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OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE

**ISSUES ASSOCIATED WITH THE IMPLEMENTATION OF THE OPERATIONAL
PROCEDURES:**

**DRAFT WORKING PAPER ON PREPARING INTERNAL PROPOSALS
AND DECISION GUIDANCE DOCUMENTS FOR SEVERELY HAZARDOUS
PESTICIDE FORMULATIONS**

Note by the secretariat

1. At its third session, the Interim Chemical Review Committee (ICRC) developed a working paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations with the understanding that it would be updated in the light of experience gained in its implementation
2. The working paper was used by the drafting group on Granox TBC/Spinox T established at the third session of the ICRC. The comments provided by the members and co-chairs of the drafting group have been used to revise the working paper and as the basis for a brief list of issues to consider by the Committee in reviewing the amended document.
3. Annexed to this note is a revised version of the working paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations and a brief list of issues for the Committee to consider in its review.

* UNEP/FAO/PIC/ICRC.4/1.

Annex

Issues to consider

1. In order to assist countries in better understanding the reason why a particular formulation has been included in the PIC procedure it has been suggested that Section 2 of the decision guidance document include a summary of why the chemical was included. Alternatively it has been suggested that the rationale prepared in support of the recommendation of the ICRC for inclusion of the formulation in the PIC procedure be annexed to the decision guidance document.

- The latter approach would avoid potential problems with paraphrasing the results of the Committee's deliberations.

2. At its third meeting the ICRC agreed that given the difficulty in collecting information on the use of individual pesticide formulations a different approach was warranted (see UNEP/FAO/PIC/ICRC.3/13). The proposed approach would include consideration of a combination of information specific to the pesticide or formulation in question (that included in parts 1 and 2 of Annex IV), as well as more generic information on pesticide use in countries. This would involve at least three elements:

- (a) The inherent toxicity of the active ingredient or formulation;
- (b) Conditions of registration (e.g., the need for personal protective equipment) for the active ingredient and the same or similar formulations in countries with more developed regulatory infrastructure;
- (c) Information on how pesticides are commonly used in developing countries or countries with economies in transition. This latter information would not have to be country-specific, it might be based on information on common agricultural practices associated with certain commodities, or how pesticides are generally applied in such countries, e.g., the use of backpack sprayers, accessibility to personal protective equipment.

- It is clear that this information will be a key input to the work of the Committee in reviewing candidate formulations. It will be reflected in the rationale developed in support of a recommendation and possibly in Sections 7 and 10 of the current decision guidance document format. The Committee may wish to further consider whether or how this information might be reflected in the decision guidance document.

3. Consider reversing the order of sections 9 and 10 to parallel the order of sections 7 and 8 and provide a more logical flow to the information contained in the document e.g. information on handling restrictions followed by information on poisoning incidents.

4. In developing the current format the information needed by the Committee to determine inclusion of a formulation in the PIC procedure was distinguished from that needed by a DNA to make an import decision for a specific formulation. In line with this approach and in the light of the difficulty experienced in collecting formulation specific information for some elements in the current decision guidance document format further consideration of the content of the decision guidance document may be needed. For example:

- Concern was expressed that Sections 8, 9 and 10 were too precise and that they were likely to contain redundant information.
- In the case of information on the physical chemical properties of a formulation it is not clear how such information might be used by a country in making an import decision.



*Interim Secretariat for the Rotterdam Convention on the
Prior Informed Consent Procedure for Certain Hazardous
Chemicals and Pesticides in International Trade*



**WORKING PAPER ON PREPARING INTERNAL PROPOSALS
AND DECISION GUIDANCE DOCUMENTS FOR SEVERELY HAZARDOUS
PESTICIDE FORMULATIONS CAUSING HUMAN HEALTH PROBLEMS**

Headings 1- 4 relate to part 1 of Annex IV

1. Identification:

Purpose: To clearly identify the pesticide formulation(s) subject to the PIC procedure.

- This is basic information for the formulation and should be obtained directly from part A of the submitted report form on severely hazardous pesticide formulations.
- It should include as much information as possible on the composition of the formulation. As a minimum: the type of formulation, concentration the individual active ingredients and the CAS numbers.

Headings:

- 1.1 **Name or trade name of the hazardous pesticide formulation;**
- 1.2 **Name of the active ingredient or ingredients in the formulation;**
- 1.3 **Relative amount of each active ingredient in the formulation;**
- 1.4 **Type of formulation;**
- 1.5 **Name(s) of the producer(s), if available;**

2. Reason for inclusion in the PIC procedure:

Purpose: To provide a generic statement that clearly identifies category within which the chemical is included in the Rotterdam Convention. In this case the specific formulation(s) of a pesticide as a result of problems under conditions of use in a developing country or country with economy in transition.

Generic text may include:

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

- (name active ingredient(s) and relative concentrations, and specific formulation(s))
- This severely hazardous pesticide formulation 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.

Note: The specific formulation identified in a proposal submitted in accordance with Article 6 is the basis for including a severely hazardous pesticide formulation in the PIC procedure. However formulations containing the active ingredient or ingredients at or above the specified concentrations and in the same formulation type would also be included if supported by the technical documentation supporting the proposal.

- As many different formulations may be called by the same or similar names a disclaimer that clearly defines the formulations that are subject to the PIC procedure should be included.

3. Description of common and recognized pattern of use of the formulation in the reporting country.

Purpose: To provide a clear description of how the formulation is typically used in the reporting country (should include description of degree to which individual formulations are regulated)

- 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.
- This information should be available to the drafting group, from the incident report form on severely hazardous pesticide formulations and/or from additional information collected by the Secretariat, in line with part 2 of Annex IV.

Headings

3.1 Permitted uses of the formulation

- space fumigation, seed treatment, crops treated etc.,
- application method – how it is used
- pests controlled
- rate and frequency of application

3.2 Restrictions in handling or use

- relevant to worker exposure or environmental exposure;

3.3 Availability/applicability of protective clothing;

3.4 Actual uses

- description of how the formulation is typically used e.g. crops treated, pests controlled, application methods, rate and frequency of application etc., particularly where it might differ from the officially permitted uses.

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

Purpose: To briefly describe the incident, the resulting adverse effects, and relate how the formulation was used to the common and recognized patterns of use.

Note: The description of the incident and the adverse effects should be based on the information in Part B of the submitted incident report form. Reference should also be made to the completed incident report forms appended as Annex I and the data sheets in Annex II.

Headings

4.1 Description of the incident – Summary of key points could include the following:

- Where the incident occurred;
- Main activity at the time of exposure;
- Application method;
- Route of exposure;

- Conditions of use when the incident occurred e.g. prevailing climatic conditions

4.2 Description of the adverse effects

- Summary of key points described in the incident report form (Annex I)

4.3 Relationship of the adverse effects observed to recognized acute toxicological effects of the active ingredient(s)

- The simplest approach is to reference/quote from the relevant sections of the data sheet included in Annex II

4.4 Extent of incident (e.g. number of people affected for human health incidents)

- Summary of information in the incident report form (Annex I)

5. Any regulatory, administrative or other measure taken, or intended to be taken, by the Party in response to the incidents

Purpose: To briefly outline any administrative/regulatory action that may have been taken by the reporting country.

- This information could be taken directly from PART A of the submitted incident report form.

6. WHO hazard classification of the formulation.

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 should be calculated based on the best available information. The values and possible hazard classification should be based on the principal routes of exposure (e.g.: dermal, oral), and presented in a tabular format.
- The WHO recommended classification of pesticides by hazard should be used as the primary reference for oral LD₅₀ values. Where several LD₅₀ values for other routes of exposure e.g. dermal have been published the lowest deemed reliable will be used (and referenced). This is in line with the approach used by the WHO in compiling the oral LD₅₀ values.
- Where a formulation consists of more than one active ingredient the fact that the calculated hazard classification cannot account for possible synergistic effects or the potentiation of toxicity, as a result of interaction among the active ingredients, should be noted.

Headings 6-11 relate to part 2 of Annex IV

7. Existence of handling or applicator restrictions for the formulation in other countries

Purpose: To provide information of how the formulation in question is used in other countries not just developing countries or countries with economies in transition and the measures they may have put in place to reduce the risks associated with its use.

The type of information reflected here could include:

- Conditions of registration (e.g. limitations to specific crops, to certain geographic locations or timing of application)
- The 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.

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

Purpose: To provide an opportunity for other countries not just developing countries or those with economies in transition, that may have experienced problems with this formulation of the active ingredient(s) in questions, to relate their experience.

- Where reports of other incidents or poisoning information have been made available to the Committee in making their recommendation to include a chemical in the PIC procedure they should be cited here. This could include reports from adverse effects reporting systems as well as those reported by non-governmental organizations and international governmental organizations.
- Additional reports on incidents involving the formulation that were not available to the Committee could be posted on the Rotterdam Convention website.

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

Purpose: Provide an opportunity for other countries not just developing countries or those with economies in transition, that may have experienced problems with other formulation(s) of the active ingredient(s) in questions, to relate their experience.

- Information from other countries available to the Committee could be included here, e.g., in adverse effects reporting systems.
- Additional reports on incidents related to other formulations of the pesticide that were not available to the committee could be posted on the Rotterdam Convention website.

10. Information on other formulations of the active ingredient(s) in the country reporting the incident and in other countries.

Purpose: To provide a context to better understand the potential for related formulations to cause problems under conditions of use in developing countries or countries with economies in transition. This could include information on handling restrictions/risk mitigation measures of other formulations of the active ingredient(s) contained in the formulation of concern

Note: This information could be voluminous and that which might be usefully included here will need to be looked at on a case by case basis. It might be possible to reflect generic information on formulation types for a specific active ingredient e.g. liquid formulations.

- Where there are multiple active ingredients in the subject formulation, this would include information on related formulations of the individual active ingredients.
- Types of formulation could include:
 - different formulation types e.g. emulsifiable concentrate, wettable powder, granular, etc
 - the same formulation containing different concentrations of the same active ingredients.

11. Physico-chemical properties of the formulation

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

The properties to be specified vary according to the type of technical active ingredient or formulation involved. Based on the list of physical chemical properties of formulations identified in the FAO Manual on the Development and Use of FAO Specifications for Plant Protection Products (Fifth Edition, 1999) this list would be expected to include the following:

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

Where formulation specific information is not available a reference to the relevant information on the active ingredient(s) available in Annex II could be referenced.

12. Summary of toxicological properties

Purpose: Summarize key elements in the toxicological profile of the formulation

For mammalian toxicological 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).

Where there is a risk or hazard evaluation on the formulation either from a national government or international source it could be summarised here.

- Where this information is not available for a given formulation, consideration should be given to:
 - material safety data sheet (MSDS) for the formulation.
 - or reference the risk or hazard information in Annex II on the active ingredient(s) from an internationally recognized source such as: the INCHEM database, the EXTOWNET Profile, IPCS International Chemical Safety Cards (ICSCs), summaries from Environmental Health Criteria documents etc.

13. Alternative pest-control practices

Purpose: To provide countries with brief information about alternatives that have been identified by the country submitting the proposal or others.

- Where available, information on the pests controlled should be included in order to ensure that appropriate alternatives might be identified.
- It may not be feasible for the decision guidance document to contain a comprehensive list of specific pest crop complexes and recommended pesticides or non-chemical alternatives, particularly for pesticide formulations that have a broad spectrum of activity. As the available alternatives are constantly evolving, identifying sources of information is likely to be more useful and more reliable than a list of specific recommendations.

Note: While recognizing that a range of chemical and non-chemical alternatives may be available, this section should include a generic statement on the need for caution in considering them or using them and should remind parties of the need to ensure that they are appropriate to national circumstances.

In order to maintain the timeliness and accuracy of this information, it is preferable to include references to additional sources of information (electronic links, etc) for a specific chemical on the Rotterdam Convention website. Such new sources of such information could be included in a series of up-dates that could be distributed to designated national authorities along with the PIC circular and also used in workshops.

The following is an example of standard text for this section:

There are a number of alternative methods involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop-pest complex under consideration. Countries should consider promoting, as appropriate, integrated pest management (IPM) strategies as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through National IPM focal points, the FAO, agricultural research or development agencies. Where it has been made available by governments, additional information on alternatives to XXXX may be found on the Rotterdam Convention website www.pic.int

It is essential that before a country considers substituting alternatives for a given formulation, 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 should include specific information submitted by the notifying country:

- Summary of 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

The relevant data sheet(s) for the individual active ingredients should be inserted in their entirety.

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 of readily available information that might be used to complete this annex include the IPCS International Chemicals Safety Cards (ICSCs), summaries from Environmental Health Criteria documents etc., These documents are freely accessible at www.inchem.org
