside of Europe/ North America). One approach to dealing with this would be to consider separate evaluations, and listings if appropriate, on the various broader CP substances themselves. This would certainly be warranted as these are highest volume CP produced globally. Considering the existing POP listing of C10-13 chloroalkanes ("SCCP") has yet to be globally adopted and applied to all CP substances that contain C10-13 chloroalkane constituents, there is strong possibility that this could also occur with C14-17 chloroalkanes. The term congener is used in Paragraph 2 without any definition and in the specific context appears to equate "CP products" with "these congeners". Given that the term congener is used extensively, it should be clearly defined at the beginning of the report. In addition, the discussion on defining congeners should state that these are groupings of CP isomers based on molecular weight and that they are themselves complex groupings without any identifiable constituents. It should also be noted that the analytical method employed in a CP analysis to determine congener groups will have an impact on the identification/quantification of the specific congeners present as it is known that there can be considerable variability from laboratory to laboratory on the identification/ quantification of congeners (a feature already identified in the published scientific literature on these substances). Paragraph 6 – An additional reference to Tomy 1997 regarding the thousands of individual isomers present in CPs is Yuan (2020). This paper also contains a statistical analysis on the chlorination locations on alkane chains. Table 5 – The predicted total releases are not necessarily consistent with those predicted by the ECHA-recognised Chesar tool. Chesar uses calculations based on established phys/ chem properties of MCCP so it remains unclear why such a large proportion released into air is attributed when considering the low vapour pressure of MCCP. In addition, any releases that go through sewage treatment sludge, and subsequently to incineration, should not count as a release into the environment. Paragraph 51 – The summary of the newly completed OECD 314B biodegradation study on C14-17 chloroalkanes at 52% Cl (wt.) is not correct. First, this is a simulation study, as explicitly stated in the guideline, for the biodegradation of a substance in wastewater treatment. It is not a screening assay and thus should be considered under 'environmental simulation data'. Secondly, follow-up studies confirm that the tritiated test material behaves similarly to the non-radiolabelled test material in this bioassay (study available upon request). This hot versus cold comparison study was run at much higher concentrations (~150 times higher)	

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			to allow for the use of GC-μECD to measure the disappearance of the cold test material. Even at this much higher concentration, there was relatively rapid and extensive (over 90%) biodegradation in this test system of both the radiolabelled and non-radiolabelled chloroalkanes within 9 days. Furthermore, the pattern of biodegradation was roughly the same for both test materials. Given this follow-up study we believe it is inappropriate to include speculative comments regarding the nature of tritium in "protein related substances" and the reference to Nivesse et al., 2021. Finally, this study was appropriately conducted based on the globally accepted guideline which allows for the accommodation of poorly soluble chemicals using techniques to disperse the test material. Surfactants are commonly present in wastewater in the milligram/L range (Matthijs et al. 1999) and thus would be expected to be present at concentrations higher than those used in this study (443 µg/L final added concentration). It should also be noted that the test concentrations of MCCPs used in this testing were approximately 10 times higher than its water solubility limit in the primary study and over 1000 times higher in the comparison study. As such we question the dismissal of this study, and its results, simply because the results do not align with other biodegradation studies. This study simply illustrates that MCCP is biodegradable under some test conditions and not under others. This is likely true for most chemicals, particularly poorly soluble chemicals, which are not readily bioavailable to the inoculum in the test system. Paragraph 78 – We believe that is unreasonable to summarily reject the BAT evaluation (a tool which ECHA have been consulted on). This evaluation does not rely primarily on any single study and, moreover, it considers a range of different metrics as opposed to primarily focusing on BCF. Whilst BCF may be the primary metric for the evaluation bioaccumulation in some regulatory schemes, it is not the only metric and in the global assessment considering a range of metrics (as the BAT tool does) is worthy of consideration. Paragraph 184 – As the EFSA 2020 review of CPs is cited in this paragraph, we believe it would be appropriate to capture the risk conclusions from this assessment (see section 4.4.1 of the 2020 EFSA review). Appendix 3, Table 10 – Slackwax (petroleum), chloro, CAS 2097144-44-8, is not a CP substance that contains C14-17 chloroalkanes. This substance was just recently added to the U.S. chemical (TSCA) inventory in 2017 and is a C18+ chloroalkane substance. U.S. EPA has a full chemical characterisation of this substance.	