

POPRC-9/7: Approach to the evaluation of chemicals in accordance with Annex E to the Stockholm Convention

The Persistent Organic Pollutants Review Committee

1. *Endorses* the document set out in the annex to the present decision outlining examples of practices used and decisions made in the evaluation of chemicals by the Persistent Organic Pollutants Review Committee in accordance with Annex E to the Stockholm Convention;
2. *Decides* to take into account the examples set out in the annex in its future evaluation of chemicals proposed for listing in Annexes A, B and/or C to the Stockholm Convention;
3. *Takes note* of the paper on views on open issues in the evaluation of chemicals in accordance with Annex E to the Stockholm Convention;¹
4. *Decides* to consider adding further examples to the document set out in the annex to the present decision in the light of future experience.

Annex to decision POPRC-9/7

Examples of practices used and decisions made in the evaluation of chemicals by the Committee in accordance with Annex E to the Stockholm Convention

1. Background of the evaluation of chemicals in accordance with Annex E

1. According to paragraph 7 (a) of Article 8 of the Stockholm Convention on Persistent Organic Pollutants (POPs), the Persistent Organic Pollutants Review Committee prepares a risk profile for a chemical proposed for listing under the Convention to provide a basis for deciding 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”.

2. The information requirements for a risk profile are identified in Annex E to the Convention. The first paragraph of Annex E, quoted below, which is substantially the same as that in paragraph (7) (a) of Article 8, has raised some discussions in the development of risk profiles and at the meetings of the Committee:

“The purpose of the review is to evaluate 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.”

3. At its first meeting, the Committee developed and agreed on an outline of a risk profile.² The Committee also agreed that the length of a risk profile should be 20 pages and that there should be no annexes to the document.

4. The chapters on “synthesis of information” and “concluding statement” of a risk profile, as risk profiles have been formatted by the Committee to date, contain critical parts of the summary rationale. Those chapters explain the Committee’s conclusion as to whether a chemical under review 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. Most of the risk profiles adopted so far by the Committee have had comprehensive summary rationales that draw on the critical data elements contained in the body of the report and linked them to an overall weight-of-

¹ UNEP/POPS/POPRC.9/INF/20.

² UNEP/POPS/POPRC.1/10, annex IV.

evidence evaluation to support the conclusion related to paragraph 7 of Article 8 and Annex E.³

1.1 Scope of a risk profile

5. The development of risk profiles by the Committee has involved consideration of sources (production data, uses, releases); an assessment of hazards, including consideration of toxicological interactions; data on environmental fate (physical and chemical properties, persistence and coupling to environmental transport, degradation and transformation to other chemicals, bioconcentration and biomagnification factors based on measured values, except when monitoring data are judged to meet this need); monitoring data; exposure in local areas and, in particular as a result of long-range environmental transport, including information regarding bioavailability; national, international evaluations and peer-reviewed scientific studies; and the status of the chemical under international conventions.

6. Those components are analysed together using a weight-of-evidence approach to answer the question in paragraph 7 of Article 8 and 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”.

1.2 Relationship between the evaluation in accordance with Annex E and the screening phase in accordance with Annex D

7. 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; and
- (e) Adverse effects”.

8. In accordance with paragraph 3 of Article 8 of the Convention, the Committee examines the proposal and applies the Annex D 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 screening criteria in Annex D, concludes for each criterion whether it has been fulfilled, and draws an overall conclusion on whether the screening criteria in Annex D have been fulfilled in accordance with paragraph 4 of Article 8.

9. As provided in the first paragraph of Annex E, the risk profile “further elaborates on, and evaluates, the information referred to in Annex D”.

10. The following information requirements set out in paragraphs 2 and 3 of Annex D do not constitute screening criteria:

(a) The proposing Party shall provide a statement of the reasons for concern including, where possible, a comparison of toxicity or ecotoxicity data with detected or predicted levels of a chemical resulting or anticipated from its long-range environmental transport, and a short statement indicating the need for global control;

(b) The proposing Party shall, to the extent possible and taking into account its capabilities, provide additional information to support the review of the proposal referred to in paragraph 6 of Article 8. In developing such a proposal, a Party may draw on technical expertise from any source.

11. The above-mentioned information is to be reviewed and further elaborated on in a risk profile in accordance with Annex E. In other words, the screening of the

³ The intersessional working group has revised the text contained in document UNEP/POPS/POPRC.8/INF/10.

proposed chemical against the criteria in Annex D, in accordance with paragraph 3 of Article 8, does not address the question of potential risks of the proposed chemical as a result of its long-range environmental transport, and the risk profile should address that question.

12. It should be noted that the fact that the criteria in Annex D are fulfilled is not in itself an argument that the evaluation in accordance with Annex E has been completed. According to paragraph 6 of Article 8, the Committee shall further review the proposal, taking into account any relevant additional information received and shall prepare a draft risk profile in accordance with Annex E.

1.3 Risk profile phase – Annex E

13. Under paragraphs 4 (a) and 6 of Article 8 of the Stockholm Convention, a chemical that has been proposed for addition to Annexes A, B and/or C to the Convention and has passed the screening criteria set forth under Annex D moves forward to review under Annex E. At this stage, the Committee prepares a risk profile based on the information specified in Annex E. Information relevant to the development of the risk profile is collected from all possible sources, including literature, parties and observers. An intersessional working group prepares a draft risk profile based on the information received. The Committee considers the draft risk profile at its meeting and decides “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”.

14. A risk profile builds on the work undertaken through the evaluation of the Annex D criteria provided in the original proposal, elaborating further the specific types of information specified in subparagraphs (a) to (g) of Annex E. It contains an analysis of “sources”, “environmental fate”, “monitoring data”, “exposure”, “hazard assessment for the endpoint or endpoints of concern, including a consideration of toxicological interactions involving multiple chemicals”, “national and international risk evaluations, assessments or profiles and labelling information and hazard classifications, as available” and the “status of the chemical under international conventions” to make the case why the Committee considers either that global action is warranted (Article 8, paragraph 7 (a)) or that the proposal should not proceed (Article 8, paragraph 7 (b)).

15. Article 1 of the Convention calls attention to the potential consideration of a precautionary approach with the following statement:

“Mindful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Convention is to protect human health and the environment from persistent organic pollutants.”

16. The reference to the precautionary approach in Article 1 is echoed in paragraph 7 of Article 8, and thus in Annex E. Paragraph 7 provides:

“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, the proposal shall proceed. Lack of full scientific certainty shall not prevent the proposal from proceeding. The Committee shall, through the Secretariat, invite information from all Parties and observers relating to the considerations specified in Annex F. It shall then prepare a risk management evaluation that includes an analysis of possible control measures for the chemical in accordance with that Annex.”

17. The Convention deals with persistent chemicals that are dispersed throughout the globe, putting a special emphasis on the prediction of fate and effects compared to rapidly degrading chemicals with only local impact.

18. Socio-economic considerations are not included in the risk profile because they do not contribute to the scientific analysis defining whether a chemical is a persistent organic pollutant. Socio-economic information is essential, however, for the development of the risk management evaluation in accordance with Annex F to the Convention.

2. Examples of Committee decisions in accordance with Annex E

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

19. The data that are measured in biota or abiotic compartments from areas close to the source of release of a chemical are included in the risk profile for that chemical as specified in subparagraph (e) of Annex E. This information can be considered as one line of evidence in the assessment of the fate and the potential for uptake and effects in biota. As indicated in the same subparagraph, information on exposure resulting from long-range environmental transport (often referred to as exposure in remote areas) and information on bioavailability and metabolism within the biota are critical for decision-making.

2.2 Comparison of exposure levels and effects data

20. The risk profile further elaborates and evaluates the information referred to in Annex D, including the information specified in paragraph 2 of Annex D, which calls for, "where possible, a comparison of toxicity or ecotoxicity data with detected or predicted levels of a chemical resulting or anticipated from its long-range environmental transport". The preparation of a *risk profile* in accordance with Annex E and its decision-making on the risk profile does not involve a quotient based *risk assessment*.⁴

21. While a comparison of exposure and effect levels is not a requirement of the Convention, it has been carried out in the past, where possible, to more clearly illustrate the need for global action. The exposure levels and effects data for remote regions have been compared in chapter 2.4, on "hazard assessment for endpoints of concern", of the risk profiles adopted so far by the Committee.⁵

22. In the risk profile for hexabromocyclododecane,⁶ the Committee evaluated concentrations in species against relevant adverse effect data near point sources and source regions, in remote areas and for human health.⁷ While the concentrations near point sources could not be used to conclude that the chemical was likely as a result of its long-range environmental transport to lead to significant adverse human health and/or environmental effects, the available studies for remote areas suggested that there was a potential for endocrine effects in fish, as well as a risk of reproductive and developmental effects in wild birds.

⁴ The definition of a risk assessment according to *IPCS Risk Assessment Terminology* (Inter-Organization Programme for the Sound Management of Chemicals, World Health Organization 2004)

(<http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf>) is 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."

⁵ For example, chapter 2.4.6 of the risk profile on hexabromocyclododecane (UNEP/POPS/POPRC.6/13/Add.2).

⁶ UNEP/POPS/POPRC.6/13/Add.2.

⁷ UNEP/POPS/POPRC.6/INF/25.

23. In the risk profile for pentabromodiphenyl ether,⁸ a comparison using risk quotient data was made available to the Committee. In the risk profile for pentachlorobenzene,⁹ analyses on lethal and critical body burden were submitted by industry, and peer reviewed critical whole body residue information was also made available to the Committee. Nevertheless, the Committee concluded that the exposure assessment was uncertain, stating in the risk profile that “expressing the toxicological effects as internal dose or, whenever possible, [as] critical body burdens, improves the effect assessment but only reduces partially its uncertainty”.

24. At its second meeting, the Committee stated that in the risk profile for perfluorooctane sulfonate¹⁰ the ad hoc working group on perfluorooctane sulfonate “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.”

25. In the past, when the Committee compared exposure and effects data attention was paid to restrictions and limitations as further described in chapter 3 of the present paper. When making comparisons, the Committee has taken note of uncertainties in exposure (risk profile on pentachlorobenzene),¹¹ the fact that environmental levels have been on the rise during the last decades and the fact that the effects of exposure may depend on the timing of exposure (risk profile on hexabromocyclododecane).¹²

26. While there was no data on hexabromocyclododecane in polar bears and seals in remote areas, it was noted that there might be effects on Arctic mammals that would become evident due to normal emaciation in winter. The fact that environmental levels are below effect levels cannot be interpreted to mean there is no risk of concern. However, when exposure levels have been in the same range as or greater than adverse effect levels, the Committee has considered this as one line of evidence that global action is warranted in accordance with paragraph 7 (a) of Article 8 of the Convention.

2.3 Comparison of the data for a candidate chemical with the data for a listed persistent organic pollutant

27. One of the ways of evaluating the characteristics and effects of a substance for which not enough information exists is to compare it with better known chemicals with similar characteristics.

28. In respect of Annex E, comparison may involve comparing the properties or the concentrations of a candidate chemical in biota from remote areas with those of an already listed persistent organic pollutant.

29. As additional information in the risk profile on endosulfan,¹³ endosulfan properties were compared with those of existing persistent organic pollutants. Results from the CliMoChem model showed that overall persistence (POV) and long-range transport potential (LRTP) of the endosulfan substance family were similar to those of aldrin, DDT, and heptachlor.¹⁴

⁸ UNEP/POPS/POPRC.2/17/Add.1.

⁹ UNEP/POPS/POPRC.3/20/Add.7.

¹⁰ UNEP/POPS/POPRC.2/17.

¹¹ UNEP/POPS/POPRC.3/20/Add.7.

¹² UNEP/POPS/POPRC.6/13/Add.2.

¹³ UNEP/POPS/POPRC.5/10/Add.2.

¹⁴ The initial 12 persistent organic pollutants listed in the Convention were assessed for their persistent organic pollutants properties during the international negotiating committee’s process.

30. Endosulfan levels in remote areas, as well as no observed effect concentration (NOEC) and no observed adverse effect level (NOAEL) values, were compared with those for lindane, a persistent organic pollutant listed in the Convention in 2009. This approach showed that lindane and endosulfan were found in comparable concentrations in biota from remote areas. Endosulfan was also considered to have similar or higher toxicity than lindane. This information strengthened the decision-making on endosulfan.

31. In the risk profile on hexabromobiphenyl,¹⁵ the potential for long-range transport was determined by comparing the water solubility, vapour pressure and Henry's Law Constant for the substance to those for DDT and endrin.

32. If the concentrations of a candidate chemical and a listed persistent organic pollutant in biota from remote areas are comparable, and the toxicity of the candidate chemical is comparable or higher than the toxicity of the listed persistent organic pollutant, it has been considered to be support for deciding that the candidate 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.

33. If, however, benchmarking shows concentrations that are not comparable or the candidate chemical is less toxic than the benchmark chemical, it is not possible to conclude that the candidate chemical is of no concern without information on potential exposure (e.g., current and future releases, bioaccumulation over time).

2.4 Use of environmental modelling for chemicals withdrawn from the global market

34. For chemicals that have been long withdrawn from the global market, such as chlordecone and hexabromobiphenyl, environmental concentrations and concentrations in biota may be very low. Also, data on environmental concentrations may be limited. If analytical techniques for detection in various media are still in development, concentrations may have not yet been determined. 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. Listing such chemicals under the Convention prevents their reintroduction on the global market.

35. The Committee has used information from environmental modelling in the risk profile for chlordecone¹⁶ when there were no measured environmental concentrations or concentrations in biota in remote areas as chlordecone had been long withdrawn from the global market. The assessment of the potential for long-range transport of chlordecone (table 2.2 of the risk profile on chlordecone) was based on physical properties due to lack of concentration data in remote areas. Persistence, vapor pressure and the Henry's Law Constant were considered to be the most relevant properties.

36. Modelling was also used in other risk profiles, such as those for hexabromobiphenyl,¹⁷ pentachlorobenzene¹⁸ and endosulfan,¹⁹ to strengthen the evaluation of long-range transport potential.

2.5 Evaluation of time trends of releases or concentrations in the environment in remote areas

37. An example of a risk profile for which the Committee considered time trends of exposure levels in remote areas is that for pentabromodiphenyl ether, about which it

¹⁵ UNEP/POPS/POPRC.2/17/Add.3.

¹⁶ UNEP/POPS/POPRC.3/20/Add.10.

¹⁷ UNEP/POPS/POPRC.2/17/Add.3.

¹⁸ UNEP/POPS/POPRC.3/20/Add.7.

¹⁹ UNEP/POPS/POPRC.5/10/Add.2.

was noted in the report of the Committee's second meeting:²⁰ "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".

38. Evidence or likelihood of an increase in concentrations of a chemical in the environment over time is an additional argument for the Committee to consider that global action is warranted.

3. Guidance developed by the Committee

3.1 Bioaccumulation evaluation

39. The Committee has prepared and has taken note of the "Preliminary guidance paper on bioaccumulation evaluation" for the related criteria under Annex D to the Convention²¹ as a useful aid to its work. The paper considers how to apply the bioaccumulation criteria in subparagraphs 1 (c) (ii) and (iii) of Annex D when the criterion in subparagraph 1 (c) (i) is not fulfilled.

3.2 Consideration of toxicological interactions

40. The Committee has prepared "Guidance for drafters of risk profiles on consideration of toxicological interactions when evaluating chemicals proposed for listing"²² and agreed that it could be used as guidance for drafters preparing risk profiles.

3.3 Possible impact of climate change

41. The Committee has prepared and adopted "Guidance on how to assess the possible impact of climate change on the work of the Persistent Organic Pollutants Review Committee",²³ an approach to the consideration of climate change interaction with the chemicals proposed for listing in Annexes A, B and/or C to the Stockholm Convention,²⁴ and recommendations developed on the basis of the guidance,²⁵ and it has decided to use the guidance and approach for its future evaluation of chemicals proposed for listing in Annexes A, B and/or C to the Stockholm Convention.

²⁰ UNEP/POPS/POPRC.2/17, para. 47.

²¹ UNEP/POPS/POPRC.3/20, annex VI.

²² UNEP/POPS/POPRC.8/16, annex V.

²³ UNEP/POPS/POPRC.9/INF/15.

²⁴ Decision POPRC-9/8, annex I.

²⁵ Decision POPRC-9/8, annex II.