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INTERIM CHEMICAL REVIEW COMMITTEE

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OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE

STATUS OF 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

Note by the secretariat

1. At its second session, the Interim Chemical Review Committee established four task groups to work intersessionally. Task group 2 was entrusted with working on the preparation of an outline for a decision guidance document for severely hazardous pesticide formulations, the goal being to facilitate the process for developing a decision guidance document based on the information expected to be available to the Committee;
2. Annexed to the present note is the report of task group 2 as submitted to the secretariat. The report provides brief background information on the objective and composition of the task group and information on how its work was organized. Finally, in sections E and F, respectively, the report identifies issues for consideration by the Interim Chemical Review Committee and provides specific recommendations on how the Committee might proceed. A draft outline of a decision guidance document for a severely hazardous pesticide formulation and a draft working paper that may serve as the basis for guidance to future drafting groups are appended to the task group report (appendices I and II).

* UNEP/FAO/PIC/ICRC.3/1

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Annex

TASK GROUP 2: DEVELOPMENT OF A FORMAT FOR A DECISION FOR SEVERELY GUIDANCE DOCUMENT HAZARDOUS PESTICIDE FORMULATIONS

A. Objectives of the task group

1. The objectives of task group 2, established at the second session of the Interim Chemical Review Committee, were:

(a) To prepare an outline for a decision guidance document for severely hazardous pesticide formulations for proposals pursuant to article 6 based on Annex IV parts 1 and 2; and

(b) To develop a process to facilitate the development of a decision guidance document for a severely hazardous pesticide formulations based on the information expected to be available to the Committee.

B. Composition of the task group

2. The members of task group 2, assigned at the second session of the Interim Chemical Review Committee, were:

Bill Murray (secretariat lead)

Cathleen Barnes

Andre Mayne

Dudley Achu Sama

Bill Cable

Yang Yong-Zhen

Observers :

CropLife International (Michael Neale)

Pesticide Action Network UK (Barbara Dinham)

World Health Organization (Nida Besbelli)

C. Background

3. The Rotterdam Convention, through its article 6, provides a mechanism for any Party that is a developing country or a country with an economy in transition and is experiencing problems caused by a severely hazardous pesticide formulation under conditions of use in its territory to propose to the secretariat the listing of that formulation in Annex III of the Convention. The proposal shall contain the information required by part 1 of Annex IV.

4. Article 6, paragraph 2 and 3, requires the secretariat, when it has received a proposal that it has verified meets the requirements of part 1 of Annex IV, to forward a summary of the proposal to all Parties and to collect the additional information set out in part 2 of Annex IV regarding the proposal. The Interim Chemical Review Committee is to 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

Intergovernmental Negotiating Committee whether the severely hazardous pesticide formulation in question should be made subject to the interim PIC procedure.

5. The submitted proposals and additional information collected by the secretariat are the main documents upon which the Interim Chemical Review Committee will base its work on severely hazardous pesticide formulations.
6. As a result of work undertaken by the Committee during its first two sessions, significant progress has been made in developing a standard format for collecting information on incidents involving severely hazardous pesticide formulations and the submission of a proposal to the secretariat.
7. The challenge will be to develop decision guidance documents on severely hazardous pesticide formulations that reflect the information available to the Committee and that also meet the needs of designated national authorities. The experience gained in developing the format for the decision guidance document has been proposed as the basis for a working paper that could serve as guidance to future drafting groups established by the Committee.

D. Organization of work

8. On June 15 2001 a package of information was circulated to all task group members with a request for comments. The package consisted of an outline of the work to be completed, background information including a tabular summary of the information elements listed in parts 1 and 2 of Annex IV, possible sources of this information and the relevance of this information to the criteria in part 3 of Annex IV. This was accompanied by an initial list of issues to consider and proposed next steps.
9. The comments received indicated support for the project outline and work plan, while one participant proposed a format for the decision guidance document. The comments and proposals were taken into account in preparing an initial format of the decision guidance document and a working paper as basis for future guidance to drafting groups.
10. A status report on the work of the task group was distributed on 14 August 2000 to all task group members with a request for comments by 30 September 2001. This included a revised list of issues to consider and an initial draft format consisting of key headings for the decision guidance document based on the information elements in parts 1 and 2 of Annex IV. This was accompanied by a draft working paper that included a statement as to the purpose of each of the headings in the draft format for the decision guidance documents and identified specific issues that needed further consideration.
11. In preparing the draft format an attempt was made to distinguish the information that was needed by the Committee in making a recommendation regarding inclusion of a formulation in Annex III from that needed by a designated national authority in making an import decision for a specific formulation. For this reason, not all of the points in parts 1 and 2 of Annex IV are explicitly cited.
12. It was clear that there are a number of issues that need to be discussed and agreed upon by the Committee before further significant progress can be achieved in finalizing the format for the decision guidance document.

E. Issues to consider

13. The level of detail needed regarding the composition of specific formulations is important to the following:

- (a) The Committee, in deciding whether to recommend inclusion of the formulation, in the light of such considerations as the following:

- (i) In some instances it may be clear that the adverse effects observed or reported are the direct result of exposure to the active ingredient or ingredients, this may be further supported by the World Health Organization (WHO) classification and information on the toxicity of the active ingredient or ingredients;
 - (ii) In other instances it may be the formulants (or inerts) that make up the formulated product that contribute to the adverse effects observed either through direct toxicity themselves or in potentiating the toxicity of the active ingredient or ingredients;
 - (b) Designated national authority, in order that it might understand the relationship between the formulations listed in Annex III to those formulations used nationally; in other words, where there are differences in the composition of the formulations subject to the Rotterdam Convention and those used nationally, what information is needed for the designated national authority to determine the significance of these differences in making an import decision.
14. Where there are other formulations of the active ingredient or ingredients used in both the country reporting the incident as well as other developing countries (which may or may not be associated with incidents), consideration must be given to how the Committee is to ensure that this information is reflected in the decision guidance document.
15. It is clear that detailed toxicological and ecotoxicological information is not expected to be available on individual formulations. What is not clear is the extent to which such information on the active ingredient or ingredients should be included in a decision guidance document on a specific formulation. It will be difficult for a drafting group to determine how and what toxicological or ecotoxicological information to include in a decision guidance document, given that the information available would not necessarily include a risk evaluation.
16. One option could be to consider the use of a safety data sheet. Safety data sheets capture key information and are available for a wide range of active ingredients. A safety data sheet could be incorporated into a decision guidance document as an annex. It may be that use of a safety data sheet containing basic information on the active ingredient or ingredients, coupled with the WHO classification of the formulation and information on experience in other countries with the same or related formulations may be sufficient for the decision guidance document. The use of the publicly available safety data sheet would allow the drafting group to focus on those aspects of the decision guidance document directly relevant to the formulation or formulations.
17. Of relevance to this discussion is a separate issue paper prepared by the secretariat on characterizing common and recognized patterns of use, which is available to Committee in document UNEP/FAO/PIC/ICRC.3/13.
18. Among the members of task group 2, there appeared to be general agreement that a decision guidance document for a severely hazardous pesticide formulation or formulations identified as a result of problems under conditions of use in a developing country or country with economy in transition would not necessarily be expected to mirror that for chemicals that have been banned or severely restricted.
19. Initial efforts in developing the format have focused on defining the key headings. It is clear that additional consideration will need to be given to the content and level of detail of the decision guidance document. It is also recognized that experience with the type of the information that is to be available in support of a proposal for a severely hazardous pesticide formulation will necessitate a degree of flexibility in developing the decision guidance document particularly until some practical experience is gained.
20. A draft of the key headings for a decision guidance document for a severely hazardous pesticide formulation has been prepared, based on the work of the task group, and is attached to the present note as appendix I. A draft working paper that provides insight into the individual headings proposed has also been

prepared and is attached as appendix II. The working paper should serve to facilitate discussion within the Committee and represent a basis for developing guidance to drafting groups.

F. Recommendation to the Interim Chemical Review Committee

21. The Committee should consider the following measures:

(a) Reviewing the outcome of the work of the task group with particular focus on the content of the draft format of the decision guidance document for a severely hazardous pesticide formulation (appendix I) and considering whether, in the light of the notes in the draft working paper, the proposed headings adequately reflect the type of information and level of detail expected to be available to the Committee and might be expected to meet the needs of designated national authorities in making import decisions;

(b) Reviewing the list of issues to consider and those specific issues embedded in the draft working paper (appendix II) and identify possible options to address the concerns identified;

(c) Considering whether the draft working paper would be the basis for guidance that could facilitate the development of a decision guidance document by future drafting groups.

22. Possible outcomes of the discussion could be:

(a) Adoption of a draft format for a decision guidance document for severely hazardous pesticide formulation including the key headings and subheadings, as the basis for further work;

(b) Clear understanding on the part of Committee of :

(i) How the information contained in a proposal for a severely hazardous pesticide formulation (part 1 of Annex IV) will be combined with the information collected by the secretariat (Part 2 of Annex IV) and be reflected in a decision guidance document;

(ii) The issues associated with developing a decision guidance document for a severely hazardous pesticide formulation and how they might be addressed;

(iii) The appropriate level of detail for the individual sections of the decision guidance document;

(iv) Where to find the information proposed for inclusion in each section of the decision guidance document;

(c) Adoption of the draft working paper on developing a decision guidance document, as amended by the Committee, as the basis for further work.

Appendix I

TASK GROUP 2: KEY HEADINGS FOR A DECISION GUIDANCE DOCUMENT ON HAZARDOUS SEVERELY PESTICIDE FORMULATIONS

A. Background

1. The present document contains an initial list of possible headings for a decision guidance document on severely hazardous pesticide formulations subject to the Rotterdam Convention. In some instances representative subheadings have been included. The document should be considered in conjunction with the initial draft working paper.

B. Introduction/rationale

2. The first 5 sections (based on part 1 of Annex IV) serve to indicate the precise basis on which the formulation has entered the Rotterdam Convention. The aim is to describe how the formulation was used in the reporting country, to identify the problem(s) that led to its being listed in Annex III and to define the scope of the formulation or formulations subject to the Convention. The WHO classification provides a universally recognized baseline that might assist countries in making their import decision.

3. Sections 6-11 reflect information elements in part 2 of Annex IV:

- *Sections 6-8* are intended to reflect experience in other countries in using the same or closely related formulations. Collectively this information should provide the designated national authority with a weight of evidence regarding the extent of the problems resulting from use of the formulation(s) in question and assist them in making a more informed assessment of the potential risks associated with the use of the specific formulation(s) in their country;
- *Section 9* is intended to characterize in more detail the formulation(s) in question. The proposed subheadings reflect the traditional physical chemical properties used to characterize a formulation. This section will need to be considered closely as it may be that information concerning the composition of the formulation should be included here in order to facilitate comparison of the formulation involved in the reported incident (and subject to the decision guidance document) with those formulations that may be used in other countries;
- *Section 10* attempts to combine at least two of the points from part 2 of Annex IV. The initial set of subheadings reflects the toxicological information typically available for a formulation. It may be that use of a safety data sheet (SDS) with basic information on the active ingredient(s), coupled with the WHO classification of the formulation and information on experience in other countries with the same or related formulations, is sufficient for the decision guidance document;
- *Section 11* provides possible information on alternatives to the formulation subject to the decision guidance document.

KEY HEADINGS FOR A DECISION GUIDANCE DOCUMENT CONCERNING SEVERELY HAZARDOUS PESTICIDE FORMULATIONS

Headings 1-4 relate to part 1 of Annex IV

1. Reason for inclusion in the PIC procedure:

The following formulation(s) of +++++ are subject to the Rotterdam Convention:

(name active ingredient and specific formulation(s))

This severely hazardous pesticide formulation(s) is subject to the Rotterdam Convention as it was found to cause problems under conditions of use in line with article 6 and Annex IV of the Convention.

2. Identification:

Headings could include:

- Name of the hazardous pesticide formulation;
- Name of the active ingredient or ingredients in the formulation;
- Relative amount of each active ingredient in the formulation;
- Type of formulation;
- Trade names and names of the producers, if available;

3. Description of common and recognized pattern of use of the formulation

Notifying country – brief description of degree to which individual formulations are regulated

Headings could include:

- Permitted uses;
- Application method;
- Restrictions in handling or use – relevant to worker exposure or environmental exposure;
- Availability/applicability of protective clothing;
- Actual uses.

Other countries ??

Brief description of how the formulation is used in other countries where incidents have not been observed or reported ??

4. Description of the incident(s) including adverse effects and way in which the formulation was used

Type of incident: **Adverse effects on human health or environment**

Human health-related Incident

Summary of key points for an occupational (worker exposure) incident could include the following: (*specific details e.g. completed incident report form (part B) could be included as Annex I to the decision guidance document*)

- Location of exposure;
- Main activity at the time of exposure;
- Application method;
- Use/availability of protective clothing;
- Route of exposure;

- Description of adverse effects;
- Extent of incident (number of people affected).

Environment-related incident

Summary of key points for environmental incident to be developed: (*specific details, e.g., completed incident report form could be included as annex I to the decision guidance document*)

5. WHO classification of the formulation(s)

- Tabular summary of WHO classification

Headings 6-11 relate to part 2 of Annex IV

6. Existence of handling or applicator restrictions in other countries

The type of information reflected here could include:

- Use of protective clothing, limitation to certain types of application equipment;
- Limiting use to specially trained or licensed applicators, existence of re-entry intervals to treated fields;
- Restricted application to certain areas, establishment of buffer zones, to protect bodies of water.

7. Information on incidents related to the formulation in other countries

The type of information reflected here could include:

- Reports of adverse effects reporting systems in developed countries;
- Information provided by non-governmental organizations/intergovernmental organizations or other interested parties.

8. Information on incidents related to other formulations of the pesticide

See working paper

- Notifying country;
- Other countries.

9. Physico-chemical properties of the formulation

Headings could include:

- Identity and content of active ingredient;
- Density properties;
- Surface properties;
- Volatilization properties;
- Particulate, fragmentation and adhesion properties;
- Flow properties;
- Solution and dissolution properties.

The list of properties proposed reflect those identified in the FAO specifications and listed in the fifth edition of the *Manual on the Development and Use of FAO Specifications for Plant Protection Products*.

The properties to be specified vary according to the type of technical active ingredient or formulation involved.

10. Summary of toxicological or ecotoxicological properties

The scope and level of detail for this section needs further consideration as part 2 of Annex IV also includes reference to consideration of risk and hazard evaluations, where available. These two pieces of information could be combined under this heading.

Toxicological properties

For human health end points, the primary data generated for a pesticide formulation are limited to a set of six acute toxicity studies. The most common and those that might be expected to be available for a given formulation are the following:

- Rat LD₅₀ oral;
- Rat LD₅₀ dermal;
- Rat LC₅₀ inhalation;
- Skin irritation;
- Eye irritation;
- Skin sensitization (test method used and result).

Ecotoxicological properties

Further consideration is needed on the nature and extent of the environmental information for a given pesticide formulation that would be readily available to the Interim Chemical Review Committee.

11. Alternative pest-control practices

It is not clear that specific information on individual formulations is readily available.

(Insert formulation name) was used on *(insert crop name(s))* to control *(insert pest names)*. There are a number of alternative methods/products available depending on the individual crop-pest complex under consideration. Limited information on alternatives that has been identified by *(insert country name(s))* and may be found in Annex XX.

It is essential that, before a country considers substituting alternatives, it ensures that the use is relevant to its national needs and the anticipated local conditions of use.

Annex I Information on reported incident from incident report

This would include specific information submitted by the notifying country, including:

- Completed incident report form (e.g., part B for a human health-related incident);
- Name of the country;
- Designated national authority contact information.

Annex II Safety data sheet on pesticide active ingredient

Safety data sheets typically contain the following key headings:

1. Chemical product identification and company identification
2. Composition of and other information on ingredients

3. Hazard identification
4. First aid measures
5. Accidental release measures
6. Handling and storage
7. Exposure controls and personal measures
8. Physical and chemical properties
9. Stability and reactivity
10. Toxicological information
11. Ecological information
12. Disposal considerations
13. Transport information
14. Regulatory information
15. Other information

Other examples such as the FAO/WHO pesticide data sheets and the IPCS international chemicals safety cards could also be considered.

Appendix II

TASK GROUP 2: DRAFT WORKING PAPER ON DEVELOPING A DECISION GUIDANCE DOCUMENT FOR A SEVERELY HAZARDOUS PESTICIDE FORMULATION

A. Purpose

1. The present working paper serves as an annotated draft outline of possible headings for a decision guidance document for severely hazardous pesticide formulations. It provides some of the initial thoughts behind the list of headings proposed in the outline of the decision guidance document format and clarifies:

- Purpose of each of the proposed sections of the decision guidance document;
- Information to be included in each section;
- Specific issues that need further consideration.

1. Reason for inclusion in the PIC procedure:

Purpose: To provide a generic statement that clearly identifies the fact that it is a specific formulation(s) of a pesticide that is subject to the Rotterdam Convention based on problems under conditions of use in a developing country or country with economy in transition.

2. Identification:

Purpose: Unequivocally to identify the pesticide formulation(s) subject to the Rotterdam Convention.

- This is basic information for the formulation(s) and should be directly obtainable from part A of the submitted report form on severely hazardous pesticide formulations.

Notes: Updated or additional information on trade names, for these formulation(s) as well as manufacturers/formulators will be sought from members of the Interim Chemical Review Committee and other interested parties during the consultation phases.

Issue: *Clarification is required on the need for or importance of information on the composition of the formulation and on the level of detail. This is also relevant to section 9: "Physico-chemical properties".*

3. Description on common and recognized patterns of use of the formulation

Purpose: To provide a clear description of how the formulation(s) in question is (are) typically used

- This is basic information for the formulation(s) and should be directly obtainable from part A of the submitted incident report form on severely hazardous pesticide formulations.
- This is a key section of the decision guidance document, as it will help countries that use the formulation to determine how closely the reported incident reflects use in their country. This would be useful information to countries when making import decisions

Issue: *There may be a need to consider two distinct sections one concerning the use in the notifying country and a second on use in other countries.*

- *Information on other formulations of this pesticide that may still be permitted for use in the notifying country would also be of interest and could be included here.*
- *Uses in other countries may also need to be considered, where there are handling or application restrictions on the formulation this information should be reflected in part 6,*
- *There may be situations where the formulation(s) in question or other formulations of the pesticide are used in other countries; consideration could be given to including such information either here or in an annex.*

4. Description of the incident(s) including adverse effects and way in which the formulation was used.

Purpose: Briefly to describe the incident, specifically how the formulation was used and the resulting adverse effects (human health or environment).

- This section should clearly distinguish between human health based incidents and those related to the environment.
- The key points should be taken directly from the submitted incident report form. The completed incident report form could be attached as an annex.

5. WHO classification of hazard

Purpose: This section should provide an internationally recognized baseline from which countries can better understand the potential concerns with the formulations in question relative to others that they may be using.

- This section would be included for each formulation for which the reported incidents involve human health

6. The existence of handling or applicator restrictions in other countries

Purpose: To provide an understanding of how the formulation in question is used in other countries (including developed countries) and the measures in place to reduce risk associated with use of the formulation

- This section should clearly distinguish between human health-related incidents and those related to the environment.
 - From a human health perspective this information could include the type of protective clothing required for workers (mixers/loaders/applicators), restrictions on re-entry intervals, on the type of application equipment permitted, limitations to licensed applicators etc.;
 - From an environmental perspective this could include need for buffer zones around bodies of water, limitations on application equipment, regional or seasonal restrictions on registrations to protect vulnerable areas/species etc.

Issue: *Further thought is needed on the scope and type of information and level of detail to be included here as well as how it would be solicited from countries.*

7. Information on incidents related to the formulation in other countries

Purpose: Provide an opportunity for other countries (including developed countries) that may have also experienced problems under conditions of use with the formulation(s) in question to relate their experiences

- Where other incidents have occurred they should be cited in the decision guidance document; these could include reports from adverse effects reporting systems in developed countries as well as those reported by non-governmental organizations and international governmental organizations.

Issue: *Questions that need to be considered include the appropriate level of detail and the degree of verification of the reported incidents that might be needed in order that this information might be considered by the Committee.*

8. Information on incidents related to other formulations of the pesticide

Purpose: Provide an opportunity for countries (including developed countries) that may have experienced problems under conditions of use with other formulation(s) of the pesticide in question to relate their experiences

This could be information that would be important to the Committee in determining the scope of the formulations to include in the decision guidance document but might also be of interest to designated national authorities to understand the experience that other countries may have had with other formulations.

- There may be situations where the formulation permitted for use in a different country is slightly different from that notified, yet which still resulted in problems in countries, e.g., notified formulation is 500 g/l ai while another country has 425 g/l permitted and has also experienced problems instituted handling or applicator restrictions

- Where the decision guidance document is focused on an incident related to adverse effects on health, this section could include information on other formulations that may have had an impact on wither health or the environment.
- Information from developed countries on how they have managed other formulations could be included here, e.g., information on handling restrictions, etc., as proposed for section 6.

Issue: Questions that need to be considered include:

- *Does this section need to be included or is it information more relevant to the deliberations of the Interim Chemical Review Committee?*
- *What is the appropriate level of detail and the degree of verification of the reported incidents that might be needed in order that this information might be considered by the Committee?*

9. Physico-chemical properties of the formulation

Purpose: This section should include information that clearly characterizes the formulation.

- This information may or may not be available from the notifying country. Updated or additional information for the formulation(s) in questions could be solicited from members of the Interim Chemical Review Committee and other interested parties, including the manufacturers/formulators during the consultation phases.

Issues: The present proposal includes the standard physico-chemical properties typically used to characterize formulations. It is not clear how this information would be used by a designated national authority.

10. Summary of toxicological or ecotoxicological properties

Purpose: Briefly to summarize key elements in the toxicological or ecotoxicological profile of the formulation where relevant to the reported incident.

- This section should clearly distinguish between human health-related incidents and those related to the environment and should focus on the basis of the reported incident, e.g., ecotoxicological profile for an environmental incident and toxicological profile for an incident related to human health.
- For human health end points, the primary data generated for a pesticide formulation are limited to a set of six acute toxicity studies. The most common and those that might be expected to be available for a given formulation are listed. It is not clear how useful this would be to a designated national authority in making an import decision on a given formulation.

Issue: Toxicological and ecotoxicological information on individual formulations is limited. Need to consider how consistently and concisely to provide relevant toxicological and ecotoxicological information on the pesticide formulation in question.

- *From a toxicological perspective relevant information could include a safety data sheet or FAO/WHO pesticide information sheets.*
- *This information, when coupled with the WHO classification (section 5 above), would provide countries with a basic understanding of the hazard associated with the formulations in question.*
- *Further thought is needed as to sources of information on ecotoxicological effects.*

11. Alternative pest-control practices

Purpose: To provide countries with information about alternatives to the pesticide formulation in question.

- At present notifying countries have not been requested to provide information about chemical and non-chemical alternatives that are being used within their jurisdictions. This could be requested as part of the follow-up action

by the secretariat in reviewing submitted proposals and those solicited from countries in the course of the development of the decision guidance document.

- It is not feasible for this section to contain a comprehensive list of specific pest crop complexes and recommended pesticides or non-chemical alternatives. As the available alternatives are constantly evolving, reliance should rather be placed on identifying sources of information rather than attempting to compile a list of specific recommendations.

Note: If such a section is to be included, it should parallel that for banned and severely restricted chemicals and include a generic statement on the need for caution in considering/using alternatives to remind parties of the need to ensure that they are appropriate to national circumstances.

Issue: *Should we allow other countries the opportunity to identify additional sources of information on alternatives?*

How can we ensure that as broad a range of information on alternatives as possible is made available?

Possible approaches will be considered by the Interim Chemical Review Committee in its future sessions and will include the Rotterdam Convention website, the PIC circular, workshops, etc.
