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Item 9 (e) of the provisional agenda^{*}

Consideration of draft risk profiles on: beta hexachlorocyclohexane

**Comments and responses relating to the draft risk profile on
beta hexachlorocyclohexane**

Note by the Secretariat

The draft risk profile on beta 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.3/18. 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.

Annex

Comments and responses relating to the draft risk profile on beta 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).
Section 2.3.2	IPEN	Additional information on constant HCH and increased beta-HCH levels in the in Canadian Arctic biota should be included.	It is already stated in the DRP that beta-HCH levels in seabirds, ringed seals and polar bears have increased. No text addition is at the moment proposed.
Section 2.3.2	IPEN	Additional information on beta-HCH residues in chicken eggs should be included.	Agreed.
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 2.4.1	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 beta-HCH. No additional text is proposed.
Section 2.4.1	IPEN	On beta- HCH the draft risk profile limits itself to stating that the isomer “demonstrates hepatotoxicity”	It is stated in the DRP “...studies have demonstrated hepatotoxicity and Neurotoxicity”, which means these effects are documented.
Section 2.4.1	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 2.4.1	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 2.4.1, 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 of Draft	Source of Comment	Comment	Response
Section 2.4.1, carcinogenicity	IPEN	Please include study by Li et. al (2006).	Agreed (study is in Chinese, drafter could not read the article).
Section 2.4.1, reproductive effects	IPEN	Please include more information/data on reproductive toxicity (submitted Annex E information by IPEN in January)	The reproductive effects have been described in the subchronic section, now these effects are also mentioned under reproductive effects. Studies concerning human reproductive impact of beta-HCH are already mentioned in the actual version of the DRP.
Section 2.4.1, reproductive effects	IPEN	Reproductive effects of HCH isomers during fetal development. This is of particular concern given the recent findings of the U.S. Centre for Disease Control and Prevention that more than half the participants in a national survey of chemicals in blood and urine carried beta-HCH in their blood, with the highest levels found among women of childbearing age.	It is documented in the exposure section that concentration levels (2001/2002) in females were higher (54.5 ng/g) than in males (29.2 ng/g), also increasing concentrations with increasing age is described in this section. Therefore no change is suggested.
General	Norway	Agree with conclusions	No action required.
General: quotation	Australia	Please quote the submitted Annex E information in the DRP in a scientific style.	Agreed.
Section 2.4	Australia	Comment on alpha-HCH: Please state the NOAEL and LOAEL in the paragraph "Chronic toxicity".	For consistency reasons this comment submitted on the alpha-HCH DRP was also addressed in the beta-HCH DRP. Value was added.
Section 1.1.1	SE	In order to facilitate comparison between substances SI-units are preferred for the physicochemical properties.	Agreed. Comment was used to improve Table 1 (in line with the suggestion by Canada).
Section 2.2.1.2 §5	SE	"Under various field conditions it is assumed that degradation rates are in the order of alpha > gamma > beta." It is unclear from which reference this conclusion originates, or if this is a conclusion drawn by the risk profile authors based on all available data.	Agreed. Text amendment is provided
Section 2.2.1.2 §5	SE	The studies Suzuki et al. (1971) and Phillips et al. (2005): Is it possible to be more quantitative than "low concentrations"?	Agreed, concentration is added (Suzuki et al., 1971). Phillips et al. (2005) is a review article.
Section 2.2.1	SE	2.2.1.1 Biotic degradation should be 2.2.1.2 Comment on alpha-HCH: The half-lives do not distinguish between volatilisation/ leaching, in addition it most likely does not distinguish between abiotic and biotic degradation. Therefore, these results have limited applicability as estimates of biotic degradation.	For clarity reasons the headings referring to abiotic and biotic degradation are removed.
Section 2.2.3	SE	Monte Carlo uncertainty analysis using uncertainties in chemical properties was used. Please provide briefly the results of this analysis in this section.	Due to text constraint (limit of 20 pages) and a comment received from Australia (on alpha-HCH that suggested deletion of this para.) no additional text concerning the Monte Carlo uncertainty analysis is added at the moment. This point can be discussed at POPRC3
Section 2.3.4	SE	Suggestion: given the potential for significant exposure for agricultural workers during application of HCHs a section on occupational exposure could be warranted.	Occupational exposure is already mentioned in the current DRP. Because of text constraint no additional section is added at the moment. This point can be discussed at POPRC3

Section of Draft	Source of Comment	Comment	Response
Section 3 §3	SE	Please include a sentence stating that these data does not represent the degradation loss process only, and should therefore be considered as minimum estimates of DT50-values.	Agreed. Text addition is made.
Section 3 § 3	SE	Avoid using words with subjective values. The phrase "low levels" does not mean anything unless levels are being compared. Please delete first sentence.	Agreed. Sentence is deleted now.
Section 4 § 1	SE	For clarity reason please add: These waste isomers are still a worldwide problem " <u>and contribute to the releases into the environment</u> ".	Agreed. Text addition is made
General	DE	Based on the toxicological profile represented there are no objections to that.	No action required.
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 1.1.1	Switzerland	Revision of the log Koa value suggested.	Table 1 was revised after comments from SE and Canada.
Section 2.2.3 § 3	Switzerland	Correction of a reference proposed	Agreed.
Section 2.4.1	Switzerland	Rewording of the heading "Neuroendocrine mediated toxicity" suggested.	Agreed.
Section 2.4.1 Risk characterisation	Switzerland	Please replace the RfD of 0006 (changed by previous comments) by 0.00002 mg/kg/day for beta-HCH based on a NOAEL of 0.02 mg/kg/day for observations	Agreed.