SC

UNEP/POPS/POPRC.4/INF/11

Distr.: General
18 August 2008

English only

Stockholm Convention on Persistent Organic Pollutants

Persistent Organic Pollutants Review Committee
Fourth meeting
Geneva, 13–17 October 2008
Item 7 (b) of the provisional agenda*

Consideration of chemicals newly proposed for inclusion in Annexes A, B or C of the Convention: hexabromocyclododecane

Discussion paper on risk profiles: a comparative assessment of the basis for conclusions by the Review Committee

Note by the Secretariat

The annex to the present note contains a discussion paper prepared by a consultant with funding from Germany. The paper provides a detailed analysis of the basis for conclusions of the first 10 risk profiles prepared by the Committee and makes recommendations for consideration by the Committee. The paper is being circulated as submitted and has not been formally edited.

* UNEP/POPS/POPRC.4/1.

** Stockholm Convention, Article 8, paragraph 1.

K0841615 270808

Annex

Discussion paper on risk profiles: A comparative assessment of the basis for conclusions by the Review Committee

I. Background

1. Under the provisions of the Stockholm Convention, a substance which has been proposed for addition to Annexes A, B or C of the Convention, and has passed the screening criteria set forth under Annex D, moves forward to a fuller review 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". The mechanisms and data requirements for evaluation by the POPRC for a Risk Profile are provided in Article 8 Paragraphs 4 (a), 6, 7 (a) (b) and Annex E of the Convention respectively.

2. As of May 1, 2008, ten substances (single chemicals or mixtures of chemicals) have been proposed for addition to the Convention's control annexes:

Lindane
alpha-hexaclorocyclohexane (a-HCH)
beta-hexaclorocyclohexane (b-HCH)
Chlordecone
Commercial octabromodiphenyl ether (C-OBDE)
Hexabromobiphenyl (HBB)
Commercial pentabromodiphenyl ether (C-PBDE)
Pentacchlorobenzene (PeCB)
Perfluorooctanesulfonate (PFOS)
Short chain chlorinated paraffins (SCCP)

3. Nine of the ten have resulted in a conclusion that the proposed substance is a persistent organic pollutant (POP) as defined by the Stockholm Convention and Risk Management Evaluations have been developed or are under development. The POPRC agreed to gather additional data on toxicity and eco-toxicity for one substance, short chain chlorinated paraffins (SCCPs), prior to deciding whether or not the substance was a POP.

4. The objectives of this paper are:

(a) To examine the conclusions presented in nine completed Risk Profiles and one draft Risk Profile;

(b) To compare the data and logic used by the POPRC in forming its conclusions; and

(c) To provide recommendations for consideration by the POPRC on changes to the Risk Profile evaluation process.

II. Annex E Considerations

5. Annex E of the Convention describes the purpose and general content needs of a Risk Profile. A Risk Profile shall "*further elaborate[s] on, and evaluate[s], the information referred to in Annex D and include[s], as far as possible, the following types of information:*

(a) *Sources, including as appropriate:*

(i) *Production data, including quantity and location;*

(ii) *Uses; and*

(iii) *Releases, such as discharges, losses and emissions;*

(b) *Hazard assessment for the end points or endpoints of concern, including a consideration of toxicological interactions involving multiple chemicals;*

(c) *Environmental fate, including data and information on the chemical and physical properties of a chemical as well as its persistence and how they are linked to its environmental transport, transfer within and between environmental compartments, degradation and transformation to other chemicals. A determination of the bio-concentration factor or bio-accumulation factor, based on measured values, shall be available, except when monitoring data are judged to meet the need;*

(d) *Monitoring data;*

(e) *Exposure in local areas and, in particular, as a result of long range environmental transport, and including information regarding bioavailability;*

(f) *National and international risk evaluations, assessments or profiles and labelling information and hazard classifications, as available; and*

(g) *Status of the chemical under international conventions."*

6. A Risk Profile is intended to build on the work undertaken through evaluation of the Annex D elements provided in the proposal. Annex E is only semi-prescriptive, inasmuch as it outlines general content and recognizes that this content should include *'as far as possible'* the elements it lists. Nor is it limiting, i.e., it recognizes that the list of elements refers to *'types of information'*. Inherently, other relevant information which might improve the strength of a conclusion is welcome.

7. Annex E also anticipates the need for evaluation of the individual elements in a dynamic and integrative manner. For example, the Risk Profile should only contain source data on production, use and release *'as appropriate'*; the hazard assessment need not contain all that is known about effects and may focus on *'endpoints of concern'*; measured values of bio-concentration and bio-accumulation are required except when monitoring data are *'judged to meet the need'*; and, the Risk Profile should list other risk evaluations, assessments , profiles, labelling information and hazard classifications, *'as available'*.

8. The conclusions forthcoming from a completed Risk Profile are to be based on expert judgement of the members of the POPRC. The Committee focus is on the significant data under the element headings in Annex E which define whether or not the substance should be named as a POP under the Convention. Article 8 (7) (a) is clear that: *'Lack of full scientific certainty shall not prevent the proposal from proceeding'*. Socio-economic considerations are not included in the Risk Profile because they do not contribute to defining a POP; they are considered by the Committee (see Article 8 (7) (a) and (9) and Annex F of the Convention) in control or management recommendations to the Conference of the Parties after the Risk Profile has been adopted and a conclusion has been reached that the substance warrants global action.

9. Risk Profiles were intended to be up-dated summaries key information found in existing national and international chemical assessment documents. POPRC Risk Profiles were also not intended to be lengthy reports because of the potential workload for Parties to draft the profiles and the time needed by POPRC Members to review documents in plenary and in small group meetings. There is a practical administrative limit of 20 pages of text (excluding the cover and references) for a Risk Profile (see UNEP/POPS/POPRC.3/19 and paragraph 30 of UNEP/POPS/POPRC.3/20). This relates to the United Nations policy on translation of documents and is designed to keep operating costs for meetings as low as possible while maintaining a high level of information available in six languages. Supplementary information related to Risk Profiles may be distributed to meeting participants as INF documents in English only.

III. Evaluation of Summary Rationale provided in Risk Profiles for Concluding that a Chemical Warrants Global Action

10. Each Risk Profile contains a 'Synthesis of Information' and a 'Concluding Statement' to make the case why the POPRC considered that global action is warranted. These statements provide a combined weight-of-evidence argument for the conclusion drawn. **Table 1** shows a listing of the key components used in these two summary sections. The absence of an 'x' does not indicate that the main text of the Risk Profile was necessarily missing this information. Rather, it indicates that the information or logic was not used in the summarizing statements. Additional data on some document parameters (format and style) are provided in **Table 2**.

11. **Appendix 1** to this report provides tabulated data taken from the nine adopted Risk Profiles and the one draft Risk Profile. Data used in the Risk Profiles is grouped by subsection headings according to the listing in Annex E. This information permits a systematic and comparative review of the basic data

used for evaluation according to the general guidance provided in Annex E of the Convention. The data in **Appendix 2** can also be used as a rough cross check with the summary of key components found in the summary rationales shown in **Table 1**, i.e., were the data available in the body of the Risk Profile for use in the summarizing statement.

A. Main Findings

12. Review of the data collected and presented in Table 1 indicates that, in general:

(a) all Risk Profiles were based on chemicals which had meet the Annex D criteria even though only (4/10) considered that it was important to repeat this information in the rationale;

(b) most Risk Profiles identified production and use issues (7/10) and stockpile/waste issues (8/10) as a significant element of the conclusion;

(c) degradation or transformation issues were identified in the rationales for PFOS and C-OBDE but not for Chlordecone which can degrade from Kevelan according to its Risk Profile (see Appendix Table A);

(d) long range transport , i.e., world wide distribution (6/10), model derived (8/10) or measured levels in remote locations (5/10), was confirmed in the rationale of 9 substances but not for C-OBDE (even though there is evidence of levels of several brominated compounds increasing in several countries as shown in Appendix Table D);

(e) all 10 rationales identified that the substance under review was persistent and bio-accumulative;

(f) all rationales except HBB indicated that measured levels had been found in wildlife or domestic animals near or remote from use/production/waste sites even though there is little evidence of these data for Chlordane (see Appendix Table D);

(g) only 5/10 rationales indicated that measured levels had been found in human tissues near or remote from use/production/waste sites even though the Risk Profiles reported that up to 7 or 8 chemicals were found in human tissues in remote locations (see Appendix Table D, E);

(h) four of the substance rationales (C-PBDE, a-HCH, b-HCH, PeCB) indicated that levels in the environment were either increasing or not decreasing;

(i) all substance rationales, except for PFOS, mentioned effects on laboratory animals even though the Risk Profile for PFOS does provide some toxicology data (see Appendix Table B);

(j) consistent with the Risk Profiles, very few substance rationales identify observed effects in biota (3/10) or human (1/10) populations at actual exposure concentrations;

(k) all five of the substances identified in the Risk Profiles as 'possibly carcinogenic for humans' are identified in the rationales as being of concern because of their carcinogenic potential;

(l) only one substance (HBB) is noted as an endocrine disruptor in the rationales, even though in the Risk Profiles, 5/10 substances are identified as having endocrine mediated toxicity;

(m) most rationales (7/10) mention the concept of relative risk (the ratio of the ambient exposure to estimated safe exposure levels) even though this was more common for biota (7/10) than for human populations (3/10);

(n) only two substance rationales (Lindane and b-HCH) mention the potential for interactive effects of contaminants as a factor of concern;

(o) four substances use comparisons with other POPs as part of a rationale for concern;

(p) although 9/10 Risk Profiles mention that one or more international chemical control instruments are in use or under development (see Appendix Table F) , only 3 substance rationales include this aspect;

(q) one substance rationale (C-OBDE, which only has a little toxicology data and is subject to degradation to lower brominated substances) mentions that despite a lack of full scientific certainty, this should not prevent the proposal from proceeding to the control phase under the Convention. One other Risk Profile (Chlordecone) indicated that there was only modelling data to support long range transport and that the lack of actual data should not prevent a conclusion; however, this was not mentioned in the summary rationale for Chlordecone. The draft Risk Profile for SCCP has not been

finalized and may require more toxicity and exposure data (currently being collected intersessionally); and

(r) a slightly larger number of key components were used to develop the rationale for global control in Risk Profiles adopted at POPRC 3 (12.7 ± 2.4) than at POPRC 2 (10.5 ± 5.7, see Table 1);

Table 1. Key components cited in the summary rationale for each Risk Profile

Critical Component Mentioned	Lindane[1]	HBB[1]	C-PBDE[1]	PFOS[1]	a-HCH[2]	b-HCH[2]	Chlordecone[2]	C-OBDE[2]	PeCB[2]	SCCP[2]
Meets Annex D Criteria		x	x				x		x	
Production and use issue	x	x	x	x			x		x	x
Stockpile or waste problem	x	x	x	x	x	x		x	x	
Degradation or transformation product(s) an issue				x				x		
World-wide environmental distribution	x		x		x	x			x	x
Measured levels in air, water, soil or sediment remote from source which indicate long range transport			x	x	x				x	x
Modelling data which indicate long range transport	x	x		x	x	x	x		x	x
Persistent in the environment	x	x	x	x	x	x	x	x	x	x
Bio-accumulative (measured or predicted)	x	x	x	x	x	x	x	x	x	x
Measured levels in wildlife or domestic animals near use, production or waste sites	x		x		x	x	x		x	x
Measured levels in wildlife or domestic animals far from use, production or waste sites	x		x	x	x	x		x	x	x
Measured levels in human tissues near use, production or waste sites	x		x		x	x				x
Measured levels in human tissues far from use, production or waste sites	x		x		x	x				x
Environmental, wildlife or human levels increasing or not declining			x		x	x			x	
Health effects in laboratory species	x	x	x		x	x	x	x	x	x
Health effects in wildlife at ambient concentrations	x			x		x				

Critical Component Mentioned	Lindane[1]	HBB[1]	C-PBDE[1]	PFOS[1]	a-HCH[2]	b-HCH[2]	Chlordecone[2]	C-OBDE[2]	PeCB[2]	SCCP[2]
Health effects in humans at ambient or occupational concentrations	x									
Confirmed, probable, possible human carcinogen	x	x			x	x	x			
Endocrine disruption is an issue		x								
Health risk ratio (exposure:safety level) close to or >1 in wildlife	x		x	x	x	x		x		x
Health Risk ratio (exposure:safety level) close to or >1 in humans	x					x		x		
Possibility of chemical interactions (additivity, synergism)	x					x				
Comparison with other POPs (toxicity, levels, structure, etc.)	x						x	x		x
Regulated under other international instrument		x					x			x
Application of precaution								x		
Total key components cited	**18**	**10**	**14**	**10**	**14**	**16**	**10**	**10**	**12**	**14**
Mean (SD)	**10.5 (5.7)**				**12.7 (2.4)**					

1 Evaluated at POPRC 2
2 Evaluated at POPRC 3

Table 2. Document parameters for POPRC Risk Profiles

Chemical	Length (Pages)	References Listed	Use of Summary Data Tables		
			None	Some	Many
Lindane[1]	12	61		X	
HBB[1]	19+ 6 (annexes)	27		X	
C-PBDE[1]	24	154			X
PFOS[1]	17	43			X
Mean (SD)	**19.5 (6)**	**71 (57)**			
a-HCH[2]	13	116		X	
b-HCH[2]	13	96		X	
Chlordecone[2]	18	24			X
C-OBDE[2]	14	89	X		
PeCB[2]	15	99	X		
SCCP[2]	17	107		X	
Mean (SD)	**15 (2)**	**87 (32)**			

1 Evaluated at POPRC 2
2 Evaluated at POPRC 3

IV. General Evaluation of the Content and Form of Current Risk Profiles

13. Risk Profiles follow a format adopted by the POPRC at its first meeting in 2005 (UNEP/POPS/POPRC.1/10/EXC/AnnexIV). How and what information is used under the headings is up to the drafting team and the Members of the POPRC. As a result, data reported in one Risk Profile may not be reported in the same way in another. For example, under the headings related to production and use, some Risk Profiles describe the production process and past uses, others describe the quantities produced (past and/or present) and current uses, and another a combination of both. There are also inconsistencies in how physical/chemical properties, levels, effects and relative risks are reported; some appear in great detail in text, others are summarized in data tables and still others are noted only by a reference to a particular study. The combination of these elements are important for determining whether, due to past or present use, long range transport and bioaccumulation, exposures are likely to increase or decline and the extent to which they pose, or may pose, a risk to human health and the environment.

14. Not all Risk Profiles attempted to compare exposure in the environment to health guidelines or levels of concern. Those that did, used different methods or cited a range of approaches. Understanding current or future safety margins is a critical component of the Risk Profile.

15. Reporting of exposures in toxicology studies varies between and within Risk Profiles. For example, significant figures vary, units may be expressed as mg/kg rather than as mg/kg bwt/d, some references are to mg/L and others are to ug/L and identification of wet weight versus lipid weight values are occasionally missing. These differences can make the data very difficult to read and assess without returning to the original references.

16. While most effect levels used in the Risk Profiles come from repeat dose exposures (sub-chronic or chronic), the effect levels themselves are frequently reported inconsistently. Some effect levels are reported incorrectly as ‘no-observed-adverse-effect-levels’ (NOAELs) when they are ‘no-observed-effect-levels’ (NOELs) and vice versa. The same applies to some reports of LOAELs (lowest-observed-adverse-effect-levels), LOELs, NOAECs (no-observed-adverse-effect-concentrations) and NOECs.

17. There is very little attention paid in the Risk Profiles to the potential for interactive effects between POPs, especially those which appear to have dioxin like activity (growth and development impacts, thyroid changes, liver damage). Endocrine mediated effects are reported in toxicology studies for several substances reviewed. This mode of action can be critical for successful reproduction and early neurological development.

18. In addition to these scientific and technical findings, a number of general format and style issues are evident:

(a) the mean number of text pages per Risk Profile adopted at POPRS 2 (19.5 pages) has declined slightly for Risk Profiles at POPRC 3 (15 pages) while the mean number of references has increased moderately between the two groups of Risk Profiles (71 to 87, Table 2); and

(b) better use of tables to present data on chemical properties, levels in the environment/biota/human populations, effects, risk ratios, etc. occurred in the first four profiles prepared and adopted at POPRC 2 (Tables 2).

V. Conclusions and Recommendations

A. Use of up-to-date peer reviewed science

19. Risk Profiles appear to be building on existing international hazard or risk assessments. A substantial number of references have been used in the POPRC risk profiles, many adding data from recent peer reviewed publications. The POPRC Risk Profiles currently prepared appear to be making appropriate use of new science. A focus on the best and most recent data will provide the POPRC with the best opportunity to decide whether or not a substance warrants global control under the terms of the Convention at this time.

Recommendation: *The Committee should continue to use the most recent and reliable peer reviewed data to update existing international hazard and risk assessments.*

B. Tabulation of critical data elements

20. Data presentation can be a problem in Risk Profiles limited to only 20 text pages. Since Risk Profiles are intended to be based on existing international hazard and risk assessments and to update areas of critical importance for evaluation by the POPRC, it would be helpful to focus on the best and the critical data. Standardization of terms, abbreviations and data types of key interest and consistent application of units would also help comprehension of the Risk Profiles and cross comparison of substances. Listing these data in tables (see the Risk Profile for Chlordecone as an example) could make preparation and review simpler and eliminate lengthy descriptions of study methods and conditions. All tabulated data would need to be referenced to the original study and special attention needs to be paid to units. Data tables could include:

(a) Chemical/physical properties

(b) Production volumes, quantities in use and dates

(c) Manufacturers (current and historical) and dates

(d) Persistence and bio-concentration/bioaccumulation values (measured, derived)

(e) Levels in the air, water, soil, sediment, in biota (some lower and upper trophic levels from the aquatic and terrestrial ecosystems) and in human populations (blood or breast milk) for local and remote locations

(f) Estimates of exposure (aquatic species, top of the food chain predators, human populations in local and remote locations)

(g) Effect levels (NOAELs, NOAECs) for multi day (sub-chronic or chronic) exposures for key laboratory species (e.g., crustaceans, fish, birds, rats, mice)

(h) Calculated risk ratios or safety margins for animals and humans and the estimated reliability of the calculation

(i) International control instruments being used or proposed to be used for management of the substance

Recommendation: *The Committee should consider undertaking intercessional work to develop clearer guidelines on terms, units, abbreviations, and key data elements. This intercessional group could also address the issue of data tables by defining more precisely information type, quantity and quality.*

C. Evaluating mixtures of substances

21. Several current Risk Profiles have evaluated complex mixtures of chemicals (e.g., commercial C-PBDE, OBDE, SCCPs,) or chemicals which are ultimate breakdown products of other parent compounds (e.g., PFOS, Chlordecone). These are technically difficult to evaluate because:

(a) Metabolic and abiotic degradation pathways and rates are unclear under real time ecosystem conditions;

(b) How and what is transported long range is uncertain; and

(c) The toxicity of mixtures and transitional metabolites is hard to measure.

22. How a proposed substance might be listed could focus on the precursor(s), the mixture or the degradation products. The committee has considered this issue in part at its second meeting (UNEP/POPS/POPRC.2/4).

Recommendation: *The Committee should attempt to provide chemical, physical and biological data for the critical product(s) together with the pathways and rates of degradation in the Risk Profile. This would enable the POPRC to more fully evaluate which substance(s) may lead to the greatest risk and require global control.*

D. Interactions between POPs

23. The physical and chemical properties of POPs place them in many of the same sub-regions, in the same environmental media and in the same species concurrently. Evaluating individual POPs must take into account their presence with other POPs of different type and origin. While the predominant modes of action of POPs can differ, many can be grouped together because they cause similar effects (e.g., chlorinated dioxins, chlorinated biphenyls and brominated biphenyls). However, not all POPs have similar potencies, i.e., they may cause similar effects but at different exposure doses, which has lead to evaluation techniques which employ 'toxicity equivalents' for different congeners of different chemicals which have similar modes of action. Some research indicates that some POPs potentiate specific effects, others cause an effect outright. How these POPs interact, i.e., additively, antagonistically, or synergistically, is difficult to determine toxicologically because there are so many possible test combinations, so many adverse effects to test, wide variations in species responses, dissimilar laboratory and ecosystem conditions, and different responses to acute and chronic exposures.

Recommendation: *The Committee should investigate how they might factor multiple chemical exposures into assessments of substances proposed for addition to the Convention.*

E. Evaluating Bioaccumulation and Bio-magnification

24. Measured bio-concentration factors, measured lipophilicity, calculated bio-accumulation factors, and the use of monitoring data for inferring environmental bio-accumulation and bio-magnification have recently been discussed by the POPRC (October 2007). A paper presented by Dr. M. Kitano (Japan) provided recommendations for how to interpret data under varying conditions (UNEP/POPS/POPRC.3/INF/8). Evaluating bio-accumulation and bio-magnification are critical to a conclusion that a substance warrants global action.

Recommendation: *Past recommendations on the interpretation of data related to environmental bio-accumulation and bio-magnification should be revisited during the drafting of future Risk Profiles.*

F. Preparations of summary rationales

25. 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. In the ten Risk Profiles reviewed, most had comprehensive summary rationales which drew on the critical data elements contained within the body of the report and linked them into an overall weight of evidence. However, not all summary rationales made full use of the data in the body of the report. The logic applied and described in the 'Synthesis of Information' and 'Concluding Statement' of a Risk Profile is likely to be the most carefully examined text in each report. Parties and observers to the Convention will need to be convinced that the case is strong.

Recommendation: *The Committee may wish to consider the data element listed in Table 1 as a check list for developing the 'Synthesis of Information' and 'Concluding Statement' of a Risk Profile to ensure that they have considered all the available data in the profile and linked it convincingly.*

G. Length of Risk Profiles

26. Currently, only two risk profiles (HBB and C-PBDE) have exceeded the 20 page text limit; most have been between 12-18 pages. The 20 page limit for Risk Profiles appears to be workable. This will keep drafting workloads from becoming too onerous and should encourage Parties to consider working together to draft documents for the POPRC to review. This will also help to keep translation costs down.

Recommendation: *The 20 page limit for Risk Profiles should be maintained*

VI. References

UNEP/POPS/POPRC.1/10/EXC/AnnexIV Risk Profile outline

UNEP/POPS/POPRC.2/4 Consideration of chemicals the transformation products of which are chemicals proposed for listing in Annexes A, B or C of the Convention

UNEP/POPS/POPRC.2/17/Add.1 Risk Profile for commercial pentabromodiphenyl ether

UNEP/POPS/POPRC.2/17/Add.3 Risk Profile for hexabromobiphenyl

UNEP/POPS/POPRC.2/17/Add.4 Risk Profile for lindane

UNEP/POPS/POPRC.2/17/Add.5 Risk Profile for perflurooctane sulfonate

UNEP/POPS/POPRC.3/INF/8. Additional information related to assessment of bioaccumulation data under Annex D of the Convention: Discussion Paper on Bioaccumulation Evaluation prepared by Masaru Kitano, Meiji University. 16 pp including Appendices. Stockholm Convention Web Site

UNEP/POPS/POPRC.3/16/Rev.1 Revised draft Risk Profile for short-chain chlorinated paraffins

UNEP/POPS/POPRC.3/19 Translation costs and document length

UNEP/POPS/POPRC.3/20 Report of the Persistent Organic Chemicals Review Committee on the work of its third meeting

UNEP/POPS/POPRC.3/20/Add.6 Risk Profile for commercial octabromodiphenyl ether

UNEP/POPS/POPRC.3/20/Add.7 Risk Profile for pentachlorobenzene

UNEP/POPS/POPRC.3/20/Add.8 Risk Profile for alpha hexachlorocyclohexane

UNEP/POPS/POPRC.3/20/Add.9 Risk Profile for beta hexachlorocyclohexane

UNEP/POPS/POPRC.3/20/Add.10 Risk Profile for chlordecone

Appendix 1 Comparative tables of information provided in nine Risk Profiles prepared by the POPRC

Information in the following tables has been taken directly from Risk Profiles adopted by the POPRC or from documents provided for the use of the POPRC (see Table C, and UNEP/POPS/POPRC.3/INF/8). It is a short summarization and comparison of key information. Details (range of values, authors, species specific information, etc.) and verification should come directly from the actual Risk Profile.

The tables cover the following substances: Lindane, alpha-hexachlorocyclohexane (a-HCH), beta-hexachlorocyclohexane (b-HCH), Chlordecone, commercial octabromodiphenyl ether (C-OBDE), hexabromobiphenyl (HBB), commercial pentabromodiphenyl ether (C-PBDE), pentachlorobenzene (PeCB), perfluorooctane sulfonate (PFOS), short chain chlorinated paraffins (SCCP)

Table A. Annex E (a): Sources

Chemical	Production Quantity (i)			Production Locations (i)		Overall Uses (ii)			Total Releases (iii)		
	Small	Medium	Large	Few	Many	Few	Several	Many	Small	Medium	Large
Lindane		Declining production and use. Estimated at 3,222 tons/yr (1995)		Probably 2-3 manufacturers.			Public health and agricultural use for ecto-parasites, seeds, soils and trees.				2005 estimate of 4.3 million tons in technical HCH residual.
a-HCH	Only as component of HCH or Lindane, quantities unknown			HCH prod'n sites unknown, but probably few		No uses, except as a component of technical HCH					2005 estimate of 4.3 million tons in technical HCH residual.
b-HCH	Only as component of HCH or Lindane, quantities unknown			HCH prod'n sites unknown, but probably few		No uses, except as a component of technical HCH					1990 estimate of 9.8 million tons in technical HCH residual.

Chemical	Production Quantity (i)			Production Locations (i)		Overall Uses (ii)			Total Releases (iii)		
	Small	Medium	Large	Few	Many	Few	Several	Many	Small	Medium	Large
Chlordecone	Production quantity unknown, probably small.			Formerly USA and Brazil.			Agricultural insecticide and household pests (ants and roaches).			No estimate. Dispersive pesticidal use in the environment. Breakdown product of Kelevan. Loss from one manufacturing site in USA was extensive.	
C-OBDE	Production has declined to <4000 T/yr			Unknown, perhaps in and some developing countries			Added as a flame retardant to a wide variety of materials and products.			Majority of releases are in discarded products containing flame retardants.	
HBB	As of 2006, production has ended in most countries, if not all.			Unknown, production may be occurring in developing countries or those with economies in transition.			Added as a flame retardant to cable coatings and polyurethane foam.			Majority of releases are in discarded products containing flame retardants.	
C-PBDE	Most known production has declined significantly. Estimated as 7.5- 70 KT/yr in 2001.			Unknown.			Added as a flame retardant to coatings, furnishings, textiles, plastics, foams, and electrical equipment.			Majority of releases are during application to products and in discarded products containing flame retardants.	

Chemical	Production Quantity (i)			Production Locations (i)		Overall Uses (ii)			Total Releases (iii)		
	Small	Medium	Large	Few	Many	Few	Several	Many	Small	Medium	Large
PeCB	Unknown, probably very small			No known production in Europe or North America		Few current uses. Was used in PCBs, dyes, herbicides and perhaps as an inter-mediate.			Global releases estimated at 85T/yr in 2007. Wastes and incineration of products containing PeCBs are issues.		
PFOS	US production (3M) ceased in 2003. World production unknown.			Probably still produced in Japan, Brazil and possibly other countries.			Widespread uses in manufactur-ing and in products as surface-acting agents.			Production sites, fire-fighting foams, sewage and degradation of PFOS-related substances	
SCCP	Reported consumption in NA and Europe was about 12 KT/yr in 1990s				Several pro-ducers around the world		Widespread uses in metal working, sealants, paints, adhesives, flame retardants, textiles, polymers			Production sites and product losses are extensive.	

Table B. Annex E (b): Hazard Assessment

Chemical	Endpoints of Concern	Guidance Values*	Interactions
Lindane	Hepatotoxic, neurotoxic, immunosuppression, haematological effects, endocrine mediated toxicity, reproductive toxicity, fetotoxic, cancinogenic (IARC, 2B), tumor promotion in mammals.	NOAEL not provided for mammals. NOAEC 2.9 - 54 ug/L in invertebrates and fish USEPA Level of Concern (non-cancer effects): 1.6 ug/kg bwt/d	Unknown. Lindane may contain <1% of a-HCH and b-HCH.
a-HCH	Hepatotoxic, neurotoxic, immunosuppression, cancer (IARC, 2B), tumor promotion in mammals.	NOAEL 0.1 – 2.5 mg/kg bwt/d in mammals. NOEC not provided. USEPA Level of Concern (non-cancer effects): 0.06 ug/kg bwt/d	Unknown. Found in combination with b-HCH and g-HCH isomers
b-HCH	Hepatotoxic, neurotoxic, immunosuppression, endocrine mediated toxicity, reproductive toxicity, cancer (IARC, 2B), tumor promotion in mammals.	NOAEL 0.1 mg/kg bwt/d in mammals. NOEC 32 ug/L in fish USEPA Level of Concern (non-cancer effects): 1 ug/kg bwt/d	Unknown. Found in combination with a-HCH and g-HCH isomers
Chlordecone	Hepatotoxic, neurotoxic, haematological effects, endocrine mediated toxicity, reproductive toxicity, fetotoxic, cancinogenic (IARC, 2B), tumor promotion in mammals. Highly toxic to lower aquatic life	NOAELs between 0.5 - 5 mg/kg bwt/d in mammals NOEC 25 ug/L in daphnia	Unknown. Strongly related chemically to Mirex and can occur as a breakdown product of Kelevan.
C-OBDE	Fetotoxic, neurotoxic (mammals); immune modulation (birds)	NOAELs between 2 - 15 mg/kg bwt/d in mammals. NOEC not provided.	Aquatic effects could be greater if the food exposure route were included. C-OBDE is a complex mixture of brominated congeners. Breakdown to hexaBDE may pose additional risk.
HBB	Hepatotoxic, thyroid toxicity, enzyme induction, endocrine mediated toxicity, reproductive toxicity, fetotoxic, cancinogenic (IARC, 2B), tumor promotion mammals.	NOAELs between 0.04 - 14.3 mg/kg bwt/d in mammals. NOEC not provided.	Probable, mode of action very like PCBs and PCDDs.
C-PBDE	Hepatotoxic, thyroid toxicity, endocrine mediated toxicity, reproductive toxicity, neurotoxicity (pentaBDE) in mammals.	NOAELs between 0.06 - 3 mg/kg bwt/d in mammals. NOEC not provided. Risk quotients: benthic organisms, 45.2 wildlife consumers, 149	BDE-47 and BDE-99 most toxic and behave somewhat like PCBs.
PeCB	Hepatotoxic, nephrotoxic, fetotoxic in mammals. Highly toxic to aquatic life.	NOAELs between 2.4 - 24 mg/kg bwt/d in mammals. NOECs 2 – 14 ug/L in fish and crustacean. Risk ratios between 1 and <0.01	Unknown.

Chemical	Endpoints of Concern	Guidance Values*	Interactions
PFOS	Fatalities in most experiments reported, reproductive effects, fetotoxic, embryotoxic, hepatotoxicity, thymic atrophy in mammals. Highly toxic to some aquatic species.	LOAELs 0.07 - 2 mg/kg bwt/d and NOAEL 0.1 mg/kg bwt/d in mammals. NOEC 50 - 300 ug/L in chironomids and fish.	Unknown. PFOS precursors, which may not be very toxic, will ultimately degrade to PFOS.
SCCP	Hepatotoxicity, nephrotoxic, thyroid toxicity in mammals. Highly toxic to most aquatic species.	NOAEL 10 mg/kg bwt/d in mammals. NOEC 5 - 7.3 and ug/L in daphnia and mysids	Unknown.

***** NOAEL : No observed adverse effect level in a laboratory study

NOAEC : No observed adverse effect concentration in a laboratory study

NOEC : No observed effect concentration in a laboratory study

Table C. Annex E (c): Environmental Fate

Chemical	Phys/Chem Properties	Persistence	Env. Transport	Degradation/Transformation *	BCF/BAF/Monitoring*
Lindane	Well documented	Half-life: 2.3d-96d (air) ; 3d-300d (water) ; 2yr-3yr (soil). Hydrolytic degradation very slow especially at lower temperature (1.1-110 yr). No appreciable photolysis.	Release from contaminated soil and use of HCH/Lindane. Atmospheric long range transport to the Arctic.	Unproven transformation to a-HCH. Biological half life: 0.71 d – 2 d	BCF: 3-20,000 and 327-893 cited. Bio-accumulates in top of the food chain mammals and in human breast milk around the world, especially in the Arctic.
a-HCH	Well documented	Hydrolytic degradation very slow especially at lower temperature (0.8-63 yr). No appreciable photolysis.	Release from contaminated soil and use of HCH/Lindane. Atmospheric long range transport in the Arctic and retention in cold Arctic water.	No significant transformation product. Biological half life: 1.6 d - 6.9 d	BCF: 60-13000 Bioaccumulates in top of the food chain mammals and in human breast milk around the world, especially in the Arctic.
b-HCH	Well documented	Hydrolytic degradation very slow especially at lower temperature (no values provided). No appreciable photolysis. More persistent than a-HCH	Release from contaminated soil and use of HCH/Lindane. Atmospheric long range transport, rain deposition, ocean currents and retention in cold Arctic water.	No significant transformation product. Biological half life: 2.5 d – 154 d	BCF: 250-1500 Bioaccumulates in top of the food chain mammals and in human breast milk around the world, especially in the Arctic.

Chemical	Phys/Chem Properties	Persistence	Env. Transport	Degradation/Transformation *	BCF/BAF/Monitoring*
Chlordecone	Well documented	Not expected to hydrolyse or biodegrade in aerobic aquatic environments or in soil, perhaps some anerobic degradation. Very stable chemical	Some local transport bound to dust. High stability. Comparison method (using other POPs) indicates LRT is possible. Combined air borne particles and water current transport of sediment particles may occur along with biotic transport in oceans.	Also formed from the breakdown of Kelevan. Biological half life: 8.5 d – 165 d; also reported in workers as 63 – 148 days (Risk Profile).	BCF: 6.2-60,200 Little remote monitoring data.
C-OBDE	Well documented	No aerobic degradation of hexa- to nonaBDE. Anerobic degradation of Deca- and nonaBDE to octaBDE. Higher brominated BDEs may photodecompose quickly (2 hours).	Hexa- to nonaBDE will bind to airborne particles and be removed by wet or dry deposition. Modeling indicates environmental transport similar to other POPs.	Higher brominated BDEs may photodegarde to penta- and tetraBDE. Biological half life: 100 d	BCF: <10-36 Some remote monitoring data.
HBB	Well documented	No or low degradation in water, soil or sediment (lab and field data). Probably little in air. Highly persistent.	Modelling data and levels in the environment support LRT.	Biological half life: 22 d - >35,000 d lab animals 8-12 yrs in humans	BCF: 47-18,100 and 4,700 – 16,000 Some HBB found in whales in the North Atlantic.
C-PBDE	Well documented	Half-lives estimated by model indicate hexa- penta- and tetraBDE are very stable (air water, soil and sediment)	Measured in air and deposits over the ocean and land and around sources (manufacturing sites and environmental sinks). PBDEs bind to carbon but can desorb, volatilize and redeposit under specific environmental conditions.	Biological half life: Unknown	BCF: 17,700 Monitoring data from remote locations and worldwide.

Chemical	Phys/Chem Properties	Persistence	Env. Transport	Degradation/Transformation *	BCF/BAF/Monitoring*
PeCB	Well documented	Very persistent based on modeled and measured half-lives in air, water, soil and sediment.	Comparison method (using other POPs) indicates LRT is possible. Also measured in air and deposits over the ocean and land and around sources (manufacturing sites and environmental sinks). Also found in the environment and biota in remote regions.	Biological half life: 53 d	BCF: 577-23,000 Monitoring data from remote locations and worldwide.
PFOS	Well documented	PFOS is extremely persistent. It does not hydrolyze, photolyze or biodegrade in any environmental test.	Not very volatile and probably travels bound to particles (very surface active) and not as a gas. PFOS precursors may volatilize and travel before they degrade to PFOS in situ.	Biological half life: 13.6 d - 1,428 d	BCF: 240-3,100 and 200 – 1,500 Monitoring data from remote locations and worldwide.
SCCP	Well documented	Persistent in sediment and air. Unknown persistence in water or soil.	Comparison method (using other POPs) indicates LRT is possible, predominantly by air. Also measured in air over the ocean and land in the Arctic. Also found in the environment and biota in remote regions.	Biological half life: 7.1 d – 86.6 d	BCF: <1 -138,000 and 2,500 – 11,000 Monitoring data from remote locations and worldwide.

***** Data taken from UNEP/POPS/POPRC.3/INF/8

Table D. Annex E (d): Monitoring Data

Chemical	Aquatic	Aerial	Terrestrial	Humans
Lindane	>0.1 ug/kg ww	>10 ug/g ww	Cows milk: 2-187 ug/kg lipid	Breast Milk: 84 ug/kg lipid (India); 0.23 ug/kg lipid (Australia); 1-100 ug/L ww (Mexico)
a-HCH	>10 ug/kg ww	>10 ug/g ww	Cows milk: 1-200 ug/kg lipid Polar Bears: 600 ug/kg lipid (Alaska), 290 ug/kg lipid (Hudson Bay, Canada). Levels not declining.	Breast Milk: 190 ug/kg lipid (Finland); 510 ug/kg lipid (Denmark); 45 ug/L ww (India)
b-HCH	>10 ug/kg ww	19-5500 ug/kg ww (migratory birds)	Polar bears: 770 ug/kg lipid (Canada). Levels no decreasing	Breast Milk: 40-3100 ug/kg lipid (Arctic region)
Chlordecone	Fish: 12 -2008 ppb (national sampling in the USA)	Not provided. Very little monitoring data available.	Not provided. Very little monitoring data available.	Blood: Occupationally exposed individuals, 0.0 - 32 mg/L ww
C-OBDE	Fish: 11 – 53 ug/kg lipid (Great lakes)	Birds: Increasing levels from 6.7 ug/kg ww in 1981 to 195.6 ug/kg ww in 2000 (BDE 153, 154, 183; Great lakes); about 1 ug/kg ww for each of BDE 153, 154, 183 (Norway)	Cows milk: 0.03 ug/kg (ww or lipid unknown)	Blood: Increasing levels from 0.5 ug/kg lipid in 1977 to 48 ug/kg lipid in 1998 (sum of congeners; Norway); mean value of 7.2 ug/kg lipid (Spain)
HBB	Fish: nd – 52 (PBB 153) ug/kg lipid (Arctic)	Birds: 2 – 43 (PBB 153) ug/kg lipid (Belgium)	Cows milk: 0.03 (PBB 153) ug/kg lipid and 0.002 – 28 ug/kg lipid for penta- to octabromobiphenyl (Germany) Polar Bear: 33 -44 ug/kg lipid (Greenland) Seals: 0.3 – 8 ug/kg lipid (Arctic)	Breast Milk: 1 (PBB 153) ug/kg lipid (Germany) Breast Milk: Much higher values in Michigan, USA following accidental release.
C-PBDE	Fish: 0.2 – 77 (BDE 99) ug/kg lipid (Pacific and Atlantic Ocean)	Birds: 6 – 9,200 (BDE 99) ug/kg lipid (Scandinavia)	Polar Bear: 0.7 – 11.3 (BDE 99) ug/kg lipid (Arctic)	Breast Milk: 0.2 – 28 (BDE 99) ug/kg lipid (multiple countries) Blood: 0.8 – 2.3 (BDE 99) ug/kg lipid (multiple countries)
PeCB	None provided	Declined from 50 to 1 ug/kg ww in gulls (southern Canada)	Polar Bear: 7.9 mean ug/kg ww (Greenland) Seals: 1 - 12 ug/kg ww (Arctic)	Breast Milk: Trace amounts (I – 5 ug/kg lipid (Canada)
PFOS	Fish: 1,000 ug/kg ww (max value)	Birds: 2,570 ug/kg ww (max value)	Polar Bear:1,700 – 4,000 ug/kg ww (Canada) Arctic Fox: 6 – 1,400 ug/kg ww (Canada)	Blood: 3 - 67 ug/kg lipid (Sweden)
SCCP	Fish: 7 – 2,630 ug/kg ww	Not provided	Marine mammals: 95 – 626 ug/kg ww	Breast Milk: 4.5 - 820 ug/kg lipid (UK)

Table E. Annex E (e): Exposure (human)

Chemical	Local to Source	Remote from Source	Bioavailability
Lindane	Present in breast milk in regions with last known uses.	Present in breast milk in remote regions	Highly bioavailable
a-HCH	Present in breast milk in regions with last known uses.	Present in breast milk in remote regions	Highly bioavailable
b-HCH	Present in breast milk in regions with last known uses.	Present in breast milk in remote regions	Highly bioavailable
Chlordecone	Only reported in blood of occupationally exposed individuals	None reported in human populations in remote regions	Probably bioavailable
C-OBDE	Present in blood and breast milk	Not reported, but found in several countries studied	Highly bioavailable
HBB	Present in blood and breast milk in regions with last known uses.	Not reported, but found in several countries studied	Highly bioavailable
C-PBDE	Present in breast milk in regions with last known uses.	Present in breast milk in remote regions	Highly bioavailable
PeCB	Present in breast milk in regions with last known uses.	Present in breast milk in remote regions	Highly bioavailable
PFOS	Present in blood and milk in several countries studied	Present in blood and milk in several countries studied	Highly bioavailable
SCCP	Present in blood and milk in several countries studied	Present in breast milk in remote regions	Highly bioavailable

Table F. Annex E (f) (g): International Risk Profiles and Existing Controls

Chemical	Key International Risk Profiles Identified*	Controls (International Conventions) **
Lindane	7 (USEPA, ATSDR, NARAP, WHO, UNECE)	PIC (HCH isomers), NAACC (Lindane and HCH isomers), OSPAR (HCH isomers), UNECE (Lindane and HCH isomers), EC (HCH), EU (HCH isomers), GLBTS (HCH isomers).
a-HCH	4 (USEPA, IPCS, ATSDR, NARAP)	PIC (HCH isomers), NAAEC (Lindane and HCH isomers), EC (HCH), EU (HCH isomers), OSPAR (HCH isomers), UNECE (Lindane and HCH isomers).
b-HCH	4 (USEPA, IPCS, ATSDR, NARAP)	PIC (HCH isomers), NAAEC (Lindane and HCH isomers), EC (HCH), EU (HCH isomers), OSPAR (HCH isomers), UNECE (Lindane and HCH isomers).
Chlordecone	3 (IPCS, ATSDR)	UNECE
C-OBDE	3 (EU, Environment Canada, WHO)	OSPAR, UNECE
HBB	3 (IPCS, ATSDR)	PIC, UNECE
C-PBDE	Not listed specifically in text	PIC, OSPAR, UNECE
PeCB	Not listed specifically in text	UNECE-proposed, EC
PFOS	7 (USEPA, OECD, EU, UK-DEFRA, Environment Canada)	OSPAR, UNECE
SCCP	3 (EU, Environment Canada, UK-DEFRA)	OSPAR, UNECE

*****Key Risk profiles of the following agencies: USEPA, US Environmental Protection Agency; ATSDR, US Agency for Toxic Substances and Disease Registries; NARAP, North American Regional Action Plan; WHO, World Health Organization; UNECE, United Nations Economic Commission for Europe (POPs Protocol to the LRTAP Convention); IPCS, International Program on Chemical Safety; EU, European Union; UK-DEFRA, United Kingdom Department of Environment, Food and Rural Affairs.

******As noted above and, in addition, the following international agreements: PIC, Rotterdam Convention on Prior Informed Consent; NAAEC, North American Agreement on Environmental Cooperation; OSPAR, Convention for the protection of the marine environment of the north-east Atlantic; EU, European Union Rule; EC, European Commission Rule; GLBTS, Great Lakes Binational Toxics Strategy (US and Canada)