UNITED NATIONS

PIC

United Nations Environment Programme

Food and Agriculture Organization of the United Nations

Distr.
GENERAL

UNEP/FAO/PIC/ICRC.3/5
29 November 2001

ENGLISH ONLY

INTERIM CHEMICAL REVIEW COMMITTEE
Third session
Geneva, 17-21 February 2002
Item 5 (a) (i) of the provisional agenda*

OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE: STATUS OF THE WORK OF THE INDIVIDUAL TASK GROUPS ESTABLISHED AT THE SECOND SESSION OF THE COMMITTEE

TASK GROUP 1: PILOT-TESTING – SEVERELY HAZARDOUS PESTICIDE FORMULATION REPORT FORM

Note by the secretariat

1. At its second session, the Interim Chemical Review Committee established four task groups to work intersessionally. For task group 1 it was agreed that the secretariat, in cooperation with interested Committee members and observers, would undertake a pilot test of the draft incident report form and guidance. On the basis of the results of this pilot test a further version of the severely hazardous pesticide formulation report form and guidance were to be developed for review by the Committee at its next session.

2. Annexed to the present note is the report of task group 1 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 revised version of the severely hazardous pesticide formulation report form is appended to the task group report.

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

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Annex

TASK GROUP 1: PILOT-TESTING OF THE SEVERELY HAZARDOUS PESTICIDE FORMULATION REPORT FORM

A. Objective of the task group

1. The objective of task group 1, established at the second session of the Interim Chemical Review Committee, was to pilot-test and revise as needed the severely hazardous pesticide formulation report form and guidance.

B. Composition of the task group

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

Secretariat (Bill Murray) (coordinator)
Azhari Omer Abdelbagi
Reiner Arndt
Dudley Achu Sama
Mohamed Ammati
Fatoumata Jallow Ndoye
Julio Monreal Urrutia
Bhakta Raj Palikhe
Sandra de Souza Hacon
Kasumbogo Untung

Observers:

World Health Organization (Nida Besbelli)
Pesticide Action Network UK (Barbara Dinham)
Global Crop Protection Federation (Michael Neale)

C. Background

4. 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 1of annex IV.

5. Article 6, paragraphs 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 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 Intergovernmental Negotiating Committee whether the severely hazardous pesticide formulation in question should be made subject to the interim PIC procedure.

6. The submitted proposals and additional information collected by the secretariat are thus the main documents upon which the Interim Chemical Review Committee will base its work on severely hazardous pesticide formulations. It is of importance to the Committee that the information collected in accordance

with parts 1 and 2 of annex IV is of sufficient quality and of relevance to their review of the criteria in part 3 of annex IV of the Convention.

7. There is no standard format for collecting information on incidents involving severely hazardous pesticide formulations or for submission of a proposal to the secretariat. At its first session (February 2000), the Interim Chemical Review Committee assigned high priority to the development of an incident report form and guidance on how to provide information on severely hazardous pesticide formulations consistent with the information requirements and the criteria given in annex IV (parts 1 and 3, respectively) of the Convention.

8. At the second session of the Interim Chemical Review Committee (March 2001), a provisional incident report form and guidance for the collection of information on severely hazardous pesticide formulations were considered. It was agreed that a round of comment from individuals with practical experience concerning the collection of information on pesticide poisoning incidents in the field would help to ensure the applicability and utility of the form prior to its general release. Task group 1 was formed to work with the secretariat to develop a further version of the severely hazardous pesticide formulation incident report form and related guidance based on the results of limited pilot-testing in selected countries (UNEP/FAO/PIC/ICRC.2/11).

D. Organization of work

9. The pilot test was undertaken in a limited number of countries where projects related to pesticides and pest management were in place. The provisional incident report form, a list of guidance questions and issues to consider were distributed to the participants of the pilot test on 17 May 2001 with the request that they respond by 1 September 2001. Comments were received from 8 of the 12 participants. In some instances, the comments provided reflected discussions with a broader group of experts at the field level.

10. The comments received on the form, responses to the list of questions and a revised list of issues to consider were compiled. A revision to the severely hazardous pesticide formulation report form was proposed based on the responses from the participants in the pilot test. These documents were distributed to the members of the task group on 19 September 2001 with a request for a response by 15 October 2001.

11. This report reflects the comments received from the task group members on the results of the pilot-testing and consists of a revised severely hazardous pesticide incident report form, a consolidated list of issues to consider and draft recommendations for consideration by the Committee. A list of the participants in the pilot test and copies of all of the comments received in the course of the inter-sessional work will be available at the third session of the Committee.

E. Issues to consider

12. There are a number of issues that will need to be considered by the Committee in finalizing the incident report form. To facilitate consideration of these issues by the Committee, they have been organized into three groups. The first consists of those issues that had been addressed by the Committee in developing the report form. They have been included here in the interest of completeness as they are points that may be useful in developing further guidance and training materials on the use of the forms. The second group includes those issues for which there appears to be general agreement on a way forward, while the final reflects outstanding – or what might be considered "new" – issues that will need to be considered by the Committee.

1. Issues addressed in developing the incident report form

13. The focus of the incident report form is in line with subparagraph 1 (g) of Annex IV, in which countries are to provide "a clear description of incidents related to the problem, including adverse effects and the way in which the formulation was used". Pesticide formulations that are acutely toxic have been targeted in the form since these are the formulations most likely to cause problems under conditions of use in

developing countries. Formulations that have chronic toxicity are more likely to have been subject to a ban or severe restriction in a developed country and thus could be identified as candidates under article 5. It would be very difficult to relate pesticide exposure in a given incident to chronic toxicity.

14. The form is not intended to capture information regarding the infrastructure to support safe use of pesticides. Nor is the intention to capture incidents that result from improper storage or management of pesticides stocks as these are more likely to be a function of the active ingredient itself rather than a specific formulation and would not be addressed by including a given formulation in the Convention.

15. An ongoing concern is the level of detail included in the form. Thus, on the one hand, there is a concern that the detail included is insufficient, while, on the other, concerns were expressed that the form was too complicated and requested too much detailed information.

16. A key challenge has been to develop a form and associated guidance that is easy enough to understand, that will be widely adopted and yet at the same time allows sufficient flexibility to ensure that an adequate level of detail is provided, to meet the needs of the Interim Chemical Review Committee.

17. The form has been modelled on work completed by the World Health Organization (WHO) and Pest Action Network (PAN) UK. In order to facilitate completion of the form and to try to strike a balance between the need for detail and keeping the form manageable a check-list approach has been used to the collection of the minimum information, supplemented by opportunities to provide further information where it is available. Clearly, the format will continue to evolve as experience is gained in its implementation.

18. It must also be noted that the form has been developed to facilitate the preparation of submissions by countries. If there are other report formats available at the national level, they may also be used provided they contain comparable information.

2. Issues on which there is general agreement

19. Training will be needed in the use of the form. It is also expected that the both the form and guidance will necessarily evolve as experience is gained.

20. At its eighth session, the Intergovernmental Negotiating Committee, in its discussion of the problems frequently encountered by Parties in their presentation of notifications of final regulatory actions, recommended the development of a more comprehensive guidance manual for designated national authorities, clearly setting out all the actions required of those authorities in performing their functions in accordance with the Convention. The form and guidance will also be discussed at training workshops for designated national authorities.

21. The challenge is to collect information on individual formulations when the reality is that in many instances workers may in fact be exposed to more than one formulation. There are two related issues:

(a) Individuals may spray different pesticides over several days. It is important to ascertain whether or not the adverse effects observed relate to the most recent exposure, reflect the previous days' exposure or result from cumulative exposure.

(i) Question 19 of part III of the incident report form has been designed to address this concern, by enquiring into the time that elapsed between handling the pesticide and the observation of the adverse effects. Given the difficulty in obtaining reliable information on individual formulations at the best of times, the reported exposure incident may only realistically focus on the formulation used at the time the adverse effects were observed;

(b) Individuals mix more than one formulation together rather than spraying individual formulations. It is important to ascertain whether or not the observed adverse effects are the result of one of the individual pesticides or are the result of some synergistic effect of the mixture.

(i) Question 13 of part II is an attempt to simplify this issue by requesting that, where there are mixtures of formulations used, these be identified and that the information in part I on the individual pesticides or formulations be provided. Those instances where it may appear that there was more than one active ingredient or formulation applied during a reported incident but where only a single formulation is identified will have to be considered on a case-by-case basis.

3. Outstanding and new issues

22. 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 in the formulation. 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 their own direct toxicity or in potentiating the toxicity of the active ingredient or ingredients. Information on the composition of the formulation may be of importance in at least two ways:

(a) For the designated national authority, in understanding the relationship between the formulation subject to the Rotterdam Convention and those used domestically; and

(b) For the Interim Chemical Review Committee, in considering the formulation and the decision whether or not to include it in the Convention.

23. Clarification is needed on how to characterize “misuse”. Part 3 of Annex IV presents the criteria for the listing severely hazardous pesticide formulations in Annex III and it states that “intentional misuse is not in itself an adequate reason to list a chemical in Annex III ”. A separate thought-starter on characterizing “common and recognised patterns of use” relevant to this specific issue is scheduled for discussion under item 5 (b) (iv) of the provisional agenda (UNEP/FAO/ICRC.3/13).

24. The general question of implementation, relating, in particular, to how the forms are to be dispatched in order to reach the people who will make use of them, and how the needed information can be collected in a consistent, reliable way at the national level, remains and will likely be best addressed as experience is gained in using the form.

F. Recommendations to the Interim Chemical Review Committee

25. At its next session, the Interim Chemical Review Committee should consider the following measures:

(a) Reviewing the outcome of the work of the task group, with a particular focus on the form for submitting a proposed severely hazardous pesticide formulation;

(b) Reviewing the issues to be considered and, for the new and outstanding issues in particular, proposing possible ways in which they might be addressed;

(c) Considering the need to revise the form and associated guidance as experience is gained in their implementation.

26. Possible outcomes of the discussion could be:

(a) Adoption of the revised form and guidance and agreement that they be released for general use and included on the agenda of training workshops for designated national authorities;

(b) Common understanding of the issues to consider in the implementation of the form;

(c) Recommendation to the Intergovernmental Negotiating Committee to encourage participating countries to distribute the form to people who will use it to collect information on severely hazardous pesticide formulations causing problems under conditions of use in their territory as the basis for the submission of proposals to the secretariat in line with article 6;

(d) Reconsideration of the form and guidance by the Committee, once experience has been gained in its implementation.

Appendix

Introduction to the Severely Hazardous Pesticide Formulation Report Form

The severely hazardous pesticide formulation report form consists of three sections:

(a) Introduction: the text is intended to provide relevant background information on the Rotterdam Convention and how the information collected by the form and submitted by the designated national authority will be used;

(b) Part A: this is to be completed by the designated national authority once he or she receives part B from the field. It reflects the information requirements of part 1 of Annex IV of the Convention. There is some redundancy between parts A and B of the form, particularly with respect to information on product identity. It was thought that this redundancy might help countries to consolidate responses, by using part A of the form to report on more than one incident for the same formulation.

(c) Part B: this is designed to provide "a clear description of the incidents related to the problem, including the adverse effects and the way in which the formulation was used" (part 1, paragraph (g), of Annex IV of the Convention). The form has been constructed around these points. It consists of a series of closed questions or checklist that captures the basic information needed with options for including additional information where it is available.

Severely Hazardous Pesticide Formulation Report Form

Purpose of the form

The severely hazardous pesticide formulation (SHPF) report form was developed to facilitate the identification of candidate formulations for inclusion in the Rotterdam Convention. The Convention provides a mechanism for countries to decide whether or not they wish to receive future shipments of such pesticide formulations and for ensuring compliance with these decisions by exporting countries.

What is the Rotterdam Convention?

The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade promotes a shared responsibility between importing and exporting parties in the international trade of certain hazardous chemicals. It gives importing countries the power to decide which chemicals they want to receive and to exclude those that they cannot manage safely. The Convention includes provisions for developing countries and countries with economies in transition that are experiencing problems with severely hazardous pesticide formulations under conditions of use, to identify the formulations as candidates for inclusion in the Convention. Further information on the operation of the Rotterdam Convention may be found at www.pic.int

What is the severely hazardous pesticide formulation report form?

This form consists of two parts: A and B. Part A (the transmittal form) is to be used by the designated national authority (DNA) to transmit an incident report form to the secretariat. Part B (the pesticide incident report form) has been developed to meet the information requirements of the Convention, that is, to provide a clear description of the incidents related to the use of a severely hazardous pesticide formulation, including the adverse effects and the way in which the formulation was used. Part B of the form consists of a series of closed questions or a checklist that captures the basic information needed, with options for including additional information where it is available. It is fully compatible with programmes collecting quantitative information on pesticide poisonings in support of epidemiological studies or national programmes concerning the reporting of adverse effects associated with pesticide use. The format has been developed so that it might be widely used by States, aid agencies, intergovernmental organizations and non-governmental organizations etc., in reporting on pesticide incidents. If there are other formats available, they may be used in preparing a submission to the secretariat and forwarded through the DNA using part A of the SHPF form, provided that they meet the information requirements of parts 1 and 3 of Annex IV of the Convention. There is some redundancy between parts A and B of this form. It was thought that this might help countries to consolidate responses by using part A of the form to report on more than one incident for the same formulation.

What happens to the completed form?

Once part B – the incident report form – has been completed to the extent possible based on the information available, it should be forwarded to the DNA. The DNA is to coordinate the completion of part A – the transmittal form – and forward the entire document to the secretariat. The secretariat is required to collect additional information, including physico-chemical and toxicological properties of the pesticide formulation, information on incidents related to the formulation in other States, the existence of handling or applicator restrictions in other states and risk or hazard evaluations where available. This information, along with the completed form, is reviewed by the Interim Chemical Review Committee (ICRC). The ICRC will decide whether or not to recommend the inclusion of the pesticide formulation in the Rotterdam Convention.

Your cooperation in completing this form and your contribution for the identification of severely hazardous pesticide formulations posing problems under conditions of use is greatly appreciated. If you have any questions or comments relating to the completion of this form please contact the secretariat at one of the addresses below.

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

PART A - TRANSMITTAL FORM - DESIGNATED NATIONAL AUTHORITY

	Information required from a designated national authority
1	Name of the formulation: .....
2	Type of formulation: (*for example, EC, WP, DP, GR, TB*)
3	Trade name and name of producer, if available
4	Name of the active ingredient or ingredients in the formulation:
5	Relative amount of each active ingredient in the formulation: (*% concentration*)
6	Attach copy of the label(s), if available (or describe the key aspects of the label: language, etc.).
7	Common and recognized patterns of use of the formulation within the country – ➢ Is the formulation registered or permitted for use in the country? ➢ What uses are permitted? ➢ Are there any handling or applicator restrictions specified as a condition of registration? ➢ Provide information on the extent of use of the formulation, such as the number of registrations or production or sales quantity (indicate the source of information). ➢ Provide other information on how the formulation is commonly or typically used in the country (***This information should be submitted on a separate sheet attached to the completed form***)
8	A clear description of incidents(s) related to the problem, including adverse effects and the way in which the formulation was used (for example, part B – the pesticide incident report form – identifies key elements and provides an appropriate level of detail). Other report formats which may exist at the national level may also be used, provided they contain comparable information.
9	Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents.

Date, signature of designated national authority and official seal:

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

PART B - PESTICIDE INCIDENT REPORT FORM

This form should be completed for each individual exposed in a given incident - Where an incident involves more than one formulation, please complete section I and question 13 for each.

I. Product identity: *What formulation was used when the incident took place?*

1. Name of the formulation:
.....

2. Type of formulation (check one of the following)

☐ *Emulsifiable conc. (EC)* ☐ *Wettable powder (WP)* ☐ *Dustable powder (DP)*
☐ *Water soluble powder (SP)* ☐ *Ultra low volume (ULV)* ☐ *Tablet (TB)*
☐ *Granular (GR)* ☐ *other, please specify:*.....

3. Trade name and name of producer, if available:
.....

4. Name of the active ingredient(s) in the formulation:
.....

5. Relative amount of each active ingredient in the formulation: (*% concentration, g/l, etc.*)

6. Attach copy of the label(s), if available.

II. Description of the incident: *How the formulation was used.*

7. Date of incident: (month/day/year)

8. Location of incident: village/city:.....
province/state/region:.....
country:.....

9. Person exposed (identity should be checked and recorded before submission of the form)

Sex: ☐ male ☐ female ☐ age: .....

If age unknown: ☐ child (<14yrs) ☐ adolescent (14-19 yrs) ☐ adult (>20yrs)

10. Main activity at time of exposure (*check one or more of the following*):

☐ *application in field* ☐ *mixing/loading* ☐ *veterinary therapy*
☐ *household application* ☐ *vector control application* ☐ *other, please specify:*
☐ *reentry to treated field* ☐ *human therapy*

11. Was protective clothing used during application? ☐ no ☐ yes

If no, please explain why

If yes, briefly describe (check one or more of the following):

☐ *gloves* ☐ *overalls* ☐ *eye glasses* ☐ *respirator* ☐ *other, please specify:*
☐ *face mask* ☐ *boots/shoes* ☐ *long-sleeve shirt* ☐ *long trousers* .....

12. Information on how product was being used:

(a) Location of exposure/incident (*field, garden, greenhouse, house, etc.*)
.....

(b) List the animals/crop(s)/stored products treated if relevant:
.....

(c) Application method: (*How product was used – e.g., hand, bucket and brush, soil injection, spray (backpack, tractor-mounted, etc.), drip irrigation, aerial (helicopter, plane etc.*)):
.....
.....

(d) Dose applied/concentration *(or amount of pesticide applied)*.....

(e) Duration of the exposure period: ☐ hours ☐ ½ day ☐ day ☐ other (specify):
.....

13. If more than one pesticide formulation was used at the same time, please respond to points i) to iv) below for each formulation. (*see also part I: Product identity*)

(i) Was the pesticide in its original container? ☐ no ☐ yes

(ii) Was the label available? ☐ no ☐ yes

If yes, was exposed individual able to read and understand label? ☐ no ☐ yes

(iii) Does the label include the reported use? ☐ no ☐ yes

If no, describe how the use reported above differs from that recommended on the label:
(*use a separate page if necessary*)

(iv) Is the reported incident typical of how the formulation is generally used? ☐ no ☐ yes

14. Climatic conditions under which the incident occurred (eg. *temperature, relative humidity, etc.*):
.....

15. Were other individuals affected in the same incident? ☐ no ☐ yes

16. Include any other details that may be useful in describing the incident and the way in which the formulation was used, in particular how the use reported here reflects common or recognized use patterns for this formulation (*additional pages may be attached).*

III. Description of adverse effects:

17. Individual's reaction (check one or more of the following):

☐ *dizziness* ☐ *headache* ☐ *blurred vision* ☐ *excessive sweating*

☐ *hand tremor* ☐ *convulsion* ☐ *staggering* ☐ n*arrow pupils/miosis*

☐ *excessive salivation* ☐ *nausea/vomiting* ☐ *other, please specify:* .....

☐ *death*

18. Route of exposure (*check main route or more than one if applicable*)

☐ *mouth* ☐ *skin* ☐ *eyes* ☐ *inhalation*

☐ *other, please specify:*.....

19. How soon after starting handling the formulation were the adverse effects observed:
.....

IV. Management:

20. Treatment given: ☐ No ☐ Yes ☐ Unknown
Hospitalization: ☐ No ☐ Yes ☐ Unknown

21. Include any other details/information regarding treatment, including medical intervention/first aid/hospitalization/local practices, etc. *(additional pages may be attached)*:
.....

V. Reporting/communication:

22. Date of data collection/consultation: .....

23. Name and address of investigator/data collector: .....
.....
.....

24. Category of investigator/data collector:

☐ *medical* ☐ *paramedical* ☐ *non-medical*

If non-medical, specify type of person (*applicator, formulator, vendor, extension worker, manager, etc*.):.....

25. Contact if further information is needed: Tel: .....
Fax: .....
Email: .....

26. Has this incident been reported elsewhere? ☐ No ☐ Yes
If yes, where: .....

Send the completed incident report form to the designated national authority.
(Name and address of the designated national authority)
