Chloroalkane Product Group
Chlorinated Paraffins Industry Association

Comments of the to the U.K. Government Concerning Proposed Action on Medium-Chain Chlorinated Paraffins (MCCP) under Stockholm Convention
15 March 2021

Introduction

The Chloroalkane Product Group (CAPG) and the Chlorinated Paraffins Industry Association (CPIA) are providing the following comments in response to the 18 January 2021 proposal by the United Kingdom (U.K.) Department for Environment, Food & Rural Affairs (DEFRA) to nominate "Chlorinated paraffins with carbon chain lengths in the range C_{14-17} and chlorination levels ≥45% chlorine by weight" to the list of persistent organic pollutants (POPs) under the Stockholm Convention ("POP proposal"). This class of chemistry is commonly referred to as medium-chain chlorinated paraffins (MCCP) and is produced by CPIA and CAPG members in the United Kingdom (U.K.), European Union (EU) and United States of America (U.S.). These comments are intended to be complementary to the submission by the MCCP REACH Consortium, which CPIA and CAPG fully endorse. As explained further in these comments, we believe that the UK's proposal does not demonstrate that MCCP meets the criteria in Annex D of the Stockholm Convention and that this proposal should be withdrawn.

MCCP is a commercially important substance for many industries and businesses in the U.K., North America, Europe and beyond. CAPG and CPIA strongly urge DEFRA to carefully review these comments and to seek input from potentially impacted countries and businesses prior to taking any proposed action on the MCCP range under the Stockholm Convention. We understand that the ongoing manufacture and use of MCCP has been well-studied and evaluated in the U.K., EU, Canada, and U.S. These reviews have consistently demonstrated that MCCP can be managed in an environmental appropriate manner with the risk to human health and environment being well controlled and releases to the environment minimised.

CAPG and CPIA are also concerned that this POP proposal is premature as there are multiple ongoing testing programs and assessments of MCCP in the EU and U.S. CPIA is the midst of a testing programme on MCCP for the U.S. Environmental Protection Agency (EPA). Several new ecotoxicology and environmental fate studies on the MCCP range were just submitted to U.S. EPA for review. Similarly, the MCCP REACH Consortium has an ongoing biodegradation study that is expected to be completed in the next few months. Given that recent assessments have indicated that risks are controlled in the EU and U.S. and further research is ongoing, CAPG and CPIA believe that this proposal should not be forwarded for consideration at the 17th meeting of the POPs Review Committee (POPRC).

MCCPs Do Not Meet the Annex D Criteria

The criteria for establishing a substance as a POP is provided in Annex D of the Stockholm Convention and requires a chemical to meet the following:

Persistence

i. Evidence that the half-life of the chemical in water is greater than two months, or that its half-life in soil is greater than six months, or that its half-life in sediment is greater than six months; or
ii. Evidence that the chemical is otherwise sufficiently persistent to justify its consideration within the scope of this Convention;

Bioaccumulation

i. Evidence that the bio-concentration factor or bio-accumulation factor in aquatic species for the chemical is greater than 5,000 or, in the absence of such data, that the log Kow is greater than 5;
ii. Evidence that a chemical presents other reasons for concern, such as high bio-accumulation in other species, high toxicity or ecotoxicity; or
iii. 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;

Potential for long-range environmental transport:

i. Measured levels of the chemical in locations distant from the sources of its release that are of potential concern;
ii. Monitoring data showing that long-range environmental transport of the chemical, with the potential for transfer to a receiving environment, may have occurred via air, water or migratory species; or
iii. Environmental fate properties and/or model results that demonstrate that the chemical has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For a chemical that migrates significantly through the air, its half-life in air should be greater than two days; and

Adverse effects

i. Evidence of adverse effects to human health or to the environment that justifies consideration of the chemical within the scope of this Convention; or
ii. Toxicity or ecotoxicity data that indicate the potential for damage to human health or to the environment.

The following is a detailed review of each of these Annex D requirements against the current information available on MCCPs. Annex 1 also provides some detailed comments on the proposed POP nomination dossier text.

Persistence Data for MCCP

The key criteria for the evaluation of persistence are half-lives of greater than 2 months in water, greater than 6 months in soil/sediment or evidence that a chemical is "sufficiently persistent". Against these criteria, the primary test data for the evaluation of MCCP include a number of OECD 301D Closed Bottle Tests (CBT) conducted on a broad range of test materials and a single OECD 308 sediment biotransformation study conducted on C14 at 50% Cl (wt.). The current POP proposal appears to generally acknowledge these available biodegradation data for MCCP, though we do not believe these data are properly summarised and assessed in Section 5.2.

The U.K. POP proposal appears takes a very narrow interpretation of the utility of the OECD 301D studies for consideration against the Annex D criteria, though these data represent a much fuller picture of the biodegradation potential for this class of chemistry than any other available data given the range of test materials that were studied. The CBT OECD 301D studies were conducted in 25 separate experiments with 11 distinct test materials between 2009 and 2018.

The OECD 301D study, like other ready biodegradation studies, is considered a stringent test in that it uses relatively low levels of inoculum and relatively high mass of test material for the size of test system. These 301D CBT studies were conducted at 2 mg/L test material to water, which is several orders of magnitude above the actual water solubility limit of MCCP (expected to be ~6 µg/L based on recent testing). The adjustments made in these CBT studies on chloroalkanes are consistent with the OECD 301 guideline for testing poorly soluble chemicals. The POP proposal appears to reject "a number" of the 301D studies because they "used an inoculum that was not considered to be appropriate for the REACH Annex XIII assessment." CAPG and CPIA believe that all of these studies were conducted appropriately and within the OECD guideline and are not aware of any deficiencies which prevent their consideration. Further, REACH Annex XIII is not the relevant criteria for this current POP proposal.

The OECD 301D results indicate that chloroalkanes in the MCCP range up to 51% Cl had greater than 60% biodegradation within 60 days. These test materials are thus considered either readily or inherently biodegradable and therefore not persistent. The POPs proposal does not appear to properly capture these results when it states that a "C15 chlorinated n-alkane, 51% Cl wt. also failed to meet the pass threshold [of 60%] after 60 days." However, there were two OECD 301D, Closed Bottle Test (CBT), studies done on this C15, 51% Cl test material – one using river water as an inoculum and other using activated sludge. In the activated sludge study (van Ginkel 2014b) the test material was 63% biodegraded on Day 60 and the study report itself notes that this result means the test material should "be classified as inherently biodegradable and not persistent." Additionally, test materials in the 51-55% Cl (wt.) range also showed considerable biodegradation potential with results of greater than 50% degradation within 60 days. A detailed summary of these studies is provided in Attachment A.

The POP proposal also states "that it is not possible to extrapolate information from these [OECD 301D] tests to an environmental half-life" (paragraph 30, page 7). Whilst it may be technically accurate to say that these OECD 301D studies do not generate half-lives since they do not report first-order degradation kinetics, certainly one could easily estimate that the half-

lives in water are far less than 2 months in those CBT studies that report full mineralisation of over 50% in water on Day 60. Based on an assessment of the likely biochemical mechanisms for the biodegradation of chloroalkanes, there are multiple reaction steps prior to achieving full mineralisation and most of these involve the biotransformation of the chloroalkane to a different class of chemistry (e.g. chlorinated fatty acid). See Attachment B. This anticipated biochemical mechanism is supported by several 2018 CBT studies where the test solutions were analysed for loss of the parent (chloroalkane) test material. The results from these studies, which are summarised in Attachment C (August 2019 review of the MCCP P and B endpoint by the MCCP REACH Consortium), show that the vast majority of the chloroalkane test materials, even at higher chlorination levels, are removed from the CBT test system even when full mineralisation is not achieved. Base on the results, it would appear that there is clear data to demonstrate that chloroalkanes in the C14-17 range up to 55% Cl (and perhaps even up to 60% Cl) would not be expected to have half-lives in water of >2 months.

The final persistence conclusion presented in Section 5.2.4 relies almost entirely on the single OECD 308 sediment biodegradation study on C14 chloroalkane at 50% Cl (wt.). Concerns with the appropriateness of this test method for biodegradation testing of poorly soluble chemicals like MCCPs have been previously presented to ECHA and the U.K., though we think it is important to raise these concerns again given the significance placed on this study in the POP proposal against the criteria under the Stockholm Convention. Attachment D contains a letter from expert researcher, [redacted] regarding concerns with the inappropriateness of this test system for MCCP. CAPG and CPIA do not believe that the current POPs proposal for MCCP has fairly balanced the significant data available from the range of OECD 301D studies verse the single OECD 308 study. In total these CBT results are simply not consistent with a conclusion that C14-C17 chloroalkanes at or above 45% Cl (wt.) meet the criteria established in Annex D.

Evaluation of Bioaccumulation of MCCP

The basis for a bioaccumulation determination under the Stockholm Convention includes metrics such as the bioconcentration factor (BCF), the bioaccumulation factor (BAF), and the octanol-water coefficient (K_{ow}). However, the Convention text also mentions biota monitoring data and the website specifically focuses on biomagnification, noting POPs "accumulate in the fatty tissue of living organisms including humans, and are found at higher concentrations at higher levels in the food chain." And that "fish, predatory birds, mammals, and humans are high up the food chain and so absorb the greatest concentrations." Given the POP focus on biomagnification in the food chain, it is surprising that the bioaccumulation synthesis (Section 5.3.7) in the POP proposal is based almost entirely on experimentally derived BCF values whilst declaring the results of field bioaccumulation/biomagnification studies as "equivocal." CAPG and CPIA believe that the approach taken on the bioaccumulation endpoint could be greatly improved with a more balanced, systematic weight of evidence (WoE) approach.

The comments already submitted by the MCCP REACH Consortium provide an excellent overview of the recently conducted WoE assessments on MCCP bioaccumulation, including the new Bioaccumulation Assessment Tool (BAT) assessment of MCCP. In considering these WoE

assessments and comments of the REACH Consortium, CAPG and CPIA would like to emphasise that:

- All of the recently conducted MCCP bioaccumulation assessments by Arnot and Thompson and Vaughan relied upon well-established and consistent frameworks developed by scientists from academia, industry and regulatory agencies including ECHA, EPA and RIVM. See Burkhard et al. (2012), Gobas et al. (2009), and ECHA/Cefic 2014 bioaccumulation conference[1].
- There are a number of field data that address the potential for biomagnification and tropospheric magnification. These data were considered reliable and highly relevant for this assessment.
- The overwhelming weight of the evidence, including all of the measured values for tropospheric magnification factor (TMF), indicate that MCCP does not biomagnify in the environment.

Beyond taking a more balance approach to the bioaccumulation assessment of MCCP for the POPs proposal, we also feel it is important to note that the proposal has chosen to focus on the BCF metric – even for studies where the researchers did not report/derive BCF values. There is no clear reason for doing this since Annex D considers a range of possible metrics for the evaluation of bioaccumulation beyond BCF. For example, the POPs proposal reports BCF values of >5000 for C16 from the study by Fisk et al. (1996), whereas the study authors reported their results in biomagnification factors (BMFs). This study of C16 chloroalkanes was conducted on two different chlorination levels (35% and 69% Cl) and at several different feeding concentrations. Fisk (1996) reported 5 different BMF values for C16 in the range of 0.44 to 1.07. The one value that was just over 1, the B criterion for BMF, was for C16 at 35% Cl - a substance whose chlorination level is outside of the scope of this POP proposal. The other values were all below 1, indicating that C16 chloroalkanes do not biomagnify. Similar comments could be made on the treatment of the results from Fisk et al. (1998) and Fisk et al. (2000). All three of these studies are consider in the WoE and BAT assessments previously submitted and are thus considered in its conclusions.

Potential for Long-Range Transport

The physicochemical properties of chloroalkanes in the MCCP range generally do not suggest that long-range transport is a significant phenomenon. MCCPs have high molecular weights, very low vapour pressure and decompose at temperatures above 200^{o}C. MCCPs have very low water solubility and are not expected to be mobile in soil and sediment. We do not believe that there is compelling evidence that they "become widely distributed throughout the environment as a result of natural processes involving soil, water and, most notably, air" (pops.int).

The basis for concluding that MCCPs experience long-range transport is largely on the fact the modelling results for MCCP are slightly lower than SCCP (which is itself below the reference POP standards for this endpoint) and monitoring data in remote regions. Regarding remote

[1] CEFIC-LRI and ECHA Workshop on Recent Scientific Developments in Bioaccumulation Research;.Helsinki, Finland, 24 September 2014

(artic) monitoring data, Vorkamp (2019) found that here were notable differences between the monitoring results from MCCP and SCCP "possibly indicating long-range transport as the main source for SCCPs as opposed to MCCPs emitted from local sources." Figure 3 from Vorkamp illustrates the difference between SCCP and MCCP in these remote air monitoring studies. It should be noted that during the period of this sampling (2013-2017) SCCP production was completely ceased in North American and Europe, though as discussed later in these comments SCCP and broad range CPs that contain the SCCP range continues in parts of Asia.

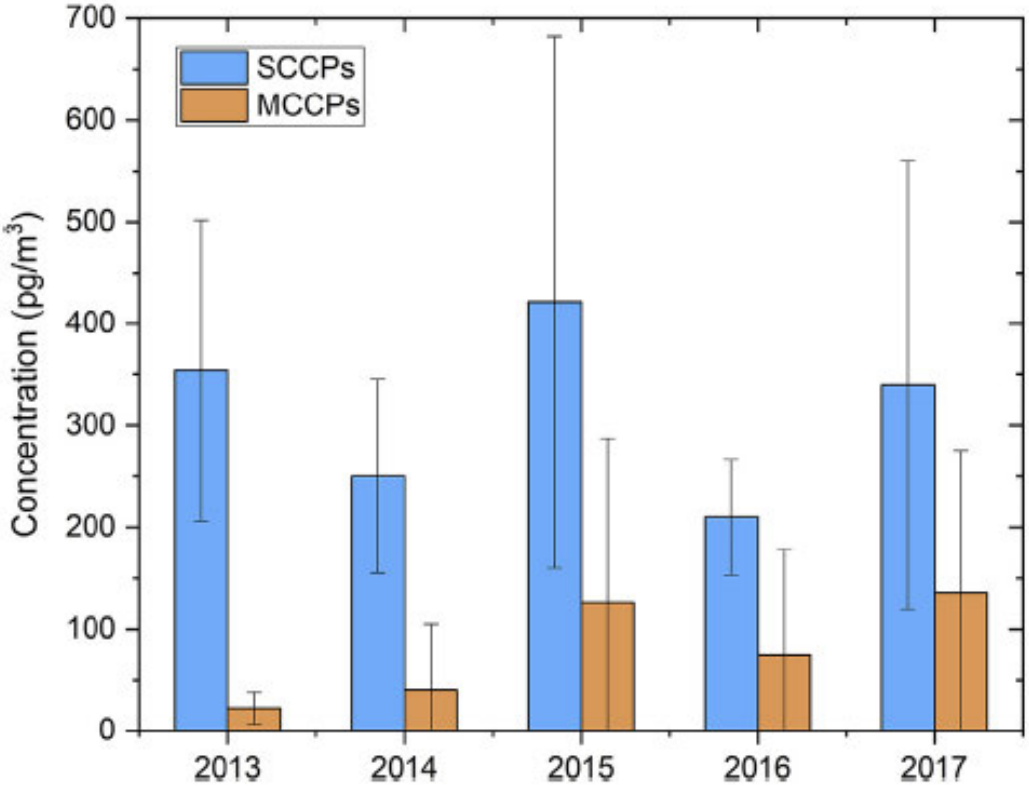


Fig. 3. Concentrations of ΣSCCP and ΣMCCP (pg/m^3) in air samples (gaseous and particle phase) at Zeppelin (Svalbard, Norway), 2013–2017 [40–44]. The figure shows annual means and standard deviations. For values below the limit of quantification, the value for the limit of quantification was used.

In should be further noted that the units for this air monitoring data reported in Vorkamp (2019) and the other air data summarised in the POP proposal are in picograms per cubic metre (pg/m^3). This is a unit that is equivalent to parts per quadrillion (1 x 10^{-15}). For comparison, the general population DNEL for MCCP in the REACH dossier is 2 mg/m^3 (~0.1 ppm) – 7 to 8 orders of magnitude higher than these reported MCCP monitoring values. These monitoring results represent an impressive effort in sample air collection (the air volumes needed to quantitate to these low concentrations is massive) and sample analysis, but we believe some perspective on the levels is needed.

Overall, CAPG and CPIA believe that there is not a compelling case that MCCP is "widely distributed throughout the environment as a result of natural processes". Areas with the highest monitoring levels appear to be due to localised contamination and detectable concentrations in remote areas are extremely low.

Adverse Effects

CAPG and CPIA believe that to justify "consideration of the chemical within the scope of this Convention" that evidence of adverse effect should demonstrate that existing control measures are insufficient to address the chemical hazards. In the case of ongoing production and use of MCCP in the U.K., Europe and North America, we do not believe this is the case. Our position is supported by numerous evaluations of environmental and human monitoring studies that show actual levels of MCCP are well below safety standards (e.g. Predicted No Effect Concentrations (PNECs), Derived No Effect Levels (DNELs), etc.). The U.K. reached this conclusion in 2019[2], when it found that none of the ongoing uses of MCCP in Europe and the U.K. presented an unacceptable risk (i.e. the risk characterisation ratios were all below 1). U.S. EPA made a similar determination noting in September 2019[3] that MCCPs "have been manufactured, processed and used for the uses described in the PMN[s] for more than 40 years; manufacture, processing, distribution in commerce, use and disposal of the PMN substances [MCCPs and LCCPs] in accordance with the provisions of the TSCA section 5(e) order do not create an unreasonable risk of injury to health or the environment."

A 2018 review of the published environmental monitoring data on MCCP has been previously provided to the U.K by the MCCP REACH Consortium, for convenience it is attached to these comments (Attachment E). In this review, 29 studies that measured MCCPs in sediment, water, and biota were identified and fully assessed. A subset of 22 studies were summarized in data tables by media. Studies were eliminated if unreliable analytical techniques were used or if the study was a review paper or repeated data already considered. This subset was further refined to include only those that were deemed relevant as a basis of comparison to the PNECs and modelled concentrations. A complete description of this decision process is provided in the attached Excel spreadsheet. From this assessment, it was determined that no measured concentrations of MCCP in water or biota were above PNEC and the one study that found sediment concentrations above the PNEC was from a highly polluted industrial area in China. These results were consistent with modelling results in Europe which likewise found that no predicted environmental concentrations of MCCPs to be above the corresponding PNECs.

The POPs.int website specifically notes that POPs "are toxic to both humans and wildlife". In considering the toxicity to humans, it should be noted that the observed mammalian toxicological effects for MCCP are high dose effects and have little relevancy for occupational, environmental and general public exposure. For example, the lactation hazard effect mentioned in the draft dossier is due to a phenomenon where the oral doses of MCCP are so high that it interferes with the absorption of Vitamin K. Vitamin K is a necessary nutrient needed for the formation of clotting factors and must be absorbed from dietary sources. MCCP is poorly absorbed in the

[2] Substance Evaluation Report of MCCP. December 2019.
[3] 49044 Federal Register. Vol. 84, No. 181. Wednesday, September 18, 2019.

dietary track and appears to reduce the absorption of Vitamin K, mostly likely by increasing the elimination of Vitamin K in the faeces.

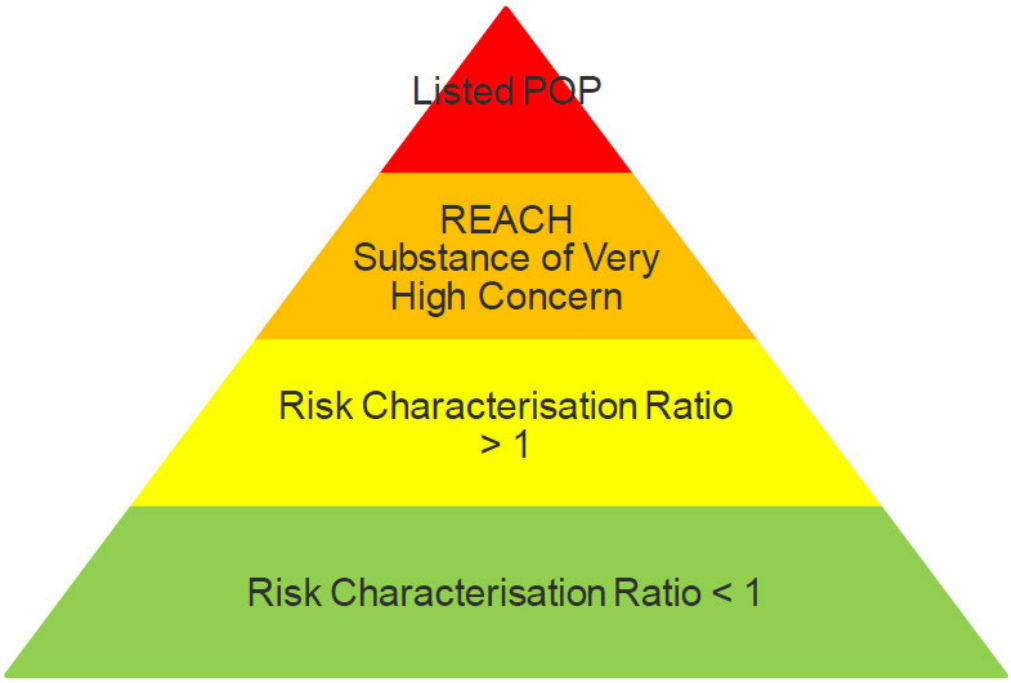
Another good source for evaluating the likelihood of MCCP causing adverse effects to human health is the recent exposure assessment of MCCP by the European Food Safety Agency (EFSA 2020). EFSA conducted a chronic exposure assessment for SCCPs and MCCPs for the consumption of fish meat and human milk in Europe.

ESFA fish meat assessment of MCCP was based on a data set consisting of 422 analytical results from 184 samples of fish meat collected in Germany between 2014 and 2017, which were collected specifically for use in this study. The mean and P95 occurrence levels for MCCP in fish were 13 µg/kg wet weight (ww) lower bound (LB) and 44 µg/kg ww upper bound (UB). The mean LB and UB exposure estimates ranged from 3.2 to 59 ng/kg bw per day. At the 95th percentile exposure, the LB and UB estimates ranged from 8.5 to 148 ng/kg bw per day. The lowest exposures were found in the Adult groups whilst the highest were for Toddlers. Comparison of the MCCP dietary exposures from fish consumption to the $BMDL_{10}$ of 36 mg/kg bw per day resulted in margins of exposure (MOEs) of 6.9×10^5 and 3.9×10^5 or higher for the mean and 95^{th} percentile exposures, respectively. The EFSA CONTAM Panel concluded that these MOEs do not suggest a health concern from MCCP, for the consumption of fish in the EU.

For the exposure assessment of breastfed infants, data from pooled human milk samples from 11 European countries between 2014 and 2016 were analysed within the WHO/UNEP Coordinated Survey of Human Milk for POPs. For MCCPs, the exposure ranged from < 25 to 514 ng/kg bw per day, and from < 38 to 771 ng/kg bw per day, respectively, for average and high consumption of human milk. Similar to the fish exposure assessment, these exposures were compared to the $BMDL_{10}$ of 36 mg/kg bw per day and resulted in MOEs of 7.9×10^4 and 5.9×10^4 or higher for average and high human milk consumption, respectively. The EFSA CONTAM Panel also concluded that these MOEs do not suggest a health concern from MCCP.

These fish and human milk measured data for MCCP are relevant not only to the evaluation of exposure but also speak to whether the long-term use of MCCP in Europe has caused bioaccumulation of MCCP. Meat fish are relatively high in the environmental food web and certainly humans are the generally considered the apex of the food web. MCCP had been manufactured and used in Europe for at least 70 years prior to the collection of these samples (between 2014-2017). To the extent that meaningful bioaccumulation is occurring within the environment and food-web in Europe, direct samples such as these provide a real-world evaluation of this. With MOEs in the range of 10^4 to 10^5 and higher, it appears that decades of continuous manufacture and use of MCCP is not resulting in the primary concern evaluated by the bioaccumulation endpoint – that long-term production and use is leading to higher levels of environmental exposure. These EFSA results are not unusual and are very consistent with other environmental studies of MCCP in regions with good management practices (Canada, Norway, UK, U.S., etc.).

During its recent Stakeholder web-meeting on this POP proposal, the U.K. noted that there is hierarchical approach to chemicals management that is illustrated by the pyramid below:



Given the preponderance of data that indicate risks are well control and risk characterisations ratios are well below 1, we continue to believe that a POP listing MCCP is simply not consistent with this hierarchical approach.

<u>No assurances that POP listing on MCCP will be implemented in a globally consistent manner</u>

Listing MCCP or the MCCP range as a POP is a poor risk management tool to address insufficient regulation and poor handing measures in countries that have demonstrated elevated risk levels. The risk assessments by the U.K., U.S. and other have shown that properly managed manufacture and use of MCCP can be done in a manner that does not produce excess risk to human health or the environment. Approaches to better managing MCCP in countries where monitoring data suggest risk levels are being exceeded is likely to be far more effective than a POP listing.

For example, whilst short-chain chlorinated paraffins[4] (SCCPs) were added to the POPs list in 2017, they or products that contain significant constituents in the C10-C13 range are still manufactured and used in several countries (primarily in Asia) today. In fact, several exemptions to allow for ongoing manufacture and use of SCCP were just reviewed and allowed to continue at the January 2021 16th meeting of the POPs Review Committee (POPRC-16).

[4] Officially listed as "Short-chain chlorinated paraffins (Alkanes, C10-13, chloro): straight-chain chlorinated hydrocarbons with chain lengths ranging from C10 to C13 and a content of chlorine greater than 48 per cent by weight." And that "occurs in mixtures at concentrations greater than or equal to 1 per cent by weight."

When SCCPs were added to the POPs list, they had already been removed from the market years prior in the U.K., Europe and North America. It should be noted that SCCPs were not banned in 2000 as DEFRA notes in this current notice. The SCCP listing on POPs did nothing for the risk management of this substance in the U.K., Europe or North America since SCCP products had already been removed from the marketplace by domestic regulatory actions. Similarly, it appears to have had little apparent impact on Asian production of SCCP, which continues. This ongoing production of SCCP and/or broad-range products that contain significant amounts of C10-C13 is having a significant and negative impact on chemical and polymer producers in the U.K., Europe, and North America. These manufacturers must compete against polymer articles made in countries where SCCP production and use continue and by manufacturers that may be devoting less resources to minimising environmental release. A POPs listing on MCCP will only further benefit manufacturers in those countries/regions where CPs manufacture and use is less controlled and further erode the competitiveness of manufacturers in the U.K., Europe and North America.

Ongoing Research and Assessments on MCCP

There are several ongoing regulatory-driven testing programmes and assessments of MCCP currently in the U.S. and Europe. These testing programmes include new biodegradation and ecotoxicology testing and may include additional bioaccumulation testing. These programmes should be concluded prior to any proposed action on MCCP under the Stockholm Convention.

Conclusions

In conclusion, we believe these comments and the submissions of other impacted parties demonstrate that:

A) MCCP-range chloroalkanes do not meet the POP criteria as established in Annex D of the Stockholm Convention because:
    a. Biodegradation data on MCCP materials at and above 45% Cl (wt.) show them to be readily or inherently biodegradable. These materials are therefore not persistent.
    b. MCCPs are not bioaccumulative in food webs and do not biomagnify.
    c. MCCPs appear to have limited, if any, potential for meaningful long-range transport.

B) Monitoring data are below environmental and health safety levels demonstrating that adverse effects to human health and environment are not occurring. These data support the fact that MCCPs can be safely manufactured and used when appropriate handling measures are in place.

C) A POP listing is not an appropriate control measures for MCCPs and other regulatory alternatives should be explored have not been explored or discussed fully with industry and other stakeholders.

D) Ongoing testing and assessment on MCCPs are still occurring.

Annex 1: Specific Comments on the Proposed POP Nomination Dossier Text

Page	Line	Text	Comment	Recommendation
1	1	C14-17 and chlorination levels ≥45% chlorine by weight	We recommend adding the CAS/EINECS numbers here	
1	12	Asia (e.g. CP-52)	There is value in adding an academic reference here as CP-52 is composed of a much wider cut of alkane feedstocks. Manufacturers in Asia will argue that your definition here does not include such substances and this will likely be reflected in their comments in the POPRC discussions. This will effectively bypass this POP proposal meaning that these products can still be produced, exported and providing these Asian manufacturers with a competitive advantage which should be avoided.	Better definition of the target of this proposal is required.
1	24	Substance Evaluation report UK (ECHA)	No mention is made of the chlorination cut-off discussions, proposed by the UK, as part of the EU REACH Board Of Appeal case. These cut-offs are important given the current concept of ≥45% Cl.	
1	28	PBT properties will be submitted in January 2021	This activity is now scheduled for March 2021.	PBT properties will likely be submitted in March 2021.
2	24	chain lengths below C14 are structurally analogous to short-chain chlorinated paraffins (SCCPs 24 – see paragraph 13).	Due to nomenclature a chain length cannot be structurally analogous to a UVCB substance.	
3	9	contain chlorinated alkanes in the C14-17 range.	There is a differentiation between congeners/ components and substances as described in previous comments	chlorinated alkane components
3	26	SCCPs was listed as a Persistent Organic Pollutant 25 (POP) in 2017.	All production/ registration in UK, Europe and North America of SCCP has ceased and this should be reflected in this document	SCCPs was listed as a Persistent Organic Pollutant 25 (POP) in 2017. The REACH

Page	Line	Text	Comment	Recommendation
				registration of SCCP is no longer active and there is no production in Europe or North America.
3	28	although the identity and 27 actual concentration of the individual constituents is not known	There is a differentiation between congeners/ components and substances as described in previous comments	although these may be analogous to constituents found in SCCPs and can only be estimated.
4	5	with MCCP and SCCP chain lengths in a single product (and C<10 constituents).	There is a differentiation between congeners/ components and substances as described in previous comments	with MCCP and SCCP chain lengths in a single UVCB substance.
5	20	be qualitative indicators only in the following discussion.	Given their quantitative nature, they may be lower value in any robust weight of evidence assessment. We suggest this fact is reflected in the text.	be qualitative indicators only in the following discussion, which may impact their value during discussion on Annex D.
5	24	No measured atmospheric half-lives are available for CPs	CPs are poorly volatile and not very soluble in water. These are key for determining long-range transport potential (an essential element for proposal to the Convention). For any robust scietific assessment of these substances for inclusion, data on these are essential meaning this nomination is premature at best. Monitoring data from remote areas in Canada, Europe, UK, and USA are all below environmental and health safety levels (e.g. PNECs) demonstrating that adverse effects to human health and environment are not occurring in these regions.	
6	6	1-chlorohexane is the closest analogue to the chlorinated C14-17 structures	This substance is physicochemically different from the multichlorinated alkanes under discussion with distinct properties. As such, its use in any model is inappropriate for comparison	

Page	Line	Text	Comment	Recommendation
6	32	CPs are not expected to hydrolyse significantly	Modelling and data submitted as part of the EU REACH registration process suggests degradation via these sorts of mechanisms is occurring. Recent academic studies also seem to indicate this as well.	CPs are not expected to hydrolyse significantly but biochemical pathways to enable this have been observed.
6	Postscript	inoculum that was not considered to be appropriate for the REACH Annex XIII	No official evaluation of the inoculum quality was ever prepared or published. As such, degradation observed is likely a feature of the test vessel set up (and resulting bioavailability)	This postscript should be removed
7	15	conditions of enhanced bioavailability	Conversely, CPs perform poorly under conditions of low bioavailability. This should be reflected in this text.	the studies indicate that substances with a lower level of chlorination can be extensively degraded by micro-organisms under conditions of enhanced bioavailability. Higher chlorinated substances are often poorly degraded under conditions of reduced bioavailability, but this may be a better reflection of the test conditions.
7	22	not possible to extrapolate information from these tests to an environmental half-life.	Under Annex D criteria, this is a key requirement of any nomination suggesting any nomination is premature.	

Page	Line	Text	Comment	Recommendation
7	28	An OECD TG 308 (aerobic and anaerobic transformation in aquatic sediment systems) study has been conducted	This study of concern due to sorption and the low water solubility of the substance. Even though European authorities may feel that it is valid, a precautionary approach is not sufficient to warrant global action, particularly when a Weight of Evidence approach (required by the Convetion) is applied. Such Weight of Evidence assessments have been submitted by EU REACH registrants	Remove references to 2019 OECD 308 tests
8	7	Since the simulation test is more environmentally relevant,	Whilst this position may be shared by some EU states, it is one part of an entire Weight of Evidence which is required under the Convetion.	Remove this statement
8	7	no degradation occurred in the 6 OECD TG 308 study. Since the simulation test is more environmentally relevant, it is given the greatest weight in the assessment of persistence.	There has yet to be any conclusion on this relevancy during ECHA PBT expert group discussions. It is also worth noting the conclusions from p42 of the ECETOC Technical Report No. 133-2. This states "the applicability of OECD TG 307, 308, 309 and the gain of knowledge on the biodegradability of specific types of polymers can be rather limited. Generally, simulation tests have shown limited applicability to non-polymeric UVCBs, and similar limitations have already been observed for complex polymer products with very dissimilar components (see preceding paragraph). Also, the determination of a DT50 may be inaccurate for polymer products that are not highly homogeneous since different constituents may be biodegraded at different rates. Such issues were not considered when the simulation tests were first developed, in view of the assessment of mono-constituent substances"	
8	13	It is not known whether this finding would apply to longer chain lengths with a similarly low degree of chlorination.	There are data which show degradation of congeners at percentages higher than this so it may be argued that the 45% is overly conservative.	
8	29	Chen et al. (2011) took a sediment core from the Dongjiang River	Assessment of the materials used in this 2011 study suggests that the products were a) not from recent commercial products (45-52%) and b) that there is biodegradation of some of the lower chlorinated	

Page	Line	Text	Comment	Recommendation
		within Dongguan in the Pearl River Delta area of South China.	constituents. This means that the value of this study could be questionnable	
8	29	Chen et al. (2011) took a sediment core from the Dongjiang River within Dongguan in the Pearl River Delta area of South China.	Such areas are known to be heavily contaminated with uncontrolled releases of substances which are not MCCP. As previously mentioned, when production/ handling is conducted responsibly we do not see the same issues (as evidence from monitoring data in Europe/ North America). A global action here may not be the best mechanism to reduce the challenges seen here	
8	49	measurable levels of "MCCPs" are present in deeper (elder) sediment layers	Presentations at SETAC (2020) indicate that in pristine, remote, lakes from Scandinavia, such levels are not seen which may not be reflected in this statement.	
10	18	Several more studies provide information about fish bioaccumulation of other relevant 18 constituents, as summarised in Table 4.	In a recent Weight of Evidence assessment using the B assessment tool by [redacted] over 80% of the reliable lines of evidence report a not-Bioaccumulative conclusion for such materials. This will be included in the EU REACH dossier and as part of this consultation so should be reflected in this analysis.	
11	25	these four supporting laboratory studies are considered to indicate that 25 constituents with carbon chains longer than C14 may have significant bioaccumulation potential	Some of the conclusions from these laboratory studies are based on non-detects reported at the limit of detection. This should be reflected in this text.	
11	31	However, there is significant uncertainty for the result due to the single water	Whilst this was one of the lines of evidence used for alkanes, chloro C14-17 in the recent EU REACH assessment, this study was not on 'MCCP'. It was on CP-52 and there remain disagreements between	

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		concentration measurement and use of dry weight rather than wet weight animal concentration measurements.	authorities and stakeholders as to its validity and applicability in this case. This feature should be reflected in this proposal	
12	13	The actual CPs determined in the Jansson et al. (1993) study were of unspecified carbon chain length, with between 6 and 16 chlorine atoms per molecule,	Products of this type containing 16 chlorine atoms are commercially unheard of and would have little use on the market - more investigation should be made of this result.	
19	19		We would ask that information presented at SETAC 2020 by Arriola be included here. This details the concentrations (or lack thereof) of CPs in Norweigan Arctic Circle lakes.	
22	1	Based on the EU REACH registration information, the substance has a number of uses, such as:	All uses were considered to be safe when the UK Environment Agency conducted their assessment under EU REACH. This should be reflected in the text.	Based on the EU REACH registration information, the substance has a number of uses. All such uses were considered to be safe by the UK in their 2019 evaluation of alkanes, chloro C14-17. These uses include:
22	21	Outside Europe, Glüge et al. (2018) cite the following production volumes of “MCCPs”:	CLI has no volume threshold: one gramme and one kilotonne imported both have one notification associated with them. Also the KEMI estimate is based on an assumption that the 2100 tes are C14-17 alkanes but are actually more likely to originate from CP-52. This should be reflected in the assessment of these data.	