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Item 5 (a) of the provisional agenda*

Consideration of draft risk profiles: short-chained chlorinated paraffins

Comments and responses relating to the draft risk profile on short-chained chlorinated paraffins

Note by the Secretariat

The draft risk profile on short-chained chlorinated paraffins prepared during the intersessional period by the working group established by the Committee for that purpose is set out in document UNEP/POPS/POPRC.4/10. The annex to the present note contains a table listing the comments received in accordance with the standard workplan for the preparation of a draft risk profile and responses thereto by the working group. The annex is reproduced as submitted and has not been formally edited.

* UNEP/POPS/POPRC.4/1.

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Annex

Comments and responses relating to the draft risk profile on short-chained chlorinated paraffins

Minor grammatical or spelling changes have been made without acknowledgment. Only substantial comments are listed.

Risk Profile Section	Source of Comment	Comment	Response
Document in general	Australia	General edits	Edits made
General comment	China	Noted that revised version does not provide much new or substantial information. The new data does not support long-range transport and adverse effects of SCCPs. Suggest that until more relevant information becomes available that a second round of review of the risk profile for SCCPS is not necessary.	
General comment	Germany	Noted that although no new information was provided for determining the persistence of SCCPS, all necessary information for making a decision is included, and the information is sufficient for concluding that SCCPs is persistent. Some valuable information has been amended in different sections, but no substantial changes have been made. The risk profile contains all the relevant information necessary.	
p13, the last paragraph of 2.4.6	Japan	Based on the referenced original document (UNECE-LRTAP POPs Protocol, 2007), the sentence hereunder should be added at the end of the paragraph. ... neoplastic effects (tumor formation). However, whether this is the case or not has not been assessed. The only direct measurements of humans in the Arctic are 3 samples of breast milk from the early 1990s analysed by Tomy (1997), which showed concentrations at the low end of the range reported more recently in human milk from the UK (Thomas et al. 2006) (UNECE-LRTAP POPs Protocol, 2007).	Suggested text was added
p16, the sixth paragraph	Japan	Based on the referenced original document related with p14 third paragraph (CSTEE 1998), the sentence hereunder should be added after the paragraph. … which this classification was derived. The Science Committee on Toxicity, Ecotoxicity and the Environment suggests that the finding of lung tumours in male mice may be of importance for humans, but this information would not alter the conclusion of its risk characterisation that the use of short-chain chlorinated paraffins poses no significant risk for consumers or for man exposed via the environment (CSTEE, 1998).	Suggested text was added
p17, the third paragraph of *4 Concluding Statement*	Japan	The last sentence “SCCPs are measured in human breast milk both in temperate and Arctic populations” should be reconsidered because of uncertainty as to whether this is the case or not for the measured SCCPs in Arctic humans (see comment 1 above).	Disagree. There is some evidence of Artic population contamination.
p17, the last paragraph	Japan	The statement “SCCPs are likely, as a result of their long-range environmental transport, to lead to significant adverse environmental effects” is not an appropriate conclusion based on the definition in Japanese national law, which focuses on adverse effects on inhabitation and/or growth of animals at the top of the food chain. POPRC should consider carefully whether SCCPs are likely to lead to *significant* adverse environmental effects or not, with their limited ecotoxicity for aquatic	This will be decided at POPRC meeting in October 2009.

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		invertebrates. Furthermore, since SCCP concentration in water in remote areas is low, as stated in the third paragraph, SCCP exposure to aquatic invertebrates, where SCCPs show their toxic effects, is considerably limited. Even though SCCPs may be potentially bioaccumulative in Arctic marine mammals, such high concentrations of SCCPs accumulated inside marine mammals' bodies are not exposed to aquatic invertebrates.	
Provided source information	Korea		Added to report
General comment	Sweden	Agrees that there is sufficient data that indicates that SCCPs undergoes long-range transport. Suggests that the risk of significant adverse human health effects and/or environmental effects at these concentrations of SCCPs should be compared with concentrations of POPs with similar toxicity pattern that also are present in the Arctic environment often in similar concentrations.	Added suggested text and analysis in Section 3.
General comment and Section 3.	Sweden	As requested in Annex E of the Stockholm Convention, the risk profile has to include "consideration of toxicological interactions involving multiple chemicals", which in this case would be to consider the combined risk from exposure to both SCCP and MCCP. The hazard assessments made by EU for SCCP and MCCP (medium chain chlorinated paraffin's) have shown that these structurally very similar substances also have very similar, if not identical, hazard profiles (draft EU risk assessment report on MCCP, 2007). Only one research group has been analysing MCCPs in arctic biota, but shown presence of MCCP in two arctic bird species at concentrations somewhat exceeding the ones of SCCP (Reth et al, 2006). Therefore, we suggest that this aspect also has to be considered.	The focus of this assessment is on SCCPs. Added suggested text.
Section 2.3.1 Persistence in Water	Sweden	One chlorine molecule is a very small portion of possible SCCP congeners. In the nomination a chlorination degree of more than 48 % is described; "SCCPs are n-paraffins that have carbon chain lengths of between 10 and 13 carbon atoms and a degree of chlorination of more than 48% by weight" (UNEP/POPS/POPRC.2/14). Therefore we see little relevance of the biodegradation capacity information of the congener with one chlorine molecule and suggest that this information is removed or much more clarified.	Text deleted.
Section 2.3.1 Persistence in Water	Sweden	The photolysis study of Koh, I. and Thiemann, W. (2001) used acetone-water when concluding a rapid photolysis of SCCP. According to the OECD guideline for testing of chemicals (draft 2000), it is stated that acetone is an example of a solvent that should not be used as co-solvent for doing photolysis studies as it is a photo sensitizer thus making the reaction mixture more sensitive to light. The rapid photolysis should therefore be questioned also of this reason. We suggest the inclusion of; "*….and as acetone is a questionable solvent to use in such study as it is a photo sensitizer*. " at the end of the second last sentence.	Added suggested text.
Section 2.5.1: Adverse Effects – Mammalian Toxicity	Sweden	We note that the current text is written mainly from a human health perspective, with too little consideration that the mammalian toxicity data also should be assessed in relation to the protection of marine mammals. As we doubt there is sufficient knowledge about the "biology" of whales, seals, and walruses to rule out that toxic effects	Mammalian toxicity section was expanded.

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		occurring in rodents could be of relevance for marine mammals, all toxic effects observed in toxicity studies on rodents have to be considered when assessing the risk to marine mammals after exposure to SCCP. The present text does not reflect this, and it has either to be broadened to include all effects that could be relevant for mammalian species in general and the focus on humans has to be removed, or for simplicity, a new paragraph can be added focusing on mammals in general. For simplicity, we suggest to divide section 2.5.1 into 2 parts; • with one part being the present text aiming at the human health risk assessment (tentatively 2.5.1.1 Human toxicity) and • a new part aiming at the risk assessment of mammals (tentatively 2.5.1.2). Draft text was provided.	
Section 2.5.2, Adverse Effects, Table 2-4	Sweden	We suggest revising Table 2-4 (toxicity table), by including information on mammalian toxicity based on the draft text proposal above. This mammalian (eco) toxicity information is needed when assessing environmental risks from SCCP on e.g., marine mammals.	Table expanded
Risk in remote areas	Sweden	POPRC is asking for additional information in relation to "risk in remote areas". SCCP has so far been found in arctic whales, seals, walruses (Tomy et al, 2000), and two species of arctic birds (Little auk, *Alle alle* and Kittiwake, *Rissa tridactyla*) (Reth et al, 2006). So we do know that these animal species living in "remote areas" have a concentration of SCCP in their body fat. Based on what we know, an approach to roughly "estimate the risk level" could perhaps be to compare monitoring data on SCCP with monitoring data on POPs in arctic species. Draft text/analysis is provided.	Text added in Section 3
Consideration of toxicological interactions involving multiple chemicals	Sweden	Finally, and with reference to point (b) of Annex E of the Stockholm Convention, we believe this information requirement has not yet been fulfilled in the risk profile. The hazard assessments for SCCP and MCCP (medium chain chlorinated paraffin's) have shown that these structurally very similar substances also have very similar, if not identical, hazard profiles. Thus, for both substances, the liver, kidney, and thyroid are the target organs in mammals, with similar potency (i.e., NOAELs of the same order of magnitude) (see EU RARs on SCCP and MCCP). Only one research group has been analysing MCCPs in arctic biota, but shown presence of MCCP in two arctic bird species at concentrations somewhat exceeding the ones of SCCP (Reth et al, 2006). Thus, as requested in Annex E, the risk profile has to include "consideration of toxicological interactions involving multiple chemicals", which in this case would be to consider the combined risk from exposure to both SCCP and MCCP. There is some, although limited data available on MCCP in arctic species. Therefore, we suggest that this aspect should be considered in a qualitative manner, e.g. by stating that *the present risk profile probably underestimates the risks from SCCP as only limited data on the presence of MCCP in remote areas is available.*	Text added in Section 3

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Section 4 – Concluding Statement	Sweden	At the end of the second paragraph, we suggest that the concluding statement include the effects on mammals. A suggested text could be: " *In mammals SCCP may affect the liver, the thyroid hormone system, and the kidneys, e.g., by causing hepatic enzyme induction and thyroid hyperactivity.* SCCPs are classified as a Carcinogen Category 3 by EU and as possible carcinogenic – groups 2B by IARC. We therefore suggest that "*human health and/or*" is included in the last sentence.	Text added
Edits	United States	The last paragraph in the Executive Summary of the risk profile that begins "To prevent SCCPs from continuing…." should be struck from the risk profile as it suggests a risk management approach (prevention of release) best addressed in any risk management evaluation for SCCPs. This same sentence should be struck from the conclusion section of this document.	Sentence deleted
Section 2.4.5	United States	The following reference concerning SCCPs and MCCPs was just released on the web and should be included in the document: Houde, M., Muir, D.C.G., Tomy, G.T., Whittle, D.M., Teixeira, C., Morre, S. 2008. Bioaccumulation and Trophic Magnification of Short- and Medium-Chain Chlorinated Paraffins in Food Webs from Lake Ontario and Lake Michigan. Environ. Sci. Technol. ASAP Article 10.1021/es703184s	New data has been added
Section 2.5.2	United States	It is recommended the mysid shrimp toxicity data on page 14 be added to Table 2-4 on page 16.	Value added in Table 2-4
Section 2.5.2	United States	Why have toxicity effect level for fish, birds and mammals been deleted from Table 2-4? We believe it is important to provide toxicity information for higher trophic level organisms, which may also incur exposures via biomagnifications, when considering effects of PBT chemicals.	Values for fish and mammals have been added to Table 2-4. Value for birds has not been added to Table 2-4 because of uncertainty in interpreting results of study.
Concluding Statement	United States	The United States does not agree that the information, as presented in the document, supports the conclusion that "Based on the available evidence, it is concluded that SCCPs are likely, as a result of their long-range environmental transport, to lead to <u>significant adverse environmental effects</u>, such that global action is warranted." This view is based on the following points: • The evidence presented indicates SCCPs have low toxicity in mammals. As summarized in the document, "According to EC (2005), overall, SCCPs are of low toxicity with the principal toxicological issue being for general non-specific toxicity following repeated exposure, with NOAELs for general toxicity of 100 and 1000 mg/kg/day in rats and mice, respectively." To put this information into a context, it can be compared to the U.N. GHS criteria (as per Annex E, part (f)), which indicated that, based on NOAELs for repeated-dose toxicity of 100 and 1000 mg/kg/day, SCCPs would not qualify for classification under the U.N. GHS. • The evidence presented comparing concentrations in abiotic media <u>and</u> biota indicate that the maximal exposure concentrations (in water, sediment and soil) are one to two orders of magnitude LOWER than the	Additional arguments have been added to the Concluding Statement as suggested.

Risk Profile Section	Source of Comment	Comment	Response
		most sensitive toxicity endpoint measured (and these were for chronic tests in ecologically relevant species). This fact is stated on page 16: "For pelagic, benthic, and soil dwelling organisms, the maximum reported environmental concentrations are approximately 50 - 200 times lower than the most sensitive toxicity values". • As per the Convention, Annex E states that "For this purpose, a risk profile shall be developed that further elaborates on, and evaluates, the information referred to in Annex D..." The second Information Requirement in Annex D is: "2. The proposing Party shall provide a statement of the reasons for concern including, where possible, a comparison of toxicity or ecotoxicity data with detected or predicted levels of a chemical resulting or anticipated from its long-range environmental transport, and a short statement indicating the need for global control." [emphasis added] The Risk Profile (on page 16) provides such a comparison, therefore demonstrating that the criteria of "where possible" has been met. However, none of this information is brought forward nor does it appear to have been adequately considered in drafting the Concluding Statement. For example: o The hazard information referenced in the Concluding Statement is that to invertebrates, however, there is no comparison offered to available environmental concentration data. These data are found at page 16 where it was also stated that the maximum detected concentrations are well below the most sensitive toxicity value. Despite the fact that information is available to support such a comparison of environmental concentrations to toxicity reference values, the comparison is not discussed and the concern statement is based ONLY on the presence of SCCPs in tissues of biota. o Basing the concern on invertebrates is not supported by the information available; using maximal environmental concentrations and lowest toxicity reference values (i.e. worst case scenarios), there is a one to two orders of magnitude margin of exposure. o Furthermore, the effects on higher trophic level organisms (that would also incur exposure via biomagnifications) should be considered/discussed in the Concluding Statement. Currently, the only toxicity basis for concern in the concluding statement is focused exclusively on the lowest trophic level organisms (i.e., the only toxicity information mentioned is for invertebrates). Relative to this point, it is not clear why Table 2-4 in the current RP has been modified to exclude toxicity information on fish, birds and mammals (i.e. higher trophic level organisms); especially the trout data were presented on a tissue-concentration basis and therefore, are directly comparable to the tissue concentrations measured in the environment. Presenting this	

Risk Profile Section	Source of Comment	Comment	Response
		type of comparison is valuable for evaluating the likelihood of adverse effects occurring and should be presented in the document to make it more transparent. We believe there is ample data and methods available for making comparisons of environmental concentrations of SCCPs to toxicity benchmarks for SCCPs in several different trophic levels of organisms. Such an approach has previously been presented to the POPRC in the Pentachlorobenzene Risk Profile. o Relative to this point, in a previous version of the SCCP RP, a table comparing EECs and PNECs was included. This is the type of analysis that should be included, where possible, in the Risk Profile to <u>further elaborate on, and evaluate the information referred to in Annex D (Annex E, </u>. The inclusion of such a table comparing EECs and PNECs would strengthen the RP and it is not clear why it was removed from the RP. We strongly urge that it, or a similar analysis, be included in the RP such that the POPRC have a clearer and integrated synthesis from which to evaluate the available information and make their decisions. o In conclusion, basing the "concern" on the mere presence in biota is not justified nor is it sufficient in our view when toxicity information is available to quantitatively compare environmental concentrations to toxicity values.	
Conclusion	United States	In conclusion, the United States believes that the Concluding Statement, with its focus on the lowest trophic level organisms and lack of a comparison of the many measured environmental concentrations to toxicity levels in any organisms, does not provide a basis for demonstrating that the Convention's risk profile conclusion "Based on the available evidence, it is concluded that SCCPs are likely, as a result of their long-range environmental transport, to lead to <u>significant adverse environmental effects</u>, such that global action is warranted" has been satisfied.	Arguments have been added to support conclusion.
General comment	CPIA	The CP industry objects to the proposed amendments which propose to eliminate the production and use of SCCPs, either in entirety (Annex I: SCCPs, to eliminate production and use; or alternatively, list SCCPs in annex II and specify allowed uses and related conditions in the implementation requirements.) or to permit only specified uses (Annex II: Specify the following uses for SCCP: ["1. Dam sealants and conveyor belts for underground mining; 2. Non-emissive applications i.e. as a plasticizer in paints, coatings and sealants and as a flame retardant in rubber, textiles and plastics"). As reflected in various previous comments, the industry does not believe that SCCPs present either an environmental or human health risk at the local, regional or international level, and most notably, there is no basis on which to conclude that there is a significant risk of adverse human health or environmental effects from long range transport. The industry maintains that SCCPs have been and can continue to be safely used.	These issues will be addressed when preparing risk management options.

Risk Profile Section	Source of Comment	Comment	Response
		The CPIA believes this can best be handled by modifying the proposed language to change the description so that it is not limited just to the explicit uses specified but rather to include all uses with similar non-emissive properties. We further suggest that the language describing the allowable uses should be rearranged from an editorial standpoint as it currently provides somewhat confusing distinctions between the use as a flame retardant and the use as a plasticizer. Often, SCCPs are used to impart both properties. For this reason, we suggest the following modification: *Non-emissive applications, e.g., use as a plasticizer or flame retardant in paints, inks, coatings and sealants, rubber, textiles and plastics and insulation fiber.*	
General comment	IPEN	IPEN is disappointed that SCCPs did not proceed to the Annex F evaluation at POPRC3. Despite the POPRC's obligation to evaluate the SCCPs Draft Risk Profile in a scientific manner using the criteria outlined in Annex E, a political discussion took place that revealed the difficulties of prohibiting a currently used substance such as SCCPs. Ironically, the socio-economic elements that underlined much of the concerns are precisely the elements, which Annex F takes up. We believe the SCCPs meet all Annex E criteria and strongly support efforts to finalize the Risk Profile and begin Annex F evaluation.	
Technical Data	IPEN	Annex 3 presented information on the toxicity of SCCPs to mice and concern for aboriginal people eating contaminated food.	Data already inserted in the risk profile.
Technical Data	Norway	Suggests adding: • WHO 1996 endpoint for the general population • Upper-bound estimates of intake of SCCPs for the general Canadian population (Health Canada 2003) • The conclusion in the EU health assessment. A NOAEL 100 mg/kg/day used in the risk assessment was subsequently based on the effect of observed kidney toxicity in male rats (EC 2000) • The conclusion in the follow up of Environmental risk assessment in Canada 2004 (Environment Canada 2004)	These data are already incorporated in the Risk Profile. They are sometimes referenced using a different citation.
New EU assessment	Norway	Add updated risk assessment of alkanes, C10-13 (EU 2007)	Data added to RP
New paper	Norway	Add measured concentrations of SCCPs in human milk-fat for UK humans - Thomas GO, Farrar D, Braekevelt E, Stern G, Kalantzi OI, Martin FL, et al. (2006). Environmental International 141:30-41	New data added.
New paper	Norway	Add measured concentrations of SCCPs in food items and basket study for 1-year-old female Japanese. Fukuya Iino, Takumi Takasuga, Kurunthachalam Senthilkumar, Naoki Nakamura and Junko Nakanish. 2005. Environ. Sci. Technol. 39:859-866	New data added.
New paper	Norway	Add measured concentrations of SCCPs in environment, biota and humans. Stephane Bayen, Jeffrey Philip Obbard, Gareth O. Thomas. 2006. Review article: Chlorinated paraffines: A review of analysis and environmental occurrence. Environmental International 32:915-929	New data added.
General comment	Norway	Norway has a national regulation from 2002 with a prohibition against production, import, export and use of SCCP. It is also prohibited to produce, import, export or use chemical mixtures or products with over 0.1 % of SCCP by weight. An exception for use in sealing of dams	Defer to risk management evaluation

Risk Profile Section	Source of Comment	Comment	Response
		and conveyor belt in the mine industry ended 1 January 2005. Waste with a content of SCCP of 0,25 % or greater shall be treated as hazardous waste. SCCP is classified as harmful for the environment, extremely toxic for aquatic organisms, to cause unwanted long-term effects in the environment and with a potential for carcinogenic effects in humans. The classification is based on the EU classification.	
General comment	Norway	Information on labelling and classification in different regions and countries are not mentioned in the document. This information is asked for in annex E and is available for Canada, EU, Australia and Washington in US.	Labelling and hazard classification specific to SCCPs is not available and was not identified.
Conclusion	Norway	<u>The conclusion in the risk profile</u> Based on the recommended TDI by WHO (IPCS 1996) and the conclusions in the EU risk assessment, that are coherent with the assessments and classifications in EU, EØS-countries, Australia and Canada, the concern for human health cannot be ruled out. This concern should therefore be reflected in the conclusion of the risk profile for SCCP.	Agreed. Concern for human health has been added to conclusion
Data	Republic of Mauritius	SCCP not produced and not used.	Information has been added in risk profile
Conclusion	Slovakia	Agrees with conclusion	