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Consideration of draft risk profiles: chlordecone

Comments and responses relating to the draft risk profile on chlordecone

Note by the Secretariat

The draft risk profile on chlordecone, prepared during the intersessional period by the working group established by the Committee for this purpose, is set out in document UNEP/POPS/POPRC.2/8. 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 to those comments by the working group. The annex was prepared by the working group and has not been formally edited.

* UNEP/POPS/POPRC.2/1.

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Annex

Comments and responses relating to the draft risk profile on chlordecone (June 2006)

Section	Party, Observer	Comments	Response
General comments	Armenia	... the submitted draft risk profiles on .. Chlordecone contain comprehensive information, which confirms that all substances meet the screening criteria specified in Annex D of the Stockholm Convention. Presented information is sufficient to warrant global action on these compounds.	No change required.
General comments	Canada	The synthesis of information could be further improved with clear statements regarding evaluation of whether the chemical is likely, as a result of long-range environmental transport, to lead to significant human health and/or environmental effects	See comments for section 2.2.3.
General comments	France	It could be worthwhile to have a more consistent structure between the documents. There is some really good sections and/or tables that are available in some documents and that might be also helpful in the other documents. This is the case for example of the summary table of POP characteristics that is available in the PeBDE and PFOS document. The comparison with characteristics of POP already listed available in documents on chlordecone and hexabromobiphenyl is also really interested. The document is really clear and summarises well the information available on this chemical and particularly the information related to Annex D criteria. Some specifications are however needed as sometimes we miss some information that may clarify the concern around this chemical (see comment below).	No action taken, see below. The POP Review Committee (POP RC) is assumed to harmonise the different risk profiles as far as necessary.
General comments	ICCA-WCC	The language of the profile throughout (e.g. “could be”, “will be”, “is/is not expected”) is that of hypothesis or conjecture. The POPRC should establish an expectation of the factual basis for risk profiles for nominated substances	No changes.
Editorial	USA	The American comments include several editorials, which are not listed in this table.	Text modified accordingly.
Executive summary	USA	Given the currently listed substances were not run through the Article 8 listing process, we question the propriety of comparing chlordecone to these substances for purposes of the science-based aspects of the Article 8 listing process. In accordance with the Risk Profile outline developed by POPRC 1 (see UNEP/POPS/POPRC.1/10, Annex IV, this risk profile, in cluding the “synthesis of information” in Unit 3, should provide a basis for responding to	See comments for relevant sections, i.e. 2.2.3 and 4.

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		the question presented in Article 8, para 7a (and Annex E) on whether 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. These conclusory-type remarks do not track with the listing process under the Stockholm Convention. As currently drafted, we believe the risk profile does not present adequate information and analysis to make the case	
1.1.1	Canada	Page 4 of 24 Synonyms: "Decachloro-pentacyclo[5,2,1,02,6,03,9,05,8]decan-4-one" - The commas between the superscript numbers should also be written as superscript, i.e. 02,6,03,9,05,8 "Decachloro-octahydro-1,3,4-metheno-2H,5H cyclobuta[cd]pentalen-2-one" - There should be a hyphen between the '5H' and 'cyclobuta'	Accepted, text modified accordingly.
1.1.3	USA	(Table 1.1. Water solubility of 0.35): It is likely that the 0.35 number is an outlier. The source (HSG 41 by IPCS) did not provide the reference so it is impossible to track where this number came from. The more robust EHC 43 by IPCS did provide a reference and used 1-2 mg/l. This is in the same range with the other values in peer reviewed articles. ATSDR quotes a value of 3 mg/l from Kenega.	Accepted, text modified accordingly.
2.1	ICCA-WCC	The risk profile would benefit from a more robust source characterization. Specifically more information quantifying the production, uses and releases of chlordecone are critical in assessing the potential risk of the substance. This information will also be critical should chlordecone proceed to the next stage in the process for evaluating a chemical – since this information will be essential to evaluating possible control measures. No information is provided on trends in releases or trends of levels in the environment. The draft risk profile provides absolutely no information on current production, uses or releases. All of the information is historical. Without a more accurate understanding of the current sources, uses and potential releases it is	The risk profile suffers from lack of recent data regarding production and use of chlordecone but this should not prevent the proposal from proceeding. The latest available information was that on the use in Martinique in the 1990s but no details on amounts were available. No changes. The issue is to be addressed at the next phase where socio-economic aspects will be evaluated.

Section	Party, Observer	Comments	Response
		impossible to asses the potential risks of a substance. If this information is not readily available, the POPRC should more directly solicit such information from Parties prior to completing the risk profile or a subsequent request should be made so this information can be evaluated at the next stage of the process	
2.1.2	ICCA-WCC	The profile refers to the adduct Kelevan and suggests that it should be considered for listing. Kelevan is not a nominated substance and this reference should be deleted. It is imperative that any proposal to list additional substances include an evaluation of those substances against the Annex D criteria. To do otherwise would be to bypass the procedures outlined in Article 8 of the Convention and would undermine the integrity of the Stockholm Convention. If there is a reference to Lelevan than the POPRC should consider the process by which extrapolations to other substances and derivatives should be referenced or included	The mention of the adduct Kelevan is purely informational. No changes.
2.1.2	USA	(Second paragraph, 1st line): "In 1995" should be exchanged with "By 1976".	Accepted, text modified accordingly
2.1.3	USA	In the POPRC1/10, the EU said that it has evidence of recent use of chlordecone in banana fields. It would be useful for this information to be included in this section.	The available information regarding recent use of chlordecone in banana cultivation in Guadeloupe and Martinique is described in the section above. No change.
2.2	ICCA-WCC	The profile contains speculation on the basis for long-range transport. The LRT potential is based solely on physico-chemical properties and there are no monitoring data providing a basis for demonstrating long-range transport. POPRC should consider whether global action is warranted for a substance when there is no actual evidence of long range transport. It is the position of ICCA-WCC that action on a substance should not be recommended when there is no evidence of long-range transport	The profile contains the available information. Text on LRT modified based on new information.
2.2	USA	(Re water solubility:) It is likely that the 0.35 number is an outlier. The source (HSG 41 by IPCS) did not provide the reference so it is impossible to track where this number came from. The more robust EHC 43 by IPCS did provide a reference and used 1-2 mg/l. This is in the same range with the other values in peer reviewed articles. ATSDR quotes a value of 3 mg/l from Kenega.	Accepted, text modified accordingly. Consequential changes later in the document are not specified in this compilation.
2.2.3	USA	(Re comparison to currently listed POPs:) We believe these comparisons to be an inappropriate basis for listing under the Stockholm Convention, especially at he science-based steps where the POPRC is involved. Given the currently listed substances were not run through the Article 8 listing process, we question the propriety of comparing chlordecone to these substances. for purposes of the science-based aspects of the Article 8 listing process.	Disagree. New paragraph added to this section based on new information.

Section	Party, Observer	Comments	Response
2.2.3 end	USA	(Re: conclusion:) See comment above re comparisons with currently listed substances that were not considered in the context of the Article 8 listing process.	Disagree. New sentence added to this section based on new information.
2.3	ICCA-WCC	The profile's consideration of exposure is only based on monitoring near sources or uses. Furthermore, the profile specifically states that "the data do not provide evidence for long range transport." Consequently there is no data on remote exposure and therefore no data to determine whether the substance warrants global action	There are no monitoring data from areas distant from sources but there is other evidence of long-range environmental transport of chlordecone. No changes.
2.3.1	USA	Third paragraph, last sentence was revised with the following comment: This sentence didn't make sense as the fish tissue is a national study, not one just in Virginia near the production site. This recent tion supports the case for long-range transport and bioaccumulation.	Accepted, Text modified accordingly.
2.3.1	France	In the second paragraph where levels of chlordecone in the environment are quoted it could be worthwhile to add locations of the measures in order to have a better idea of the contamination of chlordecone. In the document there is only information such as estuaine water or even no information at all like the data reported from Lunsford et al. (1987).	Accepted, Text modified accordingly.
2.4.1	Canada	Page 16 – 17 of 24 Toxicity of chlordecone in animal studies: "Chlordecone is of moderate acute toxicity" - The word 'moderate' should be replaced by 'high' based on the LD50 values attained by both the oral and dermal routes of exposure (LD50s less than 500 mg/kg: rats and rabbits)	Accepted Text modified accordingly.
2.4.1	Canada	Page 16 – 17 of 24 "ranging from 65 mg/kg in the rabbit to 250 mg/kg in the rabbit" - The second 'rabbit' should be replaced by 'dog' since the LD50 value in rabbit studies was never 250 mg/kg; however, the dog had an oral LD50 of 250 mg/kg	Accepted. Text modified accordingly.

Section	Party, Observer	Comments	Response
2.4.1	Canada	Page 16 – 17 of 24 "with a LOAEL of 0.07 mg/kg bw/day" - A statement saying 'in males' should be added since the effects noted at that dose only occurred in males	Accepted. Text modified accordingly.
2.4.1	Canada	Page 16 – 17 of 24 "Renal effects (proteinuria and increased severity of glomerulonephrities)" - 'glomerulonephrities' should be replaced with 'glomerulosclerosis' since glomerulosclerosis is the term used in the study summary tables cited by the ATSDR (1995) and IPCS (1984) (and the term glomerulonephrities is never used)	Accepted. Text modified accordingly.
2.4.1	Canada	Page 16 – 17 of 24 "Anovulation and persistent vaginal estrus were observed in female offspring of maternal rats given chlordecone at a dose level of 2 mg/kg bw/day (Swartz et al., 1988..." - This statement needs to be checked since the literature varies slightly……	Accepted, there was confusion in the text between the studies of Swartz et al., 1988 and Gellert and Wilson, 1979. Text modified accordingly.
2.4.1	Canada	Page 18 of 24 Toxicity of chlordecone in humans: "among male workers, although motility (...), although a correlation between..." - the words 'although motility' should be removed	Accepted. The word 'motility' has been replaced it by "although fertility was not impaired" and made some consequential changes in the text.
2.4.1	Canada	Page 18 of 24 "There is no epidemiological evidence for carcinogenicity in exposed humans (US ATSDR, 1995, IPCS, 1984)" - Would it be better to include the following information from the US ATSDR (1995) to add further weight to the statement made in the risk profile? 'Extremely limited information was located ……	Accepted. Text has been amended somewhat.
2.4.1	Canada	Conclusion on effects assessment and toxicity of chlordecone: "Liver cancer was induced in rats at a dose of 1 mg/kg body weight per day," - the following could be added to this statement for completeness 'and in mice at a dose of 2.6 mg/kg bw/day"	Accepted. Text modified accordingly.

Section	Party, Observer	Comments	Response
2.4.1	Canada	Pages 19 and 20 of 24 Table 2.3 Summary of key toxicological studies on chlordecone "enlargement of the adrenal gland" stated in the 3 month feeding study by Cannon and Kimbrough - This statement needs to be checked since the enlargement of the adrenal gland was not noted in the 3 month feeding study rather it was identified in the 30 day study..."Enlargement of the adrenal gland with hyperplasia and hypertrophy of the cortical cells, was observed in a 30-day dietary study in rats (Cannon and Kimbrough 1979 in ATSDR, 1995).	This statement has been checked and it is considered that reference to the 3-month feeding is correct, as quoted both in Table 2.2, page 72 of ATSDR, 1995 and in Table 3 of the IPCS report. The statement on page 99 of ATSDR..."Enlargement of the adrenal gland with hyperplasia and hypertrophy of the cortical cells, was observed in a 30-day dietary study in rats (Cannon and Kimbrough 1979)" is incorrect
2.4.1	Canada	Pages 19 and 20 of 24 "Renal effects (proteinuria and increased severity of glomerulonephrities)" stated in the 3 month feeding study by Larson et al. - 'glomerulonephrities' should be replaced by 'glomerulosclerosis' which is the term cited in the study summary tables cited by the ATSDR (1995) and IPCS (1984)	Accepted. Text modified accordingly.
2.4.1	Canada	Pages 19 and 20 of 24 "0.07 mg/kg bw/day (LOAEL)" in 21 month gavage study by Chu et al. - should include 'in males' after the LOAEL since this effect was only noted to occur in males at this dose level	Accepted. Text modified accordingly.
2.4.1	Canada	Pages 19 and 20 of 24 "1.2 mg/kg bw/day (LOAEL, rat)" in 80 weeks feeding study by NCI, 1976 - should include '2.6 mg/kg bw/day (LOAEL, mouse)' since the mouse was included along with the rat in the species column of the study summary table	Accepted. Text modified accordingly.
3	ICCA-WCC	Given that the profile states that there are no current known production or uses of chlordecone and the basis for LRT potential is based on projection from substances properties rather than monitoring evidence, the only potential value for addition of chlordecone as a POP under the Convention is to reduce the possibility of reintroduction or use. There is no indication in the profile that is a concern. The POPRC and the Parties should carefully consider whether the global community wishes to expend its limited resources on substances that clearly do not warrant global action – especially when there are already insufficient resources for some Parties to address their existing obligations under the Convention. The Convention was designed to focus its efforts on substances of priority concern from a global perspective based on established	In the last paragraph of Section 3, the concern that chlordecone may still be produced is stated. Moreover, lack of evidence on current production and use should not prevent the proposal from proceeding as the re-introduction of the chemical cannot be excluded. The issue of current production and use is to be addressed at the next phase when socio-economic aspects will be evaluated. No changes.

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		criteria and factors. Efforts to add substances that do not clearly "warrant global action" will prevent Parties and other stakeholders from focusing their limited time and resources on those substances that are real priorities at the international level.	
		In the synthesis part it is stated that there are no monitoring data available (some remarks are made regarding historical use but these are mentioned as local issues not issues of "global concern". Because there are no monitoring data there is no comparison of exposure and effects and therefore the profile does not address a key point in the Convention. If this information is not available, the POPRC should more directly solicit specific information from Parties prior to completing the risk profile. Alternatively, information could be gathered from available resources to allow for some comparison of exposure and effects. For example, information could be collected from regional and global monitoring programmes (e.g. UNEP Global Monitoring Programme, Meteorological Synthesizing Centre East MSC-East, Arctic Monitoring and Assessment Programme - AMAP). Also, where appropriate and where there is available, quality data, efforts could be made to develop such information through the use of relevant models.	The sources mentioned have been consulted. No monitoring data are available. However, new information on modelling has been found and included in the risk profile, supporting the conclusion that chlordecone has potential for long-range environmental transport.
		This section includes no assessment of how the information presented in the risk profile relates to "whether a chemical is likely, as a result of long-range environmental transport, to cause significant adverse effects on human health and/or the environment, such that global action is warranted". In particular there is no evaluation of whether any of the identified adverse effects may occur. The Risk Profile Outline to be used in preparing the draft risk profile specifically states that this section should be "in the form of a risk characterization with emphasis on information that leads to the conclusive statement". The Risk Profile Outline also provides specific information and options that can be used to prepare the synthesis of information intended for this section. Section 3 should be revised to specifically address the guidance provided by the POPRC on how to prepare this section of the risk profile. Specifically, as outlined in Annex V of the first POPRC meeting report: This synthesis will include the integration of information on hazard, exposure and dose responses, including monitoring data, incidents and case studies, to provide an evaluation of the potential that any of the identified adverse effects may occur, including the uncertainty associated with the estimation.	Risk profile is not meant to become a full quantitative risk assessment. Annex V of the POPRC meeting report was not discussed at the meeting but is a proposal by some members on the risk characterisation. In the case of chlordecone where there are no monitoring data or data on levels of use, it is not possible to follow Annex V approach. Moreover, the precautionary principle highlighted in Article 8(7)(a) needs to be taken into account. No changes.

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		This integration can be carried out using different alternatives which can be combined in a weight-of-evidence approach. The alternatives include, among others, the comparison of toxicity and ecotoxicity data with detected or predicted levels of the chemical resulting or anticipated from its long-range environmental transport, evidence of effects on human health or the environment in remote areas, or concern on potential effects on humans or the environment (particularly on the higher levels of the trophic chain) based on the assessment of the reported trends in environmental concentrations or potential for significant increases in production or use at the worldwide level. In addition to these factors, the synthesis of information should consider the following: What are the trends in environmental levels – specifically are levels in remote areas increasing, decreasing or constant. Do levels in the environment in remote areas exceed established government "levels of concern" Verification that levels in remote areas are a result of long-range transport rather than local or regional sources.	
		A determination of "whether a chemical is likely, as a result of long-range environmental transport, to cause significant adverse effects on human health and/or the environment, such that global action is warranted", should analyze the information outlined above to determine: If levels in remote areas are due to long-range atmospheric transport, levels are increasing or constant, and levels exceed or are approaching established government "Levels of Concern" then the profile could determine that a substance is likely to cause significant adverse effects such that global action is warranted. If levels in remote areas are only due to local or regional sources then the profile should state this and recommend national or regional action outside of the Stockholm process. If levels in remote areas are due to long-range atmospheric transport, levels are decreasing and levels are below established government "Levels of Concern" then the profile should determine that a substance is unlikely to cause significant adverse effects and does not warrant global action.	The fact that there is no information on environmental levels in the environment and that one cannot deem whether they are likely to cause significant adverse effects does not necessarily mean that global action would not be warranted: As long as reintroduction of the chemical with these characteristics remains possible, the risk of meeting the levels of significant adverse effects cannot be excluded either. Concerning possible lack of the scientific evidence, the precautionary principle highlighted in Article 8(7)(a) needs to be taken into account. See also response above.

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		if sufficient information is not available to make a determination of "significant adverse effects" then the drafters should recommend to the POPRC additional monitoring of the substance and request additional information from countries and stakeholders.	
3	USA	Fifth paragraph new ending: While its physical and chemical properties suggest that chlordecone can be transported long distances bound to particles in air and water, this assumption is limited by lack of available monitoring data from remote sources or other relevant information such as modelling, and by the evidence that contamination has been found primarily close to previous production and use sites.	Not accepted. No change.
3	USA	(Re: Subsequent paragraph): Changes suggested based on revised water solubility.	Accepted. However, sentence revised based on new information
3	USA	(Re: Subsequent paragraph): These conclusory-type remarks do not track with the Article 8 listing process and the circumstances where "global action is warranted" under the Stockholm Convention.	Not accepted. No changes.
4	ICCA-WCC	As outlined in the Risk Profile Outline, the focus of this section should be on "whether a chemical is likely, as a result of long-range environmental transport, to cause significant adverse effects on human health and/or the environment, such that global action is warranted". The profile does not make this case and does not address the guidance provided by the POPRC on how to prepare this section of the risk profile.	See the response to ICCA-WCC comments in section 3. No changes.
		Furthermore, it may be appropriate not to include a concluding statement at this stage of the POPRC process. The concluding statement is ultimately a decision of the POPRC based on the information presented in the risk profile and the synthesis of information contained in Section 3. It may be more appropriate to leave this portion of the risk profile to the full POPRC. Including a concluding statement at this stage could bias the review of the full POPRC and undermine a thorough scientific review of the risk profile.	The working group/drafter is assumed to provide a draft conclusion to form a basis for discussion at the POP RC meeting. No changes.
4	USA	In accordance with the Risk Profile outline developed by POPRC 1 (see UNEP/POPS/POPRC.1/10, Annex IV, this section should directly address the question presented in Article 8, para 7a and Annex E on whether 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. As currently drafted, we believe the risk profile does not present adequate information and analysis to make the case.	Not accepted. The draft Risk Profile does address the question. Especially in the case like chlordecone where data on monitoring and current use levels are missing, it is not possible to provide a quantitative comparison. Moreover, the precautionary principle highlighted in Article 8(7)(a) needs to be taken into account. v

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4	USA	Given mirex was not run through the Article 8 listing process, we question the propriety of comparing chlordecone to mirex for purposes of the science-based Article 8 listing process.	Disagree. In the case of chlordecone where data on monitoring and current use levels are missing, comparison of properties with known POP substances is one way to come to the conclusion, even if the listed POPs have not gone through the same assessment.
4	USA	(Last sentence should be deleted:) As noted above, the concluding statement needs to address whether 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. "Harmful properties and risk from production and use" are not the bases for global action under the Stockholm Convention.	The concluding remark has been modified.
5	Canada	Page 23 of 24 Literature: The reference citations have been made in a non-standard manner. On pg 6 or 24 a note was included which indicated that reference to literature covered in other documents such as the ATSDR review would not be shown in the reference list. In the text of the document, individual citations to literature were made. At the end of the paragraph a statement such as "(quoted from US ATSDR (1995))" was included. It is somewhat unclear whether such a statement applies to all the citations in that paragraph or not. If the US ATSDR is the source the information without verification to the original, it may be more clear to either just cite the ATSDR document or to use a reference format such as (Jensen, J, (2006) from ATSDR 1995)	We realise that the citations from ATSDR and IPCS are not in conformity with standard referencing. However, the format was chosen as a compromise between merely quoting the ATSDR and full quotations, because in some passages, the number of quotations is quite high. No changes made.