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Item 9 (d) of the provisional agenda*
Consideration of draft risk profiles on: alpha hexachlorocyclohexane

Comments and responses relating to the draft risk profile on alpha hexachlorocyclohexane

Note by the Secretariat

The draft risk profile on alpha hexachlorocyclohexane prepared during the intersessional period by the working group established by the Committee for this purpose is set out in document UNEP/POPS/POPRC.3/17. 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.3/1/Rev.1.

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Annex

Comments and responses relating to the draft risk profile on alpha hexachlorocyclohexane

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

Section of Draft	Source of Comment	Comment	Response
Section 2.4	IPEN	The health impacts of HCH isomer exposure have not been adequately emphasized in the draft risk profile. Our January submission on hazard assessment for endpoints of concern includes data from studies on hepatic toxicity, carcinogenicity and reproductive toxicity, which have not been addressed in sufficient detail by the POPRC draft risk profiles on alpha- and beta-HCH.	It is mentioned in the beginning of the section 2.4 that for the HCH draft risk profiles, the most important findings concerning the hazard assessment are stressed and for further details the more comprehensive toxicological profiles IPCS, 1992; ATDSR, 2005; EPA, 2006 should be consulted. Please acknowledge also the page limit of 20 for the draft risk profile (DRP).
Exposure from food (Section 2.3.3)	IPEN	The draft risk profile does not adequately emphasize human exposure to HCH isomers from food, documented in different parts of the globe especially for Alaskan and Arctic populations. Vulnerability of Arctic People and their environment should be more emphasized.	Several parts of the DRP do already refer to the importance of traditional food for the Arctic populations as well as high measured exposure levels (in food) and associated risks (section 2.3.3, section 2.4.1.1, section 3 and 4). No addition is suggested.
Section 2.3.3	IPEN	Exposure in the U.S.: updated dietary exposure data are provided.	Agreed. Data of the DRP are updated.
Section 2.3.5	IPEN	US EPA has noted that lindane and its isomers are "efficiently transmitted" from mother to child through breast milk (US EPA, 2000)	It is stated in the beginning of section 2.3 that infants may be exposed to a-HCH during breast feeding. Also section 2.3.5 refers to the special vulnerability of this group. In addition many data on alpha-HCH levels in breast milk are reported. Therefore no additional text change is made.
Section 2.4	IPEN	Addition of data/studies concerning hepatotoxic effects is proposed.	The current DRP already includes several sections related to hepatotoxic effects including the induction of liver tumours and effects on metabolizing enzymes of alpha-HCH. No additional text is proposed.
Section 2.4	IPEN	Inclusion suggested: “The observation of serious hepatic effects in animals (e.g., fatty degeneration and necrosis) suggests that the same results could potentially occur in workers following prolonged occupational exposure.”	Agreed.
Section 2.4	IPEN	Please add that scientific literature regarding the cancer and non-cancer effects of HCH supports the U.S. EPA's expressed concern that exposures to HCH isomers may be additive.	The possible additive effects of HCH isomers are stressed in the section 2.4 and section 3. No addition is suggested.

Section of Draft	Source of Comment	Comment	Response
Section 2.4, carcinogenicity	IPEN	We would like to bring to the attention of the POPRC studies submitted by IPEN on the carcinogenicity of the alpha- and beta-HCH isomers (see p. 9 and 10 of our January submission). We contend that these studies provide sufficient evidence to strengthen the section on carcinogenicity in both the HCH isomer risk profiles prepare by POPRC.	The classification of carcinogenicity by IARC and EPA has been documented in the DRP; the statement of the DHHS was now added to the DRP.
Section 2.4 Reproductive effects		Please add the result of an Indian study (2003) that tested the association between DDT and HCH isomer exposure to Intra-Uterine Growth Retardation.	This study is already mentioned in the DRP, section 2.4, effects in humans.
Section 2.4	DE	A study of acute toxicity is described in the Hazard Assessment for endpoints of concern section even though it is stated in the introduction of this section that studies on acute toxicity are not available for alpha-HCH. Clarification is needed.	Agreed, text is adapted.
Section 2.4	DE	A study of acute toxicity is described in the Hazard Assessment for endpoints of concern section even though it is stated in the introduction of this section that studies on acute toxicity are not available for alpha-HCH. Clarification is needed.	Agreed, text addition is made in this section.
General	Norway	Agree with conclusions	No action required.
General: quotation	Australia	Quotation should be in a scientific manner and it is not sufficient to only indicate that the information was submitted by a Party as part of the Annex E information	Agreed, quotation is corrected.
Section 2.1.4	Australia	Replacement of the wording “global usage” by “global production” is suggested. Reason: there is no use for alpha-HCH	New text fragment is inserted in the draft risk profile for clarification on usage of techn. HCH/alpha-HCH.
Section 2.2.2 §1	Australia	Text addition is proposed: …. potential for bioaccumulation (ATSDR, 2005). However, the log Kow does not meet the cut-off of >5 required to be considered bioaccumulative according to Annex D paragraph 1(c)(i). Reason: the DRP should provide a clear, open and transparent assessment against the Annex D criteria.	Text amendment is made: … HCH indicates a potential for bioaccumulation (ATSDR, 2005), though it is below the value of 5 stated in Annex D paragraph 1(c)(i).” Explanation: The approach of the lindane risk profile regarding the bioaccumulation section was also applied for the risk profile on alpha-HCH due to the similarities of the isomers.
Section 2.2.2	Australia	Deletion of BCF expressed on lipid base suggested.	No text deletion is made at the moment. Reason: Also BCFs on weight basis are provided in the DRP. In addition the lindane risk profile also contains BCF expressed on a lipid base. Discussion at POPRC 3 suggested, if needed.
Section 2.2.2	Australia	Addition of “whole body” BCF suggested	Agreed.
Section 2.2.3	Australia	Especially high concentrations [such as? Examples of maximum concentrations would be useful.] compared to the source regions were reported for the Arctic Ocean.	This section focused on arguments demonstrating LRT. More details on residues levels and concentrations are reported in section 2.3.2. No text addition is proposed.

Section of Draft	Source of Comment	Comment	Response
Section 2.2.3	Australia	Section of the OECD Pov/LRT screening tool should be deleted. Reason: This "benchmarking" approach was discussed by POPRC2 which decided that it was not a valid comparison for assessing potential POP chemicals. Therefore this paragraph should be deleted.	Comments from Sweden suggested an elaboration of this paragraph. Deletion should be discussed at POPRC3. No action is taken at the moment.
Section 2.3.1 § 2	Australia	These are concentrations of HCH generally, but not of alpha-HCH specifically. Are data available only on alpha-HCH?	In the cited study/report only values for HCH isomers were available. Also other parts of the draft risk profile refer to HCHs. Therefore no text change is proposed.
Section 2.3.2, Table 2	Australia	The Table should clearly specify if concentrations for each row are for alpha-HCH and if not, then what exactly was measured.	Agree. Text is amended.
Section 2.3.4.2	Australia	None of this info is specific to alpha-HCH and should be deleted.	Agreed.
Section 2.4, subchronic toxicity	Australia	Please state also that the LOAEL was 10 mg/kg diet.	Agreed.
Section 2.4, chronic toxicity	Australia	What were the NOAEL and LOAEL?	Values are proposed.
Section 2.4 environment	Australia	Please insert exposure duration of Oliveira-Filho and Paumgarten, 1997	Text amended.
Section 2.4 environment	Australia	In fish, no histopathological changes or influence on growth and behaviour could be detected in a long-term experiment at low concentrations. Please specify the highest concentration.	Value is provided.
Section 4	Australia	Deletion suggested: "In addition, humans and wildlife are exposed to various contaminants that can influence the toxicological effects of alpha-HCH in an additive or synergistic way." Reason: Synergistic or additive effects have not been discussed in the text.	Reference and text amendment in section 2.4, risk assessment is inserted. No text change in section 4 is proposed.
General	Norway	Agree with conclusions	No action required.
Section 2.2.3 § 3	Switzerland	Correction of a reference proposed	Agreed.
Section 2.4 § 1 Risk characterisation	Switzerland	Addition and rewording suggested: "ATSDR derived a chronic RfD of 0.008 mg/kg/day for alpha-HCH based on a NOAEL of 0.8 mg/kg/day for liver effects in rats and an uncertainty factor (UF) of 100 (10 for extrapolation from animals to humans, and 10 for human variability) (ATSDR, in USEPA, 2006).RIVM derived a chronic tolerable daily intake (TDI) or RfD of 0.001 mg/kg-day based on a NOAEL of 0.1 mg/kg-day for hepato- and nephrotoxicity observed at the LOAEL of 0.5 mg/kg/day in a 90-day oral rat study and applying a UF of 100 (RIVM, 2001 in USEPA, 2006). RIVM calculated a tolerable concentration in air (TCA) or reference concentration (RfC) of …….100 (10 each for inter- and intraspecies extrapolation).	Section is reworded acc. to the comment. However we stick to the endpoints that were used in the USEPA risk assessment. Further information can be found in the reports listed under section 1.2.

Section of Draft	Source of Comment	Comment	Response
Section 3, last sentence	Trinidad and Tobago	Revise sentence to read "Nevertheless…it is strongly recommended to avoid foods in which beta-HCH levels are of concern".	Agreed. Sentence is modified acc. to the new proposal.
Section 3, second to last sentence	Trinidad and Tobago	The estimated cancer risk value has been omitted.	Sentence is reworded.