



**United Nations  
Environment Programme**

**Food and Agriculture Organization  
of the United Nations**

Distr.: General  
26 February 2004

English only

**Interim Chemical Review Committee**

**Fifth session**

Geneva, 2–5 February 2004

## **Report of the Interim Chemical Review Committee on the work of its fifth meeting**

### **I. Opening of the session**

1. The Interim Chemical Review Committee, hereinafter referred to as the Committee, was established pursuant to decision INC-6/2 of the Intergovernmental Negotiating Committee for an International Legally Binding Instrument for the Application of the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, adopted at its sixth session in July 1999, with a membership of 29 government-designated experts appointed on the basis of the interim prior informed consent (PIC) regions.
2. In accordance with paragraph 7 of that decision and pursuant to the provisions of articles 5, 6 and 7 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the functions and responsibilities of the Committee were to make recommendations on the inclusion of banned and severely restricted chemicals, make recommendations for the inclusion of severely hazardous pesticide formulations and prepare, as appropriate, relevant draft decision guidance documents.
3. The fifth session of the Committee was held at the Varembe Conference Centre in Geneva from 2 to 5 February 2004. The session was opened at 10.15 a.m. on Monday, 2 February 2004 by Mr. Reiner Arndt (Germany), Chair of the Committee, who welcomed all participants.
4. Opening statements were made by Mr. James Willis, Executive Secretary of the Interim Secretariat and Director, UNEP Chemicals, and Mr. William Murray, Coordinator, Rotterdam Convention, Plant Protection Service of the Food and Agriculture Organization of the United Nations (FAO), on behalf of Mr. Niek Van der Graaff, Executive Secretary of the Interim Secretariat and Chief, FAO Plant Protection Service.

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5. Mr. Willis commended the Committee on the excellent progress that it had made in its work thus far and noted that, with 58 ratifications already received, the Convention would be entering into force on 24 February 2004. Reviewing the progress of the Intergovernmental Negotiating Committee, he said that the outcome of that work would enable the Conference of the Parties, at its first session, to add up to 15 discrete chemicals to the Rotterdam Convention – a remarkable achievement, for which the Committee took much of the credit. Stressing the importance of the Committee's work at its current meeting, in particular, on the draft decision guidance documents for tetraethyl lead and tetramethyl lead and for parathion which would be forwarded to the Intergovernmental Negotiating Committee for adoption at its eleventh session and in considering alternatives for chrysotile asbestos, he wished the experts success in their deliberations.

6. Mr. Murray noted that the current session would be the Committee's last, at least as currently constituted, and that the Conference of the Parties would decide at its first session on the composition of the new chemical review committee, and he too congratulated experts on their work, which had underpinned the successful operation of the interim procedure. He drew attention to the need for the Committee to continue to refine its working procedures as the basis for recommendations on that matter to the Conference of the Parties. Recognizing the important role played by non-governmental organizations in the Committee's work, he looked forward to their continued involvement. Noting the importance of two issues forwarded for the Committee's consideration by the Intergovernmental Negotiating Committee – namely, the identification of alternatives to chrysotile asbestos and inconsistencies within Annex III of the Convention and between Annex III and decision guidance documents – he echoed Mr. Willis's wishes to the Committee for a successful meeting.

## II. Organizational matters

7. The following officers served on the Bureau of the Committee:

Chair:	Mr. Reiner Arndt (Germany)
Vice-Chairs:	Mr. Mohammed El Zarka (Egypt) Mr. Tamás Kőmives (Hungary) Ms. Kyunghye Choi (Republic of Korea)
Rapporteur:	Ms. Flor de María Perla de Alfaro (El Salvador)

8. The Committee welcomed the formal confirmation by the Intergovernmental Negotiating Committee of the experts nominated by Canada and the Philippines. The Committee also noted the nomination of a new expert by Samoa, who would serve on the Committee pending formal confirmation by the Intergovernmental Negotiating Committee.

9. The session was attended by the following 25 experts: Mr. André Mayne (Australia), Mr. Mahmood Hasan Khan (Bangladesh), Ms. Sandra Hacon De Souza (Brazil), Mr. Lars Juergensen (Canada), Mr. Julio Monreal Urrutia (Chile), Ms. Mercedes Bolaños Granda (Ecuador), Mr. Mohamed El Zarka (Egypt), Ms. Flor de María Perla de Alfaro (El Salvador), Mr. Ammanuel Malifu Negewo (Ethiopia), Mr. Marc Debois (Finland), Ms. Fatoumata Jallow Ndoeye (Gambia), Mr. Reiner Arndt (Germany), Mr. Tamás Kőmives (Hungary), Mr. Halimi B. Mahmud (Malaysia), Mr. Ravinandan Sibartie (Mauritius), Mr. Mohamed Ammati (Morocco), Mr. Karel A. Gijbertsen (Netherlands), Ms. Aida de Vera Ordas (Philippines), Mr. Hassan Al Obaidly (Qatar), Ms. Kyunghye Choi (Republic of Korea), Mr. Boris Kurlyandskiy (Russian Federation), Mr. Azhari Omer Abdelbagi (Sudan), Mr. Pietro Fontana (Switzerland), Ms. Nuansri Tayaputch (Thailand) and Ms. Cathleen Barnes (United States of America).

10. Observers from the following countries and regional economic integration organizations were also present: Argentina, Australia, Brazil, China, European Commission, Germany, Ghana, Iran (Islamic Republic of), Italy, Jordan, Kenya, Madagascar, Mexico, Morocco, Netherlands, Poland, Qatar, Slovenia, Switzerland, Ukraine and United States of America.

11. Representatives of the following intergovernmental organization and United Nations specialized agency were also present: League of Arab States and World Health Organization.

12. The following non-governmental organization was also represented: CropLife International.

### **A. Adoption of the agenda**

13. At its opening meeting, the Committee adopted the following agenda on the basis of the provisional agenda (UNEP/FAO/PIC/ICRC.5/1):

1. Opening of the session.
2. Organizational matters:
  - (a) Adoption of the agenda;
  - (b) Organization of work.
3. Review of the outcome of the tenth session of the Intergovernmental Negotiating Committee.
4. Operational procedures for the Interim Chemical Review Committee: Issues associated with implementation of the operational procedures: Working papers on preparing internal proposals and decision guidance documents.
5. Inclusion of chemicals in the interim prior informed consent procedure:
  - (a) Review of notifications of final regulatory actions to ban or severely restrict a chemical:
    - (i) Dimefox;
    - (ii) Endrin;
    - (iii) Endosulfan;
    - (iv) Mevinphos;
    - (v) Vinclozolin;
  - (b) Consideration of draft decision guidance documents:
    - (i) Tetraethyl lead and tetramethyl lead;
    - (ii) Parathion.
5. Other matters.
6. Adoption of the report.
7. Closure of the meeting.

### **B. Organization of work**

14. At its opening meeting, the Committee decided to conduct its work in plenary session at meetings between 9 a.m. and 12.30 p.m. and 2 p.m. and 5 p.m., with time allocated for break-out, task and drafting groups, as required.

15. The Chair introduced the scenario note (UNEP/FAO/PIC/ICRC.5/2) in which he had set out the general objectives and possible outcomes of the fifth session of the Committee. The Committee would need to finalize the decision guidance documents on all formulations of the pesticide parathion and two industrial chemicals, tetraethyl lead and tetramethyl lead, and prepare relevant recommendations for the Intergovernmental Negotiating Committee. In addition intersessional task groups would undertake a preliminary assessment of the submitted notifications and supporting documentation for five new chemicals (dimefox, endrin, endosulfan, mevinphos and vinclozolin). Those preliminary assessments would be the basis for further review by the Committee and comparison with the relevant criteria in the Convention (Annex II). The Committee would then decide whether to recommend the inclusion of any or all of those chemicals in the interim PIC procedure and form drafting groups. The Committee was also required to respond to the requests of the Intergovernmental Negotiating Committee at its tenth session.

### III. Review of the outcome of the tenth session of the Intergovernmental Negotiating Committee

16. The secretariat introduced the note on issues arising out of the tenth session of the Intergovernmental Negotiating Committee (UNEP/FAO/PIC/ICRC.5/2) and said that most of the Committee's recommendations at its fourth session had been taken up by the Intergovernmental Negotiating Committee. The Intergovernmental Negotiating Committee had approved the inclusion of DNOC, dustable formulations containing benomyl, carbofuran and thiram and the four amphibole forms of asbestos, amosite, actinolite, anthophyllite and tremolite, in the interim PIC procedure but had requested the secretariat to extract the chapter on chrysotile from the decision guidance document on asbestos and to compile a separate decision guidance document on that substance for its consideration at its eleventh session. The Intergovernmental Negotiating Committee had further requested the Committee to identify possible alternatives to chrysotile that could be transmitted to the International Programme on Chemical Safety (IPCS) for assessment of their health effects. The process used for the identification of those alternatives and the suggested list of alternatives had been provided to the Committee in documents UNEP/FAO/PIC/ICRC.5/4, INF/6 and INF/6/Add.1.

17. With regard to inconsistencies within Annex III of the Convention and between Annex III and the decision guidance documents, at its fourth session the Committee had decided that no changes were needed for most of the chemicals listed in Annex III but recommended some possible changes for consideration by the Intergovernmental Negotiating Committee. The Intergovernmental Negotiating Committee agreed to amend the listing in Annex III and the relevant sections of the decision guidance documents for 2,4,5-T, pentachlorophenol, dinoseb and dinoseb salts, and methyl parathion and decided that some further clarification was necessary. A paper had been submitted on that issue for consideration by the Committee.

18. The decision guidance documents on DNOC, on dustable powder formulations containing benomyl, carbofuran and thiram, and on the four amphibole forms of asbestos, amosite, actinolite, anthophyllite and tremolite, had been approved by the Intergovernmental Negotiating Committee and circulated on 1 February 2004. The amended decision guidance document on chrysotile would be circulated with documentation for the eleventh session of the Intergovernmental Negotiating Committee.

19. The Intergovernmental Negotiating Committee had been informed that the choline salt of maleic hydrazide with a content of free hydrazine above 1 ppm was no longer in trade. Governments were requested to notify the secretariat of any changes in that situation.

20. In response to a request for clarification, the Chair summarized the outcome of the discussion on chrysotile that had taken place at the tenth session of the Intergovernmental Negotiating Committee and reiterated that the work of the Committee had not been questioned. In addition, he stressed that inclusion of a chemical in the interim PIC procedure did not constitute a ban on that chemical: it simply indicated that an action on the chemical had been taken by at least two countries from two PIC regions. It was then the sovereign decision of any other country to decide whether or not to import the chemical and that decision could be based, among other things, on the information contained in a decision guidance document.

21. With regard to the identification of alternatives to chrysotile, the Intergovernmental Negotiating Committee had mandated the Committee to prepare a list of alternatives on which assessment of health effects could be undertaken by IPCS. There was no connection, however, between that work and the proposed listing of chrysotile in Annex III and chrysotile would not be reopened for discussion by the Committee.

22. The secretariat introduced the agenda item, noting that, although the Committee was not required to assess alternatives, it had considered it useful to provide additional information to countries on alternatives to chrysotile to assist them in making their related import decisions. The Committee was reminded that the task of identifying alternatives to chrysotile that could be assessed by IPCS had been assigned to the Committee by the Intergovernmental Negotiating Committee at its tenth session. The process used to request information on alternatives from Governments was outlined and the outcome was available to the Committee in documents UNEP/FAO/PIC/ICRC.5/4, INF/6 and INF/6/Add.1.

23. One expert expressed the view that, while complete information was available on the toxicity of amphibole forms of asbestos, there was limited information on the carcinogenicity of chrysotile. Despite the assessment undertaken by IPCS in 1998 (Environmental Health Criteria 203) in his view there had been insufficient epidemiological studies to determine whether or not chrysotile was carcinogenic to humans and currently there was insufficient data to warrant inclusion of chrysotile in Annex III. He was also of the opinion that the request from the Intergovernmental Negotiating Committee for assessment of chrysotile by IPCS had not been fulfilled.

24. The Chair reminded the Committee of the process followed in the consideration of chrysotile, and that the Committee had agreed, at its third session, that chrysotile met the criteria of Annex II and the proposal for inclusion was forwarded to the Intergovernmental Negotiating Committee for consideration at its ninth session. He also noted that the decision guidance document included the basis for the national regulatory actions considered by the Committee on chrysotile, as well as the conclusions of the evaluation by IPCS.

25. The representative of the World Health Organization (WHO) explained the process involved in producing an Environmental Health Criteria document. She noted that, from initial contacts with the International Agency for Research on Cancer (IARC), it seemed likely that a focused workshop on determinants of cancer with regard to fibrous substances could be conducted in 2005. She also recalled the assessment carried out by IPCS on chrysotile in 1998, which had concluded that chrysotile was carcinogenic. She noted, however, that in her suggested scenario for the assessment of alternatives, which would include fibres, the results would also cover chrysotile.

26. Some experts, including the expert from Canada, stressed that comparative assessments should be made of chrysotile and its alternatives while others suggested that the mandate given by the Intergovernmental Negotiating Committee at its tenth session should be followed and as such the proposed alternatives assessed individually. The representative of WHO noted that some alternatives for chrysotile had already been assessed but that those assessments might need to be updated if new information was available.

27. The Committee agreed to identify alternatives to be assessed by WHO (IPCS/IARC) for carcinogenicity and other health effects according to criteria related to the potency of hazard, the dose-effect curve and those used in largest quantities or having the greatest potential exposure.

28. The Committee decided to set up contact group to identify a list of alternatives to chrysotile based on the list of possible alternatives received from Governments, the criteria identified by the Committee and the list of those alternatives that had previously been assessed in Environmental Health Criteria documents by IPCS. The group's report is contained in annex I to the current report.

#### **IV. Operational procedures for the Interim Chemical Review Committee: Issues associated with implementation of the operational procedures: Working papers on preparing internal proposals and decision guidance documents**

29. The secretariat introduced the working papers on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals and for severely hazardous pesticide formulations (UNEP/FAO/PIC/ICRC.5/6 and 7) that had been revised in the light of the comments received from the Committee. The revised version of the paper for banned or severely restricted chemicals had been used by the drafting groups on parathion and tetraethyl lead and tetramethyl lead in preparing their draft decision guidance documents. He noted that the Committee had had less experience in developing internal proposals and decision guidance documents for severely hazardous pesticide formulations and that the co-chairs of the drafting group had worked intersessionally to develop the current document.

30. The Committee agreed to refer the papers to the Conference of the Parties for consideration at its first meeting, in order that the chemical review committee set up by the Conference of the Parties might consider them as part of procedures to be used by it in developing its own procedures for preparing decision guidance documents.

## **V. Inclusion of chemicals in the interim prior informed consent procedure**

### **A. Review of notifications of final regulatory actions to ban or severely restrict a chemical**

#### **1. Dimefox**

31. Ms Tayaputch (Thailand) presented the work of the task group, comprising Mr. Sibartie (Mauritius), Mr Al-Obaidly (Qatar) and herself. The group had reviewed and analysed the two notifications on dimefox received from Jordan and from Thailand and confirmed that both notifications, relating regulatory actions that banned all uses of dimefox as a pesticide and applied to all formulations, complied with the information requirements of Annex I of the Convention.

32. Taking into consideration the work of the task group, the Committee reviewed the criteria for listing banned or severely restricted chemicals as set out in Annex II. It agreed that, on the basis of the information currently available, the notifications had met all the criteria of Annex II with the exception of criterion (b) (iii).

33. The Committee agreed that the notifications received from Jordan and Thailand were useful as an exchange of information, as mandated by article 14, and that such notifications should be encouraged. It concluded, however, that neither regulatory action met all the criteria set out in Annex II and the chemical dimefox should not be subject to the interim PIC procedure.

#### **2. Endrin**

34. Mr. Monreal Urrutia (Chile) presented the work of the task group, comprising Mr. Khan (Bangladesh), Mr. Malifu (Ethiopia), Ms. Ndoye (Gambia), Mr. Ammati (Morocco), Ms. Choi (Republic of Korea) as members and Mr. El Zarka (Egypt) and himself as coordinators. The group had reviewed and analysed the two notifications on endrin received from Jordan and from Peru and confirmed that both notifications, relating regulatory actions that banned all uses of endrin as a pesticide and applied to all formulations, complied with the information requirements of Annex I of the Convention.

35. Taking into consideration the work of the task group, the Committee reviewed the criteria for listing banned or severely restricted chemicals as set out in Annex II. It agreed that, on the basis of the information currently available, the notifications had met all the criteria of Annex II with the exception of criterion (b) (iii) for Jordan and criteria (b) (i), (ii) and (iii) for Peru.

36. Summarizing the discussion on the issue, the Chair noted that the countries concerned had taken sensible and necessary action to ban the chemical and that the Committee's decision not to recommend it for inclusion in the PIC procedure did not in any sense constitute an endorsement of the chemical: it was simply the Committee's task to verify compliance of notifications with the criteria set out in the Convention. He also noted that, based on information available to the Committee, trade in the chemical had already ceased and that no further action would be required on it.

37. The Committee agreed that the notifications received from Jordan and Peru were useful as an exchange of information, as mandated by article 14, and that such notifications should be encouraged. It concluded, however, that neither regulatory action met all the criteria set out in Annex II and the chemical endrin should not be subject to the interim PIC procedure.

#### **3. Endosulfan**

38. Mr. Gijsbertsen (Netherlands) presented the work of the task group, comprising Mr. Debois (Finland), Mr. Khan (Bangladesh), and Mr. Malifu (Ethiopia) as members and Mr. Abdelbagi (Sudan) and himself as coordinators. The group had reviewed and analysed the three notifications on endosulfan received from Jordan, from the Netherlands and from Norway and confirmed that all notifications, relating regulatory actions that banned all uses of endosulfan as a pesticide and applied to all formulations, complied with the information requirements of Annex I of the Convention.

39. The observer from Jordan noted that endosulfan residues had been found in the soil and that the chemical had been banned because it was persistent in the environment. Following that explanation, the Chair noted that Jordan's 1994 regulatory decision had been based on the chemical's intrinsic hazard and on monitoring data and wondered whether that could be deemed to constitute a risk evaluation.

40. In summarizing the discussion, the Chair noted that Jordan's decision to ban endosulfan had been based on research findings pointing to the chemical's carcinogenic properties, which stated that it was found in groundwater. Information available to the Committee (monitoring data) indicated the presence of endosulfan in the soil, but no residues of endosulfan had been reported in groundwater in Jordan. It was not clear that presence in the soil would lead to human or environmental exposure.

41. Taking into consideration the work of the task group and the subsequent discussion, the Committee reviewed the criteria for listing banned or severely restricted chemicals as set out in Annex II. It agreed that the notifications had met all the criteria of Annex II with the exception of criterion (b) (iii) for Jordan and Norway.

42. The Committee agreed that the notification from the Netherlands was complete and met all the criteria for inclusion in the interim PIC procedure in the pesticide category and that, since the notification from Jordan did not meet all the criteria, there was only one complete notification for endosulfan at the current time. The Committee concluded that, pending the receipt of further notifications on endosulfan from a PIC region other than Europe, endosulfan could not be proposed for inclusion in the interim PIC procedure.

#### 4. Mevinphos

43. Mr. Ammati (Morocco) presented the work of the task group, comprising Mr. Khan (Bangladesh), Mr. Monreal Urrutia (Chile) and Mr. El Zarka (Egypt) as members and Ms. Choi (Republic of Korea) and himself as coordinators. The group had reviewed and analysed the two notifications on mevinphos received from Jordan and from Thailand and confirmed that both notifications, relating regulatory actions that banned all uses of mevinphos as a pesticide and applied to all formulations, complied with the information requirements of Annex I of the Convention.

44. In the ensuing discussion, a range of opinions were expressed on the acceptability of the nomination by Thailand with respect to criterion (b) (iii). The view was expressed that, as the country had based its regulatory action on the toxicity of the substance and actual incidents of poisoning under the prevailing conditions in Thailand, it could therefore be considered to have based that action on a risk evaluation.

45. The discussion revealed the need for a clear definition of risk evaluation. In particular, it was agreed that there was a need to outline possible minimum requirements for risk evaluation relevant to criterion (b) (iii), given that some countries did not have the resources to conduct full-scale evaluations. The Chair proposed that he should prepare a short note, with the assistance of a small drafting group, to stimulate discussion in the Committee on the issue of the minimum requirements for a risk evaluation.

46. The Committee considered the text prepared by the drafting group. In discussing indirect exposure via the environment, some experts held the view that the relationship between hazard and exposure was a key element for a decision to list a chemical in Annex III. Other experts were of the view that the relationship was not required by the definition provided by the Intergovernmental Negotiating Committee at its fifth session. The Committee agreed to forward the text of the explanatory note, as contained in annex II to the present report, to the future chemicals review committee for its consideration.

47. Taking into consideration the work of the task group and the subsequent discussion in plenary, the Committee reviewed the criteria for listing banned or severely restricted chemicals as set out in Annex II. It agreed that the notification for Jordan did not meet criterion (b) (iii) and that further information was required from Thailand before its notification could be considered to have met that criterion. For example, a description of the incident should be provided, which might include the extent or number of casualties, its circumstances and a description of the signs, symptoms and/or effects.

48. The Committee agreed that the notifications received from Jordan and Thailand were useful as an exchange of information, as mandated by article 14, and that such notifications should be encouraged. It

concluded, however, that neither regulatory action met all the criteria set out in Annex II and the chemical mevinphos should not be subject to the interim PIC procedure.

## **5. Vinclozolin**

49. Mr. Abdelbagi (Sudan) presented the work of the task group, comprising Mr. Kómvives (Hungary) and himself as joint coordinators. The group had reviewed and analysed the two notifications on vinclozolin received from Jordan and from Norway and confirmed that both notifications, relating regulatory actions that banned all uses of vinclozolin as a pesticide and applied to all formulations, complied with the information requirements of Annex I of the Convention.

50. Taking into consideration the work of the task group, the Committee reviewed the criteria for listing banned or severely restricted chemicals as set out in Annex II. It agreed that, on the basis of the information currently available, the notifications had met all the criteria of Annex II with the exception of criterion (b) (iii).

51. The Committee agreed that the notifications received from Jordan and Norway were useful as an exchange of information, as mandated by article 14, and that such notifications should be encouraged. It concluded, however, that neither regulatory action met all the criteria set out in Annex II and the chemical vinclozolin should not be subject to the interim PIC procedure.

## **B. Consideration of draft decision guidance documents**

### **1. Tetraethyl lead and tetramethyl lead**

52. Mr. Juergensen, co-chair of the drafting group on tetraethyl lead and tetramethyl lead, presented the draft decision guidance document (UNEP/FAO/PIC/ICRC.5/13) and outlined the process used in its preparation. He noted that the two substances were in one decision guidance document as their only use was as an additive for petrol and the control action for both substances was to limit alkyl lead additives. The notification was on the basis of health effects of lead. If, however, they were listed in Annex III it would be as two separate substances. The draft decision guidance document had been circulated for comments during 2003. A tabular summary of the comments received and the manner in which they had been addressed was given in document UNEP/FAO/PIC/ICRC.5/INF/5.

53. The Committee decided to forward the draft decision guidance document, the recommendation for inclusion of tetraethyl lead and tetramethyl lead in the interim PIC procedure, the rationale from the Committee and tabular summary of the comments on the internal proposal to the Intergovernmental Negotiating Committee for its consideration. The text of that recommendation and the Committee's rationale are provided in annex III to the present note. The draft decision guidance document will be issued separately.

### **2. Parathion**

54. Mr. Debois, co-chair of the drafting group on parathion, presented the draft decision guidance document (UNEP/FAO/PIC/ICRC.5/14) and outlined the process used in its preparation. The draft document had been circulated during 2003 and a tabular summary of the comments received and the manner in which they had been addressed was given in document UNEP/FAO/PIC/ICRC.5/INF/4. He noted that the introduction to the draft document had been modified to take into account and be consistent with the outcome of the discussion held at the ninth session of the Intergovernmental Negotiation Committee (UNEP/FAO/PIC/INC.9/21, para. 82), at which it had been noted that countries would be invited to submit a single decision regarding future imports that would apply to all forms of a chemical, including the severely hazardous formulations listed in Annex III.

55. In response to a request for clarification, it was recalled that, as per the information provided to the Committee at its fourth session, parathion was being manufactured and in international trade.

56. The Committee decided to forward the draft decision guidance document, the recommendation for inclusion of parathion in the interim PIC procedure, the rationale from the Committee and the tabular summary of the comments on the internal proposal to the Intergovernmental Negotiating Committee for



its consideration. The text of that recommendation and the rationale of the Committee are contained in annex IV to the present report. The draft decision guidance document will be issued separately.

## VI. Other matters

57. As in the paper on the issue prepared by the secretariat for the current session (UNEP/FAO/PIC/ICRC.5/5), the Intergovernmental Negotiating Committee, at its tenth session, had agreed on the basis of the Committee's recommendation to amend the listings in Annex III and the relevant sections of the decision guidance documents for certain chemicals. The Intergovernmental Negotiating Committee had requested the Committee to provide its rationale for its recommendation not to accept the proposals for amendments to other chemical listings that had been laid out in the secretariat paper for the Committee's fourth session (UNEP/FAO/PIC/ICRC.4/9). One observer requested clarification regarding the Committee's deliberations on mercury and related compounds, phosphamidon and PCBs.

58. The Committee concluded that the rationale for recommending no change to the listings of mercury and related compounds was that elemental mercury was not used as a pesticide or listed in Annex III. It was further considered superfluous to provide specific chemical descriptions for all inorganic mercury compounds as the range of compounds covered was so extensive that it would be difficult to identify all the CAS numbers that could be used.

59. The Committee recalled that the listings in Annex III and in the decision guidance document for phosphamidon were consistent (identifying each isomer separately, as well as in the mixture), even though the notifications indicated that the problem had resulted only from the use of the product containing a mixture of both isomers. The Committee did not, however, see any difficulty in retaining the individual listings.

60. In addition, the Committee had agreed not to include the extensive list of CAS numbers for PCBs as there was a common understanding of what PCBs were and to list them all would constitute an extraordinary challenge. The generic listing covered the mono- and di-substituted variants. Any import response would refer to all PCBs; importing countries could, however, provide a specific response suitable for their national circumstances.

61. A clarification was requested as to why the listing for the severely hazardous pesticide formulations methamidophos, monocrotophos and phosphamidon had not been modified to read "that equal or exceed xxx g active ingredient per litre" instead of the current wording "that exceed xxx g active ingredient per litre". The Committee agreed that consistency of listing within Annex III and between Annex III and the decision guidance documents had taken precedence over consistency in the listing of all severely hazardous pesticide formulations. It also agreed that a decision modifying the entries for those pesticides was currently beyond the scope of the Committee and suggested that the chemical review committee to be set up by the Conference of the Parties at its first session might wish to revisit that issue.

## VII. Adoption of the report

62. The Committee adopted its report on the basis of the draft report contained in document UNEP/FAO/PIC/ICRC.5/L.1, which had been circulated during the meeting, as amended, and on the understanding that finalization of the report would be entrusted to the Rapporteur, working in consultation with the secretariat.

## VIII. Closure of the meeting

63. Noting that the current meeting was the Interim Committee's last and that the Conference of the Parties at its first meeting would be determining the composition of a new chemical review committee, the Chair commended all experts on their excellent collaboration over the Committee's five sessions and thanked all those involved in that process – experts, observers, non-governmental organizations, members of the secretariat and Governments which had hosted meetings – for their valuable contribution. Following the customary exchange of courtesies, he declared the session closed at 12.30 p.m. on Thursday, 5 February 2004.

## Annex I

### Report of the contact group on chrysotile

1. The contact group considered the list of substitutes for chrysotile asbestos proposed by Governments for assessment by the World Health Organization (WHO). WHO indicated that it welcomed the guidance provided by the group on important alternatives used by Governments.
2. The list was prioritized initially on the basis of the number of Governments which had nominated the substances. Information on which substances had previously been assessed in environmental health criteria reports by IPCS was also considered. Where possible, the group's knowledge of important uses was also considered.
3. The first group of substances are listed on a priority basis, in the order in which the contact group would like them to be considered by WHO. The second group of substances, which were proposed by only one country, had undergone no previous assessment by WHO and could be considered if resources allowed.

#### Group 1: Substances identified and prioritized for assessment by WHO

Aramid and para-aramid fibres
Fibrous glass (glass fibres, glass wool)
Carbon/graphite
Ceramic fibres
Wollastonite
Cellulose fibres
Mineral wool (rock wool, slag wool)
Polyvinyl alcohol (PVA) fibres
Polypropylene fibres
Polyvinyl chloride (PVC) fibres
Attapulgate
Polyethylene fibres

#### Group 2: Substances identified as alternatives to chrysotile, to be assessed if resources allow

Aluminium silicates, basic magnesium sulphate whisker, erionite, ductile iron, mica, phosphate, polyacryl nitril, polytetrafluoroethylene, potassium titanate whisker, semi-metallics, silicon carbide whisker, steel fibres

## Annex II

### Explanatory note on criterion (b) (iii) of Annex II of the Rotterdam Convention

#### A. Background

1. In assessing notifications of banned and severely restricted chemicals used in a notifying country under article 5, problems arose with the application of the term “risk evaluation”.
2. Annex II of the Convention sets out the criteria for listing banned or severely restricted chemicals in Annex III. Paragraph (b) of Annex II states that, in reviewing the notifications forwarded to it, the Chemical Review Committee shall “Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of conditions prevailing in the Party in question.”
3. The report of the fifth session of the Intergovernmental Negotiating Committee states:
 

“The term ‘risk evaluation’ used in Annex I and Annex II is understood by the Intergovernmental Negotiating Committee to be not a risk assessment, but rather an evaluation of intrinsic toxicological and ecotoxicological properties and actual or expected relevant exposure, including actual incidents and scientific evidence of hazard.”
4. To clarify the issue it may be helpful also to consider the work of the Organisation for Economic Cooperation and Development (OECD) and the World Health Organization (WHO) in developing definitions of risk assessment and hazard assessment.<sup>1</sup>
5. It was noted that consideration of the term risk evaluation by the Interim Chemical Review Committee is in the context of the Rotterdam Convention and is not to be confused with definitions developed by OECD, WHO or other bodies.

#### B. Risk evaluation in the context of the Rotterdam Convention

6. Risk evaluation is neither hazard assessment nor risk assessment, but something in between. Risk evaluation considers information on hazard and exposure. In notifications of final regulatory actions to ban or severely restrict a chemical:
  - (a) Information on hazard assessment is normally based on internationally accepted toxicological or ecotoxicological data;

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<sup>1</sup> The following examples might be considered:

“*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;

“*Hazard assessment*: A process designed to determine the possible adverse effects of an agent or a situation to which an organism, system, or sub-population could be exposed.

“The process includes hazard identification and hazard characterization. The process focuses on the hazard in contrast to risk assessment where exposure assessment is a distinct additional step.”

*Source*: Alphabetical list of selected generic terms in hazard and risk assessment and their definitions (OECD/IPCS/WHO).

- (b) Information on exposure is to be related to the prevailing conditions of use in the notifying country.

7. For a better understanding of the minimum information on exposure that might be required by the Interim Chemical Review Committee in reviewing risk evaluations, it was considered useful to develop some examples as a means of defining the minimum requirements for information regarding exposure. Any additional information will facilitate decision-making by the Interim Chemical Review Committee. For the first two examples, where reported incidents occur in a country other than the country submitting the notification of final regulatory action the relevance to the notifying country should be described<sup>2</sup>.

8. The Interim Chemical Review Committee will consider each notification on a case-by-case basis. The use of this guidance is intended to be interpreted flexibly.

*Example 1: Incidents involving direct exposure by humans*

9. Information is required describing the direct exposure to the chemical and the adverse effects resulting from that exposure. For example, a description of the incident should be provided, which may include the extent or number of casualties, its circumstances and a description of the signs, symptoms and/or effects.

*Example 2: Incidents involving direct exposure by the environment (wildlife, livestock etc.)*

10. Information is required describing the direct exposure to the chemical and the adverse effects resulting from that exposure. For example, a description of the incident should be provided, which may include the extent or number of casualties, its circumstances and a description of the effects.

*Example 3: Indirect exposure via the environment (air, water, soil)*

11. The description of indirect exposure via the environment should address the following:

- (a) How does the presence of the chemical lead to human and environmental (actual or expected) exposure? Actual exposure can be directly measured. Expected exposure can be estimated, possible factors... [to be developed if necessary]
- (b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical, would facilitate the work of the Committee.

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<sup>2</sup> Information to be contained in the supporting documentation provided by a notifying country using a risk evaluation from another country in support of final regulatory action (UNEP/FAO/INC.10/14).

## Annex III

### Recommendation to the Intergovernmental Negotiating Committee on tetraethyl lead and tetramethyl lead

*The Interim Chemical Review Committee,*

*Noting* that at its fourth session it had reviewed the notifications of final regulatory actions by the European Community and Canada on tetraethyl lead and tetramethyl lead and, taking into account the requirements set forth in Annex II of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, had come to the conclusion that the requirements of that Annex had been met,

*Recalling* that, in line with paragraph 6 of article 5 of the Convention, at its fourth session it had accordingly recommended to the Intergovernmental Negotiating Committee that tetraethyl lead and tetramethyl lead should become subject to the interim prior informed consent procedure and noting that, as determined in annex IV to the report of its fourth session,<sup>1</sup> it was to develop a draft decision guidance document and forward it to the Intergovernmental Negotiating Committee in accordance with article 7 of the Convention,

*Recalling* also that, in accordance with the operational procedures for the Interim Chemical Review Committee, set forth in decision INC-7/6 of the Intergovernmental Negotiating Committee on the process for drafting decision guidance documents, it had established a task group to draft a decision guidance document on tetraethyl lead and tetramethyl lead and that that task group, upon fulfilling the requirements of the operational procedures and in accordance with paragraph 1 of article 7 of the Convention, had developed a draft decision guidance document on tetraethyl lead and tetramethyl lead<sup>2</sup> and had submitted it to the Interim Chemical Review Committee at its fifth session for further action,

*Noting* that the draft decision guidance document was based on the information specified in Annex I of the Convention, as required by paragraph 1 of article 7 of the Convention,

*Recalling* that, in accordance with step 7 of the process for drafting decision guidance documents, final documentation forwarded by the secretariat to all Parties and observers in advance of Intergovernmental Negotiating Committee sessions must include a draft decision guidance document, a recommendation by the Interim Chemical Review Committee for inclusion in the prior informed consent procedure, a summary of the deliberations of the Interim Chemical Review Committee, including a rationale for inclusion based on the criteria listed in Annex II to the Convention, and a tabular summary of comments received by the secretariat and how they had been addressed,

*Adopts* the following recommendation to the Intergovernmental Negotiating Committee:

#### **I. Recommendation ICRC-5/1: Inclusion of tetraethyl lead and tetramethyl lead in the interim prior informed consent procedure**

*The Interim Chemical Review Committee*

*Recommends*, in line with paragraph 5 of article 5 of the Convention, that the Intergovernmental Negotiating Committee should make tetraethyl lead and tetramethyl lead subject to the interim prior informed consent procedure:

Chemical	Relevant CAS number(s)	Category
Tetraethyl lead	CAS No. 78-00-2	Industrial chemical
Tetramethyl lead	CAS No. 75-74-1	Industrial chemical

<sup>1</sup> UNEP/FAO/PIC/ICRC.4/18.

<sup>2</sup> UNEP/FAO/PIC/ICRC.5/13.

*Forwards*, in line with paragraph 2 of article 7 of the Convention, the present recommendation, together with the draft decision guidance document on tetraethyl lead and tetramethyl lead, to the Intergovernmental Negotiating Committee for a decision on the inclusion of tetraethyl lead and tetramethyl lead in the interim prior informed consent procedure.

## **Annex**

### **Excerpt from annex IV to the report of the fourth session of the Interim Chemical Review Committee (UNEP/FAO/PIC/ICRC.4/18)**

#### **Annex IV**

##### **Rationale for the recommendation that tetramethyl lead (CAS No. 75-74-1) and tetraethyl lead (CAS No. 78-00-2) should become subject to the interim prior informed consent procedure and to establish an intersessional drafting group to prepare a draft decision guidance document**

In reviewing the notifications of final regulatory actions by the European Community and Canada, together with the supporting documentary information provided by those Parties, the Committee was able to confirm that those actions had been taken in order to protect human health. Both the European Community and Canadian actions were taken on the basis of the health effects of lead, which is considered highly toxic. Tetraethyl lead and tetramethyl lead are used as additives in gasoline as anti-knock agents. As a result of this use, lead is released in the exhaust fumes, leading to increases in the lead levels in the environment. Both Parties recognised that this increase was a significant contributor of lead in the blood of humans.

The Committee established that the final regulatory actions had been taken on the basis of risk evaluations and that those evaluations had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognised methods, and that the data reviews had been performed and documented in accordance with generally recognised scientific principles and procedures. It also showed that the final regulatory actions had been based on chemical-specific risk evaluations taking into account the conditions of exposure within the European Community and Canada.

The Committee concluded that the final regulatory actions provided a sufficiently broad basis to merit including tetramethyl lead and tetraethyl lead in the interim PIC procedure in the industrial category. It noted that those actions led to at least a 98% decrease in the quantities of the chemicals used in the notifying Parties. Several studies showed that this decrease was associated with a significant decrease in blood lead levels. Hence, the risk for human health in each notifying Party had been significantly reduced.

There was no indication that there were any pesticide uses of tetramethyl lead or tetraethyl lead. The Committee also took into account that the considerations underlying the final regulatory actions were not of limited applicability since leaded gasoline continues to be used in other countries. Many countries have taken action to reduce the use of leaded gasoline due to health concerns. On the basis of information provided by members at the fourth session of the Interim Chemical Review Committee and other available information, the Committee concluded also that there was ongoing international trade in tetramethyl lead and tetraethyl lead.

The Committee noted that the final regulatory actions were not based on concerns about intentional misuse of tetramethyl lead or tetraethyl lead.

The Committee concluded that the notifications of final regulatory actions by the European Community and Canada met the information requirements of Annex I and the criteria set out in Annex II to the Convention. It is recommended that tetramethyl lead (CAS No. 75-74-1) and tetraethyl lead (CAS No. 78-00-2) be included in the interim PIC procedure as industrial chemicals.

## Annex IV

### Recommendation to the Intergovernmental Negotiating Committee on parathion

*The Interim Chemical Review Committee,*

*Noting* that at its fourth session it had reviewed the notifications of final regulatory actions by the European Community and Australia on parathion and, taking into account the requirements set forth in Annex II of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, had come to the conclusion that the requirements of that Annex had been met,

*Recalling* that, in line with paragraph 6 of article 5 of the Convention, at its fourth session it had accordingly recommended to the Intergovernmental Negotiating Committee that parathion should become subject to the interim prior informed consent procedure and noting that, as determined in annex IV to the report of its fourth session,<sup>1</sup> it was to develop a draft decision guidance document and forward it to the Intergovernmental Negotiating Committee in accordance with article 7 of the Convention,

*Recalling* also that, in accordance with the operational procedures for the Interim Chemical Review Committee, set forth in decision INC-7/6 of the Intergovernmental Negotiating Committee on the process for drafting decision guidance documents, it had established a task group to draft a decision guidance document on parathion and that that task group, upon fulfilling the requirements of the operational procedures and in accordance with paragraph 1 of Article 7 of the Convention, had developed a draft decision guidance document on parathion<sup>2</sup> and had submitted it to the Interim Chemical Review Committee at its fifth session for further action,

*Noting* that the draft decision guidance document was based on the information specified in Annex I of the Convention, as required by paragraph 1 of article 7 of the Convention,

*Recalling* that, in accordance with step 7 of the process for drafting decision guidance documents, final documentation forwarded by the secretariat to all Parties and observers in advance of Intergovernmental Negotiating Committee sessions must include a draft decision guidance document, a recommendation by the Interim Chemical Review Committee for inclusion in the prior informed consent procedure, a summary of the deliberations of the Interim Chemical Review Committee, including a rationale for inclusion based on the criteria listed in Annex II to the Convention, and a tabular summary of comments received by the secretariat and how they had been addressed,

*Adopts* the following recommendation to the Intergovernmental Negotiating Committee:

#### II. Recommendation ICRC-5/2: Inclusion of parathion in the interim prior informed consent procedure

*The Interim Chemical Review Committee*

*Recommends*, in line with paragraph 5 of Article 5 of the Convention, that the Intergovernmental Negotiating Committee should make parathion, subject to the interim prior informed consent procedure:

Chemical	Relevant CAS number(s)	Category
Parathion	CAS No 56-38-2	Pesticide

*Forwards*, in line with paragraph 2 of article 7 of the Convention, the present recommendation, together with the draft decision guidance document on parathion, to the Intergovernmental Negotiating Committee for a decision on the inclusion of parathion in the interim prior informed consent procedure.

<sup>1</sup> UNEP/FAO/PIC/ICRC.4/18.

<sup>2</sup> UNEP/FAO/PIC/ICRC.5/14.

**Annex**

**Excerpt from annex III to the report of the fourth session of the Interim Chemical Review Committee (UNEP/FAO/PIC/ICRC.4/18)**

**Annex III**

**Rationale for the recommendation that parathion (parathion ethyl) (cas no. 56-38-2) should become subject to the interim prior informed consent procedure and to establish an intersessional drafting group to prepare a draft decision guidance document**

In reviewing the notifications of final regulatory actions by Australia and the European Community, together with the supporting documentary information provided by those Parties, the Committee was able to confirm that those actions had been taken in order to protect human health and the environment. The European Community action was based on a risk evaluation, which concluded that there were concerns about the safety of operators and environmental fate and behaviour and the possible impact on non-target organisms. The action by Australia was based on a risk evaluation of pesticide uses of parathion (parathion ethyl) that concluded that there were unacceptable risks to operators, to aquatic ecosystems and bees. In both cases the main concerns related to the acute toxic effect of the substance as a result of inhibition of acetylcholinesterase activity in the nervous system.

The Committee established that the final regulatory actions had been taken on the basis of risk evaluations and that those evaluations had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognised methods, and that the data reviews had been performed and documented in accordance with generally recognised scientific principles and procedures. It also showed that the final regulatory actions had been based on chemical-specific risk evaluations taking into account the conditions prevailing within Australia and the European Community.

The Committee concluded that the final regulatory actions provided a sufficiently broad basis to merit including all formulations of parathion (parathion ethyl) in the interim PIC procedure in the category of pesticide. It noted that those actions had led to a significant decrease in the quantities and uses of the chemical and the risks for human health and the environment. There was no indication that there were any industrial chemical uses of parathion (parathion ethyl). The Committee also took into account that the considerations underlying the final regulatory actions were not of limited applicability but of broader relevance. On the basis of information provided by the Secretariat at the fourth session of the Interim Chemical Review Committee, the Committee concluded also that there was ongoing international trade in parathion (parathion ethyl).

The Committee noted also that concern about intentional misuse of parathion (parathion ethyl) had not been a reason for the final regulatory actions.

The Committee concluded that the notifications of final regulatory actions by Australia and the European Community met the information requirements of Annex I and the criteria set out in Annex II to the Convention. It recommended that all formulations of parathion (parathion ethyl) (CAS No. 56-38-2) be included in the interim PIC procedure as a pesticide.

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