Approach to developing a discussion paper on issues and principles to be applied in the interpretation of the Annex E criteria

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1. Background

1. At its sixth meeting, the Persistent Organic Pollutants Review Committee discussed the draft risk profile and the proposed conclusions for short-chained chlorinated paraffins, but was unable to take a decision because of uncertainties in applying the criteria specified in Annex E to the Convention. It therefore established an intersessional working group to further consider this issue.[1]

2. At its seventh meeting, having discussed the application of the criteria specified in Annex E to the Convention to short-chained chlorinated paraffins and considered the outcome of the case study on toxicological interactions of chlorinated paraffins,[2] the Committee agreed to establish an ad hoc working group to undertake the following activities in accordance with a workplan to be agreed upon by the working group members:[3]

(a) To revise the relevant parts of the draft risk profile to incorporate information on toxicological interactions of chlorinated paraffins for consideration by the Committee at its eighth meeting;

(b) To compile issues and principles to be applied in the interpretation of the Annex E criteria for consideration by the Committee at its eighth meeting.

2. Issues and principles to be applied in the interpretation of the Annex E criteria

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."

4. The 'Synthesis of Information' and 'Concluding Statement' of a risk profile are critical parts of the summary rationale for why global action on a nominated chemical is warranted. Most of the risk profiles adopted so far by the Committee had comprehensive summary rationales which drew on the critical data elements contained in the body of the report and linked them into an overall-weight-of-evidence evaluation.

5. The approach to developing a discussion paper on issues and principles to be applied in the interpretation of the Annex E criteria comprises two elements:

(a) Summary of agreed principles applied in the interpretation of Annex E, according to the Committee's past experience in preparing the risk profiles for the 11 POPs. The summary has been drafted by the chair of the Committee based on his intervention at POPRC7. The intersessional working group members are expected to provide comments and propose additional principles, if any.

(b) Summary of open questions in the interpretation of Annex E. The summary has been drafted by the chair of the Committee. The intersessional working group members are expected to provide comments and propose solutions.

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1 UNEP/POPS/POPRC.6/13, annex III.

2 UNEP/POPS/POPRC/7/INF/15.

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

6. Based on the feedback from the intersessional working group, the chair of the intersessional working group, supported by the chair of the Committee, will prepare a paper for discussion and possible decision-making at POPRC8, indicating where there is agreement and where further discussion is required.

2.1 Summary of principles applied in the interpretation of Annex E as agreed by the Committee members

2.1.1 Scope of the risk evaluation

7. The risk evaluations by the Committee involves a comparison of exposure levels and effects data 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".

Screening phase – Annex D

8. The following screening criteria are set out in subparagraphs (b) to (e) of paragraph 1 of Annex D:

(b) Persistence

(c) Bio-accumulation

(d) Potential for long-range environmental transport

(e) Adverse effects

(i) Evidence of adverse effects… or

(ii) Toxicity or ecotoxicity data…

9. The Committee examines the proposal and applies the screening criteria in a flexible and transparent way, taking all information provided into account in an integrative and balanced manner. The examination addresses all the criteria in Annex D, concludes for each criterion whether it has been fulfilled, and contains an overall conclusion on whether the requirements in Annex D have been fulfilled.

10. Subparagraphs (b) to (e) of paragraph 1 of Annex D set out the screening criteria, while paragraph 2 is not a screening criterion.

11. 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.

12. Therefore it has been agreed that the fact that the criteria in Annex D are fulfilled is not in itself an argument that Annex E evaluation is fulfilled.

Risk profile phase – Annex E

13. Under the provisions of the Stockholm Convention, a substance which has been proposed for addition to Annexes A, B or C to the Convention and has passed the screening criteria set forth under Annex D, moves forward to a further review, the preparation of a draft risk profile based on the information specified in Annex E collected from Parties and observers, to determine "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".

14. On the other hand, a risk assessment is defined as follows:

"Risk assessment: A process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: hazard identification, hazard characterization (related term: *Dose–response*

assessment), exposure assessment, and risk characterization. It is the first component in a risk analysis process."[4]

15. 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 quotient based risk assessment.

2.1.2 Common approach to preparing risk profiles by the Committee

16. A risk profile is intended to build on the work undertaken through the evaluation of the Annex D elements provided in the proposal. It contains "Comparison of exposure levels and effect data", "Synthesis of Information" and "Concluding Statement" to make the case why the Committee considered that global action is warranted.

17. Paragraph 7 (a) of Article 8 provides:

"Lack of full scientific certainty shall not prevent the proposal from proceeding".

18. Socio-economic considerations are not included in the risk profile because they do not contribute to the scientific analysis defining a POP.

Use of local data or data from remote areas in the Committee's decision-making

19. 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 for the decision-making. Only data on environmental exposure and concentration of the proposed chemical in biota from remote areas are considered for the decision-making.

Comparison of exposure levels and effects data

20. In chapter 2.4 of a risk profile (hazard assessment for endpoints of concern), the exposure levels and effects data for remote regions are compared. This involves a comparison of measured concentrations in the tissues and organs of species with no effect concentrations (NOEC) or no adverse effect levels (NOAEL) and with concentrations or levels that showed adverse effects.

21. The data for the no effect levels/concentrations and adverse effect levels/concentrations are often generated by laboratory animal experiments. In the risk profile for PFOS, 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."[5]

22. 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.

Use of benchmarking

23. Benchmarking is a concept to compare the properties and the concentrations of a candidate chemical in biota from remote areas with that of an already listed POP. For example, as additional information in the risk profile of endosulfan, a benchmark approach has been performed comparing lindane with endosulfan. This approach in the risk profile showed that lindane, a listed POP, and endosulfan are found in similar concentrations in biota from remote areas and that endosulfan has similar or higher toxicity than lindane does. The use of this information strengthened the decision-making on the risk profile for endosulfan.

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[4] IPCS Risk Assessment Terminology, WHO 2004
http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf

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

24. If the concentrations of a candidate chemical and a listed POP in biota from remote areas are comparable, and the toxicity of the candidate chemical is comparable or higher than the toxicity of the listed POP, then there is a strong argument for the decision-making on Annex E evaluation.

Use of environmental modelling

25. Substances that have been withdrawn from the global market like chlordecone and hexabromobiphenyl, the environmental concentrations and concentration in biota may be very small. In such cases, a comparison of exposure data with effects data is not conclusive and therefore the potential for long-range environmental transport has been assessed using model calculations. The decision to move these substances further was mainly based on a comparison of their POPs related properties with those of already listed POPs through benchmarking. This allows listing of those substances under the Convention and prevents the reintroduction of the substances on the global market.

26. When there is no measured environmental concentration or concentration in biota in remote areas for chemicals that have been withdrawn from the global market, the Committee has used environmental modelling methods.

Use of time trends of releases or of concentrations in the environment in remote areas

27. An example of the time trend of exposure levels in remote areas used by the Committee in the risk profile is pentabromodiphenyl ether where it was stated in the risk profile "With the chemical's volatility contributing to its long-range transport, however, levels of exposure to pentabromodiphenyl ether continued to rise in North America and remote Arctic regions"[6].

28. Evidence of an increase in concentrations in the environment over time is an additional argument for that the decision-making on Annex E evaluation.

2.2 Open questions in the interpretation of Annex E and proposals for solutions

Comparison of exposure levels and effect data

29. When comparing concentration data in biota with toxicological and or ecotoxicological data or known effects data on humans, the Committee takes into account the uncertainties of the non-representative exposure data and of the effects data, especially when reading across from one species to another.

30. The Committee members expressed reservations about the applicability of laboratory test data when evaluating risks for higher-order animals living under complex and diverse environmental conditions.

31. Is this generally agreed?

32. The Convention does foresee that a POP listed in Annex A for elimination, the chemical is to be banned totally that its environmental concentration will eventually decrease to a very low level. However it does not foresee that the POP is to be taken out from the list when the environmental concentration decreases to below certain level.

33. How can this concept be used in the Committee'sdecision-making on Annex E evaluation?

Adverse effects

34. Annex D to the Convention defines adverse human health and/or environmental effects. However, the word "significant" in the Annex E evaluation ("…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.") needs to be interpreted. Significant adverse health and/or environmental effects used in the risk profiles for decision-making were hazard endpoints which lead to irreversible

[6] Report of the second meeting of the Persistent Organic Pollutants Review Committee, UNEP/POPS/POPRC.2/17, paragraph 47.

effects and/or endpoints with no or very low “no adverse effect level” such as endocrine disruptors and carcinogens.

35. How the endpoints with no adverse effect level/concentrations that are higher than the environmental concentrations or concentrations in remote biota should be addressed?

Use of environmental modelling for chemicals newly introduced to the global market

36. When there is no measured environmental concentration or concentration in biota in remote areas for chemicals that have been withdrawn from the global market, the Committee has used environmental modelling methods.

37. The same concept is proposed for chemicals newly introduced to the global market which the local releases in the environment are still very small and the concentrations measured in remote areas are expected to be very small.

38. This has not been fully agreed by the Committee.

Use of time trends of releases or concentrations in the environment in remote areas (including consideration of climate change impacts)

39. The following questions needs to be considered:

(a) What is the conclusion for Annex E if:

(i) Experimental data show no time trend?

(ii) Experimental data show reduction in concentrations?

(b) How to use future scenarios:

(i) What releases are expected?

(ii) What concentrations in the environment or biota from remote areas are expected?

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