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Consideration of draft risk profiles: hexabromobiphenyl

Comments and responses relating to the draft risk profile on hexabromobiphenyl

Note by the Secretariat

The draft risk profile on hexabromobiphenyl, prepared during the intersessional period by the working group established by the Committee for this purpose, is set out in document UNEP/POPS/POPRC/2/9. 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 hexabromobiphenyl (June 2006)

Section	Party, Observer	Comments	Response
General comments	Armenia	... the submitted draft risk profiles on ...hexabromobiphenyl.. 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 changes.
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 hexabromobiphenyl and hexabromobiphenyl is also really interested.	No changes. 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.
1.1.3	France	(Table 1.1.) The references in the table are not clear. Could you explain what the reference “1)” means? In the notes below the table there is two different meanings for the “1”. In one case it relates to an information on a CAS number in an EU Export-Import report and in another case it relates to data quoted in US ATSDR. This should be clarified in the document. Furthermore, references to notes 2 and 3 never appear in the table. This should also be clarified.	The notes 1-3 at the bottom of the page are footnotes and do not refer to the table. Reference in table has been changed.

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1.1.3	USA	(Last paragraph, Tittlemier et al. 2002) This reference apparently contains more reliable physical and chemical property data than those provided in Table 1.1. If these are better data, they should be provided in this Table, or the direct citation to this work needs to be provided.	Accepted. The information is included in Table 1.1. Text modified to clarify this.
1.3	USA	(Data sources): Note: Could also do a search with US National Library of Medicine PubMed and ScienceDirect.	It has unfortunately not been possible to extend the data search. No changes.
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 hexabromobiphenyl are critical in assessing the potential risk of the substance. This information will also be critical should hexabromobiphenyl 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. The profile specifically states that "according to information available, production and use of hexabromobiphenyl has ceased in most, if not all countries. However, it is possible that hexa-bromobiphenyl is still being produced in some developing countries or countries with economies in transition." And yet not evidence is provided for this "possibility". Without a more accurate understanding of the current sources, uses and potential releases it is 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	The risk profile suffers from lack of recent data regarding production and use of hexabromobiphenyl but this should not prevent the proposal from proceeding. The issue is to be addressed at the next phase where socio-economic aspects will be evaluated. No changes.
2.2.1	USA	(Before Conclusion): (Note: Although this section concludes that HBB may be considered to be highly persistent, there is no summary information regarding persistence in various media. By contrast, there is a reference cited that it undergoes rapid photochemical reaction in methanol.)	There is summary information regarding persistence in water, soil and sediment provided in chapter 2.2.1. The conclusion is extended to include discussion of photodegradation.

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2.2.2	France	The conclusion is really clear and summarises well the potential of bioaccumulation of the substance however the general text above the conclusion should specify when the data are available if the BCF are expressed in wet or dry weight to facilitate the comparison and the understanding of the section.	Not all sources of information have provided details regarding wet/dry or lipid based results. Text modified as far as possible. Please, note that lipid-based results are not based on fresh weight.
2.2.2	USA	(At the end of the conclusion) Evidence appears to be satisfactory to conclude high bioconcentration and biomagnification	Accepted. Text modified accordingly.
2.2.3	USA	(Addition after conclusion): Despite the incomplete physicochemical property data (especially measured), the ability of HBB to undergo long range transport is supported by the monitoring data cited to remote locations such as Greenland and the Arctic. However, it cannot be determined that such transport is likely to cause adverse human health or environmental effects.	Most of the contents of the suggested addition is included in the original wording. Furthermore, the section has been amended due to new information from a modelling study on hexabromobiphenyl. The likelihood of adverse effects is discussed in chapter 3.
2.3.4	USA	(Re conc. in pilot whale blubber) [Note: This may be too generalized and imply a risk concern when none has been demonstrated (these are very low levels). No analysis is provided to support this contention. The lowest effects seen were in monkeys at 0.012 mg/kg/day - dosed 7 months before and during pregnancy. For a 60 kg adult human, this would mean an intake of 1.2 x 10-2 x 60 kg = 0.72 mg/60kg adult/day. The concentration in pilot whale blubber is 17 x 10-3 mg/kg lipid. A person would have to eat 0.72 /17 x 10-3 = 42 kg of whale fat per day to match the dose rate reported in the monkey for toxicity. An assessor could make an argument for uncertainty factors here to reduce this number (LOAEL, intraspecies, intrahuman), but no such effort was made here -- or reference back to measured body burden levels in Faroe Islanders. Incidently, the US Agency for Toxic Substances and Disease Registry (ATSDR) acute Minimal Risk Level (MRL) is 0.01 mg/kg/day using an uncertainty factor of 100x.]	Accepted that the statement may be too generalised. Text revised accordingly.
2.4.1	USA	Comment related to lines 683 – 685 of section 2.4.1: (Note: Should mention hexabromonaphthalenes (HBNs) since the technical grade PBBs (FireMaster®) are complex mixtures also containing HBNs.)	Accepted. Reference to the HBNs has been included.
2.4.1	USA	Comment in section “Mechanism of Action” – add “some of”	Accepted. Text modified accordingly.
2.4.1	USA	Line 744, “lg” rather than “kg”	Accepted. Text modified accordingly.

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2.4.1	USA	Lines 754 – 756 Which FireMaster® was used in the NTP studies?	FF-1, this mention has been included.
2.4.1	USA	Line 815 "The PBBs (and by inference, hexabromobiphenyl) are endocrine disrupting (ED) chemicals." [Note: This is the position of the EU and does not represent the view of other governments including the US. Given the current state of the science, the US does not consider endocrine disruption to be an adverse endpoint per se, but as a step that could lead to toxic outcomes, such as cancer or adverse reproductive effects. As a result, US policy is to not designate any chemicals as Endocrine Disruptors at this time.]	Accepted. The wording has been amended to accommodate the comment and also chapter 3 has been modified accordingly.
2.4.1	USA	Lines 822, 827: Note: It would be helpful to include this primary reference (Blanck et al., 2000). in the reference list at the end of the profile.	Accepted. The reference has been included.
3	ICCA-WCC	Given that the profile states that there are no current known production or uses of hexabromobiphenyl, the only potential value for addition of hexabromobiphenyl 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 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 last paragraph of Section 3, the concern that hexabromobiphenyl 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.
		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.	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. Furthermore, it may be considered whether a risk assessment based on individual substances is at all an appropriate approach in the case of POP candidates. It has been demonstrated that hexa-bromobiphenyl has reached the Polar bears, the seals and other predators. Several other persistent organic pollutants have been demonstrated in the tissues of

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		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. 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.	these organisms. Must each contaminant reach a level where it possesses a risk on it's own before action is taken? The precautionary principle highlighted in Article 8(7)(a) needs to be taken into account, especially when considering that synergistic effects between contaminants are possible. No changes.

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		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. 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.	The levels of HBB in remote areas are very likely result of long-range environmental transport. The fact that levels are not increasing and 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. No changes.

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3	USA	[Note: The evaluation to address the question of whether the substance is likely to have significant adverse human health and/or environmental effects as a result of its long-range environmental transport, such that global action is warranted, should analyze several factors, which can be combined in a weight of the evidence approach." It is not clear that this case has been made. This approach would look at the strength, value, and veracity of the evidence relating to whether the substance is likely to have significant adverse human health and/or environmental effects as a result of its long-range environmental transport. The evaluation should consider, among others, the following factors in making this evaluation: a comparison of toxicity and ecotoxicity data with detected or predicted levels of the chemical resulting or anticipated from its long-range environmental transport, and evidence of effects on human health or the environment in remote areas; and concern for likely effects on humans and/or the environment as a result of long-range environmental transport (particularly on higher trophic levels) based on assessments of the reported trends in environmental concentrations in areas distant from sources, or potential for significant increases in environmental concentrations in areas distant from sources resulting from anticipated increases in production and/or use.]	See the response to the comments by ICCA-WCC concerning chapter 3 above.
3	USA	(Re persistence of hexabromobiphenyl) [Note: What is the basis for this?]	Section 2.2.1. No change
3	USA	(RE potential for long range transport:) [Note: Last paragraph of section 2.2.3 says long range transport of PBBs "has not been proven."]	Section 2.2.3 was changed. No change here.
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	The working group/drafter is assumed to provide a draft conclusion to form a basis for discussion at the POP RC meeting. No changes.

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		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.	
4	USA	(Before the text starts:) [Note: The conclusion should state clearly which criteria were met and how these criteria, as well as other necessary and relevant information, may contribute to making the determination that HBB is likely, as result of long-range environmental transport, to cause significant adverse effects on human health or the environment such that global action is warranted. If the dossier does not provide the relevant or adequate information to support this statement, then a clear conclusion to that effect should be stated.]	The concluding statement has been modified.
4	USA	Suggests deletion of the last sentence and insertion of: Based on the above, HBB [is][is not] 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	Accepted. Text changed accordingly.