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REVIEW OF OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE

Note by the secretariat

Introduction

1. This paper is intended to provide a guide for discussion by the Interim Chemical Review Committee on the mechanisms for making recommendations to the Intergovernmental Negotiating Committee on the inclusion of banned or severely restricted chemicals and severely hazardous pesticide formulations in the interim PIC procedure (chapters II and III respectively). It further provides a guide for discussion on the operational procedure for preparing draft decision guidance documents and on a mechanism for collecting and disseminating comments received on decision guidance documents during their development (chapters IV and V respectively).

I. MANDATE OF THE INTERIM CHEMICAL REVIEW COMMITTEE

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For reasons of economy, this document is printed in a limited number. Delegates are kindly requested to bring their copies to meetings and not to request additional copies.

2. The Interim Chemical Review Committee was established by the Intergovernmental Negotiating Committee at its sixth session, held in Rome from 12 to 16 July 1999, by decision INC-6/2, which reads as follows:

"The Intergovernmental Negotiating Committee

- "1. <u>Decides</u> to establish an interim subsidiary body, to be called the Interim Chemical Review Committee, composed of twenty-nine government-designated experts appointed by the Intergovernmental Negotiating Committee on the basis of the interim PIC regions, as follows: six experts from Africa; five experts from Asia; six experts from Europe; five experts from Latin America and the Caribbean; three experts from the Near East; two experts from North America; and two experts from the Southwest Pacific;
- "2. <u>Decides</u> that the members of the Interim Chemical Review Committee shall be experts in chemicals management and that the experts shall serve for a period of three years from the date of this decision, or until the first session of the Conference of the Parties, whichever shall occur first, and that if, on the expiration of the three years, the Convention has not yet entered into force, the Intergovernmental Negotiating Committee will take any necessary decisions regarding the extension of the term of office of its members or the appointment of new members;
- "3. <u>Decides</u> that the twenty-nine Governments identified at the sixth session of the Intergovernmental Negotiating Committee shall formally designate those experts and, through the secretariat, provide their names and relevant qualifications to the parties to the Intergovernmental Negotiating Committee by 15 September 1999 and that such experts shall serve as members of the Interim Chemical Review Committee on an interim basis, pending formal confirmation of their appointment by the Intergovernmental Negotiating Committee at its seventh session;
- "4. <u>Decides</u> that any vacancy arising during an inter-sessional period shall be filled in accordance with such procedure as the region concerned may determine; and that the qualifications of the new member shall be circulated to the parties to the Intergovernmental Negotiating Committee through the secretariat;
- "5. <u>Decides</u> that the Interim Chemical Review Committee shall normally meet once a year, approximately six months before each session of the Intergovernmental Negotiating Committee, subject to the availability of funds and work requirements of the Interim Chemical Review Committee;
- "6. <u>Decides</u> that the meetings of the Interim Chemical Review Committee shall be held in English only and that any draft decision guidance documents to be considered by the Interim Chemical Review

Committee or forwarded by it to the Intergovernmental Negotiating Committee shall be available in all six languages of the Intergovernmental Negotiating Committee;

- "7. <u>Decides</u> that the Interim Chemical Review Committee, consistent with the provisions of the Convention, in particular its articles 5, 6 and 7, shall have the following functions and responsibilities:
- "(a) Making recommendations on the inclusion of banned and severely restricted chemicals: reviewing the information provided in notifications of final regulatory actions and, in accordance with the criteria set out in Annex II of the Convention, recommending to the Intergovernmental Negotiating Committee whether the chemical in question should be made subject to the interim PIC procedure;
- "(b) Making recommendations on the inclusion of severely hazardous pesticide formulations: reviewing the information provided in proposals for the inclusion of a severely hazardous pesticide formulation in the interim PIC procedure and, in accordance with the criteria set out in part 3 of Annex IV of the Convention, recommending to the Intergovernmental Negotiating Committee whether the chemical in question should be made subject to the interim PIC procedure;
- "(c) Preparing draft decision guidance documents: specifically,
 for each chemical that the Interim Chemical Review Committee has
 decided to recommend to be made subject to the interim PIC procedure,
 preparing a draft decision guidance document, which should, at a
 minimum, be based on the information specified in Annex I of the
 Convention or, as the case may be, Annex IV, and include information on
 uses of the chemical in a category other than the category for which
 the final regulatory action applies;
- "8. <u>Decides</u> that the sessions of the Interim Chemical Review Committee shall be open to observers in accordance with the rules of procedure of the Intergovernmental Negotiating Committee."
- II. OPERATIONAL PROCEDURE FOR MAKING RECOMMENDATIONS ON THE INCLUSION OF BANNED OR SEVERELY RESTRICTED CHEMICALS

A. Definitions

- 3. The Rotterdam Convention, in article 2, defines "banned" and "severely restricted" chemicals as follows:
 - "'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been

withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment.

"'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment."

B. Notification of final regulatory action

4. In line with article 5, paragraphs 1 and 2, of the Convention, Parties¹ must inform the secretariat of final regulatory actions:

"Each Party that has adopted a final regulatory action shall notify the secretariat in writing of such action. Such notification shall be made as soon as possible, but no later than ninety days after the date on which the final regulatory action has taken effect, and shall include the information required by Annex I, where available.

"Each Party shall, at the date of entry into force of this Convention for it, notify the secretariat in writing of its final regulatory actions in effect at that time, except that each Party that has submitted notifications of final regulatory actions under the Amended London Guidelines or the International Code of Conduct need not resubmit those notifications."

C. Submission of notifications by Parties to the secretariat

- 5. Any Party submitting a notification to ban or severely restrict a chemical under the interim PIC procedure must list the information as required in the "Form for notification of final regulatory action" (UNEP/FAO/PIC/FORM/1/E/4-99). This form is available from the secretariat or can be downloaded from the Rotterdam Convention website (http://www.pic.int).
- 6. Annex I of the Convention sets out the information requirements for notifications made in pursuance of article 5 as follows:

"Notifications shall include:

^{1.} During the interim period before the Convention enters into force, a "Party" should be understood to mean any State or regional economic integration organization having nominated a designated national authority or authorities for the purpose of participating in the interim PIC procedure.

"1. Properties, identification and uses

- "(a) Common name;
- "(b) Chemical name according to an internationally recognized nomenclature (for example, International Union of Pure and Applied Chemistry (IUPAC)), where such nomenclature exists;
- "(c) Trade names and names of preparations;
- "(d) Code numbers: Chemicals Abstract Service (CAS) number, Harmonized System customs code and other numbers;
- "(e) Information on hazard classification, where the chemical is subject to classification requirements;
- "(f) Use or uses of the chemical;
- "(g) Physico-chemical, toxicological and ecotoxicological properties.

"2. Final regulatory action

- "(a) Information specific to the final regulatory action:
 - "(i) Summary of the final regulatory action;
 - "(ii) Reference to the regulatory document;
 - "(iii) Date of entry into force of the final regulatory action;
 - "(iv) Indication of whether the final regulatory action was taken on the basis of a risk or hazard evaluation and, if so, information on such an evaluation, covering a reference to the relevant documentation;
 - "(v) Reasons for the final regulatory action relevant to human health, including the health of consumers and workers, or the environment;
 - "(vi) Summary of the hazards and risks presented by the chemical to human health, including the health of consumers and workers, or the environment and the expected effect of the final regulatory action;
- "(b) Category or categories where the final regulatory action has been taken, and for each category:
 - "(i) Use or uses prohibited by the final regulatory action;

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- "(ii) Use or uses that remain allowed;
- "(iii) Estimation, where available, of quantities of the chemical produced, imported, exported and used;
- "(c) An indication, to the extent possible, of the likely relevance of the final regulatory action to other States and regions;
- "(d) Other relevant information that may cover;
 - "(i) Assessment of socio-economic effects of the final regulatory action;
 - "(ii)Information on alternatives and their relative risks, where available, such as:
 - "-Integrated pest management strategies;
 - "-Industrial practices and processes, including cleaner technology."
- D. <u>Procedures for banned or severely restricted chemicals before</u> consideration by the Interim Chemical Review Committee
 - 1. <u>Verification by the secretariat of notifications of</u> final regulatory actions
- 7. Once a notification is received from a Party, the secretariat will verify the information received, in line with article 5, paragraph 3, and Annex I of the Convention:

"The secretariat shall, as soon as possible, and in any event no later than six months after receipt of a notification under paragraphs 1 and 2, verify whether the notification contains the information required by Annex I."

- 2. Reporting by the secretariat after verification
- 8. In line with article 5, paragraphs 3 and 4, of the Convention, the secretariat will report to all Parties:

"If the notification contains the information required, the secretariat shall forthwith forward to all Parties a summary of the information received. If the notification does not contain the information required, it shall inform the notifying Party accordingly.

"The secretariat shall every six months communicate to the Parties a synopsis of the information received pursuant to paragraphs 1

- and 2, including information regarding those notifications which do not contain all the information required by Annex I."
- 9. Every six months the secretariat circulates a PIC Circular. This contains, $\underline{\text{inter alia}}$, a synopsis of the information received, including summaries of those notifications that contain the information required and information on those notifications that do not contain all information required.
 - E. Consideration of banned or severely restricted chemicals by the Interim Chemical Review Committee
 - 1. Forwarding of notifications of final regulatory action from the secretariat to the Interim Chemical Review Committee
- 10. In line with article 5, paragraph 5, of the Convention the secretariat forwards a submission to the Interim Chemical Review Committee:

"When the secretariat has received at least one notification from each of two prior informed consent regions regarding a particular chemical that it has verified meet the requirements of Annex I, it shall forward them to the Chemical Review Committee."

2. Review by the Interim Chemical Review Committee

- 11. In relation to banned or severely restricted chemicals, the Intergovernmental Negotiating Committee decided at its sixth session that:
 - "... the Interim Chemical Review Committee, consistent with the provisions of the Convention, in particular its articles 5, 6 and 7, shall have the following functions and responsibilities:
 - "(a) Making recommendations on the inclusion of banned and severely restricted chemicals: reviewing the information provided in notifications of final regulatory actions and, in accordance with the criteria set out in Annex II of the Convention, recommending to the Intergovernmental Negotiating Committee whether the chemical in question should be made subject to the interim PIC procedure".
- 12. Accordingly, the Interim Chemical Review Committee will review the notifications forwarded to it by the secretariat. Annex II of the Convention lists the following "Criteria for listing banned or severely restricted chemicals in Annex III", which the Interim Chemical Review Committee will take into account in its consideration of whether to recommend each chemical for inclusion in the interim PIC procedure:

"In reviewing the notifications forwarded by the secretariat pursuant to paragraph 5 of article 5, the Chemical Review Committee shall:

- "(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;
- "(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:
 - "(i) Data have been generated according to scientifically recognized methods;
 - "(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
 - "(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;
- "(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:
 - "(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;
 - "(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;
 - "(iii) Whether the considerations which led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;
 - "(iv) Whether there is evidence of ongoing international trade in the chemical;
- "(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III."

- 3. Recommendation by the Interim Chemical Review Committee to the Conference of the Parties and preparation of a decision guidance document
- 13. In line with article 5, paragraph 6, of the Convention, the Interim Chemical Review Committee may make a recommendation to the Intergovernmental Negotiating Committee to include the banned or severely restricted chemical in the interim PIC procedure:

"The Chemical Review Committee shall review the information provided in ... notifications and, in accordance with the criteria set out in Annex II, recommend to the Conference of the Parties whether the chemical in question should be made subject to the prior informed consent procedure and, accordingly, be listed in Annex III."

14. In line with article 7 of the Convention, the Interim Chemical Review Committee will prepare draft decision guidance documents:

"For each chemical that the Chemical Review Committee has decided to recommend for listing in Annex III, it shall prepare a draft decision guidance document. The decision guidance document should, at a minimum, be based on the information contained in Annex I ... and include information on uses of the chemical in a category other than the category for which the final regulatory action applies.

"The recommendation referred to in paragraph 1 together with the draft decision guidance document shall be forwarded to the Conference of the Parties ...".

15. The Interim Chemical Review Committee will make its recommendations in line with the procedure set out in article 18, paragraph 6 (c), of the Convention:

"The Committee shall make every effort to make its recommendations by consensus. If all efforts at consensus have been exhausted, and no consensus reached, such recommendation shall as a last resort be adopted by a two-thirds majority vote of the members present and voting."

- F. $\underline{\text{Decision}}$ by the Intergovernmental Negotiating Committee to include the chemical in the interim PIC procedure
- 16. In line with article 7, paragraph 2, of the Convention, the Intergovernmental Negotiating Committee shall decide whether a chemical is to be included in the interim PIC procedure.
 - "... The Conference of the Parties shall decide whether the chemical should be made subject to the prior informed consent procedure and, accordingly, list the chemical in Annex III and approve the draft decision guidance document."
- 17. In line with article 22 of the Convention, the Intergovernmental Negotiating Committee will take its decisions on the inclusion of a chemical in the interim PIC procedure by consensus.
 - III. OPERATIONAL PROCEDURE FOR MAKING RECOMMENDATIONS ON THE INCLUSION OF SEVERELY HAZARDOUS PESTICIDE FORMULATIONS

A. Definitions

- 18. The Rotterdam Convention, in article 2, defines "severely hazardous pesticide formulation" as follows:
 - "'Severely hazardous pesticide formulation' means a chemical formulated for pesticidal use that produces severe health or environmental effects observable within a short period of time after single or multiple exposure, under conditions of use".
 - B. Proposals relating to severely hazardous pesticide formulations
- 19. In line with article 6, paragraph 1, of the Convention, developing countries and countries with economies in transition that participate in the interim PIC procedure may make proposals for the inclusion of severely hazardous pesticide formulations in the interim PIC procedure:

"Any Party that is a developing country or a country with an economy in transition and that is experiencing problems caused by a severely hazardous pesticide formulation under conditions of use in its territory may propose to the secretariat the listing of the severely

hazardous pesticide formulation in Annex III. In developing a proposal, the Party may draw upon technical expertise from any relevant source. The proposal shall include the information required by part 1 of Annex IV."

- C. <u>Submission of proposals for the inclusion of severely hazardous</u> pesticide formulations in the interim PIC procedure to the secretariat
- 20. Any Party that is a developing country or a country with an economy in transition submitting a proposal for the inclusion of a severely hazardous pesticide formulation in the interim PIC procedure should use a special form that will be made available for this purpose. This form will be available from the secretariat or will be downloadable from the Rotterdam Convention website (http://www.pic.int).
- 21. Part 1 of Annex IV of the Convention sets out the information requirements for proposals made in pursuance of article 6 of the Convention, as follows:
 - "(a) Name of the hazardous pesticide formulation;
 - "(b) Name of the active ingredient or ingredients in the formulation;
 - "(c) Relative amount of each active ingredient in the formulation;
 - "(d) Type of formulation;
 - "(e) Trade names and names of the producers, if available;
 - "(f) Common and recognized patterns of use of the formulation within the proposing Party;
 - "(g) A clear description of incidents related to the problem, including the adverse effects and the way in which the formulation was used;
 - "(h) Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents."

- D. Procedures governing proposals for the inclusion of severely hazardous pesticide formulations in the interim PIC procedure before consideration by the Interim Chemical Review Committee
- 1. <u>Verification by the secretariat of proposals for the inclusion of severely hazardous pesticide formulations in the interim PIC procedure</u>
- 22. Once a proposal for the inclusion of a severely hazardous pesticide formulation is received from a Party that is a developing country or a country with an economy in transition, the secretariat will verify the information received, in line with article 6, paragraph 2, and Annex IV, part 1, of the Convention:

"The secretariat shall, as soon as possible, and in any event no later than six months after receipt of a proposal under paragraph 1, verify whether the proposal includes the information required by part 1 of Annex IV."

2. Reporting by the secretariat after verification

23. In line with article 6, paragraph 2, of the Convention, the secretariat will report to all Parties:

"If the proposal contains the information required, the secretariat shall forthwith forward to all Parties a summary of the information received. If the notification does not contain the information required, it shall inform the proposing Party accordingly."

24. Every six months the secretariat circulates a PIC Circular. This contains, <u>inter alia</u>, summaries of those proposals that contain the information required.

3. Collection of additional information

25. In line with article 6, paragraph 3, and Annex IV, part 2, of the Convention, the secretariat will also collect additional information:

"The secretariat shall collect the additional information set out in part 2 of Annex IV regarding the proposals forwarded under paragraph 2."

- 26. Annex IV, part 2, of the Convention outlines the additional information to be collected by the secretariat, as follows:
 - "(a) The physico-chemical, toxicological and ecotoxicological properties of the formulation;
 - "(b) The existence of handling or applicator restrictions in other States;

- "(c) Information on incidents related to the formulation in other States;
- "(d) Information submitted by other Parties, international organizations, non-governmental organizations or other relevant sources, whether national or international;
- "(e) Risk and/or hazard evaluations, where available;
- "(f) Indications, if available, of the extent of use of the formulation, such as the number of registrations or production or sales quantity;
- "(g) Other formulations of the pesticide in question, and incidents,
 if any, relating to these formulations;
- "(h) Alternative pest-control practices;
- "(i) Other information which the Chemical Review Committee may identify as relevant."
- E. Consideration of a proposal relating to a severely hazardous pesticide formulation by the Interim Chemical Review Committee
- 1. Forwarding of a proposal relating to a severely hazardous pesticide formulation from the secretariat to the Interim Chemical Review Committee
- 27. In line with article 6, paragraph 4, of the Convention, the secretariat forwards a proposal to the Interim Chemical Review Committee:

"When the requirements of paragraphs 2 and 3 [of article 6] have been fulfilled with regard to a particular severely hazardous pesticide formulation, the secretariat shall forward the proposal and the related information to the Chemical Review Committee."

2. Review by the Interim Chemical Review Committee

- 28. In relation to severely hazardous pesticide formulations, the Intergovernmental Negotiating Committee decided at its sixth session that:
 - "... the Interim Chemical Review Committee, consistent with the provisions of the Convention, in particular its articles 5, 6 and 7, shall have the following functions and responsibilities:

. . .

- "(b) Making recommendations on the inclusion of severely hazardous pesticide formulations: reviewing the information provided in proposals for the inclusion of a severely hazardous pesticide formulation in the interim PIC procedure and, in accordance with the criteria set out in part 3 of Annex IV of the Convention, recommending to the Intergovernmental Negotiating Committee whether the chemical in question should be made subject to the interim PIC procedure".
- 29. Accordingly, the Interim Chemical Review Committee will review each proposal and related information forwarded to it by the secretariat. Annex IV, part 3, of the Convention lists "Criteria for listing severely hazardous pesticide formulations in Annex III", which the Interim Chemical Review Committee will take into account in its consideration of whether to recommend the chemical for inclusion in the interim PIC procedure:
 - "(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, 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;
 - "(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;
 - "(d) The significance of reported effects in relation to the quantity of the formulation used;
 - "(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III."

- 3. Recommendation by the Interim Chemical Review Committee to the Conference of the Parties and preparation of a decision guidance document
- 30. In line with article 6, paragraph 5, of the Convention, the Interim Chemical Review Committee may make a recommendation to the Intergovernmental Negotiating Committee to include the severely hazardous pesticide formulation in the interim PIC procedure:

"The Chemical Review Committee shall review the information provided in the proposal and the additional information collected and, in accordance with the criteria set out in part 3 of Annex IV, recommend to the Conference of the Parties whether the severely hazardous pesticide formulation should be made subject to the prior informed consent procedure and, accordingly, be listed in Annex III."

- 31. In line with article 7 of the Convention, the Interim Chemical Review Committee will prepare a draft decision guidance document:
 - "1. For each chemical that the Chemical Review Committee has decided to recommend for listing in Annex III, it shall prepare a draft decision guidance document. The decision guidance document should, at a minimum, be based on the information contained in Annex I ... and include information on uses of the chemical in a category other than the category for which the final regulatory action applies.
 - "2. The recommendation referred to in paragraph 1 together with the draft decision guidance document shall be forwarded to the Conference of the Parties ...".
- 32. The Interim Chemical Review Committee will make its recommendations in line with the procedure of article 18, paragraph 6 (c), of the Convention:

"The Committee shall make every effort to make its recommendations by consensus. If all efforts at consensus have been exhausted, and no consensus reached, such recommendation shall as a last resort be adopted by a two-thirds majority vote of the members present and voting."

- F. Decision by the Intergovernmental Negotiating Committee to include the severely hazardous pesticide formulation in the interim PIC procedure
- 33. In line with article 7, paragraph 2, of the Convention, the Intergovernmental Negotiating Committee shall decide whether a chemical is to be included in the interim PIC procedure.
 - "... The Conference of the Parties shall decide whether the chemical should be made subject to the prior informed consent procedure and, accordingly, list the chemical in Annex III and approve the draft decision guidance document."
- 34. In line with article 22 of the Convention, the Intergovernmental Negotiating Committee will take its decisions on the inclusion of a chemical in the interim PIC procedure by consensus.
 - IV. OPERATIONAL PROCEDURE FOR PREPARING DRAFT DECISION GUIDANCE DOCUMENTS

A. Introduction

- 35. The objective of a decision guidance document is to provide relevant information on the chemical and to assist Parties in taking a decision regarding future import of the chemical in question.
- 36. The Convention, in article 7, provides as follows:

"For each chemical that the Chemical Review Committee has decided to recommend for listing in Annex III, it shall prepare a draft decision guidance document. The decision guidance document should, at a minimum, be based on the information contained in Annex I, or, as the case may be, Annex IV, and include information on uses of the chemical in a category other than the category for which the final regulatory action applies."

- B. Decision guidance documents for banned or severely restricted chemicals
- 37. Decision guidance documents for banned or severely restricted chemicals should contain as a minimum the information specified in Annex I of the Convention, which is as follows:

"1. Properties, identification and uses

- "(a) Common name;
- "(b) Chemical name according to an internationally recognized nomenclature (for example, International Union of Pure and Applied Chemistry (IUPAC)), where such nomenclature exists;
- "(c) Trade names and names of preparations;
- "(d) Code numbers: Chemicals Abstract Service (CAS) number, Harmonized System customs code and other numbers;
- "(e) Information on hazard classification, where the chemical is subject to classification requirements;
- "(f) Use or uses of the chemical;
- "(g) Physico-chemical, toxicological and ecotoxicological properties.

"2. Final regulatory action

- "(a) Information specific to the final regulatory action:
 - "(i) Summary of the final regulatory action;
 - "(ii) Reference to the regulatory document;
 - "(iii) Date of entry into force of the final regulatory action;
 - "(iv) Indication of whether the final regulatory action was taken on the basis of a risk or hazard evaluation and, if so, information on such evaluation, covering a reference to the relevant documentation;
 - "(v) Reasons for the final regulatory action relevant to human health, including the health of consumers and workers, or the environment;
 - "(vi) Summary of the hazards and risks presented by the chemical to human health, including the health of consumers and workers, or the environment and the expected effect of the final regulatory action;
- "(b) Category or categories where the final regulatory action has been taken, and for each category:
 - "(i) Use or uses prohibited by the final regulatory action;

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- "(ii) Use or uses that remain allowed;
- (iii) Estimation, where available, of quantities of the chemical produced, imported, exported and used;
- "(c) An indication, to the extent possible, of the likely relevance of the final regulatory action to other States and regions;
- "(d) Other relevant information that may cover:
 - "(i) Assessment of socio-economic effects of the final regulatory action;
 - - "- Integrated pest management strategies;
 - "- Industrial practices and processes, including cleaner
 technology."
- C. Decision guidance documents for severely hazardous pesticide formulations
- 38. Decision guidance documents for severely hazardous pesticide formulations should contain as a minimum the information stipulated in Annex IV, parts 1 and 2, of the Convention, which is as follows:

"Part 1. Documentation required from a proposing Party

- "(a) Name of the hazardous pesticide formulation;
- "(b) Name of the active ingredient or ingredients in the formulation;
- "(c) Relative amount of each active ingredient in the formulation;
- "(d) Type of formulation;
- "(e) Trade names and names of the producers, if available;
- "(f) Common and recognized patterns of use of the formulation within the proposing Party;
- "(g) A clear description of incidents related to the problem, including the adverse effects and the way in which the formulation was used;
- "(h) Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents.

"Part 2. Information to be collected by the secretariat

"Pursuant to paragraph 3 of article 6, the secretariat shall collect relevant information relating to the formulation, including:

- "(a) The physico-chemical, toxicological and ecotoxicological properties of the formulation;
- "(b) The existence of handling or applicator restrictions in other States;
- "(c) Information on incidents related to the formulation in other States;
- "(d) Information submitted by other Parties, international organizations, non-governmental organizations or other relevant sources, whether national or international;
- "(e) Risk and/or hazard evaluations, where available;
- "(f) Indications, if available, of the extent of use of the formulation, such as the number of registrations or production or sales quantity;
- "(g) Other formulations of the pesticide in question, and incidents,
 if any, relating to these formulations;
- "(h) Alternative pest-control practices;
- "(i) Other information which the Chemical Review Committee may identify as relevant."

D. Approval of a decision guidance document

39. Article 7, paragraphs 2 and 3, of the Convention provide as follows:

"The recommendation referred to in paragraph 1 together with the draft decision guidance document shall be forwarded to the Conference of the Parties. The Conference of the Parties shall decide whether the chemical should be made subject to the prior informed consent procedure and, accordingly, list the chemical in Annex III and approve the draft decision guidance document.

"When a decision to list a chemical in Annex III has been taken and the related decision guidance document has been approved by the Conference of the Parties, the secretariat shall forthwith communicate this information to all Parties."

V. MECHANISM FOR COLLECTING AND DISSEMINATING COMMENTS RECEIVED ON DECISION GUIDANCE DOCUMENTS

A. Introduction

40. The Rotterdam Convention, in article 7, paragraph 1, provides as follows:

"For each chemical that the Chemical Review Committee has decided to recommend for listing in Annex III, it shall prepare a draft decision guidance document. The decision guidance document should, at a minimum, be based on the information specified in Annex I, or, as the case may be, Annex IV, and include information on uses of the chemical in a category other than the category for which the final regulatory action applies."

- 41. In relation to the preparation of draft decision guidance documents, the Intergovernmental Negotiating Committee decided at its sixth session that:
 - " ... the Interim Chemical Review Committee, consistent with the provisions of the Convention, in particular its articles 5, 6 and 7, shall have the following functions and responsibilities:

. . .

- "(c) Preparing draft decision guidance documents: specifically, for each chemical that the Interim Chemical Review Committee has decided to recommend to be made subject to the interim PIC procedure, preparing a draft decision guidance document, which should, at a minimum, be based on the information specified in Annex I of the Convention or, as the case may be, Annex IV, and include information on uses of the chemical in a category other than the category for which the final regulatory action applies."
- 42. The Intergovernmental Negotiating Committee further decided at the same session that:

"the Interim Chemical Review Committee should consider a mechanism for collecting and disseminating comments received on decision guidance documents as they were developed, so that countries taking a decision based on those documents were fully aware of the reasons behind the control action."

B. Sending of information

43. Article 5, paragraph 3, of the Convention provides as follows:

"The secretariat shall, as soon as possible, and in any event no later than six months after receipt of a notification under paragraphs

1 and 2, verify whether the notification contains the information required by Annex I. If the notification contains the information required, the secretariat shall forthwith forward to all Parties a summary of the information received. If the notification does not contain the information required, it shall inform the notifying Party accordingly."

44. Article 6, paragraph 2, of the Convention provides as follows:

"The secretariat shall, as soon as possible, and in any event no later than six months after receipt of a proposal under paragraph 1, verify whether the proposal includes the information required by part 1 of Annex IV. If the proposal contains the information required, the secretariat shall forthwith forward to all Parties a summary of the information received. If the proposal does not contain the information required, it shall inform the proposing Party accordingly".

C. Collecting and disseminating comments

- 45. When a notification of final regulatory action is received, it is required to be accompanied by information specified in Annex I of the Convention. Similarly, for a proposal for listing of a severely hazardous pesticide formulation in the interim PIC procedure the information specified in part I of Annex IV of the Convention is to be included.
- 46. The Interim Chemical Review Committee will decide if a draft decision guidance document is to be prepared for a particular chemical. If the decision is positive, the information supplied by the notifying/proposing Party or Parties will form the basis of the decision guidance document.
