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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 Ninth session

Ninth session Bonn, 30 September - 4 October 2002 Item 4 (c) of the provisional agenda*

IMPLEMENTATION OF THE PRIOR INFORMED CONSENT PROCEDURE

PRESENTATION OF THE REPORT OF THE INTERIM CHEMICAL REVIEW COMMITTEE ON THE WORK OF ITS THIRD SESSION

Note by the secretariat

The third session of the Interim Chemical Review Committee was held in Geneva from 17 to 21 February 2002. The secretariat has the honour to submit to the Intergovernmental Negotiating Committee, annexed to the present note, the report (UNEP/FAO/PIC/ICRC.3/19) of that session.

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^{*} UNEP/FAO/PIC/INC.9/1.

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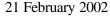




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INTERIM CHEMICAL REVIEW COMMITTEE Third session Geneva, 17-21 February 2002

REPORT OF THE INTERIM CHEMICAL REVIEW COMMITTEE ON THE WORK OF ITS THIRD SESSION

Introduction

- 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 first session of the Committee was held at the Palais des Nations in Geneva from 21 to 25 February 2000 and the second session was held at the headquarters of the Food and Agriculture Organization of the United Nations (FAO) in Rome from 19 to 23 March 2001.

I. OPENING OF THE MEETING

- 4. The third session of the Committee was held at the Varembé Conference Centre, Geneva, from 17 to 21 February 2002. The session was opened at 10 a.m. on Sunday, 17 February 2002 by Mr Reiner Arndt, Chair of the Committee.
- 5. Opening statements were made by Mr Niek Van der Graaff, Executive Secretary of the Interim Secretariat and Chief, Plant Protection Service (FAO) and Mr James Willis, Executive Secretary of the Interim Secretariat and Director, UNEP Chemicals. Mr Willis' statement was read by Mr Erik Larsson of the Interim Secretariat.

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- 6. Mr Willis commended the Committee on the excellent work done during its first two sessions and noted that at the third session the Committee would address chemicals, pesticides and severely hazardous pesticide formulations of great importance for human health and the environment. The recommendations to be made to the Intergovernmental Negotiating Committee at its ninth session would be essential to the future operation of the Convention. He noted that there were now 18 Parties to the Convention, welcomed its newest Party, Switzerland, and stressed that 50 Parties were needed for the Convention's entry into force. He called upon all members of the Committee to encourage their Governments to become Parties to the Convention with a view to ensuring that it entered into force before the World Summit on Sustainable Development, to be held in Johannesburg from 26 August to 4 September 2002. Within the context of the need for cooperation and coordination between multilateral environmental agreements (MEAs), he noted the excellent cooperation and coordination between the secretariats of the three chemicals Conventions, namely the Basel Convention on the Transboundary Movement of Hazardous Wastes and Their Disposal, the Stockholm Convention on Persistent Organic Pollutants and the Rotterdam Convention, and called on all members of the Committee to help ensure equally good cooperation at the national and regional levels.
- Mr Van der Graaff welcomed participants to the third session of the Committee which, through its support for the work of the Intergovernmental Negotiating Committee, contributed to reducing environmental and health risks by restricting access to hazardous pesticides and other chemicals. The third session would be of particular importance as, with the lessons learnt from its reviews of candidate chemicals for inclusion in the interim prior consent procedure, it would be setting precedents for the future implementation of the Convention. Pesticide use would continue and possibly even increase in some regions of the world and policies and practices were therefore required that made adequate provision for sustainability and for the protection of human health and the environment. Such policies and practices included the establishment and promotion of environmentally friendly integrated pest management methods. Pesticide use in developed countries differed significantly from pesticide use in developing countries and countries with economies in transition, where appropriate regulations might be lacking or difficult to enforce, with inadequate control infrastructures and a shortage of trained personnel, resulting in hazardous and/or poor-quality pesticides continuing to be traded and sold to unsuspecting farmers who were not capable of handling them in an acceptable manner. The mechanism provided by the Rotterdam Convention to identify such formulations and assist countries in deciding whether they wanted to accept further imports must therefore be used to its best possible advantage. The slow rate at which regulatory actions to ban or severely restrict chemicals were being notified to the Secretariat remained a matter for concern, although there had been some progress. The health-related incident report form had also occasioned the first proposal to the Committee to list a severely hazardous pesticide formulation. He acknowledged the important contribution of non-governmental organizations to the work of the Committee and to the implementation of the interim PIC procedure.

II. ORGANIZATIONAL MATTERS

8. The following officers continued to serve on the Bureau of the Committee. As Mr Dudley Achu Sama (Cameroon), Rapporteur, was unable to attend, Mr Masayuki Ikeda fulfilled that function for the third session.

Chair: Mr Reiner Arndt (Germany)

Vice-Chairs: Ms Flor de María Perla de Alfaro (El Salvador)

Mr Tamás Kömives (Hungary) Mr Masayuki Ikeda (Japan)

Rapporteur: Mr Masayuki Ikeda (Japan)

9. The Committee welcomed the formal confirmation by the Intergovernmental Negotiating Committee of the expert nominated by Australia to serve on the Committee. The Committee also welcomed the new

expert nominated by Canada, who served on the Committee pending formal confirmation by the Intergovernmental Negotiating Committee.

- 10. The session was attended by the following 26 experts: Mr André Mayne (Australia), Ms Sandra de Souza Hacon (Brazil), Mr Rob Ward (Canada), Mr Julio Monreal (Chile), Ms Yong-Zhen Yang (China), Ms Mercedes Bolaños Granda (Ecuador), Mr Mohammed El Zarka (Egypt), Ms Flor de María Perla de Alfaro (El Salvador), Mr Ammanuel Malifu Negewo (Ethiopia), Mr Marc Debois (Finland), Ms Fatoumata Jallow Ndoye (Gambia), Mr Reiner Arndt (Germany), Mr Tamás Kömives (Hungary), Mr R. R. Khan (India), Mr Kasumbogo Untung (Indonesia), Mr Masayuki Ikeda (Japan), Mr Ravinandan Sibartie (Mauritius), Mr Mohamed Ammati (Morocco), Mr Bhakta Raj Palikhe (Nepal), Mr Hassan Al Obaidly (Qatar), Mr Boris Kurlyandskiy (Russian Federation), Mr William Cable (Samoa), Mr Jan Goede (South Africa), Mr Azhari Abdelbagi (Sudan), Mr Pietro Fontana (Switzerland) and Ms Cathleen Barnes (United States of America).
- 11. Observers from the following countries and regional economic integration organizations were also present: Argentina, Australia, Austria, Bolivia, Brazil, Chile, China, Croatia, European Commission, Germany, Indonesia, Iran, Italy, Japan, Kenya, Libyan Arab Jamahiriya, Mexico, Mongolia, New Zealand, Qatar, South Africa, Thailand, Turkey, Ukraine, United Arab Emirates and United States of America.
- 12. Representatives of the following intergovernmental organizations and United Nations specialized agencies were also present: World Health Organization.
- 13. The following non-governmental organizations were also represented: Comité Permanent Inter-Etats de Lutte Contre la Sécheresse dans le Sahel (CILSS), Croplife International, the International Council of Women (ICW), Pesticide Action Network (PAN) United Kingdom of Great Britain and Northern Ireland, and Pesticide Action Network (PAN) Africa.

A. Adoption of the agenda

- 14. At its opening meeting, the Committee adopted the following agenda on the basis of the provisional agenda (UNEP/FAO/PIC/ICRC.3/1):
 - 1. Opening of the session.
 - 2. Organizational matters:
 - (a) Adoption of the agenda;
 - (b) Organization of work.
 - 3. Review of the outcome of the eighth session of the Intergovernmental Negotiating Committee.
 - 4. Status of implementation of the interim prior informed consent procedure as it relates to the work of the Interim Chemical Review Committee.
 - 5. Operational procedures for the Interim Chemical Review Committee:
 - (a) Status of the work of the individual task groups established at the first session of the Committee:
 - (i) Task group 1: Pilot testing severely hazardous pesticide formulation report form;

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- (ii) Task group 2: Development of a format for decision guidance documents for severely hazardous pesticide formulations;
- (iii) Task group 3: Development of an environmental incident report form for severely hazardous pesticide formulations;
- (iv) Task group 4: Prioritization of work on old notifications of final regulatory actions to ban or severely restrict a chemical;
- (b) Issues associated with implementation of the operational procedures:
 - (i) Consideration of the development and use of focused summaries;
 - (ii) Draft working paper on preparing internal proposals and decision guidance documents;
 - (iii) Determination of the ongoing trade in chemicals;
 - (iv) Common and recognized patterns of use of severely hazardous pesticide formulations;
 - (v) Compatibility of current regulatory practices with the notification requirements of the interim prior informed consent procedure.
- 6. 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;
 - (b) Review of proposals for severely hazardous pesticide formulations;
 - (c) Consideration of draft decision guidance documents.
- 7. Other matters.
- 8. Adoption of the report.
- 9. Closure of the meeting.
- 15. A list of session documents is given in Annex VI.

B. Organization of work

16. 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.

III. REVIEW OF THE OUTCOME OF THE EIGHTH SESSION OF THE INTERGOVERNMENTAL NEGOTIATING COMMITTEE

17. The Secretariat introduced the document (UNEP/FAO/PIC/ICRC.3/3) on the outcome of the eighth session of the Intergovernmental Negotiating Committee. The Intergovernmental Negotiating Committee had considered the report of the second session of the Committee (UNEP/FAO/PIC/ICRC.2/11) and, with respect to the issue of conflict of interest, had reviewed the draft disclosure form and procedure prepared by the Secretariat, had decided to adopt rules and procedures for preventing and for dealing with conflicts of interest relating to activities of the Committee, and had decided that a declaration of interest form should be

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completed by current members of the Committee for submission to the Committee at its third session. The status of implementation of the conflict of interest procedure was given in document UNEP/FAO/PIC/ICRC.3/INF/1.

- 18. The Intergovernmental Negotiating Committee had reviewed the recommendations of the Committee on the inclusion of maleic hydrazide in the PIC procedure. Most of the recommendations of the Committee had been adopted; however, the Intergovernmental Negotiating Committee had requested the Committee to review the confirmations from manufacturers on compliance with the limit set for free hydrazine and to follow progress made with regard to the preparation of the specification by FAO. A status report on the implementation of the decision and the text of the decision as amended by the Intergovernmental Negotiating Committee were given in document UNEP/FAO/PIC/ICRC.3/INF/2.
- 19. The Intergovernmental Negotiating Committee had endorsed the preparation by the Committee of an issue paper on the compatibility of current regulatory practices with the notification requirements of the interim PIC procedure and had requested it to report on progress to the Intergovernmental Negotiating Committee at its ninth session.
- 20. The Intergovernmental Negotiating Committee had confirmed the appointment of Mr André Clive Mayne (Australia) and had reaffirmed the provision of decision INC-6/2 with regard to the duration of the terms of service of the experts. With regard to notifications on contaminants in industrial chemicals, the Intergovernmental Negotiating Committee had supported the view that a notification should be received before that issue was considered.
- 21. The Intergovernmental Negotiating Committee had reaffirmed its decision that, while Parties should continue to be required to submit full notifications for all regulatory actions on chemicals subject to the interim PIC procedure, Parties and the Secretariat would both give priority to the submission and verification of notifications on chemicals not yet included in that procedure. The Intergovernmental Negotiating Committee had recommended that the issue of coordinating the submission and notification of final regulatory actions on old notifications should continue to be examined by the Committee on a case-by-case basis.
- 22. The Intergovernmental Negotiating Committee had noted with appreciation the excellent work of the Committee.
 - IV. STATUS OF IMPLEMENTATION OF THE INTERIM PRIOR INFORMED CONSENT PROCEDURE AS IT RELATES TO THE WORK OF THE INTERIM CHEMICAL REVIEW COMMITTEE
- 23. The Secretariat introduced the document (UNEP/FAO/PIC/ICRC.3/4) on the status of implementation of the interim PIC procedure. The document reflected the information provided in PIC Circular XIV, distributed on 12 December 2001 to all designated national authorities. The document gave numbers of notifications of final regulatory actions. While the increase in the numbers of notifications was slower than might be wished, the most recent ones had been verified as meeting the requirements of Annex I to the Convention and had allowed three candidate chemicals to be identified for inclusion in the interim PIC procedure. The document also included the first proposal for inclusion of severely hazardous pesticide formulations. Information on the transmittal of responses concerning future imports of a chemical and on transit movements was also provided in the document.
- 24. Concern was expressed about the relatively low number (50 per cent) of import responses and on the difficulties faced by developing countries and countries with economies in transition in submitting notifications that meet the criteria of Annex II. It was felt that those issues should be addressed during awareness-raising workshops.

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- 25. The Secretariat introduced document UNEP/FAO/PIC/ICRC.3/INF.5, on workshops, containing comments and proposals relating to the practical experience of designated national authorities in using the documentation available for the operation of the interim PIC procedure. Based on a recommendation of the Committee at its second session, summary reports for three workshops on the Rotterdam Convention had been reviewed and submitted by Committee members from the regions hosting the workshops. The workshops had been held in Bangkok, report prepared by Mr Reiner Arndt; Nairobi, report prepared by Mr Azhari Abdelbagi; and Cartagena, Colombia, report prepared by Ms Mercedes Bolaños Granda with the assistance of Ms Sandra de Souza Hacon. It was noted that many of the recommendations resulting from the workshops had been acted upon by the Secretariat. Also, the general comments on information contained in decision guidance documents had been taken into account in drafting the format for decision guidance documents.
- 26. Participants in the workshops had noted that a clear distinction must be made between decision guidance documents for severely hazardous pesticide formulations and decision guidance documents for banned or severely restricted chemicals. They had also noted issues arising when decision guidance documents focused on one specific type of formulation of a pesticide, as slight changes in that formulation might place the product outside the scope of the Convention. Participants also expressed the need for additional practical training in the use of the documentation. Responding to requests made at the workshops and the recommendation of the Intergovernmental Negotiating Committee at its eighth session, the Secretariat was drafting a guidance document for designated national authorities.
- 27. Information was provided to Committee members on the plan for holding workshops in 2002. Offers had been made to host workshops, as had promises of financial assistance as a result, it was planned to hold workshops for the English-speaking countries in the Latin America and the Caribbean region and for francophone countries in Africa prior to the ninth session of the Intergovernmental Negotiating Committee, which was scheduled for September 2002. It was hoped that further workshops could be held later for the Middle East region and in the Eastern European region.
- 28. A discussion took place on the merits of combined workshops covering the Rotterdam Convention, the Stockholm Convention on Persistent Organic Pollutants and the Basel Convention on the Transboundary Movement of Hazardous Wastes and Their Disposal. It was felt that while to do so would provide more broad-based information on the chemicals Conventions, it would be impossible to provide the level of focused training and information on the interim PIC procedure requested by some participants.
- 29. It was reiterated that Committee members who participated in relevant workshops should take the opportunity to present information on the work of the Committee.

V. OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE

- A. Status of the work of the individual task groups established at the first session of the Committee
 - (i) Task Group 1: Pilot testing severely hazardous pesticide formulation report form
- 30. The Secretariat introduced the document (UNEP/FAO/PIC/ICRC.3/5) containing the report of Task Group 1 and provided information on the objectives and composition of the Task Group and on issues for consideration by the Committee. The Task Group had developed a provisional incident report form to collect information that would meet the requirements of Part 1 of Annex IV to the Convention. A first draft of the incident form and guidance for collecting information had been evaluated at the second session of the Committee and circulated for comments to a limited number of countries having projects relating to pesticides and pest management. The incident form would not necessarily replace any incident forms already available at national and international levels. Countries could submit national forms so long as the requirements of Annex IV were met.

- 31. The Committee noted that the incident report form had already been used to submit a first proposal on severely hazardous pesticide formulations. It recommended its future use by developing countries and countries with economies in transition. In addition, aid agencies and other international and national bodies having pesticides management projects in developing countries and countries with economies in transition should be encouraged to promote and use the incident form. It was further suggested that training in the use of the incident form should be included in the agenda of future workshops to be held on the implementation of the interim PIC procedure.
- 32. With minor amendments contributed by the members, the Committee adopted the revised form and guidance material.
 - (ii) <u>Task Group 2: Development of a format for decision guidance documents for severely hazardous pesticide formulations</u>
- 33. The Secretariat introduced document UNEP/FAO/PIC/ICRC.3/6 containing the report of Task Group 2 and gave a description of the objectives and composition of the Task Group. Comments had been requested from Task Group members on the outline of work to be completed, background information related to elements listed in Parts 1 and 2 of Annex IV and possible sources of information relevant to Part 3 of Annex IV. Based on comments received, an initial format for the decision guidance document had been prepared. In the format, the information needed by the Committee to determine inclusion of a formulation in the interim PIC procedure was distinguished from that needed by a designated national authority to make an import decision for a specific formulation.
- 34. The Committee considered the value of including information on: active substances as well as specific formulations thereof; the use of similar formulations elsewhere in the country or in other countries; and regulatory measures taken or proposed following a reported incident. It also emphasized that information to be included must be scientifically sound. It recommended further work on gathering information related to alternative pest control practices and on how to assist countries to be aware of and to access the available data. In that regard, it was felt that responsible agencies might be invited to provide information. The Committee noted that there was a need to clarify which information should be included in the decision guidance document and which information should be included in the supporting documentation.
 - (iii) <u>Task Group 3: Development of an environmental incident report form for severely hazardous pesticide formulations</u>
- 35. The Chair introduced the report of Task Group 3 on its intersessional work contained in document UNEP/FAO/PIC/ICRC.3/7. The Coordinator of the Task Group reported that two rounds of consultations on the draft form had been held. However, for technical reasons the second round had not been completed. The Committee authorized the Task Group to hold further, intersessional, consultations, produce an updated draft and circulate it for further comment, and release a draft revised in the light of those comments for pilot testing. Consultations would be held until 22 March 2002, at which time the updated draft would be produced and circulated for further comment. The revised draft would be released for pilot testing four weeks later.
- 36. A number of members expressed the view that the draft form was somewhat intimidating and that some parts of it could be shifted into the draft guidance on completing the form. Although other members expressed the view that incidents over the whole lifecycle of the pesticide should be included, it was noted that the Convention referred only to incidents relating to the use of pesticides. The Task Group was instructed to consider and define the interpretation of the concept of "use" and to report on it to the Committee at its next session. The Committee also requested that part A of the form be made identical to the health incident form.

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- (iv) <u>Task Group 4</u>: Prioritization of work on old notifications of final regulatory actions to ban or severely restrict a chemical
- 37. Drawing the Committee's attention to the report of the work of the Task Group contained in document UNEP/FAO/PIC/ICRC.3/8, the Chair noted that progress had been made in that the new notifications coming into the Secretariat were complete and were for chemicals not already covered by Annex III to the Convention. In the absence of the Coordinator of the Task Group, Mr Karel Gijsbertsen, Ms Cathleen Barnes introduced the report on the work of the Group.
- 38. The Committee agreed that in considering the information in UNEP/FAO/PIC/ICRC.3/8, countries should be encouraged to prioritize their work to bring forward notifications where the chemicals were in ongoing international trade; where there was at least one valid notification; and where notifications of control actions had been received from two or more PIC regions. It agreed also that if a substance was covered by another international instrument such as the Montreal Protocol or was already subject to the interim PIC procedure, its priority in terms of the Convention was reduced.
- 39. The Committee recalled that the Intergovernmental Negotiating Committee encouraged the submission of second, new notifications where one old but valid notification already existed. It also recalled that under paragraph 2 of Article 5 of the Convention, old notifications need not be resubmitted; however, updating of notifications which did not meet the new criteria, and updating of the legislation they reflected, might nevertheless be desirable. The Committee requested that the tabular information in the appendix to document UNEP/FAO/PIC/ICRC.3/8 should be checked for accuracy, its clarity and ease of use improved and that it should then be published in the PIC Circular and posted on the PIC Website. The column containing information on expected notifications would be deleted.
 - B. Issues associated with implementation of the operational procedures
 - (i) Consideration of the development and use of focused summaries
- 40. The Secretariat introduced document UNEP/FAO/PIC/ICRC.3/10 on the item. At its second session, the Committee had recommended that, before the Secretariat forwarded verified notifications for review, the designated national authority should, if possible, submit a focused summary of the information used in support of the regulatory action, and cited in the notification of final regulatory action, for use by the Committee. Further guidance was requested from the Committee on the format, content, level of detail and length of that document. The Secretariat emphasized that the focused summary was not a new obligation on designated national authorities but rather a voluntary action aimed at facilitating the work of the Committee in making decisions on chemicals, and was not intended to replace documentation referenced in the notification of final regulatory action.
- 41. It was noted that the focused summaries should address all Annex II criteria, that they should be flexible, that where risk evaluation information was included it should be based on good scientific practice, and that the summaries should, in the first instance, be prepared for article 5 notifications. While the type of information provided might be different, similar summaries could, at a later stage, be developed to facilitate review of proposals of severely hazardous pesticide formulations under article 6.
- 42. A break-out group to develop guidelines for preparing focused summaries was established with Mr Azhari Abdelbagi and Mr Tamás Kömives as Coordinators and comprising also Ms Cathleen Barnes, Mr R. R. Khan, Mr André Mayne and Ms Jallow Ndoye, and observers Ms Lesley Dowling and Mr Ephraim Mathebula. Mr Kömives reported that the aim of the group had been to ensure that focused summaries not only assisted the Committee in its work, but also that the exercise of focusing should not be too difficult for the designated national authority to carry out. Indeed, it should help it in putting together the notification. The group had concluded that a sample focused summary would be useful towards that end. Mr Mayne and the observer from the Australian Health Authority offered to produce such a focused summary on the basis of the documentation for monocrotophos in time for the first workshop at which it would be useful. The recommendations of the group were accepted by the Committee and are reproduced in Annex I to this report.

- (ii) Draft working paper on preparing internal proposals and decision guidance documents
- 43. Mr André Mayne introduced document ICRC/FAO/PIC/ICRC.3/11, which had drawn on the lessons learnt in the process of developing a decision guidance document on monocrotophos. The format would be a living document that could be enhanced and developed to ease the path of future groups developing such guidance documents. Noting a number of terminological and other clarifications that would be useful for future work and the need for terminological consistency between the Rotterdam, Basel and Stockholm Conventions, the Committee adopted the working paper on the understanding that the guidance it provided would be updated in the light of experience with other draft guidance documents. In the discussion, the point was stressed that CAS numbers for the generic and all other forms of a chemical must be given. One expert indicated that the effect of substances under consideration for the prior informed consent procedure on beneficial predatory insects and parasitoids of insect pests should be taken into consideration and that full environmental and human toxicological data should be provided, as should biodegradation rates and mechanisms.
- 44. It was noted that the information on other evaluations and alternatives to products was continuously evolving. Such information or references would be posted on the Convention Website and circulated with the PIC Circular. In that connection, the Chairman urged participants to encourage the use of the Website, the Circular and the contact information they contained to help meet their needs for toxicity and other data.

(iii) Determination of the ongoing trade in chemicals

- 45. Document UNEP/FAO/PIC/ICRC.3/12 was introduced. At its second session, the Committee had agreed that after two notifications for a chemical had been received the Secretariat should collect information on the international trade in that chemical, the existence of such trade having been established in Annex II to the Convention as a criterion for listing. However, the discussion illustrated the difficulties, practical and logical, of proving a negative. On the positive side, it was agreed that while considerations of commercial confidentiality might put legal impediments in the way of quantitative statements of imports, exports, production and consumption of a chemical, they did not impede simple, qualitative statements of "yes" or "no" as requested by Annex I of the Convention.
- 46. The Committee noted that under paragraph (c) of Annex III to the Convention, the Committee was required to "consider" whether there was evidence of ongoing international trade, not to "confirm" or "establish", as was required for the criteria under paragraphs (a) and (b) of the Annex. That wording was interpreted by the Committee to mean that it had a greater degree of flexibility in respect of the paragraph (c) criteria. However, it also noted that there was no point in writing draft guidance documents for chemicals in which there was no ongoing international trade.
- 47. The Committee also recalled that production of chemicals might be restarted after an interruption and manufacturers on record as former producers of chemicals of interest should be contacted when trying to verify non-production of PIC-listed substances.
- 48. The Committee agreed to use the process as described in document UNEP/FAO/PIC/ICRC.3/12 to collect trade information.
 - (iv) Common and recognized patterns of use of severely hazardous pesticide formulations
- 49. The Secretariat introduced document UNEP/FAO/PIC/ICRC.3/13 on common and recognized patterns of use of severely hazardous pesticide formulations. For the first time, the Committee had before it a proposal for inclusion of a severely hazardous pesticide formulation. One of the criteria to be determined was whether the pesticides had been handled in a manner that was consistent with common and recognized patterns of use in the country submitting the proposal. The difficulty of collecting information on incidents in developing countries and countries with economies in transition was acknowledged.

- 50. It was noted that the Intergovernmental Forum on Chemical Safety was developing a project on how to characterize common patterns of use which included identifying common problems and patterns and would result in recommendations on risk mitigation methods that Governments might consider. Continuing information on the progress of this project was requested from Committee members participating in that activity.
- 51. The Committee agreed to use the proposed outline in document UNEP/FAO/PIC/ICRC.3/13 as a basis on which to characterise common recognized patterns of use, and to collect the information identified on a case-by-case basis.
 - (v) Compatibility of current regulatory practices with the notification requirements of the interim prior informed consent procedure
- 52. Ms Barnes introduced the issue paper prepared by Task Group 4, document UNEP/FAO/PIC/ICRC.3/9, on compatibility of current regulatory practices with the notification requirements of the interim PIC procedure. She noted that the reason for looking at these issues was to better define possible reasons as to why countries were having difficulty in submitting notifications of final regulatory actions. The issues identified in the paper could be broadly characterized into two main areas, differences between national regulatory systems and the language of the Convention and inadequate regulatory infrastructure in many developing countries and countries with economies in transition.
- 53. The Committee, during its deliberations, identified a further range of issues largely related to the lack of infrastructure in countries, particularly in respect of industrial chemicals, and the difficulty of enforcing those regulations that were in place. Countries were advised that they should raise any such concerns at the level of the Intergovernmental Negotiating Committee.
- 54. It was clear that many countries had developed complex processes for managing sub-categories of pesticides and industrial chemicals. Those processes were particularly complex for industrial chemicals that may be used across a range of sub-categories, making it difficult to define a regulatory action as a clear ban or severe restriction as defined in the Convention. It was further noted that the experience in reviewing the notifications at the current session had raised additional issues that would need to be further examined and brought to the attention of the Intergovernmental Negotiating Committee. Those included first-time refusal of chemicals proposed for approvals and so-called preventive bans for chemicals that had never been placed on the domestic market, both where they had been proposed for approval or never proposed for review. The importance of fulfilling the criteria in Annex II for inclusion in the Convention, especially in respect of undertaking appropriate risk evaluation under conditions prevailing in a country, was also raised.
- 55. The Committee agreed that the Chair, with the assistance of the Secretariat, would prepare a technical issue paper on the subject of compatibility for the ninth session of the Intergovernmental Negotiating Committee. Where possible the paper should include examples. A draft of the paper would be circulated to members of the Committee for comment.

VI. 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

DNOC

56. After a presentation by Mr Debois, Coordinator of the Task Group on DNOC, the Committee agreed that the information before it in the notifications by the European Community and Peru met the criteria for including DNOC in the list of chemicals subject to the interim PIC procedure. A draft decision guidance document would consequently be produced.

- 57. It was noted that information on ongoing international trade was not provided in the notification from the European Community. It was agreed that such information, which the Committee was required to "consider" rather than "confirm" or "establish", was not required to be present in each and every notification before the Committee for a particular chemical. Supplementary information from the Russian Federation and Ukraine given orally to the Committee confirmed the existence of ongoing international trade to the Committee's satisfaction. It was noted also that the designated national authority in Peru had provided supplementary information (UNEP/FAO/PIC/ICRC.3/16/Corr.1) amending its notification. It was agreed that the Committee could and should take cognizance of such information.
- 58. The Committee noted that the regulatory actions notified by the European Community and Peru banned all uses of plant protection products containing DNOC. The CAS number referred to in the notification documents was for DNOC acid only, while the product had also been used in its salt formulations, which had different CAS numbers. Whereas a chemist or a pesticides expert would understand that the DNOC component of the compound had been the basis for the toxicological assessment, for the purposes of the Convention all the forms must be specified, and it was agreed that further clarification must be sought from the notifying authorities as to the precise scope of their regulatory actions. That information would be reflected in the draft guidance document. It was also agreed that the Intergovernmental Negotiating Committee should be asked for guidance on including in the interim PIC procedure substances not specifically identified in notifications. The breakout group on DNOC (see below) identified this as a compatibility issue.
- 59. The notification by Thailand raised issues of principle of importance for the Committee's future work. The observer representing the designated national authority of Thailand was invited to supply further information regarding the notification and explained that the Government of Thailand banned chemicals, as a matter of policy, on the basis of the following criteria: (a) if they had an oral LD₅₀ of < 30mg/kg body weight, that is, were very hazardous; (b) they showed chronic toxicity, such as carcinogenicity; (c) they were persistent; (d) they underwent bioaccumulation; (e) they caused damage to certain indicator species; (f) they contained contaminants with the foregoing characteristics; (g) residues were frequently found in exported products; (h) they had been banned in other countries; and (i) and there were alternatives of proven lower toxicity.
- 60. The observer explained that Thailand believed that all its pesticide needs were met by the more than 300 registered substances in use. In order for new active ingredients to be permitted for use they must be proven safe. World Health Organization category 1a and 1b pesticides would not be permitted. Also, as it was aiming for sustainability in agriculture as in all other forms of development, it must comply with the requirements of its export markets, such as the European Union, Japan and the United States of America, in respect of pesticide residues.
- 61. The Committee expressed appreciation for the notification submitted by Thailand; however, members took the view that it could not meet the requirements of Annex II (b). Some members took the view that it could, and were satisfied with the extent to which it met those criteria. Other members were of the view that while there was no objection in principle to preventive action triggering the PIC procedure, the notification by Thailand failed by not meeting the criteria for risk evaluation in the conditions prevailing in Thailand. Also, a view was expressed that the action was more similar to a "before-the-fact" import response to the PIC listing of the substance than to a notification sent with a view to triggering such a listing. Several members pointed out that many developing countries and countries with economies in transition lacked the infrastructure to carry out risk evaluations and recalled that, according to the Convention, assistance should be provided to enable them to establish such infrastructure. A number of members indicated that action taken pursuant to a general policy to ban pesticides falling within a particular WHO hazard classification was not admissible and that only action taken on a specific chemical for reasons specific to that chemical could be used to determine whether the requirements of Annex II were met.

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- 62. The Committee agreed that the notification of Thailand was useful as an exchange of information, as mandated by article 14, and that such notifications should be encouraged. It was agreed also that the question of whether preventive regulatory action of pesticides met the definition of a ban under article 2 should be referred to the Intergovernmental Negotiating Committee, as should the general question of the relationship of preventive action to the Annex II criteria. A number of Committee members stated that preventive action would never meet the Annex II (c) (i) criterion of "significant reduction" in the quantity of the chemical used or the Annex II (c) (ii) criterion of "significant reduction" in risk to human health and the environment, while others were of a different opinion. Another member noted that a risk evaluation should and could assess whether the final regulatory action would be expected to result in a significant reduction of risk based on the chemical's expected applications and uses. The question of preventive action would be addressed in the issue paper on compatibility to be prepared by the Chair of the Committee for submission to the Intergovernmental Negotiating Committee at its ninth session.
- 63. The notification by Cyprus took as its risk evaluation that submitted by the European Commission. The question of Annex II (b) (iii) "prevailing conditions" therefore arose and it was agreed that the Intergovernmental Negotiating Committee should be asked to provide guidance on how to determine when countries should provide their own risk evaluations for their own prevailing conditions and conversely under which conditions the Committee could be allowed to accept information from neighbouring and other countries that had identical or similar conditions in relation to the use of pesticides.
- 64. A break-out drafting group to work on the Committee's recommendations on DNOC was established, jointly coordinated by Mr Debois and Ms Bolaños with a membership comprising also Mr Khan, Mr Abdelbagi, Mr Kurlyandskiy, Ms Barnes and Mr Kundiyev. Mr Debois presented the findings of the group, which included a detailed timetable for drafting the draft guidance document. The recommendations prepared by the drafting group and its rationale as adopted by the Committee are reproduced in Annex II to this report. The composition of the intersessional drafting group and its schedule are also given in Annex II.

Dinoterb

- 65. Mr Debois, coordinator of the task group on Dinoterb, introduced document UNEP/FAO/PIC/ICRC.3/15 and its Add.1 and 2 and gave a presentation on the work of the Task Group. The two problems that had arisen during the examination of the two notifications on Dinoterb related to the risk evaluation data provided by Thailand and the lack of evidence of ongoing international trade in the chemical.
- 66. The Committee agreed that the notification received from the European Community fulfilled the criteria set out in Annex II to the Convention but that the notification received from Thailand did not meet those criteria for the same reasons as were given for the Thailand notification submitted for DNOC. In addition, based on the information provided by industry organizations and other available information there was no current indication of ongoing international trade. The Committee agreed not to recommend the inclusion of Dinoterb in the interim PIC procedure.

Asbestos

- 67. Mr Mayne, the Coordinator of the Task Group on asbestos, introduced documents UNEP/FAO/PIC/ICRC.3/14 and its Add.1, 2 and 3. The Task Group had been set up following the eighth session of the Intergovernmental Negotiating Committee to review, in terms of Annex II to the Convention, the information on asbestos in its various forms provided by Australia, Chile, the Czech Republic and the European Community. Written comments had been solicited from all Committee members. The issues raised were addressed in presentations to the Committee.
- 68. Following presentations by the interested participants, the Committee determined that the notifications by Australia, Chile and the European Committee met the criteria of Annex II for the amphibole forms of asbestos. It also determined that the notifications by Chile and the European Community met the criteria of

Annex II for the chrysotile form of asbestos. The existence of ongoing international trade in asbestos was reconfirmed by information provided by Committee members and by reference to production, import and export figures for various countries.

- 69. The Czech legislation on amphibole had been passed consequent on its candidacy for membership of the European Community. The Czech designated national authority had indicated that the conditions prevailing there were effectively the same as in the neighbouring European Community member States. The Czech Republic was in the process of passing legislation, for the same reasons, banning chrysotile. The Committee determined that the notification did not meet all criteria of Annex II, like the notification from Cyprus on DNOC (see paragraph 63), as it did not demonstrate a clear link between the risk evaluation and conditions prevailing in the country.
- 70. The Committee agreed that all criteria for listing all the notified forms of asbestos had been met and it decided to recommend to the Intergovernmental Negotiating Committee that it should make the actinolite, anthophyllite, amosite, tremolite and chrysotile forms of asbestos subject to the interim PIC procedure.
- 71. The Committee noted that the crocidolite form of asbestos was already listed under Annex III and, in keeping with the recommendation of the Task Group, it was agreed that the crocidolite decision guidance document should be updated where appropriate and incorporated into a single draft decision guidance document covering all forms of asbestos and showing all CAS numbers for the various forms of asbestos. States would not be required to resubmit an already provided import response for their trade in crocidolite but would be invited to submit it for the first time or to update it where appropriate.
- 72. It was agreed that, in making the various forms of asbestos subject to the PIC procedure, it was the intent of the Committee that the forms should be listed in such a way that countries could take import decisions for each individual form. The Committee agreed also that the exact approach for listing might best be left to the Intergovernmental Negotiating Committee.
- 73. Some representatives of developing countries and countries with economies in transition said that asbestos was still in use in their countries, particularly for roofing materials, because of problems finding alternatives and because there were problems with disposing of asbestos and asbestos-containing construction materials removed from buildings. One representative of a West African country said that although imports had been banned, they nevertheless continued and it was felt that notification of the ban or severe restriction could not be submitted until the disposal and illicit trade problems had been solved.
- 74. An observer from the designated national authority of a southern African producer country informed the Committee that the use of asbestos had been banned in his country on the basis of health risk data and asbestosis cases covering nearly half a century. He offered to share his country's experience with finding alternatives and with disposal, and also in coping with pollution problems from mine tailings and dumps. It was agreed that that information should be made available under the Convention's article 14 information exchange provisions.
- 75. The Committee also agreed that International Labour Organization Convention 162 of 1986, which had been based on World Health Organization guidelines, on occupational hygiene in the handling of asbestos should be referred to in the draft guidance document for the information of States which chose not to ban asbestos and asbestos products totally.
- 76. A break-out drafting group to work on the Committee's recommendations on asbestos was established, jointly coordinated by Mr Mayne and Mr Monreal with a membership comprising also Mr Arndt, Mr Ward, Mr Kurlyandskiy, Mr Goede and Mr El Zarka. Mr Mayne presented the findings of the group, which included a detailed timetable for drafting the draft guidance document. The recommendations prepared by the drafting group and its rationale as adopted by the Committee are reproduced in Annex III to this report. The composition of the intersessional drafting group and its schedule are also given in Annex III.

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B. Review of proposals for severely hazardous pesticide formulations

- 77. Mr Ammati, Coordinator of the Task Group on the review of the proposals on severely hazardous pesticide formulations SPINOX T and GRANOX TBC, presented the documents under the agenda item, UNEP/FAO/PIC/ICRC.3/17 and its Add.1, 2 and 3. He described how the Task Group had reviewed the proposals submitted by Senegal and the complementary information prepared by the Secretariat according to Parts 1 and 2 of Annex IV and assessed the proposed information according to the criteria in Part 3 of Annex IV.
- 78. Members of the Committee requested clarification on the formulations involved, on the appearance of limb oedema, and whether the incidents recorded were specific to SPINOX T or GRANOX TBC. The representative from Pesticide Action Network in Africa, along with other members of the Committee, responded to those queries. Some concern was expressed on the time lag between reported exposure and effects, and on the possibility that case control studies showed no correlation between exposure and illness. The Committee noted that data on effects had been collected after the incidents and that there had been continued exposure over a period of time covered by the onset of symptoms and that the use of the pesticides had been highest where there was the highest incidence of poisonings. It further noted that certain regions where it had been expected that the formulations would be used had not received the pesticide, and in those regions no incidents of poisoning had been recorded.
- 79. In examining the criteria set forth in Part 3 of Annex IV, Committee members agreed that on the balance of evidence the incidents had occurred as a result of use of SPINOX T and GRANOX TBC and therefore criterion (a) had been fulfilled. To meet criterion (b) it was noted that a similar formulation with one different active ingredient was being used in both the Gambia and in Burkina Faso. Information received from Germany and the United States of America on criterion (c) confirmed the need to use special and protective apparel during use of at least one active ingredient in the formulation, which had not been in keeping with patterns of use in Senegal. From the documentation provided, reported effects had been determined to be related to the quantities used, as required by criterion (d). Finally, with respect to criterion (e) the incidents reported were not attributable to intentional misuse but occurred as a result of using the formulations in accordance with common or recognized practices in Senegal.
- 80. In the light of the discussion and the supporting documentation, the Committee agreed that the severely hazardous pesticide formulations SPINOX T and GRANOX TBC in the formulations given in the proposal received from Senegal should be recommended for inclusion in the interim PIC procedure. The recommendation and supporting documentation are given in Annex IV to this report, as is the composition of the intersessional drafting group and the schedule of intersessional work.
- 81. A drafting group was set up under the joint coordination of Mr Ammati and Ms Barnes and including Ms Alfaro, Mr Ikeda, Ms Jallow Ndoye, Mr Kömives, Mr Palikhe, Mr Sibartie, Mr Untung, and Ms Yang. The Task Group was mandated to draft a schedule and work plan for the intersessional work of drafting a decision guidance document and to undertake an initial review of the information available to the Committee for SPINOX T and GRANOX TBC. Along with the above-mentioned members, an open-ended drafting group was also created to examine the format for a decision guidance document on severely hazardous pesticide formulations.
- 82. Several members of the Committee expressed concern over the implications of including a single specific formulation with identified percentages of the active ingredients in the interim PIC procedure and felt that further guidance from the Intergovernmental Negotiating Committee was necessary to determine how such listings should be considered in the future. The Secretariat was requested to examine those implications and prepare an issue paper outlining the discussion and reviewing the consequences of such listings for consideration by the Intergovernmental Negotiating Committee at its ninth session.

C. Consideration of draft decision guidance documents

- 83. The Chair of the Committee presented the draft decision guidance document on monocrotophos, UNEP/FAO/PIC/ICRC.3/18, and noted the excellent intersessional work that had been done by Mr Mayne and his colleagues. Mr Mayne introduced the draft document and outlined the process used in its preparation. The draft had been circulated three times for comment and had been scrutinized twice by Task Group members. Several questions had been raised during circulation of the document and had been resolved by the Task Group. Those questions were outlined in a table presented to the Committee. He expressed his appreciation for the extensive assistance he had received from members of the Task Group and others and expressed his thanks to them for their commitment in preparing the draft document.
- 84. After clarifying a number of points, the Committee decided to forward the draft decision guidance document and the recommendation for inclusion of monocrotophos in the interim PIC procedure to the Intergovernmental Negotiating Committee for a decision. The text of that recommendation, a summary of the deliberations of the Committee including a rationale for the inclusion of monocrotophos based on the criteria listed in Annex II, and a tabular summary of comments received by the Secretariat and how they had been addressed are attached to the present report as Annex V. The draft decision guidance document will be issued separately under symbol UNEP/FAO/PIC/ICRC.3/19/Add.1.
- 85. Mr Khan, pointing out that six of the nine manufacturers listed in the decision guidance document were located in India, voiced his concern on the contents of the document. He suggested that under the section risk evaluation, the paragraph on environmental impact could include information on alternative delivery methods, if known or available, such as the use of the compound in encapsulated form. He suggested also that under the section identification and uses, the paragraph on basic manufacturers could state that the list was not exhaustive. The Committee agreed to the latter suggestion.

VII. OTHER MATTERS

Maleic hydrazide

86. The Secretariat introduced the status report (UNEP/FAO/PIC/ICRC.3/INF/2) on the implementation of the maleic hydrazide decision as modified at the eighth session of the Intergovernmental Negotiating Committee in decision INC-8/3. Only one manufacturer had so far begun the procedure to obtain a FAO specification; the Secretariat had been and remained in contact with all manufacturers, stressing the need for them to submit their documentation by June 2002 for consideration in June 2003. The Secretariat would deliver a report on progress to the Intergovernmental Negotiating Committee at its eighth session. He recalled that the manufacturers of maleic hydrazide in the People's Republic of China were not of concern to the Committee because their production was for domestic consumption only. The Committee took note of the report and of the Secretariat's intention to report further to the Intergovernmental Negotiating Committee.

Chemical Abstract Service (CAS) numbers

87. The Committee took note of the information note, introduced by the Chair of the Committee, on CAS numbers (UNEP/FAO/PIC/ICRC.3/INF.4). The Chair stressed that in its recommendations for PIC listings the Committee was obliged to specify the CAS numbers of all chemicals involved: the CAS numbers, except in rare cases, had the virtue of unambiguity. However, the possible conflict between unambiguous CAS numbers and the phrasing of bans or severe restrictions by legislators, as a possible issue of compatibility between the Convention and national legislation, remained an issue for the Committee in its handling of notifications because not only was it required to pass on specific CAS numbers in its recommendations for listing, it must first be sure that notifications from a minimum of two regions did in fact cover the same substances. He stressed that notifying authorities must be encouraged to be comprehensive and specific by stating all the CAS numbers of the chemicals which their notifications were intended to cover.

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Seventh special session of the Global Ministerial Environment Forum

88. The Secretariat reported on the decisions of the Global Ministerial Environment Forum, held in Cartagena, Colombia from 13 to 15 February 2002, in so far as they related to the work of the Committee, and briefed the Committee on developments of interest to international chemicals management in the broader international arena and in the context of the World Summit on Sustainable Development.

Presentation on the forthcoming World Summit on Sustainable Development

89. The observer from the designated national authority of South Africa gave a presentation on the forthcoming World Summit on Sustainable Development to be held in Johannesburg which gave the Committee a comprehensive overview of the Committee's place in the broader international political context and specifically in the context of international environmental governance. The observer highlighted the view that the issue of chemicals management was a human rights issue in the sense that a clean and safe environment was a human right, and an equality issue in that poor people and countries suffered the effects of hazardous, dirty and degraded environments most. The Committee thanked the observer for helping to place its work in context and a request was made for his presentation to be made available to members.

VIII. ADOPTION OF THE REPORT

90. The Committee adopted its report on the basis of the draft report contained in document UNEP/FAO/PIC/ICRC.3/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.

IX. CLOSURE OF THE MEETING

91. Following the customary exchange of courtesies, the Chair declared the session closed at 1 p.m. on Thursday, 21 February 2002.

Annex I

Report of the break-out group on the focused summary of notifications on banned or severely restricted chemicals

Background

ICRC2 decided that, if possible, the DNA should submit a focused summary of the information used in support of a regulatory action (UNEP/FAO/PIC/ICRC.2/11).

ICRC2 did not define the format of the focused summary, the level of detail or length of the document. A task group was established at ICRC3 to develop clarification for the format and content of focused summaries taking into account plenary discussion and the document UNEP/FAO/PIC/ICRC.3/10.

Purpose of focused summary

The focused summary is not a new obligation but a voluntary action aimed at facilitating the work of the Committee.

The focused summary would summarize the basis for the reported regulatory action. In situations where the supporting documentation is not available in English the focused summary could be that part of the documentation that is translated. Similarly where the supporting document is extensive the focused summary could be the part that is circulated to the Committee for its initial consideration.

Noting that it may be that documentation already produced and published by national Governments may be adequate as a focused summary.

Recommendations on focused summary

The breakout group's recommendations are as follows:

- 1. A focused summary should summarize and demonstrate how the notification meets the relevant criteria in Annex II by providing a summary of key decisions and key findings with references to associated documents.
- 2. It should be as informative and as short as possible. Depending on the nature of the notification it could be up to 10 pages.
- 3. The focused summary has to focus on the information that is relevant to the action.
- 4. The information presented should address the criteria in Annex II for listing banned or severely restricted chemicals.
- 5. The focused summary should have the following key headings:

I. INTRODUCTION

This section should provide a brief statement/summary of the final regulatory actions and the reasons for the actions taken (e.g. occupational health concerns, environmental concerns). Could include:

- (a) The events that led to the final regulatory action;
- (b) Significance of regulatory action, e.g. one use or many uses, level or degree of exposure;
- (c) An overview of the regulatory system of the notifying country if relevant;
- (d) Scope of the regulatory action precise description of the chemicals subject to the regulatory action.

II. RISK EVALUATION

This section should provide evidence that a risk evaluation was carried out under the prevailing conditions of the notifying country. It should confirm that criteria Annex II (b) are met. May include:

- (a) Key findings of the national risk evaluation;
- (b) Key data reviews consulted and a brief description;
- (c) Reference to national studies, e.g. toxicological and ecotoxicity studies;
- (d) Summary of actual (or potential) human exposure and/or environmental fate.

III. RISK REDUCTION AND RELEVANCE TO OTHER STATES

This section should provide evidence that the control action is of relevance to other States. Could include information on the following:

- (a) Estimates of the quantity of chemicals used, or imported/exported at the time of the regulatory action and, if possible information on ongoing trade;
 - (b) Relevance to other States, i.e. those with similar conditions of use;
- (c) Comments on the typical use of the chemical within the notifying country, with comments on possible misuse (if appropriate).

Annex II

Rationale for the draft recommendation that DNOC should become subject to the 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 Peru together with the supporting documentary information and supplementary information provided by those Parties, the Committee was able to confirm that those actions had been taken in order to protect human health, (particularly as regards operator exposure) and the environment (risks to non-target species). The European Community action stemmed from a risk evaluation based on data that contained some gaps. However, the unaddressed endpoints were not relevant for the evaluation, which concluded that there were concerns about human health and the environment. The action by Peru was based on hazard data supplemented by a study of poisoning incidents in the country. Taken together, that material demonstrated that there had been a risk evaluation that took into account prevailing conditions in that country.

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 recognized methods, that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures, and that the final regulatory actions had been based on chemical-specific risk evaluations taking into account the conditions prevailing within the European Community and Peru.

The Committee concluded that the final regulatory actions provided a sufficiently broad basis to merit including DNOC in the interim PIC procedure. 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. 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 from Peru and other available information, the Committee concluded also that there was ongoing international trade in DNOC.

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

The Committee concluded that the notifications of final regulatory actions by the European Community and Peru met the criteria set out in Annex II to the Convention.

DRAFT RECOMMENDATION TO THE INTERGOVERNMENTAL NEGOTIATING COMMITTEE ON THE INCLUSION OF DNOC IN THE INTERIM PIC PROCEDURE

<u>Recalling</u> Article 5 of the Convention and paragraphs 4 and 8 of the resolution on interim arrangements adopted by the Conference of Plenipotentiaries,

<u>Concluding</u> that the notifications of final regulatory actions by the European Community and Peru meet the criteria set forth in Annex II to the Convention,

<u>Noting</u> that further clarification is required on the intended scope of the notifications of the final regulatory actions by the European Union and Peru in relation to the various salts of DNOC,

<u>Decides</u>, in accordance with paragraph 6 of Article 5 of the Convention, to recommend to the Intergovernmental Negotiating Committee that it should make DNOC and the salts common to both notifications subject to the interim PIC procedure.

Composition of the Intersessional Drafting Group on DNOC

Ms Bolaños (Coordinator) Mr Kurlyandskiy

Mr Debois (Coordinator) Mr Cable

Mr Abdelbagi Mr Al Obaidly

SCHEDULE FOR THE INTERSESSIONAL DRAFTING GROUP ON DNOC (and its Salts)

Tasks to be carried out, responsible persons, and deadlines:

- All members of the Task Group to provide available information on the individual formulations and salts Responsible: All members Deadline: 31 March 2002.
- Draft "internal proposal" on DNOC based on two notifications and accompanying documents Responsible: M. Debois, M. Bolaños Deadline: 15 June 2002.
- Send draft "internal proposal" to group members for comments via e-mail. Responsible:M. Debois, M. Bolaños Deadline: 16 June 2002.
- Send comments on the draft proposal to TG-Chairs

Responsible: All Deadline: 30 June 2002.

- Update "internal proposal" based on the comments and the additional information from group members.
 Responsible: M. Debois, M. Bolaños Deadline: 15 July 2002.
- Send updated "internal proposal" to the ICRC and its observers for comments via e-mail.

Responsible: M. Debois, M. Bolaños Deadline: 16 July 2002.

• Send comments on the draft proposal to TG-Chairs

Responsible: All Deadline for replies: 1 September 2002.

• Draft a decision guidance document (DGD) based on the comments related information from the ICRC and its observers.

Responsible: M. Debois, M. Bolaños Deadline: 27 September 2002.

• Send draft DGD to group members for comments via e-mail.

Responsible: M. Debois, M. Bolaños Deadline for replies: 27 September 2002.

• Send comments on the draft DGD to TG-Chairs

Responsible: All Deadline for replies: 22 October 2002.

• Finalize draft DGD based on the comments of the group.

Responsible:M. Debois, M. Bolaños Deadline: 15 November 2002.

Send the draft DGD to secretariat.

Responsible: M. Debois, M. Bolaños Deadline: 15 November 2002.

• ICRC-4 meeting. 3-7 March 2003.

Annex III

Rationale for the draft recommendation that asbestos (amphibole forms and chrysotile) should become subject to the 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 from the European Community, Chile and Australia that cover amphibole forms of asbestos (crocidolite, amosite, actinolite, anthophyllite, tremolite), and the notifications from the European Community and Chile that also cover chrysotile, and considering the supporting documentation and supplementary information provided at the meeting by the notifying Parties, the Interim Chemical Review Committee was able to confirm that the regulatory actions had been taken in order to protect human health. The European Community action was based on a risk evaluation made by an independent scientific committee. Its conclusions were that all forms of asbestos were carcinogenic to man and that there was no threshold of exposure below which asbestos did not pose carcinogenic risks. The Chilean regulatory action was taken on the basis of a review of the health effects of asbestos, the evaluation of occupational exposure and the fact that there were no thresholds for the carcinogenic effect of asbestos. The basis of the Australian regulatory actions was human health risk assessments, taken at national and state level that focused on the carcinogenicity of inhaled asbestos and conditions of exposure in that country.

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 recognized methods, that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures, and that the final regulatory actions had been based on chemical-specific risk evaluations taking into account the conditions prevailing within the European Community, Chile and Australia respectively.

The Committee established that the final regulatory actions provided a sufficiently broad basis to merit including amphibole forms of asbestos and chrysotile in the interim PIC procedure, and that those actions had led to a significant decrease in the quantities and uses of asbestos and the risks for human health in each notifying Party. The Committee also took into account that the considerations underlying the final regulatory actions were not of limited applicability but of broader relevance and that on the basis of information from Chile and Australia, and other relevant information provided by members at the meeting, there was ongoing international trade in asbestos.

The Committee noted that intentional misuse was not relevant to this chemical and that one of the forms of asbestos, crocidolite, was already listed in Annex III to the Convention.

The Committee concluded that the notifications of final regulatory actions by the European Community, Chile and Australia in respect of amphibole forms of asbestos met the criteria set out in Annex II to the Convention and that the notifications of final regulatory action from the European Community and Chile in respect of chrysotile also met those criteria.

DRAFT RECOMMENDATION TO THE INTERGOVERNMENTAL NEGOTIATING COMMITTEE ON THE INCLUSION OF ASBESTOS (ACTINOLITE, ANTHOPHYLLITE, TREMOLITE, AMOSITE AND CHRYSOTILE) IN THE INTERIM PIC PROCEDURE

The Interim Chemical Review Committee:

<u>Decides</u>, in accordance with paragraph 6 of Article 5 of the Convention, to recommend to the Intergovernmental Negotiating Committee that it should make the actinolite, anthophyllite, tremolite, amosite and chrysotile forms of asbestos subject to the interim PIC procedure;

<u>Agrees</u> to revise the existing Decision Guidance Document on crocidolite to cover all the six forms of asbestos (actinolite, anthophyllite, tremolite, amosite, crocidolite and chrysotile);

<u>Recommends</u> that each form of asbestos that is agreed by the Intergovernmental Negotiating Committee to be made subject to the interim PIC procedure should be listed in such a way as to allow countries to apply the relevant provisions of the Convention to each individual form of asbestos separately.

Composition of the Intersessional Drafting Group on Asbestos

Mr Arndt (Coordinator)

Ms Barnes

Mr El Zarka

Mr Goede

Ms Hacon

Mr Khan

Mr Kurlyandskiy Mr Malifu Negewo

Mr Mayne

Mr Monreal

Intersessional Drafting Group on Asbestos

Task	Responsible parties	Deadline:	Comments:
Draft "internal proposal" on asbestos	Inner Group: Mayne/Arndt/Monreal.	1 June 2002.	14 weeks drafting period; Call for info from all parties for identification as accompanying info.
Send draft "internal proposal" to drafting	Mayne (on behalf of	1 June 2002.	
group members for comments via e-mail	the inner group)		
Replies from drafting group members to lead coordinator.	All drafting group members	1 July 2002.	4 weeks review period
Update "internal proposal" based on the comments and the additional information from drafting group members.	Inner Group: Mayne/Arndt/Monreal	1 August 2002.	4 weeks working period
Send updated "internal proposal" to the ICRC and its observers for comments via e-mail.	Mayne (on behalf of the inner group)	1 August 2002	6 weeks review period
Replies from all ICRC members and its observers.	All ICRC members and its observers	Mid-September 2002	
Draft a decision guidance document (DGD) based on the comments and additional information from the ICRC and its observers.	Inner Group: Mayne/Arndt/Monreal	Mid-October 2002.	4 weeks working period
Send draft DGD to drafting group members for comments via e-mail.	Mayne (on behalf of the inner group)	Mid-October 2002.	2 weeks review period
Replies due from drafting group	All drafting group	1 November	
members	members	2002.	
Finalize draft DGD based on the	Inner Group:	1 December	4 weeks working period
comments of the group.	Mayne/Arndt/Monreal	2002.	
Send the draft DGD to secretariat.	Mayne (on behalf of the Drafting Group)	1 December 2002.	
ICRC meeting.		March 2003.	

Annex IV

Rationale for the draft recommendation that SPINOX T AND GRANOX TBC should become subject to the prior informed consent procedure and to establish an intersessional drafting group to prepare a draft decision guidance document

(a) The reliability of the evidence indicating that the use of the formulations, in accordance with common or recognized patterns of use within the proposing party result in the reported incidents.

The reported poisoning incidents were well documented, documents available were the completed incident report forms, a separate epidemiological study undertaken by representatives of the Senegalese government, the World Health Organization and others. They were further supported by information on the individual active ingredients collected from internationally recognized sources.

In reviewing this documentation there was concern that the onset of symptoms was not consistent with carbamate intoxication, given that it appeared that the majority of symptoms, including fatalities, occurred 45 to 120 days after the first exposure. However, it was recognized that this may be an artefact of the way in which the data were reported and probably reflected the time from when users first started applying the formulation, rather than the time between the last exposure and the onset of symptoms. In all cases, a precise link between the time of exposure and the onset of symptoms was difficult to establish. The reasons include: the data were collected retrospectively; the principal exposure occurred during sowing of treated seeds, an activity that takes place over a period of 5 to 10 days and may occur from May through August; and, written records of pesticide use are not typically maintained in the region. However, in some cases symptoms were reported from within a few hours to two days after exposure.

It was also noted that symptoms reported did not reflect the full range of those typically associated with cholinesterase inhibition. For carbamates, such symptoms as miosis and excess salivation are typically of short duration. Given that the data were collected some time after exposure, those symptoms would not be expected to be observed. In addition, it was noted that the forms used to collect the data may have influenced the symptoms reported, since it did not list the full range of symptoms representative of cholinesterase inhibition. The reported respiratory problems were considered to be indicative of lung oedema, normally a symptom of severe carbamate poisoning, and possibly a pre-condition to the reported limb oedemas. In addition, supplementary information relevant to the nature and scope of the illness related to the use of the formulations was not available due to inadequate record keeping in health centres and posts in the region.

In the design of the supporting epidemiological study there was a potentially confounding case controls selection, in that the controls may have also been exposed to pesticides. It was determined that while this was a potential weakness in the study it should not lead to discounting the overall results. The reasons for this include the following:

"There was no difference between cases and controls regarding their participation in farm work. Nonetheless, distribution of sick cases in space and time shows that they were concentrated in the peanut farming areas soon after the beginning of the rainy season and during the season of agricultural labour, with a major peak in August, when all farmers started or ended sowing. ... Most controls were less exposed because they were ill during the period of sowing." (UNEP/FAO/PIC/ICRC.3/17/Add.3, Annex II, section 6, third para.)

The reported incidents were limited to the Kolda region of Senegal. The formulations were not evenly distributed across the region, thus some areas had no exposure to the formulation and no incidents were reported in those areas. Kolda was the region in which it was also reported that as a result of a new agricultural policy there was an increase in the yield of peanuts associated with more intensive farming practices. This increased intensity of production was associated with increased pesticide use. It was reported that associated with the increased peanut production the quantities of pesticides available to farmers doubled and even tripled (see ibid., section 5.4.3).

It was confirmed that the 22 incident reports considered by the Committee involved exposure to the Spinox/Granox formulations only. In addition a representative from PAN Africa confirmed that the Spinox T and Granox TBC were the only pesticide formulations directly available to farmers in the region. This information was considered to reinforce the link between exposure to these formulations and the observed effects.

While it was recognized that there some elements of the data available to the Committee could be challenged, it was agreed that the overall weight of evidence clearly indicated that the use of the formulations in accordance with common and recognized practices within Senegal resulted in the reported incidents.

(b) The relevance of such incidents to other States with similar climate conditions and patterns of use of the formulation.

It was agreed that the information about the reported incidents and the formulation was relevant to other Parties particularly those with similar climatic conditions and levels of awareness among agricultural workers and that are producing peanuts using similar cropping systems.

(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in states lacking he necessary infrastructure.

Information on restrictions about this specific formulation is not available. However, for carbofuran most formulations are restricted to trained personnel wearing suitable protective clothing (e.g. protective impermeable boots, clean overall, gloves and a respirator or other technology designed to minimize applicator exposure such as closed cabs or closed systems of mixing, loading and application). It was also noted that based on the request for information on these formulations no powdered formulations of carbofuran were approved in 25 countries or the European Community.

It was agreed that such techniques and technologies considered necessary to reduce exposure to acceptable levels in developed countries would not be expected to be available or feasible in developing countries lacking the necessary infrastructure and with a hot and humid climate.

(d) The significance of reported effects in relation to the quantity of pesticide used.

The reported effects included mortality and were observed with increased frequency in the region where there was increased use of the formulations.

(e) Intentional misuse is not in itself an adequate reason to include a formulation in the interim PIC procedure.

The incidents reported were not the result of intentional misuse but occurred as a result of using the formulations in accordance with common or recognized practices in Senegal.

DRAFT RECOMMENDATION TO THE INTERGOVERNMENTAL NEGOTIATING COMMITTEE ON THE INCLUSION OF SPINOX T AND GRANOX TBC IN THE INTERIM PIC PROCEDURE

<u>Recalling</u> Article 6 of the Convention and paragraphs 4 and 8 of the resolution on interim arrangements adopted by the Conference of Plenipotentiaries,

<u>Concluding</u> that the proposal for inclusion of the severely hazardous pesticide formulations SPINOX T and GRANOX TBC by Senegal meets the criteria set forth in Part 3 of Annex IV to the Convention,

<u>Decides</u>, in accordance with paragraph 5 of Article 6 of the Convention, to recommend to the Intergovernmental Negotiating Committee that it should make SPINOX T AND GRANOX TBC subject to the interim PIC procedure.

Composition of the Intersessional Drafting Group on Granox TBC and Spinox T

Mr Ammati (Coordinator)

Mr Arndt

Ms Barnes (Coordinator)

Mr Cable

Mr Debois

Mr Ikeda

Mr Kömives

Mr Mayne

Ms Ndoye

Mr Palikhe

Mr Sibartie

Mr Untung

Mr Ward

Ms Yang

Tasks to be carried out, responsible persons, and deadlines:

Task	Desponsible persons	Doodling
Draft a single "internal proposal"	Responsible persons Cathleen Barnes and	Deadline 15 May 2002
	Mohamed Ammati	13 May 2002
on Spinox T and Granox TBC based on the information available	Wionamed Ammad	
to ICRC-3.		
Send draft "internal proposal" to	Cathleen Barnes and	15 May 2002
	Mohamed Ammati	13 May 2002
group members for comments via e-mail.	Wonamed Ammad	
• 1110111	All DG members	15 June 2002
Replies	Cathleen Barnes and	
Update "internal proposal" based		15 July 2002
on the comments from group	Mohamed Ammati	
members		15.1.1.2002
Send updated "internal proposal"	Cathleen Barnes and	15 July 2002
to the ICRC and its observers for	Mohamed Ammati	
comments via e-mail		
Replies	All ICRC members and observers	1 September 2002
Draft a decision guidance	Cathleen Barnes and	1 October 2002
document (DGD) based on the	Mohamed Ammati	
comments from the ICRC and its		
observers		
Send draft DGD to group	Cathleen Barnes and	1 October 2002
members for comments via e-mail	Mohamed Ammati	
Replies	All DG members	22 October 2002
Finalized draft DGD based on the	Cathleen Barnes and Mohamed	1 November 2002
comments of the group	Ammati	
Send a draft DGD to secretariat	Cathleen Barnes and	1 November 2002
	Mohamed Ammati	
ICRC meeting		March 2003

Annex V

Monocrotophos

The Interim Chemical Review Committee,

Noting that at its second session it had reviewed the notifications of final regulatory actions by Australia and Hungary on monocrotophos 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, and 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 second session it had accordingly recommended to the Intergovernmental Negotiating Committee that monocrotophos should become subject to the interim prior informed consent procedure and noting (recommendation B of its report of its second session (UNEP/FAO/PIC/ICRC.2/11)) that 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 monocrotophos 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 monocrotophos (UNEP/FAO/PIC/ICRC.3/18) and had submitted it to the Committee at its third session for further action.

<u>Noting</u> 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:

Recommendation ICRC-3/1: Inclusion of monocrotophos in the interim prior informed consent procedure

The Interim Chemical Review Committee

<u>Recommends</u>, in line with paragraph 5 of Article 5 of the Convention, that the Intergovernmental Negotiating Committee should make monocrotophos subject to the interim prior informed consent procedure;

<u>Forwards</u>, in line with paragraph 2 of Article 7 of the Convention, this recommendation, together with the draft decision guidance document on monocrotophos, to the Intergovernmental Negotiating Committee for a decision on the inclusion of monocrotophos in the interim prior informed consent procedure.

Appendix I

Rationale and summary deliberation for the inclusion of monocrotophos in the prior informed consent procedure based on the criteria set forth in Annex II to the Convention

In reviewing the notifications of final regulatory actions by Australia and Hungary on monocrotophos, the Interim Chemical Review Committee was able to confirm that those actions had been taken in order to protect human health or the environment.

The Committee established that the final regulatory actions had been taken consequent on 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 recognized methods, that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures, and that the final regulatory actions had been based on risk evaluations taking into account the conditions prevailing within Australia and Hungary.

The Committee concluded that there was ongoing trade in monocrotophos and the final regulatory actions notified to it provided a sufficiently broad basis to merit including monocrotophos in the interim PIC procedure.

Appendix II

Task Group on monocrotophos

Second-round comments on the draft internal working document for monocrotophos

China	The trade name and formulation type in DGD should be current in international trade. It's very difficult in collecting all the trade names and formulation types including the product used domestically and no necessary for the PIC procedure	Noted - Issue to be discussed in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
China	In part 2 of Annex 1 "Toxicological properties" we need detail information on the item which is the basis for the final regulatory action. Other toxicity information can be a conclusion	Agree. We consider that the DGD summary adequately covers the key end-points underpinning the national actions.
China	About alternatives and regulatory measures to reduce exposure, as much information as possible should be provided. The Secretariat can get the information from other countries through Website after the draft DGD distributed.	Noted - Issue to be discussed in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
Samoa	P1: CAS-No.(s) omits Hungary'sICRC.2/INF.6?Add.2 page 3 2157-98/4 (mixture of isomers)	Only common form of the chemical captured by the two notifications is the E-ISO form. There is an issue of consistency in using CAS numbers. This will be discussed in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
Samoa	P2: Risk evaluation could be combined with p.4 (Classification of) Hazards and risks).	The current layout is consistent with that agreed at ICRC3.
Samoa	P2: Environmental Impact should be moved to p.3	The current layout is consistent with that agreed at ICRC3.
Samoa	P3: Other measures to reduce exposure could be combined with p.4 Exposure limits.	The current layout is consistent with that agreed at ICRC3.
Samoa	P4: Hazards hazard class 11 could be 2 or II	Editorial – done
Samoa	P4: Exposure limits for Air and soil not established as for drinking water?	Not relevant to the national decisions.
Samoa	P5: Packaging could include storage stability as perICRC.2/11 paragraph (para.) 21 Annex III 8 suggestion by Amb. El Zarka et al. [N.B. your (15 Aug. 2001 fax) ICRC3 TG2 D.G.D. format S.H.P.F. 9. Physico-chemical bullet 7dissolution properties (p.10) & p.12 Annex II S.D.S. 9. Stability and reactivity}	Noted. Stability information may be included where is it appropriate. In this case, stability is not relevant to the national decision(s).
Samoa	P10 @ S2.2.7: Australia (2001) "volunteers received daily oral doses" - The latter is also to be queried about paraquat with or without earth (Fullers) and efficacy of emetic.	Noted.

Samoa	P11 @ S3.3: Water - Not relevant?	Not relevant to the national decision(s).
Samoa	P14 @ S4.2.5: Soil microorganisms - No toxicity data recalls note that	No data provided.
	one page SDS do not contain ecotoxicology information.	
Samoa	P17 @ S5 Alternatives ModeratelySlightly hazardous by WHO and/ or	WHO is the standard adopted in this Draft DGD. Issue to be discussed in
	Australian classification?	the context of the 'Working Paper on the contents of a DGD for a Banned
		of Severely Restricted Chemical'.
Sudan	List of Abbreviations:	
	Add >> greater than;	Editorial – done
	Replace ec with EC for emulsifiable concentrates, without dots, it is	Editorial – done
	distinguish able from European Community;	
	Replace EC50, ED50 and IC50 with EC ₅₀ , ED ₅₀ and IC ₅₀ respectively.	Editorial – done
Sudan	Final Regulator action:	
	Dogo 2 and an exhibit Ham some line 5 delete the extre T	Editorial - done
Sudan	Page 2 under subtitle Hungary, line 5 delete the extra <u>T</u> .	Editoriai - done
Sudan	Risk Evaluation:	
	Crops and pests are sometime written with Latin names and sometimes	Editorial. Requirement for uniformity agreed in principle. Standards to be
	written with common names. I guess it is better to be consistent in using	adopted to be discussed in the context of the 'Working Paper on the
	names. If the list of crops and pest is not too long it is better to give the	contents of a DGD for a Banned of Severely Restricted Chemical'.
	Latin name for proper identification. Thus it may be appropriate to always	tonionia of a 2 of 101 a familion of 20 total famil
	use Latin names specially for citing pests and disease causing organisms	
	throughout the DGD	
Sudan	P3, line 4, end of the line, replace is killed with were killed.	Editorial - done
US	Under Reasons for inclusion in the PIC procedure', include in addition to	The reference made in the opening paragraph is to the original listing of
	the impact on human health, the concerns for its effect on birds, mammals	monocrotophos as a severely hazardous pesticide formulation. The reason
	and invertebrates	for the original listing was on human health grounds only. The two
		references to national action are correctly reported.
US	Under 4.2.1 mammals, indicate whether the single dose at 80 to 100	Clarification – Editorial - done
	mg/kg bw was an oral or dermal dose	

UNEP/FAO/PIC/ICRC.3/19

US	Under 4.2.1 birds last sentence, it is Swainson's hawks (with an 'I')	Editorial.
	The ecological incidents associated with the use of this chemical reported on the Internet are very significant. We would suggest that this information get more emphasis and earlier in the birds section (e.g., nearly	No particular emphasis contained in the material supporting the national decision(s).
	6,000 Swainson's hawks were killed on the Pampas of Argentina between 1995 and 96 the Internet piece on this called this incident "unrivalled	Two issues are raised by the second group of comments.
	in recent history due to the large numbers of animals affected and the speed with which international interests responded")	(i) whether the DGD should include comprehensive references to original source material or whether to omit them but refer the reader to the overarching national papers which were produced in support of the
	Apparently, raptors are >10 times more sensitive to this pesticide than other bird species and it is "highly toxic" to the other species based on	national actions ((i.e. probably the focused summary in most cases).
	LD50s.	The strategy adopted in the draft DGD has been to not include detailed referencing to source material, but leave the reader to pursue particular source references by referral to the national overarching documentation.
		(ii) whether supporting material which may not have been used directly by the responsible national authority in taking a final regulatory action should be introduced.
		Both of these issues have been identified for discussion in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.
US	S5.1 – Birds. Again emphasize that raptors are particularly sensitive.	As above.
US	S5.2 - Fish/aquatic invertebrates. Add the concept that invertebrates are the food source for higher aquatic organisms and their diminution ultimately affects fish at a slower rate.	As above
Saudi Arabia	No comments requiring changes	No action required.

EC	Identification and uses	
	BSI, E-ISO, ULV should be defined in the abbreviations list (<i>p. ii-iv</i>) (or for ULV full name to be included). Basic manufacturers: The name of the country where the firm Comlets Chemical Industrial is established (ROC) should be spelt out.	Editorial - done Editorial - done Note Pesticide Manual gives: Aimco, BASF, CAC, Comlets, Crystal, DE_NOCIL, Hindustan, Hui Kwang, India Pesticides, Cheminova, Makhteshim-Agan, Nagarjuna Agrichme, Parry, Q.W.A.C.A., Rallis, Sabero, Shenzhen Jiangshan, Sinon, Sudarshan, Sundat, Taiwan Tainan Giant, Tantech, United Phosphorus
EC	Final regulatory action:	
	Australia: According to the footnote, "occupational" includes workers involved in manufacture and re-packaging. However, it appears that the final regulatory action was taken only because of concerns for operators	The current text reflects Australia's OH&S terminology in the national risk assessment. The footnote clarifies the basis for the regulatory action.
	and environmental protection during the use of this insecticide. We wonder therefore whether to avoid any possible confusion or misunderstanding it may be appropriate to replace the word "occupational" by "operators" and to delete the footnote.	These definitions cover the different worker activities considered in the Australian OH&S risk assessment and the proposed amendment may lead to confusion particularly where the terms are loosely used to refer to certain activities (e.g. operating machinery and not mixing and loading).
EC	Risk Evaluation:	
	Australia : The sentence "The ADI was used as the point of reference." might be usefully be added for clarification to the end of the first paragraph in the section on occupational health and safety.	NOHSC does not commonly use the ADI, which is the point of reference for <u>dietary</u> intake studies.
	In the section on environmental impact, IPM should be defined in the abbreviations table.	Editorial - done
	Hungary: "our country" should be replaced by "Hungary"	Editorial - done
EC	Hazards and Risks to human health and/or the environment:	
	<u>WHO:</u> In the table columns for oral and dermal toxicity, the words "see annex 1" should be deleted as the given LD_{50} values are not consistent with the values found in annex 1.	Editorial - done
	EC: In the second column EC is unnecessary and can be deleted.	Editorial – done

UNEP/FAO/PIC/ICRC.3/19

EC	Food:	
		Editorial - done. Note to be included in the 'Working Paper on the
	For the Codex, dates should be included where possible.	contents of a DGD for a Banned of Severely Restricted Chemical'.
EC	Physico-Chemical properties (<i>Pesticides Manual – 12th Ed. 2000</i>	
	$K_{ow}logP$ should be replaced by $logP_{ow}$.	Reference taken directly from the <i>Pesticides Manual</i> – 12 th Ed. 2000
	S2.2.1. Acute toxicity	
	A sub-heading for the last paragraph should be added to distinguish it	Editorial - done
	from the paragraph titled "Irritation". This sub-heading might be "ARfD".	

2.2.7. Summary and overall evaluation

In the penultimate sentence of the second paragraph, the reference should be to skin and eye irritant "in rabbits".

In the third paragraph, considering the metabolites present in urine (§2.1.3), the route of administration should be specified as dimethyl phosphate is detected after dermal exposure, whereas N-methyl acetoacetamide and 3-hydroxy-N-methyl butyramide are found after oral exposure. The text should therefore read "The major metabolite following dermal application"

In the 6th paragraph, "genotoxic" should be replaced by "mutagenic".

In the eighth paragraph RBC ChE should be defined in the abbreviations table or put in plain words in the text.

More generally, it seems to us that much of the information in this section is very detailed and is not strictly a summary of the evaluation. Much of it would be more appropriate to the preceding individual sections (e.g. the last sentence of paragraph 7 might be better placed in section 2.2.4; the material in the Australian section on ADI and ARfD is much more detailed than the corresponding passages in sections 2.2.1 and 2.2.2 and might be more appropriately reported there etc).

Clarification – Editorial - done

Clarification – Agree, the text is not optimal! – note that N-methyl acetoacetamide and 3-hydroxy-N-methyl butyramide metabolites come from the other end of the monocrotophos molecule than the part which forms dimethyl phosphate and methyl phosphate i.e. these metabolites are not mutually exclusive. We have dealt with this in the following manner:-

- 1. at Section 2.1.3, to delete the sentence "Following dermal exposure to monocrotophos in humans and intra-peritoneal exposure in rats, dimethyl phosphate was the most common urinary metabolite detected."; and
- 2. at Section 2.2.7 (paragraph 3) to replace the sentence "The major metabolite is dimethyl phosphate (DMP)." with the following:- "The metabolic pathway is a detoxification route ultimately involving the ester cleavage of monocrotophos, with the formation of N-methyl acetoacetamide and 3-hydroxy-N-methyl butyramide, as well as dimethyl phosphate and/or monomethyl phosphate."

Clarification: should be 'genotoxic' since this is the general term for effects on nuclear material, 'mutagenic' refers solely to the induction of mutations in genes i.e. effecting a specific measured gene output. Gross chromosome damage (gaps, breaks, etc) and induction of unscheduled DNA synthesis are genotoxic actions, not necessarily mutagenic. Sentence amended.

Editorial - done

Noted. Our preference is to have a summary addressing all the key endpoints expected of a toxicological analysis.

S4.2.1 - Terrestrial vertebrates

Mammals:

In the first paragraph "mammals" should be replaced by "rats" and LC_{50} should be changed to LD_{50} .

Furthermore there is an inconsistency in the figures quoted. The LD_{50} values previously given for terrestrial mammals (rats, \$2.2.1) were 8 mg/kg, not 18 mg/kg, for the oral route and 119 mg/kg, not 354 mg/kg, for the dermal route.

In the last paragraph "EC" should be deleted.

Birds:

In the first sentence exposure duration (5-10 days) should be given for dietary route studies to allow comparisons with other data.

Office of Pesticide Program: the abbreviation OPP appears further on in the text and should be defined here and/or in the abbreviations table.

Literature toxicity values as set out in the Australian NRA Review should be added at the end of the last sentence of the first paragraph, which should read as follows: "Results in the literature for toxicity also indicate very high toxicity to birds- acute toxicity:1.0-4.21 mg/kg, chronic toxicity: NOEC 0.5mg/kg/d (Japanese quail, 21d.)

Clarification & Correction – Editorial - done

Clarification – Editorial - done This Section should refer back to Section 2.2.1. When Australia has done a detailed toxicology evaluation, it is not appropriate to refer to the US EPA figures.

Standard protocols are implied in the draft DGD. Issue identified for discussion in the context of the 'Working Paper on the contents of a DGD for a Banned of Severely Restricted Chemical'.

Editorial - done

Editorial - done

Environmental Exposure/Risk Evaluation	
Throughout this whole section the word "hazard" should in our view be replaced by "risk".	Standard language adopted – Editorial – done
Birds	
We suggest that the LC ₅₀ duration of exposure (10 days) be added.	As per S4.2.1 above.
Fish/Aquatic invertebrates	
AgDRIFT, vmd, IPM should be defined in the abbreviations.	Editorial – Latter two done. First will be included later
Annex 2, S7 – Other	
The stated Health Value of 0.0001 mg/l is a little puzzling. If this is normally set at 10% of the ADI, as the text states, one might have expected a health value of 0.00003 mg/l given that the ADI is 0.0003.	Clarification Health value (mg/l) = (ADI x bodyweight x 10%)/volume water drunk per day
Perhaps some clarification/explanation should be provided.	$= (0.0003 \times 70 \times 0.1)/2$ = 0.0001
Annex 4 – Regulatory control actions	
Regulatory control actions	
Hungary: Appropriate references should be added.	Editorial - done
Documentation used for Accident reporting and poison management	
In the fifth entry referring to the Basel Convention the date in brackets is repetitive and can be deleted. Likewise the date in brackets at the end of the sixth entry is unnecessary.	Editorial - done
The seventh entry appears to be referring to the same document as the fourth entry. If so, the reference can be deleted.	Editorial - done

Annex VI

LIST OF DOCUMENTS

UNEP/FAO/PIC/ICRC.3/1	Provisional Agenda
UNEP/FAO/PIC/ICRC.3/1/Add.1/Rev.1	Annotated Agenda
UNEP/FAO/PIC/ICRC.3/2	Scenario note for the third session of the Interim Chemical Review Committee
UNEP/FAO/PIC/ICRC.3/3	Review of the outcome of the eighth session of the Intergovernmental Negotiating Committee
UNEP/FAO/PIC/ICRC.3/4	Status of implementation of the Interim Prior Informed Consent Procedure as it relates to the work of the Interim Chemical Review Committee
UNEP/FAO/PIC/ICRC.3/5	Operational procedures for the Interim Chemical review Committee: Status of the work of the individual task groups established at the second session of the Committee. Task Group 1: Pilot-Testing - Severely Hazardous Pesticide Formulation report form
UNEP/FAO/PIC/ICRC.3/6	Operational procedures for the Interim Chemical review Committee: Status of the work of the individual task groups established at the second session of the Committee. Task Group 2: Development of a format for Decision Guidance documents for Severely Hazardous Pesticide formulations
UNEP/FAO/PIC/ICRC.3/7	Operational procedures for the Interim Chemical review Committee: Status of the work of the individual task groups established at the second session of the Committee. Task Group 3:Development of an Environmental Incident report form for Severely Hazardous Pesticide Formulations
UNEP/FAO/PIC/ICRC.3/8	Operational procedures for the Interim Chemical review Committee: Status of the work of the individual task groups established at the second session of the Committee. Task Group 4: Prioritization of work on Old Notifications of Final Regulatory Action to ban or severely restrict a chemical
UNEP/FAO/PIC/ICRC.3/9	Operational procedure for the Interim Chemical Review Committee: Issues associated with Implementation of the Operational Procedures. Compatibility of Current Regulatory Practices with the Notification Requirements of the Interim Prior Informed Consent Procedure

UNEP/FAO/PIC/ICRC.3/10	Operational procedure for the Interim Chemical Review Committee: Issues associated with Implementation of the Operational Procedures. Consideration of the Development and Use of Focused Summaries
UNEP/FAO/PIC/ICRC.3/11	Operational procedure for the Interim Chemical Review Committee: Issues associated with Implementation of the Operational Procedures: Report of the Drafting Group on monocrotophos. Draft Working Paper on Preparing Internal Proposals and Decision Guidance Documents.
UNEP/FAO/PIC/ICRC.3/12	Operational procedure for the Interim Chemical Review Committee: Issues associated with Implementation of the Operational Procedures: Determination of the Ongoing Trade in Chemicals
UNEP/FAO/PIC/ICRC.3/13	Operational procedure for the Interim Chemical Review Committee: Issues associated with Implementation of the Operational Procedures: Common and Recognized Patterns of Use of Severely Hazardous Pesticide Formulations
UNEP/FAO/PIC/ICRC.3/14	Inclusion of Chemicals in the Interim Prior Informed Consent Procedure: Review of Notifications of Final Regulatory Actions to Ban or Severely Restrict a Chemical. Asbestos.
UNEP/FAO/PIC/ICRC.3/14/Add.1	Inclusion of Chemicals in the Interim Prior Informed Consent Procedure: Review of Notifications of Final Regulatory Actions to Ban or Severely Restrict a Chemical. Asbestos.
UNEP/FAO/PIC/ICRC.3/14/Add.2	Inclusion of Chemicals in the Interim Prior Informed Consent Procedure: Review of Notifications of Final Regulatory Actions to Ban or Severely Restrict a Chemical. Asbestos.
UNEP/FAO/PIC/ICRC.3/14/Add.3	Inclusion of Chemicals in the Interim Prior Informed Consent Procedure: Review of Notifications of Final Regulatory Actions to Ban or Severely Restrict a Chemical. Asbestos.
UNEP/FAO/PIC/ICRC.3/15	Inclusion of Chemicals in the Interim Prior Informed Consent Procedure: Review of Notifications of Final Regulatory Actions to Ban or Severely Restrict a Chemical. Dinoterb.
UNEP/FAO/PIC/ICRC.3/15/Add.1	Inclusion of Chemicals in the Interim Prior Informed Consent Procedure: Review of Notifications of Final Regulatory Actions to Ban or Severely Restrict a Chemical. Dinoterb.

11

UNEP/FAO/PIC/ICRC.3/15/Add.2	Inclusion of Chemicals in the Interim Prior Informed Consent Procedure: Review of Notifications of Final Regulatory Actions to Ban or Severely Restrict a Chemical. Dinoterb.
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40

UNEP/FAO/PIC/ICRC.3/19	Report of the Intergovernmental Review Committee on the work of its third session
UNEP/FAO/PIC/ICRC.3/19/Add.1	Draft Decision Guidance Document – monocrotophos
UNEP/FAO/PIC/ICRC.3/INF/1	The status of implementation of the conflict of interest procedure adopted in decision INC-8/1
UNEP/FAO/PIC/ICRC.3/INF/2	Status report on compliance with decision INC-8/ on maleic hydrazide
UNEP/FAO/PIC/ICRC.3/INF/3	Operational procedures for the Interim Chemical Review Committee – process for drafting Decision Guidance Documents
UNEP/FAO/PIC/ICRC.3/INF/4	Information note on CAS numbers
UNEP/FAO/PIC/ICRC.3/INF/5	Experience by DNAs in implementing the interim PIC procedure
UNEP/FAO/PIC/ICRC.3/INF/6	Availability of documents
UNEP/FAO/PIC/ICRC.3/INF/7	New expert on the Interim Chemical Review Committee
UNEP/FAO/PIC/ICRC.3/INF/8	List of participants.
