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Item 5 (c) of the provisional agenda*

Technical work: intersessional work on short-chained chlorinated paraffins

Comments and responses relating to the draft risk profile on short-chained chlorinated paraffins and on the discussion paper on issues and common practices in the application of the Annex E criteria

Note by the Secretariat

1. Annex I to the present note contains a table listing comments and responses relating to the draft risk profile on short-chained chlorinated paraffins set out in document UNEP/POPS/POPRC.8/6. Annex II contains a table listing comments on the discussion paper on issues and common practices in the application of the Annex E criteria set out in document UNEP/POPS/POPRC.8/INF/9.

2. The annexes are reproduced as submitted by the intersessional working group that prepared them and have not been formally edited by the Secretariat. The documents in which the comments were submitted are reproduced on the website of the Stockholm Convention at http://chm.pops.int/tabid/2745/Default.aspx.

* UNEP/POPS/POPRC.8/1.

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Annex I

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

1. Table 1 lists the comments that relate to information on toxicological interactions of chlorinated paraffins, as per the proposal on next steps for short-chained chlorinated paraffins approved by the Persistent Organic Pollutants Review Committee at its seventh meeting.[a] Any other comments are listed in table 2.

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

Table 1. Comments on the draft risk profile on short-chained chlorinated paraffins related to toxicological interactions

Source of Comment	Page	Paragraph	Comments	Response
Executive Summary				
Norway	3	General	Add summary information on toxic interactions	Modified paragraph 8 accordingly.
IPEN	3	8	The other contaminants also need to be considered, as mentioned in the mixtures section.	Modified paragraph 8 accordingly
Toxic Interactions				
Australia	24	141	Minor comment: Suggest amending the first sentence as: "SCCPs are amenable for consideration as having toxic interactions with..."	Paragraph deleted.
Slovakia	24-25	General	There are insufficient studies on interaction of the SCCP with other chlorinated paraffins. It can be assumed that combinated effect will be higher, than SCCP own	Agreed. Wording revised to indicated “assumed” to be higher.
IPEN		143 (equation), 150 (text on potential data for toxic interactions analysis)	Too much detail, and recommends deletion.	Agreed – deleted. Overall section shortened significantly.
Sweden	24-25	General	A common mode of action is not required when discussing what substances are relevant for cumulative assessment.	Do not disagree. Text is revised to acknowledge the diverse range of substances which could have co-exposure. However, text continues to note the example where co-exposure/bioavailability to a common receptor may affect common endpoints due to common mode of action.
Sweden	25	150	Re. *However, it maybe most useful to consider no-effect levels (e.g., EC0 or predicted no effect concentrations (PNECs)) to determine whether combined exposure would likely have no effects.* Statement should either be further explained or deleted. Also concentrations below NOEC/NOEL can add to the	Text deleted.

a UNEP/POPS/POPRC.7/19, annex IV.

Source of Comment	Page	Paragraph	Comments	Response
			effects of the mixture, especially when there is a common mode of action. The concentration addition method adds all concentrations, also PNEC.	
Japan	24-25	General	Brooke and Crookes (2011) have a number of assumptions and limitations. In order to promote appropriate understanding of the result of the paper, those assumption and limitation should be quoted precisely in the Risk Profile.	It is considered that a detailed review of limitations and assumptions is outside the scope of presentation in the Profile.
Japan	24	142	Re. *"eco-toxicity and mammalian toxicity to MCCPs and LCCPs are suggestive of a common mode of action (narcosis) with SCCPs (Brook and Crookes 2011)."* And *"a concentration (dose) addition method."* Information for MCCPs and LCCPs is limited and is insufficient to evaluate the mode of action. ・ Regarding eco-toxicity, insufficient data is available, especially for LCCPs due to its extremely low water solubility, and it is considered to be impossible to evaluate the mode of action. ・ Regarding mammalian toxicity, further consideration (e.g. target organs and/or no adverse effect level) is considered to be required to evaluate the mode of action.	This specific information has been reworded. Revised text recognizes potential uncertainty respecting common mode of action among groups of CPs.
Japan	24, 25	143, 147, 149	There are some statements that no quantitative data is shown even it should be, such as a calculation result of TUm for equation shown in para 143, "SCCPs, MCCPs and LCCPs are all very persistent and share common fate characteristics in the environment" in para 147, and "SCCPs, MCCPs and some LCCPs are highly bioaccumulative" in para 149.	Statements requiring quantitative support removed. Quantitative analysis of MCCP and LCCP outside scope of SCCP Profile.
Japan	25	Add to end of section and para 161 Section 5 Conclusions	Brooke and Crookes (2011) concluded that, given the assumption and the limitation, the result for the conservative screening evaluation depends on the monitoring data, and the result of TUm which actually become more than 1 is the one using marine sediment concentration near the SCCPs manufacturing plant. Therefore, SCCPs, MCCPs and LCCPs are not likely, as a result of long-range environmental transport, to lead to significant adverse effects on human health and environment in the remote area by toxic interactions. Also add revised statement to para 161 as follows: "..., it <u>might</u> be expected <u>based on the limited evidence</u> that there would be cumulative <u>exposure and</u> effects associated with exposure to CPs	This paragraph has been deleted. Revised text recognizes potential limitations/lack of data in evaluations of cumulative effects (see. Paragraph 144)
Japan	25	152	… to promote scientific discussion on the impact of climate change on environmental fate of POPs chemicals in general, however, the paragraph 152 refers narrative prediction on possible	Some mention of possible implicating impact of additional stressors like climate change considered appropriate for mention as it

Source of Comment	Page	Paragraph	Comments	Response
			secondary emission which is to be predicted as one of the impact of climate change, not specifically on the SCCPs. Therefore, it is open for question whether we may wish to include these general statements in the risk profile which is served for the discussion on determination whether SCCPs should be listed under POPs Convention.	may affect overall severity of risk to biota.
Netherlands	24-25	General (141-152 and 161)	The Netherlands does agree that toxic interactions may play an important role in determining the risks of POPs and thus should be considered in the judgement whether substances should be listed or not. Our objections against the present text concerns: 1. the fact that an explanation for the need of this text is lacking, 2. the place within the risk profile, 3. the general considerations and 4. the fact that statements are made without any justification, i.e. no references are added on MCCPs and LCCPs. The Netherlands would strongly recommend: 1. to add some explanation why a chapter on interactions has been added, 2. to find another place for the chapter on toxic interactions (e.g. before the synthesis), and 3. to shorten it considerably. It now comprises 1½ page, which is as much as the parts on bioaccumulation and persistence. 4. to focus a synthesis on interactions more on the already nominated POPs rather than on MCCPs and LCCPs.	1. Explanation provided as to the importance of toxic interactions and relevance to SCCPs. 2. Chapter considered an additional consideration and so left in current place. The synthesis does not consider toxic interactions and so not appropriate to place before synthesis section. 3. Text shortened significantly. 4. Text still mentions potential interaction with MCCPs and LCCPs, but no longer attempts to describe any properties (needing referencing) associated with these substance groupings. Text identifies potential for interaction if there is co-exposure and bioavailability. Text continues to mention potential interactions with other POPs.
Norway	24	Title of section	Revise to: ”Toxiccological Interactions Involving Multiple Chemicals”	Revised based on proposed revision.
Norway	24, 25, 26	General	Please make the text a bit more consise, coherent and to the point with regards to how mixture toxicity affects or potentially affects the hazards/ endpoints of concern associated with SCCP exposure. Moreover, references are generally missing from the text and should be included, in particular include relevant references documenting: 1) The presence of SCCP along with other environmental pollutants and POPs in the environment, 2) Evidence from environmental samples that SCCP co-exist with MCCP and LCCP or has the potential to do so, 3) References providing information on toxicological interactions and hazards/ effects involving SCCP in particular (e.g. the case study from POPRC7 Brooke and Crookes, 2011), 4) References on mixture toxicity in general (e.g. the case study from POPRC7 Vighi and Villa, 2011, Kortenkamp et al. 2009).	Text shortened significantly. Revised text. Largely adopted, with some minor changes, proposeded text provided by Norway (including referencing).

Source of Comment	Page	Paragraph	Comments	Response
Norway	25, 26	144-151	Explanations on the underlying principles of mixture toxicity and how mixture toxicity can be conducted for SCCP draws attention away from what ought to be the main focus of this chapter i.e. how mixture toxicity affects or potentially affects the hazards/ endpoints of concern associated with SCCP exposure. This information has been thoroughly explained/ dealt with by Vighi and Villa 2011, Brooke and Crookes 2011 as well as Kortenkamp 2009. We therefore suggest to delete most of the information/ text provided in para 144-153 and instead write a much shorter text which cites/ provides references to relevant literature. See also similar comments and text proposal.	Agreed. Text deleted. Largely adopted, with some minor changes, proposed text provided by Norway (including referencing).
Norway	26	154	Rewrite para 154 to fit with the above text and include relevant references in the text. See suggested proposal for new text.	Proposed revisions adopted.
Norway	26	155 and 156	Proposes new paragraph summarizing the rationale/significance to consider toxic interations and additional implicating factors affecting the severity and risk for adverse effects.	Proposed revisions adopted. Text summarizing rationale/significance to consider toxic interactions moved to "Conclusions" section – replaces paragraph 161 in old report (now is paragraph 153
Norway	26	157	Re. paragraph on global climate change. Additional references identified: Sagerup K, Helgason LB, Polder A, Strøm H, Josefsen TD, Skåre JU, Gabrielsen GW. Persistent organic pollutants and mercury in dead and dying glaucous gulls (Larus hyperboreus) at Bjørnøya (Svalbard). Sci Total Environ. 2009 Nov 15;407(23):6009-16. Epub 2009 Sep 6. PubMed PMID: 19735935. UNEP/ AMAP 2010. Climate change and POPs: Predicting the Impacts Letcher RJ, Bustnes JO, Dietz R, Jenssen BM, Jørgensen EH, Sonne C, Verreault J, Vijayan MM, Gabrielsen GW. Exposure and effects assessment of persistent organohalogen contaminants in arctic wildlife and fish. Sci Total Environ. 2010 Jul 1;408(15):2995-3043.	References added based on revised text proposed by Norway.
Norway	26	156, 157	Move text on implicating factors (including global warming) to a different chapter to avoid confusion between mixture toxicity effects and other complicating factors	Text considered appropriate as additional factor to consider in relation to toxic interaction and so remains in current section.
International Chlorinated Paraffins Industry Association (CPIA)	24	141	Makes edit to text (MCCPs and LCCPs are themselves mixtures with potentially very different properties). Comments that bioavailability is major issue.	This paragraph is replaced with revised text. However, these messages are considered for the revised text of paragraph 143.

Source of Comment	Page	Paragraph	Comments	Response
CPIA	24	142, 147, 150	Edits text (SCCPs are "assumed to" present effects via narcosis mode of action. Comments that co-occurance does not imply effects – bioavailability needs to be considered. Bioavailability is a critical consideration for exposure.	These paragraphs are replaced with revised text. Some changes to revised text reflecting these comments are found in revised paragraphs 143 and 144.
CPIA	25	144	Text relating to analysis of CPs revised.	Paragraph deleted. No further discussion of analytical methods in subject section.
CPIA	25	145, 146	Text relating to CPs revised (different applications and physical – chemical, perisistence and bioaccumulation properties).	Paragraph deleted. No further discussion on applications CPs in the revised text. Revised text of paragraph 143 indicates potentially differing properties.
CPIA	25	147	Rephrase information on persistence	Paragraph deleted. Discussion of properties of different forms of CPs considered outside scope.
CPIA	25	147	"Thus, one might expect to find SCCPs to be the main driver of cumulative risk in water." - Statement is unclear, to general, should be rephrased to clarify meaning.	Statement deleted.
CPIA	25	148	Edits made to paragraph (relating to variability of fate of CP constituents)	Paragraph deleted. Revised text discusses co-exposure in more general manner.
CPIA	25	149	Comments that MCCP and LCCP are not highly bioaccumulative according to literature and several jurisdictions.	Paragraph deleted. No further reference made to whether substance is bioaccumulative/not within scope of this section.
CPIA	25	150	Comments that LC50's are less inaccurate than NOECs; why not refer to Brooke and Crookes 2011 for the effect assessment part, who address this specifically for this risk profile?	Paragraph deleted. Discussion on how a cumulative assessment could be undertaken considered outside scope of the section.
CPIA	25	151	Considers that the number of substances co-occuring with SCCPs to be infinitite, ignores exposure/bioavailability.	Paragraph deleted.
CPIA	25	152	Comments respecting climate change and potential implication on exposure and and mixture toxicity.	This paragraph is deleted; however, there is still reference to other stressors which can add severity of and adverse effects risk in the Arctic. Climate change noted as one among other stressors.
China	24, 25	General	Although considers that SCCPs are low toxicity chemicals, it is reasonable to predict the toxicity effects of the mixture of CCPs of different chain lengths with consideration to points below.	Detailed consideration of specific levels of toxicity considered outside the scope of the Profile.
China	24, 25	General	In previous toxicity research on SCCPs, only the lethality does, body weight, morphological change and physiological feature were comprehensively studied. The endocrine disrupting effects, genetic toxicity, developmental toxicity or carcinogenicity of CCPs to organisms are not well understood. Hence, it is necessary to evaluate the potential	Do not disagree, but revision of the Profile to include more detailed analysis of toxicity considered outside the scope of the Profile.

Source of Comment	Page	Paragraph	Comments	Response
			toxicity such as ER, AR and TR activities according to the Tier 1 and 2 of EPA's Endocrine Disruptor Screening Program (EDSP). These mechanistic studies are important reference on toxicity evaluation of SCCPs prior to the prediction methods such as the total toxicity units calculation formula. These research data on toxicity mechanism will provide us with more scientific assessment.	
China	24, 25	General	In TUm formula, the total toxicity effect of SCCPs, MCCPs and LCCPs mixture was simply considered as the toxicity potential sum of each component. Though this method reflect the toxicity potential theoretically, it doesn't consider the possibility of synergistic effect and antagonistic effect. Also the low concentration of SCCPs in environmental matrix and the relative high ECx were contributed to the underestimation on eco-toxicity of the mixture. Some corrected factors should be involved in the situation of great concentration difference between each component and low bioavailability of the long chain SCCPs.	Considered outside scope of the Profile
China	24, 25	General	The physical and chemical properties of SCCPs, MCCPs and LCCPs are quite different from each other. The bioavailability decreases with the increasing chain length. There are discrepancies in the absorption, distribution, metabolism and excretion of SCCPs components in organisms, which will lead to the accumulation and toxicity in target organs. All the factors should be considered into the toxicity prediction.	A detailed description of factors affecting toxicity interactions considered outside scope of this profile. However, incorporated text stressing the importance of bioavailability in a general way.
Paraguay	24, 25	General	On the SCCP draft risk profile: They do not have any scientific information at the moment about the influence toxic interactions of these substances can have on human health and the environment. They do not have registers about incidents related to these substances, which is why their consideration and evaluation as potentially harmful substances at the national level has not lead to the adoption of any measures.	The intent of the section is to discuss how toxic interactions potentially affects the hazards/ endpoints of concern associated with SCCP exposure. Further referencing is provided.
Paraguay	24, 25	General	On the approach: Categories to present information required in Annex E should be established by producing countries or users of these substances. Procedures for the evaluation of risks to human health and transport to the environment should also be established in order to be able to generalize and adopt the information by all members states of the Stockholm Convention.	Considered outside scope of the Toxic Interactions section.
Concluding statement				
CPIA and Japan	26	161	Revise paragraph to reflect comments provided on "Toxic Interactions"	Deleted and replaced with new text more reflective of the revised text of the "Toxic Interactions" section. See paragraph 153.

Source of Comment	Page	Paragraph	Comments	Response
CPIA	26	161	Re. Given similarities in uses, releases, environmental fate, co-occurrence and mode of action of SCCPs, MCCPs and LCCPs, it can be expected that there would be cumulative effects associated with exposure to CPs.] Consider that this paragraph should be rephrased based on comments provided on chapter 4	Deleted and replaced with new text more reflective of the revised text of the "Toxic Interactions" section. See paragraph 153.

Table 2. Comments on the draft risk profile on short-chained chlorinated paraffins not related to toxicological interactions

Source of Comment	Page	Paragraph	Comments
Australia	26 16	158 94, 95	…pleased to see that the previous comments provided by Australia have been comprehensively addressed. In particular we are pleased to note that the authors have included the recommended Gomez-Eyles JL *et al*. (2009) reference on over- and under- prediction of actual toxicity based on the concentration-addition (CA) approach (refer para. 158), additional explanation of the use of the equilibrium partitioning method in the supplied calculations (refer para. 94 and 95), and additional statements regarding uncertainties in the assessments (e.g., para. 247). The authors have also added a calculation of toxic units for mixtures (TU_ms) based on the 21-day EC50 of chlorinated paraffins to *Daphnia magna* regarding the availability of this end-point for short, medium and long-chained chlorinated paraffins (refer para. 171).
Slovakia			Criteria specified in Annex E to short-chained chlorinated paraffins: It has been performed a lots of tests with SCCP on various level and several species. Some of the tests have been executed many years ago, they do not fulfil present legislation criteria, but they are usefull for preparing risk profile of short-chained chlorinated paraffins. Requirements specified in Annex E for the risk profile have been carried out.
Slovakia			Risk profile is well elaborated. All available information have been used. SCCP fulfills criteria for classification as POPs substances.
Japan			For whole draft Risk Profile, it is not enough clear whether the statement is a view of drafters or based on some references. If the latter, references should be added, so that a reader can validate whether the statement is appropriate.
Japan	3, 12	3, 54	Please correct BCFs range to “1530 – 138 000” to reflect the BCFs of C=13, Cl=4-9 SCCP described in paragraph 48.
Australia	4	11	Re. Chemical Identity. Suggest including Table 2 from UNEP/POPS/POPRC.3/INF/22 - the possible homologues and isomers, although not all are known to be produced by industrial manufacturing processes. The chemicals presented in this table better illustrate the SCCPs that conform to the definition in the nomination. Suggest adding any known impurities. The information document UNEP/POPS/POPRC.3/INF/22, mentions that products containing SCCPs “may also contain lower and higher chlorinated alkanes as impurities” Minor Comment: Reference the decision document (UNEP/POPS/POPRC-2/8 Annex 1) as it provides the SCCP definition as considered in the nomination.
IPEN	5	20	Edit to reflect that CPIA does not represent Brazil, Russia, China, EU, etc. Edit to reflect that production volumes of SCCPs in Russia and China have not been reported to POPRC (also comment added that data on China does exist as presented at Dioxin 2009).
Australia	6	27	Re. Uses and Releases. Suggest amending Australian information as: "Use of SCCPs in Australia... of SCCPs as lubricants in the metal working industry (NICNAS 2004)."
Japan	11	47	Re. *“BCF measurements were taken at two test concentrations (0.1 and 1 µg/L) and test organisms were exposed between 12 and 60 days”*

Source of Comment	Page	Paragraph	Comments
			Exposure period of this study is 60 days. Please correct the sentence to "……test organisms were exposed for 60 days"
Japan	11	48	Re. "*; however, it is unclear if these concentrations were for the congeners at each chlorination level or for the mixture itself.*" Please replace "; however, it is unclear if these concentrations were for the congeners at each chlorination level or for the mixture itself. The measured concentrations of C=13 at each chlorination level suggest the test concentration was for congeners at each chlorination level." by "; these concentrations were described as concentration level for the mixture itself, however, it does not affect absolute BCF s as BCFs were calculated by dividing concentrations in the test fish by concentrations in the test water. According to the result, C_{13} SCCP is not considered to meet the criteria for bioaccumulation in Annex D"
Japan	12	54	Please correct BCFs range to "1530 – 138 000" to reflect the BCFs of C=13, Cl=4-9 SCCP described in paragraph 48.
IPEN	13	66	Provides edit to add Zeng et al. (2012) on wastewater treatment sewage SCCP levels in China.
IPEN	14, 15	71 & 80	Adds China to locations where SCCPs are detected in sediments. Then edits paragraph 81 to add this information (Gao et al. 2012; Chen et al. 2012)
IPEN	15, 16	81 & 89	Adds China to locations where SCCPs measured in biota. Then add Yuan et al. (2012) data on molusks.
Australia	14, 15	71-80	Re. Section 2.4.4 Sediments [exposure] Summary details of the following two recent research articles on determination of chlorinated paraffins in sediments could be added to the section. These studies could also be added to Table C2: Summary of levels of chlorinated paraffins in sediment, in UNEP/POPS/POPRC.7/INF/15 if the intention is to keep this table up to date Reference 1: Chlorinated Paraffins in Sediments from the Pearl River Delta, South China: Spatial and Temporal Distributions and Implication for Processes by Chen et al., in Environ. Sci. Technol., 2011, 45 (23), pp 9936–9943 <http://dx.doi.org/10.1021/es202891a> Reference 2: Determination of chlorinated paraffins in sediments from the Firth of Clyde by gas chromatography with electron capture negative ionisation mass spectrometry and carbon skeleton analysis by gas chromatography with flame ionisation detection by Hussy et al., in Chemosphere Volume 88, Issue 3, July 2012, Pages 292–299 <http://dx.doi.org/10.1016/j.chemosphere.2012.02.040>.
IPEN	17	101	Add information on SCCP human dietary exposure and statement on occupational exposure.
Romania		NA	Perhaps add to Annex E short-chained chlorinated paraffins references: reference from Estonia "Report Hazardous Substances Screening Results in the Aquatic Environment of Estonia (Prepared by O. Roots & H. Nõmmsalu), Tallinn 2011, 97 p. (ISBN 978-9949-9218-2-9). There are information about 134 hazardous substances or Substances Groups (among these SCCP and MCCP) analyses results from rivers and lakes surface waters, effluent (treated waste water, bottom sediments of surface waters and sewage sludge, etc. Information about selection of sampling matrices, sampling methods and handling of samples and methods of chemical analyses. The chemical analyses were carried out in two laboratories GALAB laboratories GmbH, Germany and EERC lab, Estonia). Standard EN ISO/IEC 17025 has been fulfilled by them.
International Chlorinated Paraffins Industry	13	65	Re. Agricultural soils may also be a potentially major reservoir of CPs due to sewage sludge application (Stevens et

Source of Comment	Page	Paragraph	Comments
Association (CPIA)			al. 2002; Nicholls et al. 2001). Asks relevancy considering para 43.
CPIA	17	100	Re. [Human Breast Milk and Food] For the remaining age groups, intakes ranged from 5.1 µg/kg bw per day for adults over 60 years of age to 26.0 µg/kg-bw per day for infants who were not formula fed. Ask if this correct? are infants not formula fed similar to breast-fed ? Needs clarification.
CPIA	17	104	*Re. Based on these studies, the International Agency for Research on Cancer determined in 1990 that there is sufficient evidence for the carcinogenicity (possibly carcinogenic – groups 2B)* Notes that this is incorrect, please revise (it is not a carcinogen but a *possible* carcinogen *2B*) Re. Section 2.5.1 Dose abbreviation varies (mg/kg-bw per day, mg/kg/day, mg SCCP/kg/day) although essentially reporting the same unit. Suggest standardising the unit of dose throughout this section.
IPEN	22, 23	Tables 3-3 and 3-4	To help meet the length requirements of the report, the authors might consider moving these tables to an INF document
Australia	23	138 and Table 3-4	Exposure scenarios to humans - Consider including the equation used in estimating the exposure estimates as presented in Table 3-4. The derivation of the exposure values are better understood if the equation used is defined in the document. Minor Comment: Please provide the bibliographical detail of the study by "Muir et al. 2004 NCP Synopsis report".
Australia	23	Table 3-4	Clarify the choice of 13 ug/kg lipid wt, the mean concentration from the study of Tomy (1997), used in estimating exposure for a breast-fed child. The study appears to be pooled samples since the median value was not provided. Results from the use of pooled samples give limited information and the Tomy (1997) study may not be suitable to take forward in estimating the exposure to breast milk.
Australia	23	Table 3-4	Please consider including the studies in the UK (Thomas and Jones (2002) and the follow-up study by Thomas et al. (2003; 2006)). These were well-conducted surveys of human breast milk samples and presented more comprehensive characterisations of breast milk levels. The median value of SCCPs from Thomas et al. (2003; 2006) of 180 µg/kg lipid is more appropriate in estimating human breast milk exposure. Note that due to range of SCCP values, 49 to 820 µg/kg lipid, detected in this study, the mean value is strongly affected by variations in the few values at the high concentration end, thus the median is chosen.
IPEN	26	161	Many edits made to this paragraph. Also notes that data from China are strong indication of increases in environmental and human exposure.
Japan	26	162	UNECE Aarhus (POPs) Protocol to the Convention on Long Range Transboundary Air Pollution (LRTAP) is a different regime from POPs Convention. The decision of listing SCCPs as a POP under the Protocol per se would not directly prejudge the discussion under POPs Convention. While the scientific knowledge which were served for the discussion of LRTAP on SCCP listing would be useful and could be inserted in risk profile, however, it is not appropriate to state it abruptly as one of the concluding statement of risk profile of POPs Convention.

Source of Comment	Page	Paragraph	Comments
Australia	23	138	Please provide the bibliographical detail of the study by "Muir et al. 2004 NCP Synopsis report".
Estonia			Add reference from Estonia "Report Hazardous Substances Screening Results in the Aquatic Environment of Estonia (Prepared by O. Roots & H. Nõmmsalu), Tallinn 2011, 97 p. (ISBN 978-9949-9218-2-9).

Annex II

Comments relating to the discussion paper on issues and common practices in the application of the Annex E criteria

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

Source of comment	Page	Paragraph	Comments
Mexico	Section 2.1 / 2.1.2	22	Is it possible to compare the exposure levels and adverse effects within different organism groups or is it necessary that they are taxonomical or ecological equivalents?
Mexico	Section 2.1.2	24	In this regard, which features must the listed POP meet in order to be used as benchmark to compare the candidate? Must there be a chemical similarity or a common mechanism of action?
Mexico	Section 2.1.2	28	In agreement with the criterion, provided that it would be considered as an additional argument, not as a decisive criterion, because data relevant to the chemical substance under evaluation may or may not exist.
Mexico	Section 2.2	29	Would it be possible to establish an uncertainty value that could serve as breaking point or threshold to define that uncertainty is scientifically acceptable?
Mexico	Annex E		It isn't convenient to take out a POP listed in Annex A because it ensures that it will be used never again. In Mexico, and perhaps in other countries, there is no national regulation that prohibits all POPs listed in Annex A and it is the Convention itself that establishes this obligation (a Convention becomes a national law once it has been signed by the country and is legally binding). If a compound is taken out from this list, that obligation is lost. Therefore, they should not be taken out, even if their concentrations have reached sufficiently low values.
Mexico	Annex E		If there is sufficient evidence (in various remote areas, in several species and in various matrices) that environmental concentrations are lower than concentrations that produce adverse effects, the chemical substance could not be included in the Convention. However, if the evidence is insufficient, the case should be reconsidered in the light of new studies that confirm or refute this fact. The criteria that are proposed here are not applicable for compounds with carcinogenic properties).
Mexico	Annex E	36 and 37	The criterion appears to be logical and acceptable, but the question to be answered is not clear enough.
Mexico	Annex E	39	It would be advisable to use the trends over time only as additional criteria. In the case that no trends are shown, the best thing would be to try to establish the causes of this situation (level of compliance by the Party countries; regional bans, changes in environmental processes, etc.). In the case of declining trends it would be important to determine that levels below the threshold of adverse effects have been reached (for non-carcinogenic compounds)

Source of comment	Page	Paragraph	Comments
The Netherlands	Section 2.1.1.	7	The word "risk evaluation" is not incorporated in the text of the Convention. Therefore we advocate not using it here, but replacing it by the word "risk profile" which has been used throughout the text of the Convention. We think that the word risk profile has been used in the Convention in order not to mix the evaluation in Annex E of the Convention with the risk evaluations carried out in other forums, which in general use a deterministic or quantitative approach. We think that such deterministic risk evaluation of the risks of POPs overlook a number of characteristics, like the unexpected and unwanted effects in remote areas (see also our comments on paragraph 20-22).
The Netherlands		10	For clarity a brief summary of paragraph 2 is helpful.
The Netherlands		11	Add: "The screening of the properties of the proposed chemical against the criteria in Annex D does not address the question of potential risks of the proposed chemical as a result of its long-range environmental transport. The potential risks (or the comparison of toxicity or ecotoxicity data with detected or predicted levels of a chemical) are addressed in article 2 of Annex D, which is not a criterion.
The Netherlands		15-18	We would like to suggest moving par. 15, because in par. 16 and 17 arguments are given which support the conclusion of par. 15. Therefore we propose to place current par. 15 after par. 18.
The Netherlands		15	Add new wording: "It has been agreed that the preparation of a risk profile in accordance with Annex E and its decision-making on the risk profile is not a deterministic or quantitative risk assessment."
The Netherlands		19	We propose to delete par. 19, because all data can and should be used for decision-making. In Annex E it is evaluated if long-range environmental transport will lead to adverse effects. Measured data in biota from local areas will in itself not contribute to knowledge on long-range transport.
The Netherlands		20-22	We have reservations about the interpretation in these paragraphs, because there are several caveats in the approach where exposure levels are compared to effects data: ▪ It is questionable if the concentrations in remote areas are already in steady state or if they are increasing or decreasing. A few samples from remote areas do not provide a solution for that. Preferably time series should be considered; ▪ It is questionable whether the surface water is the most relevant environmental compartment. POPs will tend to accumulate in sediment and biota rather than in surface water; ▪ The ability to accumulate substances varies considerably among species. It is not clear if species with a poor ability to degrade or transform the substance of concern are included in the comparison. ▪ Effects can become apparent after a long period of time; ▪ It is noted that laboratory animals usually are considered to be equally or less sensitive to chemicals than wild roaming environmental species and humans. Assessment factors and/or SSDs are used to correct for this. The term "laboratory-derived effect levels" should be defined better incorporating this notion. The uncertainties mentioned should be incorporated in the comparison. Thus, we think that the statement in par. 22 could be much sharper. Firstly, we think that already below the effect levels determined on basis of an available NOEC

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			global action may be warranted, depending on emission and exposure trends and uncertainties identified and secondly "in the same range" should be defined.
The Netherlands		25	This paragraph should begin with "For substances…" instead of just "Substances…"
The Netherlands		26	Change: When there is no measured environmental concentration or concentration in biota in remote areas for chemicals, the Committee can use environmental modeling methods conform Annex D,1.d (iii) of the Convention."
The Netherlands		29-31	We propose moving these paragraphs to the part on the comparison of exposure levels and effects data (par. 20-22). We agree on par. 29 and 30. We fully understand the reservations about the applicability of laboratory test data and the uncertainties in translating these data to higher order animals. However, these uncertainties should not lead to 'do nothing'; given the persistent nature of these chemicals a precautionary approach should be applied.
The Netherlands		32-33	In our view it is not problematic that a POP cannot be removed from the list when the environmental concentration decreases to below a certain level, because (a) the hazard properties are still the same and therefore the need for strict risk management measures and (b) it is important to avoid re-introduction of the chemical.
The Netherlands		34-35	See our remarks on par. 20-22.
Norway	General		POPRC have never discussed the use of the Annex E criteria in plenary in a general way before and most of the principles that are defined as "agreed principles" in this document have never been explicitly agreed upon in any discussions in POPRC.
Norway	General		Many of the "agreed principles" are taken from individual risk profiles and the basis for those principles is not explained in this discussion paper. Evaluations of and decisions on new POPs by POPRC in the past have generally have been undertaken on a case by case basis and have been based on a weight of evidence approach. We therefore believe that important information is lost when these "agreed principles" are taken out of their context in the risk profile and that generalizing from an individual risk profile in this way is not the correct approach for developing a discussion paper on the interpretation of the Annex E criteria. A more correct approach would perhaps be to denote these principles as common practice and where possible in the text provide a reference to previous risk profiles where such approaches have been use and also possibly provide a practical "case" scenario/ example derived from one of these risk profiles to explain.
Norway	General		The "agreed principles" as put forward in this document also includes a category of "agreed principles" that are directly derived from the text of the Convention. Given that this category of "agreed principles" is derived from the text Convention itself they may be considered to have a particular status and their bearing on the work of the POPRC should therefore be given particular weight in discussion paper. The current mix-up between the two categories of "agreed principles" can create confusion and should in our view be avoided. Rather than presenting these as "agreed principles"

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			the discussion paper should point out relevant paragraphs of the Convention and describe how these paragraphs have been practically applied in the work of the POPRC and how they should be/ have been interpreted by providing practical examples e.g. from previous risk profiles as mentioned above.
Norway	General		In light of the above comments and given the context in which this approach to a discussion paper will be used we believe that the best would be to develop a discussion paper that solely focuses on the application and interpretation of Annex E and other relevant parts of the text of the Convention in relation to the draft risk profile on short-chain chlorinated paraffins. Principles or approaches that have been used in the Annex E phase and the practical assessment of other chemicals in the past can then be presented as relevant examples or common practices to explain how this may be done.
Norway	General		In our view, the document should be restructured in line with the above comments and more explanatory text including practical examples from previous POPRC work should be provided, in particular: ▪ The chapter"Background" in paragraphs 1-2 should more clearly and in a more elaborate manner describe why this document is being developed. Paragraph 3. should be moved up and included in this chapter where it may function as an introduction to the entire chapter: 3. The assessment of a risk profile for a substance against the wording in the chapeau of Annex E to the Convention, quoted below, has raised some discussions in the development of risk profiles and in the meetings of the Committee: "…that the chemical is likely as a result of its long-range environmental transport to lead to significant adverse human health and/or environmental effects such that global action is warranted." ▪ For the purpose of clarity and to avoid confusion, the discussion paper should before the issue of interpretation of the Annex E criteria and risk profiles is introduced in the text describe the "normal" or "standard" process for substance evaluation under POPRC. In particular the Annex E process, its purpose and scope and the role of the POPRC, as well as information on what risk profiles are, the information requirements for risk profiles set by Annex E, a description of their the content of risk profiles, the purpose of developing risk profiles together with relevant and necessary information on the Annex D and F processes should be presented. This may be achieved by introducing a new chapter entitled something like "Evaluation of new candidate POPs under the Convention - the Annex E criteria". Key principles set out by the text of the Convention and their bearing on the work and decisions the POPRC should be explained here. As part of this chapter we also propose to highlight common practices that have been established in the POPRC over the years. In particular the reader should be reminded that: 1. Article 1 of the Convention provides: "Mindful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Convention is to protect human health and the environment from persistent organic pollutants."

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			2. Particle 7 (a) of Article 8 provides that "Lack of full scientific certainty shall not prevent the proposal from proceeding" i.e. full scientific certainty is not necessary for a substance to be listed in the convention and that the practice of the POPRC has been to use a weight of evidence approach. 3. As defined by the text of the Convention, Annex E paragraph (b), the risk profile should assess the hazard, not the risk, for the endpoint or endpoints of concern. 4. The Annex D, E and F evaluations are represent individual and separate steps in the evaluation of new candidate POPs e.g. the fact that the criteria in Annex D are fulfilled does not necessarily mean that the Annex E criteria are fulfilled. 5. It has been common practice for POPRC to take all information presented in the risk profile and as part of the Annex E phase into account and to use this information for their decision making in a weight of evidence approach ▪ The document should thereafter in a separate chapter recall which parts of the Convention text and the Annex E evaluation process have raised discussions in POPRC in the past. Issues which have raised discussions in relation to the SCCP risk profile may then be presented and it should be made clear in the text which of these issues are open for debate/ interpretation and which are not considering the guiding principles set forth by the text of the convention. For the first category i.e., relevant examples from evaluations of other chemicals already assessed by the POPRC can be provided to guide the committee in their work. If a common practice has been established this may also be highlighted here.
Norway	General		To avoid further controversy over paragraph (b) of Annex E it should be clearly stated in the text that Annex E paragraph (b) provides that a "hazard assessment for the endpoint or endpoints of concern, including a consideration of toxicological interactions involving multiple chemicals" should be conducted as part of the risk profile. The definition of a hazard assessment and a risk assessment should be provided and the distinction between the two should be made clear to the reader. It would be beneficial if the text could highlight more clearly that the term hazard assessment relate to a chemicals intrinsic properties or intrinsic potential to cause harm/ adverse effects.
Norway	General		We believe that certain statements in the discussion paper such as e.g. the statement "The risk evaluations by the Committee involves a comparison of exposure levels and effects data to answer the question in Annex E…." made in paragraph 7 does not correctly reflect the text of the Convention and that they should be deleted/ modified to better reflect the text of the Convention, not only Annex E but the Convention text as a whole. What particular statements we would like to see modified/ deleted are indicated directly in the discussion paper itself. With regard to the statement made in paragraph 7 of the discussion paper we would like to emphasise that the text of the Convention and Annex E in particular does not specify or explicitly require that a risk profile have to compare exposure levels and effects data. If such information has been provided in some risk profiles it is because it was possible because the data were available to the drafting team (e.g. the HBCD risk profile). However, this is not straight forward as exposure levels are typically derived from field studies and effect data

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			are mostly obtained from controlled lab studies. This is problematic and the POPRC need to consider/ take into account that: ▪ The two sets of data can rarely be directly compared because of how exposure is measured/ reported; Field data typically report exposure as concentration of a given chemical in a given tissue whereas most lab studies report the dose administered to the organism via diet or via its environment. ▪ Field data represent chronic long term exposure over the entire life time of the organism, whereas lab data is more short term and more acute. ▪ The model organisms used in controlled lab studies are not directly representative for wild organisms, particularly wild Arctic organisms whose biology and physiology differ from organisms living in more temperate regions e.g. organisms living in a cold climate may be more exposed to POPs because they acquire and store more fat than organisms living in temperate regions. ▪ Controlled lab studies are conducted at standard temperatures and may be quite different from the real temperatures experienced in remote areas such as the Arctic: The temperature difference may affect degradation, metabolism and biotransformation. ▪ Besides pollutant exposure wild organisms also experience other types of stress that may affect their ability to cope with the pollution stress and that may render them more sensitive. Many Arctic organisms for example experience highly elevated pollutant loads during starvation and reproductive periods because pollutants stored in their fat tissue become reactivated and are released to the blood stream once again. Such pollutants and their effects may be transferred from parent to off-spring either via genetic/ epigentetic modifications and/ or by transfer of pollutants from mother to off-spring. This remobilization of pollutants poses an additional risk to the off-spring which during the embryonic stage and just after birth are particularly sensitive due to rapid developmental changes involving key organs such as the brain. ▪ Wild organisms are typically exposed to a complex cocktail of chemicals. Controlled lab studies typically only report effects of one single chemical.
Norway	General		A similar point to that above can also be made in relation to other statements that are made in this discussion paper. As we see it the interpretation of Annex E and other parts of the Convention as presented in the discussion paper has to be based on the full text of the Convention including Article 1, where the precautionary approach is set forth as a guiding principle for the Convention, Paragraph 7 (a) of Article 8 and the preamble to Annex 2. For example, in relation to the open question on adverse effects and how the POPRC should evaluate hazard in cases where environmental levels in remote areas are below observed effect levels presented in paragraphs 34-35 we believe that data that suggests that environmental levels are below observed effect concentrations should not prevent a proposal from proceeding from the Annex E phase to the Annex F stage if the chemical by its inherent properties can be demonstrated to pose a potential risk. We also propose that the opposite

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			approach i.e. not to take global action before environmental levels exceed observed effect concentrations ultimately may represent a breach with Article 1 of the Convention and possibly also paragraph 7 (a) of article 8 which states that "lack of full scientific certainty shall not prevent the proposal from proceeding".
Norway	General		From our perspective, the discussion paper seems to give more weight to some of the Annex E criteria than others. The reasons for doing this are not explained in the text. We believe that this is an incorrect representation of Convention text and that the text needs to be more balanced. In relation to this and as already mentioned, we would like to point out that it has been common practice for POPRC to use a weight of evidence approach as a basis for decision making and propose to highlight this in the text. Such information may be provided in the chapter “Evaluation of new candidate POPs under the Convention - the Annex E criteria” as proposed above.
Norway	General		With reference to the second sentence of paragraph 16 we would like to stress that it is important to distinguish and not confound the Annex E criteria with the outline and contents of the risk profile. The Annex E criteria on one hand are laid down in the Convention itself, the outline for the risk profiles and the contents of the risk profile on the other hand, while based on the Annex E criteria, is not entirely fixed and may vary some depending on the chemical that is being assessed. It is for example not correct that all risk profiles contains a separate chapter with the title “Comparison of exposure levels and effect data” e.g. while the risk profile for HBCD contains such a chapter the risk profiles for pentaBDE and chlordecone does not.
Norway	1	1-2	The chapter “Background” in paragraphs 1-2 should more clearly and in a more elaborate manner describe why this document is being developed.
Norway	Section 3 (page 1)		Move to section 1 “Background”
Norway	2	7	We believe that this statement does not adequately reflect the Convention text and that it should be deleted/ modified to better reflect the text of the Convention, not only Annex E but the Convention text in its entirety. As we see it the interpretation of Annex E and other parts of the text has to be based on the full text of the Convention including the preamble i.e. Article 1, where the precautionary approach is set forth as a guiding principle for the Convention. We would also like to stress that the text of the Convention and Annex E in particular does not specify or explicitly require that a risk profile have to compare exposure levels and effects data. If such information has been provided in some risk profiles it is because it was possible to do it as such data were available to the drafting team (e.g. the HBCD risk profile).
Norway	2	12	We believe that this point is better addressed as part of a separate chapter that describes/ outlines the Annex D, E and F processes and the guiding principles set by the text of the Convention and their bearing on the work and decisions the POPRC. We also believe that such a chapter should put these Annexes and Annex E in particular in the context of the full Convention text and that in particular Article 1 and paragraph 7 (a) of Article 8 should be mentioned. We also believe it should be highlighted that it has been common practice for POPRC to use a weight of evidence approach as a basis for decision making e.g. as in Annex E to decide “whether the chemical is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects”. To clarify the point made here to the reader the Annex D, E and F processes may be

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			highlighted as individual processes with separate decisions. See proposal for restructuring/ introduction of new chapters and further comments in the document “Discussion paper Annex E – general comments Norway”.
Norway	2	15	This sentence is a bit ambiguous and is not sufficiently clear on the distinction between hazard and risk assessment. It should therefore modified. First of all it needs to be made clear that the “agreed principle” is that POPRC should perform a hazard assessment, not a risk assessment, and that this is a requirement set forth by the text of the Convention. In other words, the discussion paper needs to highlight/ quote paragraph (b) of Annex E. Secondly, it is necessary to clarify the distinction between a hazard assessment.
Norway	3	16	We suggest deleting the second sentence of paragraph 16. In this regard respect we would like to stress that it is important to distinguish and not confound the Annex E criteria with the outline and contents of the risk profile. The Annex E criteria on one hand are laid down in the Convention itself, the outline for the risk profiles and the contents of the risk profile on the other hand, while based on the Annex E criteria, is not entirely fixed and may vary some depending on the chemical that is being assessed. It is for example not correct that all risk profiles contains a chapter with the title “Comparison of exposure levels and effect data” See also our previous comment that the Convention text do not explicitly require the comparison of exposure levels and effect data in the risk profile as suggested here.
Norway	3	19	We do not agree that this is an “agreed principle” as it has not formally been agreed upon and has never been discussed in plenary at POPRC. From our perspective the text put forward here is too simplistic: 1) The convention text does not explicitly put forward that data from local areas should not be considered, 2) the text as presented does not in a satisfactory way describe the relevant guiding principles set forth by the Convention itself or 2) what has been common practice in POPRC in the past. It is also problematic that the first sentence of para 19. does not specify what kind of data we are talking about. "Data" may be interpreted as all data both environmental levels and data on effects. In our view, the text need to highlight that POPRC in their evaluation and decision making normally consider all available data in a weight of evidence approach. The text also need to highlight in what particular context data from remote areas may be given more weight than other data. This may be done by providing examples.
Norway	3	20	This statement should be modified to better reflect the text of the Convention and to better highlight what has been the practice of POPRC in the past. First, the statement is not in line with the precautionary approach as outlined in Article 1 of the Convention. Second, it does in our view not correctly reflect how hazard assessments have been undertaken by POPRC in the past. For arguments see comments above and the “Discussion paper Annex E Norway”.
Norway	3	22	We do not agree that this is principle has been agreed upon. The text needs to be modified to point out and make it clear that this does not mean that global action should only be warranted when exposure levels e.g. in the Arctic are at the same level or above the level where adverse effects are observed. As the sentence stands now it may as a worst case scenario be interpreted as if global action is only warranted when effects can be observed in the Arctic i.e. when it is too late.
Norway	3	Heading	“Use of Brenchmarking”: We would prefer that the section on benchmarking is only portrayed a possible approach to how POPRC may assess the hazard in line with Annex E paragraph (b) and decide “….whether the chemical is likely as a result of its long range transport. To lead to

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			significUsant adverse human health and/ or environmental effects, such that global action is warranted."
Norway	3	24	We do not agree that this is an "agreed principle" as it has not formally been agreed upon and has never been discussed in plenary at POPRC. See also comments above.
Norway	3	Heading	"Use of environmental modelling: We would prefer that the section on environmental modeling is only portrayed a possible approach to how POPRC may assess the hazard in line with Annex E paragraph (b) and decide "….whether the chemical is likely as a result of its long range transport. To lead to significant adverse human health and/ or environmental effects, such that global action is warranted."
Norway	4	26	We do not agree that this is an "agreed principle" as it has not formally been agreed upon and has never been discussed in plenary at POPRC. See also comment above.
Norway	4	Heading	"Use of time trends of releases or of concentrations in the environment in remote areas": We would prefer that the section on time trends of releases or of concentrations in the environment in remote areas is only portrayed a possible approach and an example on how POPRC may assess the hazard of a chemical in line with Annex E paragraphs (b)-(e) and decide "….whether the chemical is likely as a result of its long range transport. To lead to significant adverse human health and/ or environmental effects, such that global action is warranted."
Norway	4	28	We agree that it has been the practice of POPRC in the past but we do not agree that this is an "agreed principle" as it has not formally been agreed upon and has never been discussed in plenary at POPRC. However it should be highlighted in the draft approach that this has been a commonly accepted approach in the possibly with reference to risk profiles where such an approach has been used. The sentence also needs to be rewritten to clearer indicate that increasing time-trends is an additional argument but not an absolute requirement for decision-making on Annex E evaluation. This is important in order to provide coherence with the statements made paragraphs 25-26 above.
Norway	4	Comparison of exposure levels and effect data	From a scientific point of view laboratory tests, both in vitro and in vivo, may provide relevant and valid information/ knowledge on the hazard posed by a certain chemical not only for the model organisms themselves but also for wild organisms and humans. However, it is important that such comparisons are done on a case by case basis and that the POPRC when drawing conclusions on this basis use a weight of evidence approach where all available data are taken into account. As part of this process POPRC need to recognice that this may not simply be done by comparing exposure levels. First, comparing such datasets directly is not straight forward as laboratory studies typically only report the dose administered to the organisms while field data are reported as internal dose in a tissue or organ. Secondly, the POPRC should also consider how the results from a laboratory study may be extrapolated to a real life scenario by taking into account; 1) that laboratory organisms may have a different biology and physiology from the model organisms typically used in laboratory tests e.g. Arctic organisms typically have a high level of body fat which may render them more susceptible to POPs 2) that wild organisms are exposed to a complex chemical cocktail, not only one single chemical 3) that wild organisms particularly in the Arctic also experience other forms of stress such as starvation episodes, reprodutive phases etc. that may affect their sensitivity to the chemical in question 4) that climate may have an impact on exposure and toxicity

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			5) that exposure for wild organisms and humans, in contrast to laboratory animals, are exposed over their entire life time
Norway	4	35	This is a very important question that we believe is answered by the text of the Convention and in particular Article 1, which sets forth the precautionary approach as a guiding principle for the Convention. To deliberate a bit: For the majority of chemicals observed effect concentrations will always be above measured environmental concentrations. This may particularly be the case e.g. for newer candidate POPs that haven't been around long enough for environmental level to reach this critical level and candidate POPs for which production and use is generally low. From an environmental perspective and in line with the precautionary approach set forth in Article 1 of the Convention it is desirable to put a stop to production and use before critical environmental levels that cause adverse effects are reached. Thus, that environmental levels are low should not prevent a proposal from proceeding from the Annex E phase to the Annex F stage if the chemical by its inherent properties can be demonstrated to pose a potential risk. In this regard we would like to point to the word "likely" in the preamble of Annex E which suggests that it should only be "likely" that significant adverse effects will occur if, as in this case, environmental levels were to increase in the future. To turn the argument upside down. If the opposite was the case i.e. that environmental levels should exceed observed effect levels before global action is warranted it would mean that no chemical could be listed in the Convention before or until the environmental levels of that chemicals are so high that adverse effects are or can be observed in wild organisms. In our view such an approach would worst case scenario represent a breach with Article 1 of the Convention and possibly also paragraph 7 (a) of article 8 which states that "lack of full scientific certainty shall not prevent the proposal from proceeding".
Norway	4	Use of environmental modelling for chemicals newly introduced to the global market	We agree that modelling can be used, but POPRC should have some reservations in terms of how much weight such data are given in the overall evaluation and the final decision. The weight given to such data will have to be determined on a case to case basis and the reliability/ inherent uncertainty of the model and the data generated used should be taken into account. See also previous comments on environmental modelling.
Norway	5	39	In our view the questions (a) and (b) need to be considered on a case to case basis and the final conclusion may vary depending on the chemical in question and the available data. It is however also important to bear in mind that these questions are closely tied to definition and interpretation of the term "hazard assessment" under Annex E paragraph (b) and how much emphasis is given to the the precautionary approach set forth in Article 1 in the overall evaluation of "wether a chemical is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and/ or environmental effects, such that global action is warranted". In relation to questions (a) (i) and (ii) we would like to note that a hazard assessment is distinct from a risk assessment and that the focus of a "hazard assessment" is the identification and characterization of "hazard" i.e. the chemicals' intrinsic properties or intrinsic potential to cause harm/ adverse effects and that POPs or chemicals with POP like properties may solely by their inherent properties be seen to pose a risk to the environment and/ or human health. From this perspective, neither the lack of clear time trend or lowering or reduction in environmental concentrations should prevent a proposal from proceeding from the Annex

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			E to the Annex F phase. As regards questions (b) (i) and (ii) on what future releases and environmental concentrations are expected and how such data may be used it should be kept in mind that such data will be generated by modelling. Thus, when such data are used in a risk profile it is necessary to take into account and address the uncertainty related to the model used. All in all such data may be anticipated to be given less weight in the overall evaluation and conclusion than measured data and may be seen as a supplement to measured data when such data exist.
IPEN	1	5(a)	Replace “intervention at POPRC7” with “analysis”.
IPEN	2	Section 2.1.1	Change the paragraph to “The risk evaluation by the Committee involves consideration of releases, current and likely future exposures and assessment of its hazards and consideration of toxicological interactions, environmental fate, monitoring data, and national and international evaluation. These components are analyzed to answer the question in Annex E, “whether the chemical is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects, such that global action is warranted.”” as the way it was originally written assumes no consideration of interactions or other Annex E requirements.
IPEN	3	14	Change the paragraph to “It has been agreed that the preparation of a risk profile in accordance with Annex E and accompanying decision-making on the risk profile is not an evaluation or decision based on a quotient based risk assessment”. This key point reflects the intention of the negotiating Parties of the Stockholm Convention. It should be emphasized to Committee Members to ensure that Convention goals and intentions are fulfilled.
IPEN	3	15	Delete “Comparison of exposure levels and effect data”.
IPEN	3	17	Add “It has been agreed that socio-economic considerations are not relevant to Annex E and that the Committee is obligated to utilize the precautionary approach in deciding whether to move the proposal to evaluation under Annex F.”
IPEN	3	18	Change the paragraph to “The data that are measured in biota from local areas close to the source of release are included in the risk profile as specified in paragraph (e) of Annex E; however those are not used as the sole criteria for the decision-making. The decision-making for Annex E also includes data on environmental exposure and concentration of the proposed chemical in biota from remote areas if available and of sufficient quality.” This is obviously dependent on monitoring data which is often lacking hence why POPRC should also consider data from local areas closer to the source, as stated in (e).
IPEN	3	19	Change the paragraph to “In a risk profile, the Convention provides for a hazard assessment for endpoiunts of concern along with a consideration of toxicological interactions involving multiple chemicals. The hazard assessment for endpoints of concern may involve some comparison of the exposure levels and effects data for remote regions. This could include a comparison of measured concentrations in the tissues and organs of species with no effect concentration (NOEC); no adverse effect levels (NOAEL); and/or with concentrations or levels that showed adverse effects.”

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			This designation “chapter 2.4 of a risk profile” does not correspond to the Convention or the Committee’s Annex E submission form. The paper should indicate what is clearly required by the Convention.
IPEN	3	20	Change the paragraph to “The data for the no effect levels/concentrations and adverse effect levels/concentrations are usually generated by laboratory animal experiments, and are often inadequate to assess hazards to species other than those used in the lab experiments. For example, more sensitive species or those such as marsupials for which no review of adverse effects levels exists. In addition, the simple comparison usually does not account for toxicity relating to the timing of the exposure, chronic effects, and synergistic or additive interactions with other substances in the environment. An example of how this comparison has been used by the POPRC is in the risk profile for PFOS, where it was stated “It had also concluded that all the elements of Annex E had been addressed; that the data used were recent, of high quality and reflected current monitoring in remote regions; and that current concentrations in birds and mammals were in the same range as laboratory-derived effect levels.”[b]
IPEN	3	21	Change the paragraph to “Simple comparison of exposure levels and effects data may not permit an adequate evaluation for endpoints of concern. However, if the exposure levels are in the same range of the adverse effect levels or above then for the adverse effect, global action is warranted.”
IPEN	4	Use of benchmarking	Suggest avoiding the term benchmarking as it may be confused by with the use of the risk assessment process of benchmark does methodology (BMD) or Modified BMD.
IPEN	4	24	Add: “For substances that.....” Add: “The Decision to move these substances further in the evaluation process was mainly based.....”
IPEN	4	25	Add to end of para: “This approach is also appropriate when monitoring data is scarce for a chemical still in use.”
IPEN	4	28	Add: “.....ecotoxicological data or known effects data on humans, the Committee should take into account....”
IPEN	4	30	Add “Standard laboratory tests may have little applicability when evaluating other endpoints such as behavioural disturbances, endocrine disruption, epigenetic effects and harm to species other than standard northern hemisphere lab animals.”
IPEN	5	31	Add “This indicates the totality of POPs characteristics justify continued prohibition.”
IPEN	5	32	Add “If the comparison between concentration data in biota and toxicological and/or ecotoxicological data appears to show much lower levels in biota, then other factors need to be carefully considered. These include uncertainties and relevance of the comparisons; inability of the comparison to include possibly important endpoints; and the obligation for decision-making based on the precautionary approach.”
IPEN	5	33	Change: “.....such as endocrine disruptors, carcinogens or mutagens and substances with epigenetic potential.”

b Report of the second meeting of the Persistent Organic Pollutants Review Committee, UNEP/POPS/POPRC.2/17, paragraph 72.

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IPEN	5		Add “For endpoints with no adverse effect level/concentrations that are higher than the environmental concentrations or concentrations in remote biota a precautionary approach to evaluation is needed. As POPs, these chemicals will continue to bioaccumulate and they have demonstrated long range transport activity. The candidate substance may have additive or synergistic impacts with other chemicals including POPs. The committee needs to make its decisions, based on the consideration of the totality of information and should decide whether it is plausible and within the realm of credibility that the chemical will lead to important adverse human health and/or environmental effects, noting that Article 8.7.a states “Lack of full scientific certainty shall not prevent the proposal from proceeding,” to the next stage of evaluation.”
IPEN	5	36	Add “Application of this concept for newly introduced chemicals has not been fully agreed by the Committee. However, the Committee has used modelling methods for decision-making in Annex E.”
IPEN	5	37	Add “particularly when experimental data is lacking.”
IPEN	5	37(a) (i)	Add “POPRC should consider the adequacy of experimental data including monitoring data, and review production and use data. It needs also to assess remobilisation potential from climate change impacts and the probable interaction with other POPs and make a decision based on precaution and prevention.”
IPEN	5	37(a) (ii)	Add “POPRC should assess the adequacy of experimental data and include consideration of production and use data.”
IPEN	6	37(b) (i)	Add “Predicted or evidence of secondary releases or mobilisation due to climate change should be considered as well as use and production data."
IPEN	6	37(b) (ii)	Add ”Secondary releases from contaminated sites, waste sites and other environmental sinks are to be expected. Releases coming from the breakdown of parent compounds are also to be expected.”
WCC	2	9	Change: “All the criteria in Annex D” Not 100% clear as stated but I suppose this refers to screening criteria
WCC	2	9	Change: “the requirements in Annex D” This clearly and correctly refers to the entire Annex D, not only the screening criteria
WCC	2	10	Change: “while paragraph 2 is not a screening criterion” This is correct and clear from the text in Annex D, but it is not clear how para2 information is used?
WCC	2	13	Change: “moves forward to a further review” This seems to ignore the statement made under 9: “requirements of Annex D fulfilled”.
WCC	3	14	Change word: “analysis” If “management” is meant here it is correct, otherwise it is not clear what it means.
WCC	3	15	Change: “is not a quotient based risk assessment” Not sure if and where this was agreed, would need clarification. This would contradict common practice; risk quotients are not the only way to assess risks, but surely are a very useful and broadly applied element of risk assessment
WCC	3	18	Add “but they are an essential element of Annex F”

Source of comment	Page	Paragraph	Comments
WCC	3	23	This is scientifically/logically not correct. If exposure of a substance is known, similar to another or not, it still needs the toxicity level' information to be compared to the substance's exposure to indicate the likely risk. Information on other substances as benchmark is irrelevant. Benchmarking for POPs is usually applied on substance properties to indicate the potential for risk (see also para 25), but it is therefore by definition limited to hazard and cannot indicate the likeliness of risks.
WCC	3	24	Change para:" If the concentrations of a candidate chemical in biota from remote areas are comparable or higher than the toxicity then there is a strong argument for the decision-making on Annex E evaluation." The deleted text is superfluous because the statement remains equally true. Therefore in this case comparison or benchmarking does not help the decision-making (see also 23)
WCC	4	25	Change: "This allows" The preceding sentence only mentions properties, so it is not clear how this limited information can 'allow' listing while not meeting the legal requirements expressed in the first sentence of Annex E
WCC	4	30	This para should be an element of para 29 and would provide the reason for 'taking into account uncertainty'
WCC	4	34	Change wording: "hazard endpoints" So by definition not suited to inform on risks
WCC	4	34	Change wording: "irreversible effects" This was not evaluated I think
WCC	4	34	Change wording: no or very low "no adverse effect level" such as endocrine disruptors and carcinogens. It is scientifically debated if this is scientifically correct for carcinogens and it is not supported for endocrine disruptors
WCC	5	36	Change wording: "withdrawn" Does not seem to fit under the heading of this section-(and duplicates 26?)
WCC	5	37	This in itself is plausible, but given the importance of the decisions based on the results, this would put very high demands on the quality, interpretation and validation of the models to be used.
WCC	5	Use of time trends of releases or concentrations in the environment in remote areas (including consideration of climate change impacts)	Delete "(including consideration of climate change impacts)". Climate change is not an element of Annex E and therefore not relevant for its interpretation