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Chemical Review Committee
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Item 4 of the provisional agenda*

Policy guidance and working procedures related to the work of the Chemical Review Committee

Working procedures and policy guidance for the Chemical Review Committee

Note by the Secretariat

At its first and second meetings, held in 2005 and 2006, the Chemical Review Committee adopted several papers on policy guidance and working procedures covering a broad range of issues related to the work of the Committee.

At its second meeting in September 2004, the Conference of the Parties adopted decision RC-2/2 on the process for preparing draft decision guidance documents and took note of the working paper on the preparation and use of focused summaries (UNEP/FAO/RC/CRC.1/10) and the working procedures for determining existing trade in chemicals (UNEP/FAO/RC/CRC.1/8).

At its third meeting, the Conference of the Parties took note of the procedures for the preliminary review of notifications of final regulatory action and prioritizing the work of the Chemical Review Committee (UNEP/FAO/RC/CRC.2/6). It considered the working paper on the application of criterion (d) of Annex II (UNEP/FAO/RC/COP.3/7) and agreed that the Committee should consider notifications involving intentional misuse on a case-by-case basis. It also endorsed the approach recommended in the policy guidance on the trade restrictions under other multilateral environment agreements (UNEP/FAO/RC/COP.3/9) and the policy guidance on risk evaluations under other multilateral environment agreements and their relevance to candidate chemicals (UNEP/FAO/RC/COP.3/10).

* UNEP/FAO/RC/CRC.3/1.

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The working procedures and policy guidance outlined above are intended to facilitate the work of the Committee and help ensure consistency and transparency. They should be revised, if necessary, in the light of experience.

Since the second meeting of the Chemical Review Committee, three additional documents have been developed for consideration by the Chemical Review Committee at its third meeting: a document on bridging information (UNEP/FAO/RC/CRC3/4), a working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals (UNEP/FAO/RC/CRC3/5), and a working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II of the Rotterdam Convention (UNEP/FAO/RC/CRC3/6).

The annex to the present note contains a compilation of the working procedures and policy guidance documents for the Chemical Review Committee. The documents have not been formally edited by the Secretariat.

Annex

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Process for drafting decision-guidance documents and accompanying explanatory notes

Introduction

The Chemical Review Committee (CRC) at its first session reviewed a paper on the process for drafting decision-guidance documents and accompanying explanatory notes, which was originally developed by the interim CRC. The Committee adopted the paper as amended, and forwarded it to the Conference of the Parties (COP). The COP at its second session adopted the process for drafting decision guidance documents and accompanying explanatory notes in its Decision RC-2/.

The purpose of the document is to guide the work of the CRC in developing decision guidance documents for banned and severely restricted chemicals and severely hazardous pesticide formulations. It contains a flow chart of the process and explanatory notes.

Process for drafting decision-guidance documents and accompanying explanatory notes

A. Process for drafting decision-guidance documents

Flow chart

Article 5
When the secretariat has identified at least one verified notification from each of two PIC regions

Article 6
When the secretariat has verified that a proposal contains the information required (Annex IV, part 1) and has collected additional information (Annex IV, part 2)

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1. The secretariat forwards the notifications/proposal and accompanying documentation to the Chemical Review Committee experts.

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2. Chemical Review Committee experts, by correspondence, provide comments on the accompanying documentation and a Chemical Review Committee task group is established.

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3. The Chemical Review Committee task group incorporates comments and presents the notifications at a full meeting of the chemical Review Committee. When the Committee decides that a chemical meets the requirements of the Convention, a drafting group is formed to develop an internal proposal.

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4. The internal proposal is circulated to the Chemical Review Committee and its observers (States, intergovernmental organizations, non-governmental organizations) for information and comments.

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5. The Chemical Review Committee drafting group incorporates, as appropriate, comments from the members of the Chemical Review Committee and takes note of the comments made by observers of the Chemical Review Committee on the internal proposal and prepares a draft decision-guidance document.

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6. The draft decision-guidance document is distributed as a meeting document (in the six official languages of the United Nations) for discussion at a Chemical Review Committee meeting for finalization and approval.

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7. The Chemical Review Committee forwards the recommendation and draft decision-guidance document to the Conference of the Parties for decision.

B. Explanatory notes to the process for drafting decision-guidance documents

1. Decision-guidance documents for chemicals notified as banned or severely restricted in accordance with Article 5

The secretariat will forward to members of the Chemical Review Committee the notifications determined to meet the information requirements of Annex I and relevant supporting documentation provided by the notifying Parties (per Annexes I and II).

The Chemical Review Committee must deem a notification and relevant supporting documentation to meet the requirements of the Convention prior to developing a decision-guidance document.

(1) * When the information in the notification is deemed sufficient, the secretariat will forward the notifications and accompanying documentation to the experts of the Chemical Review Committee (2) for an initial round of comment. A Chemical Review Committee task group will be established.

(3) The task group will incorporate comments provided by experts, as appropriate, indicating those comments that are taken up and those that are not, and why.

The task group will present the notifications and the accompanying documentation to the Chemical Review Committee along with the tabular summary of comments. The Chemical Review Committee will decide whether to make a recommendation to include the chemical in Annex III of the Convention. When the decision is to recommend inclusion of a chemical, a drafting group will be established. The drafting group will prepare an internal proposal and circulate it within the drafting group for comments. A revised internal proposal will be prepared.

(4) The internal proposal will then be circulated to the Chemical Review Committee and its observers for information and comments. Any comments will be directed to the secretariat, which will prepare a tabular summary for review by the drafting group.

(5) The drafting group will incorporate, as appropriate, comments from the members of the Chemical Review Committee and take note of the comments made by observers of the Chemical Review Committee on the internal proposal and prepare a draft decision-guidance document.

(6) The draft decision-guidance document (and the tabular summary of comments) will be distributed as a meeting document for discussion at a Chemical Review Committee meeting (in six languages) for finalization and approval.

(7) The Chemical Review Committee will forward the recommendation and draft decision-guidance document to the Conference of the Parties for decision. The final documentation forwarded by the secretariat to all Parties and observers in advance of the Conference of the Parties meeting at which it is to be considered will include the draft decision-guidance document, the Chemical Review Committee recommendation for inclusion in Annex III and a summary of the Chemical Review Committee deliberations, including a rationale based on the criteria listed in Annex II as well as the tabular summary of comments received under step 4 and how they were addressed.

Regional coordination by members of the Chemical Review Committee in preparing and providing comments is encouraged.

2. Decision-guidance documents for severely hazardous pesticide formulations proposed in accordance with Article 6

The secretariat will forward to members of the Chemical Review Committee the proposal and accompanying documentation, based on the information contained in the proposal and the additional information collected by the secretariat in accordance with Annex IV, part 2.

The Chemical Review Committee must deem the proposal to meet the requirements of the Convention prior to developing a decision-guidance document.

* Numbers refer to steps in the flow chart.

(1) * When the information in the proposal is deemed sufficient, the secretariat will collect the information in part 2 of Annex IV from designated national authorities and non-governmental organizations and forward the proposal and accompanying documentation to the experts of the Chemical Review Committee (2) for an initial round of comment. A Chemical Review Committee task group will be established.

(3) The task group will incorporate comments, as appropriate, indicating those comments that are taken up and those that are not, and why.

The task group will present the proposal and the accompanying documentation to the Chemical Review Committee along with the tabular summary of comments. The Chemical Review Committee will decide whether to make a recommendation to include the pesticide formulation in Annex III of the Convention. When the decision is to recommend inclusion of the formulation, a drafting group will be established. The drafting group will prepare an internal proposal and circulate it within the group for comment. A revised internal proposal will be prepared.

(4) The internal proposal will then be circulated to the Chemical Review Committee and its observers for information and comments. Any comments will be directed to the secretariat, which will prepare a tabular summary for review by the drafting group.

(5) The drafting group will incorporate comments as appropriate from the members of the Chemical Review Committee and take note of the comments made by observers of the Chemical Review Committee on the internal proposal and prepare a draft decision-guidance document.

(6) The draft decision-guidance document (and the tabular summary of comments) will be distributed as a meeting document for discussion at a Chemical Review Committee meeting (in six languages) for finalization and approval.

(7) The Chemical Review Committee will forward the recommendation and draft decision-guidance document to the Conference of the Parties for decision. The final documentation forwarded by the secretariat to all Parties and observers in advance of the Conference of the Parties meeting at which it is to be considered will include the draft decision-guidance document, the Chemical Review Committee recommendation for inclusion in Annex III and a summary of the Chemical Review Committee deliberations, including a rationale based on the criteria listed in Annex IV as well as the tabular summary of comments received under step 4 and how they were addressed.

Regional coordination by members of the Chemical Review Committee in preparing and providing comments is encouraged.

* Numbers refer to steps in the flow chart.

Working paper on preparing internal proposals and decision-guidance documents for severely hazardous pesticide formulations

Introduction

This document was developed to serve as guidance to inter-sessional drafting groups of the Chemical Review Committee (CRC) in the preparation of decision guidance documents for severely hazardous pesticide formulations. It is designed to clarify the purpose of each section of the decision guidance document and to characterize the information to be included.

The working paper, originally developed by the interim CRC, was considered at the first session of the CRC. The Committee adopted the document, as amended, as guidance and agreed to develop it further in the light of future experience.

Working paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations

Introduction/purpose

1. This working paper is to serve as guidance to drafting groups established by the Chemical Review Committee for the preparation of decision guidance documents for severely hazardous pesticide formulations in accordance with Article 6 of the Rotterdam Convention.

2. This working paper is intended:

- To clarify the purpose of each section of the decision guidance document
- To characterize the information to be included
- To define acceptable sources of information for each section

3. This working paper is expected to evolve as further experience is gained in the preparation of decision guidance documents. A separate working paper has been developed for the preparation of decision guidance documents for banned or severely restricted chemicals in accordance with Article 5 of the Rotterdam Convention.

General guidance

4. In preparing each decision guidance document a standard cover/title page will be added, as will a version of the standard introductory text developed at the fourth session of the Interim Chemical Review Committee and amended by the Intergovernmental Negotiating Committee at its tenth session. This text provides a brief summary of the process through which the individual decision guidance document was developed and includes three separate sections, *introduction, purpose and disclaimer.*

5. A standard list of "core" *abbreviations* has been prepared based on experience in drafting decision guidance documents to date. It is intended that this core list should serve as the basis for decision guidance documents and that it should be augmented by abbreviations used in the individual decision guidance documents relevant to the chemical(s) in question. This core list of abbreviations is appended to this working paper. As a general rule it is preferable for acronyms used only once in the text to be spelled out rather than included in the list of abbreviations.

6. In preparing a decision guidance document, it may be that not all sections are relevant to the chemical under consideration. It is preferable, in that case, to include a phrase along the lines of "not applicable", rather than deleting the section or leaving it blank. This clearly indicates that the drafting group has considered that section.

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 of the individual active ingredients and the CAS numbers.

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 formulations 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 differing 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.

1. 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 their own patterns of use. 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.

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 such use differs 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 and the resulting adverse effects, and to 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.

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 tabular format.
- The WHO recommended classification of pesticides by hazard should be used as the primary reference for oral LD_{50} values. Where several LD_{50} values for other routes of exposure, e.g. dermal, have been published, the lowest deemed reliable is used (and referenced). This is in line with the approach used by WHO in compiling the oral LD_{50} 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.

7. 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 may 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 specific chemicals on the Rotterdam Convention web site. Such new sources of such information could be included in a series of updates 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, FAO and 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 web site 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 Rationale for the recommendation by the Chemical Review Committee to include the severely hazardous formulation in the PIC procedure

Part 2 of Annex IV of the Convention refers to a range of information that is to be collected by the secretariat. This information will need to be considered by the Chemical Review Committee. In order to assist countries in better understanding the reason why a particular formulation has been included in the PIC procedure, this section will contain the rationale prepared in support of the recommendation of the Chemical Review Committee for inclusion of the formulation in the PIC procedure.

Annex II Information on reported incident from incident report

This should include specific information submitted by the notifying country:

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

Annex III Safety data sheet(s) on pesticide active ingredient(s)

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, summaries from environmental health criteria documents etc. These documents are freely accessible at www.inchem.org.

Annex III Summary of toxicological properties

Purpose: Summarize key elements in the toxicological profile of the formulation (where available)

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 LD_{50} oral
- Rat LD_{50} dermal
- Rat LC_{50} 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 an international source it may be summarized here.

- Where this information is not available for a given formulation, consideration should be given to including:
    - The material safety data sheet (MSDS) for the formulation;

- A reference to the risk or hazard information in annex II on the active ingredient(s) from an internationally recognized source such as the INCHEM database, the EXTOXNET Profile, IPCS International Chemical Safety Cards, summaries from environmental health criteria documents etc.

Appendix. Standard core set of abbreviations

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
>>	much greater than
µg	microgram
µm	micrometre
ArfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
ADP	adenosine diphosphate
ATP	adenosine troposphere
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CA	Chemicals Association
cc	cubic centimetre
CHO	Chinese hamster ovary
cm	centimetre
DNA	deoxyribose nucleic acid
EC	European Community
EC_{50}	effect concentration, 50%
ED_{50}	effect dose, 50%
EEC	European Economic Community
EHC	environmental health criteria
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
i.m.	intramuscular
i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC_{50}	inhibition concentration, 50%
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 1000)
kg	kilogram
Koc	organic carbon-water partition coefficient
l	litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LD_{LO}	lowest lethal dose
LOEL	lowest observed effect level
m	metre
m.p.	melting point
mg	milligram
ml	millilitre
mPa	millipascal
MTD	maximum tolerated dose
ng	nanogram
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
PCM	phase contrast microscopy
Pow	octanol-water partition coefficient
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used).

RfD	reference dose for chronic oral exposure (comparable to ADI)
SMR	standardized mortality ratio
STEL	short term exposure limit
TLV	threshold limit value
TWA	time weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VOC	volatile organic compound
WHO	World Health Organization
wt	weight

Process for determining evidence of ongoing trade

Introduction

After two notifications for a chemical had been received the Secretariat should collect information on the international trade in that chemical. Evidence of ongoing international trade for the chemical will be provided to the Chemical Review Committee (CRC) for its consideration, along with the verified notifications and supporting documentation. The working paper described the process to be followed in determining ongoing trade.

The CRC at its first session agreed to follow the process described in the paper which was originally developed by the interim CRC. The COP at its second session noted the paper and encouraged industry bodies, non-governmental organizations and Parties to provide the information requested for the determination of ongoing trade in chemicals.

Process for determining evidence of ongoing trade

1. The process for determining whether or not there is ongoing international trade in a chemical must be as simple and pragmatic as possible, in order that it does not needlessly complicate the process for the development of decision-guidance documents.

2. The simplest solution would be to have trade (import/export) information provided by countries as part of their submitted notifications of regulatory action. Where no information on imports or exports is provided by the notifying countries specific follow-up with industry associations and designated national authorities in other countries will be needed.

3. When the secretariat has received at least one notification from each of two PIC regions, the collection of information on evidence of trade could be undertaken from all possible sources simultaneously, as follows:

(a) For notifying countries, as a first step, the guidance on completing the notification form should make countries aware of the importance of including information on their imports and exports. Second, as part of the letter sent to countries to verify the completeness of their submitted notification of final regulatory action, they will be informed that, once a second notification from another PIC region is provided, they will be requested to provide, where available, information on:

(i) Whether or not they manufactured the chemical and, if so, whether they continue to export it;

(ii) The last time that they imported the chemical;

(b) The relevant industry association (pesticide or industrial chemical) will be requested to provide a response as to whether the particular chemical is manufactured and traded. A positive response would be taken as evidence of trade. A negative response would require specific follow-up;

(c) A general call for information on continued use, import and export of the chemical could be posted on the Rotterdam website or included in the PIC circular each time that there were two verified notifications from two regions. This would also allow non-governmental organizations and others to provide information on evidence of continued production, use or trade.

4. Evidence of ongoing international trade for the chemical will be provided to the Committee for its consideration, along with the verified notifications of final regulatory action and supporting documentation submitted by the notifying countries.

Common and recognized patterns of use of severely hazardous pesticide formulations

Introduction

Noting the difficulty of collecting information on pesticide poisoning incidents in developing countries and countries with economy in transition, the working paper was developed to characterize common recognized patterns of use of pesticides and also how the information might be collected for the implementation of Article 6 of the Convention.

The CRC at its first session adopted the working paper which was originally developed by the interim CRC, and agreed to develop it further in the light of future experience.

Common and recognized patterns of use of severely hazardous pesticide formulation

Note by the Secretariat

1. The purpose of the present is note is to identify issues for consideration by the Chemical Review Committee when reviewing information on common and recognized patterns of use relevant to proposals for severely hazardous pesticide formulations submitted in accordance with article 6 of the Convention.

A. Background

2. At the first meeting of the Interim Chemical Review Committee, work was initiated on a report form to facilitate the collection and reporting of information on severely hazardous pesticide formulations in support of proposals under article 6 of the Convention. It is evident that consideration should also be given to better defining the type of information needed by the Committee in complying with the requirement in part 1 of Annex IV for the provision of information on "Common and recognized patterns of use of the formulation in the proposing party". This information will be important to the work of the Committee, as in its review of a proposal for a severely hazardous pesticide formulation it is to take into account the criteria in Annex IV, part 3, in particular:

(a) 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) Relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;

(c) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.

B. Defining the Problem

3. There are widely varying views on what constitutes common and recognized patterns of use largely as a result of the varying levels of control over pesticide uses that exist under different regulatory systems. In developed countries common use may be considered equivalent to the legal use, e.g., those uses listed on the product label. In countries with a less developed regulatory infrastructure, however, the degree to which individual pesticide formulations are regulated and the role of the label in the national regulatory process varies widely such that common use practices may be more difficult to define.

4. The key challenge is determining what information is needed to characterize common and recognized patterns of use in a country and also how it might be collected.

5. The present paper identifies some of the issues associated with collecting information on common and recognized patterns. It also considers how it might be combined with other information available to the Committee and the possible use of surrogate or generic data to characterize pesticide use in developing countries.

C. Issues to Consider

C1. Widely differing methods of regulating pesticides in developing countries and their direct implications for defining common and recognized patterns of use

6. There is a need for a clear understanding of how individual formulations are regulated and managed in countries submitting proposals for severely hazardous pesticide formulations. For example:

(a) The pesticide active ingredient is registered or authorized for agricultural use perhaps on specific crops but individual formulations are not regulated;

(b) The pesticide active ingredient and individual formulations may be authorized for use in agriculture in general and not restricted to specific crops;

(c) For countries that do not have an active pesticide control scheme in place label claims will be those made by the manufacturer or formulator, which may not necessarily be relevant to the conditions of use in a specific country.

7. In such cases there is little or no control over how the individual formulations available in the market place are used. As a result common and recognized patterns of use will necessarily include uses other than those that may be on the label and should not be considered to represent illegal or misuse.

C2. Type of information needed to characterize common and recognized patterns of use – what is available to the Chemical Review Committee

8. The incident report form submitted by a Party in support of a proposal to include a severely hazardous pesticide formulation in Annex III will contain basic information on how a formulation is regulated and used in a proposing country (see UNEP/FAO/PIC/ICRC3/5), part A of the form requesting information on the "regulatory" status of the formulation in the country and part B providing a description of how the formulation was used in the specific incident reported.

9. Part A of the form requests the following information regarding the formulation:

(a) Is it registered / permitted for use in the country?

(b) What uses are permitted?

(c) Are there any handling or applicator restrictions specified as a condition of registration;

(d) Information on the extent of use, such as the number of registrations or production or sales quantity;

(e) Other information on how the formulation is commonly used in the country

10. Consideration is needed as to whether or not additional information on common and recognized patterns of use in the reporting country, over and above that provided in the completed incident report form (part A and part B), might be required by the Committee.

11. The secretariat is to collect relevant information related to the formulation listed in part 2 of Annex IV. The information to be collected includes the toxicological and ecotoxicological properties of the formulation, incidents related to the formulation in other states and risk or hazard evaluations where available. The quantity of formulation specific information that will be available is likely to be limited. It is not clear to what extent information on closely related formulations or the active ingredients under consideration might also be collected for consideration by the Committee.

12. Given the likelihood that only limited formulation-specific information may be available to the Committee under point (i) in part 2 of Annex IV ("Other information which the Chemical Review Committee may identify as relevant is also to be collected"), further thought is needed as to what other information might be useful to the Committee in its consideration of individual proposals. It is clear that at least some of this information might only be identified on a case-by-case basis; however, an understanding

of what this might realistically be expected to include would facilitate a proactive approach to preparing for the work of the Committee.

C3. Collecting country specific information on common and recognized patterns of use for individual formulations

13. In preparing a proposal on a severely hazardous pesticide formulation for consideration by the Committee, the designated national authority is to provide information on common and recognized patterns of use for the specific formulation.

14. Current information on how individual formulations are typically used in a country may be very difficult for a designated national authority to collect. It is not clear whether or to what extent such information is routinely collected or documented and, where it has been collected, whether it is readily available to a designated national authority.

15. A systematic approach by designated national authorities to the collection of information on common and recognized patterns of use for a formulation could include the development and circulation of a questionnaire. Alternatively extension personnel, non-governmental organizations including the pesticide industry, commodity groups, public interest groups or project staff providing technical assistance might all possibly play a role in assisting a designated national authority in collecting or verifying use information.

16. Where information on use of a specific formulation is provided from sources other than the designated national authority, e.g., industries, public interest groups or commodity groups, the Committee will need to consider how it might be used. This would be important particularly in those situations where it suggested a different pattern of use from that presented by the designated national authority.

C.4 Alternative to collecting specific information on common and recognized patterns of use for individual formulations

17. Given the difficulty in collecting information on the use of individual pesticide formulations a different approach may be warranted. This could include 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 that could be made available to the Committee. This could involve consideration of at least three elements:

(a) 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.

D. Next Steps

18. The Chemical Review Committee may wish to consider the issues identified in the present paper, the information available through a completed incident report form and, in the light of its experience with actual proposals for severely hazardous pesticide formulations, consider the need for further work.

Procedure for dealing with notifications of final regulatory action to ban or severely restrict a chemical

Introduction

This document contains a procedure for dealing with notifications with the objective of improving the efficiency of the operation of the Chemical Review Committee. It provides guidance on the steps and time lines for inter-sessional work of the Committee and the setting of priorities.

The procedure was adopted by the second session of the CRC with the understanding that it was a work in progress and would be amended in the light of experience gained. Subsequently, it was amended by the secretariat to include the conclusion of COP3 regarding the priority for chemicals subject to other multilateral environment agreements.

Procedure for dealing with notifications of final regulatory action to ban or severely restrict a chemical

Background

The Chemical Review Committee (CRC) at its first meeting considered a number of operational procedures relevant to its work. One of the outcomes of this consideration was recognition of the need for measures to promote the efficiency of intersessional work including the setting of priorities and deadlines.

The CRC proposed that the secretariat, working with the bureau, undertake a preliminary review of notifications of final regulatory action submitted in accordance with article 5 of the Convention. For those notifications that appear to meet the requirements of the Convention, intersessional task groups would be created prior to the session of the CRC, in line with the agreed process for drafting decision-guidance documents. Intersessional task groups would not be formed for notifications that appear not to meet the requirements of the Convention. The notifications and available supporting documentation for all candidate chemicals would be available to the CRC. The goal would be to help ensure that those notifications that are the subject of preliminary work in task groups are those for which it appears that sufficient information is available to determine that the criteria of Annex II have been met.
The work of the secretariat and the Bureau to establish priorities for the intersessional work of the CRC does not preclude the obligation of the CRC to review all of the submitted notifications and relevant supporting documentation for candidate chemicals.

At its second meeting, the Conference of the Parties (COP) considered the issue of trade restrictions under other multilateral agreements and requested the secretariat to prepare a paper for consideration by the CRC at its second meeting on how a substance whose trade was prohibited, severely restricted or managed in some way under other multilateral agreements should be treated under the Rotterdam Convention. The CRC discussed that paper, and forward it for consideration by the COP at its third meeting.

Introduction

The present paper sets out a procedure for identifying priorities for intersessional work by members of the CRC based on a preliminary review of the notifications of final regulatory action to ban or severely restrict a chemical that are submitted in line with Article 5 of the Convention. It contains four chapters: chapter I provides an overview of the current process for dealing with notifications and in preparing documents for the CRC including the individual steps involved and the approximate time required for each; chapter II sets out measures to promote the efficiency of intersessional work; Chapter III proposes some deadlines and a possible process for the secretariat, working with the Bureau, to undertake a preliminary review of notifications as well as specific deadlines for the preparation of documents for meetings of the CRC. Chapter IV reflects the conclusion of COP3 on priority to chemicals which were already included in other multilateral environmental agreements.

I. Overview of the current process for dealing with notifications and in preparing documents for the CRC

Brief description of the process for the review of notifications

Individual notifications are verified for completeness with respect to the information requirements of Annex I of the Convention. For those notifications verified as complete, a letter is sent to the notifying country informing them of this and alerting them to the fact that when a second notification complete notification is received from a different PIC region they will be requested to provide the supporting documentation referenced in the notification. At this stage, where necessary, notifications verified as complete are translated into English.

Upon receipt of a further complete notification from a second PIC region for the same chemical, all countries that have submitted complete notifications are requested to submit the supporting documentation referenced

in their notifications and if possible a focussed summary. Where necessary, focused summaries and, depending on its volume, supporting documentation are translated into English upon receipt.

The completed notification forms and the supporting documentation submitted by the countries are formatted as meeting papers for the CRC. The documents are circulated to all members of the CRC and posted on the Convention website.

In line with the process for the development of decision guidance documents, the members of the CRC are invited to form intersessional task groups to undertake initial assessments of the notifications and supporting documentation in the light of the information requirements of Annex I and the criteria of Annex II of the Convention (UNEP/FAO/RC/COP.2/19, annex I, decision RC-2/2). The task groups are provided with an opportunity to meet immediately preceding the meeting of the Committee to finalize their reports and their recommendations. Task group reports are presented to the full CRC for its consideration.

Steps and approximate length of time for the preparation and circulation of notifications and relevant supporting documentation for the CRC

The meeting documents for the CRC, including the notifications and supporting documentation for the candidate chemicals, are sent by courier to all members of the CRC and posted on the Convention website at least eight weeks in advance of the meeting at which they are to be considered. This includes the time available for the work of any intersessional task groups that may be established on individual candidate chemicals.

In preparing the final versions of the documents for a meeting of the CRC, there is a need to consider processing by the Division of Conference Services of the United Nations Office at Nairobi, which generally requires up to six weeks once the final documents have been prepared by the secretariat.

The time allowed for notifying countries to provide documentation in support of their notifications is eight weeks. The result is that the last date for notifications to be considered eligible for review by the Committee would be on the order of 14 weeks prior to the date of dispatch of the final documents for the CRC.

II. Measures to promote the efficiency of intersessional work: prioritization and deadlines

The CRC at its first meeting proposed that the secretariat, working with the Bureau, undertake a preliminary review of notifications of final regulatory action submitted in accordance with article 5.

It is proposed that the secretariat prepare an initial assessment of the notifications and submitted supporting documentation in the light of the requirements of the Convention (information requirements of Annex I and the criteria of Annex II). Following this initial assessment, the secretariat will propose priorities for the work of the CRC by clustering the candidate chemicals into three groups. The groups will be composed of those chemicals for which it appears that:

Group 1: Notifications from at least two PIC regions meet the requirements of the Convention

Group 2: Only some of the notifications (e.g., one or two notifications from a single PIC region) meet the requirements of the Convention

Group 3: None of the notifications meet the requirements of the Convention.

Where necessary, the report will also highlight those aspects of individual notifications for which it is not clear whether the requirements of the Convention have been met and which would benefit from closer scrutiny by the Bureau and the full CRC.

The initial assessment and proposals of the secretariat will be provided to the Bureau for review and comment along with the notifications and available supporting documentation. The Bureau would be requested to review the information and proposed priorities within 2–4 weeks. The comments received would be used to amend the initial assessment as necessary and form the basis for a report of the Bureau to the CRC setting out proposed priorities for the review of chemicals by the CRC, including those that would be the basis for the work of intersessional task groups. The report would be a meeting document for the CRC.

In line with the recommendation of the CRC at its first meeting, intersessional task groups would be established only for those chemicals for which there appear to be notifications that meet the requirements of the Convention from at least two PIC regions (Group 1). The CRC, however, will also need to develop rationales for chemicals for which there may only be a single notification that meets the requirements of the Convention (Group 2). Lower priority would be assigned to those chemicals for which there are no notifications that appear to meet the requirements of the Convention (Group 3). In order to promote efficiency in the work of the CRC, the Chair, working with the Bureau, would propose experts from among the CRC members to be responsible for leading the discussion on individual chemicals. This would include presenting to the CRC an assessment of whether individual notifications and supporting documentation meet the requirements of the Convention and, as appropriate, developing rationales as to how the requirements of the Convention have been met. The conclusion of these assessments and the text of the individual rationales would form part of the report of the meeting. The lead experts for individual chemicals would be selected based on a consideration of a number of factors including the country or region from which the individual notifications for a chemical have been received and the need to ensure participation of a full range of experts in the work of the CRC.

As a further measure to promote efficiency in the review and processing of notifications of final regulatory action, and in preparation for meetings of the CRC, it is proposed that the secretariat request supporting documentation immediately upon receipt of a complete notification pertaining to a given chemical rather than wait until until another complete notification realting to that chemical from a second PIC region is received. Thus, supporting documentation would be requested on an ongoing basis. For example, if the Secretariat received a notification for chemicals not included in Annex III that was verified as complete, the notifying country would be requested to submit the supporting documentation and focussed summary immediately. This would mean that the Secretariat's task of collating the supporting documentation, preparation of focussed summaries and, if necessary, translation into English, would be an ongoing process as notifications are reviewed and verified for completeness.

III. Proposed timeline for the preparation of documents for meetings of the Chemical Review Committee

The CRC at its first meeting also requested that specific deadlines be established for the preparation of documents for the meetings of the CRC. In the light of the comments received at the first meeting of the CRC regarding the summer holiday period in southern countries, dispatch of the documents for the CRC earlier in December rather than later was preferred.

It is proposed that the dates for dispatch of CRC documents (1 December) and the cut-off date for the eligibility of notifications for consideration by the CRC (15 August) be more or less fixed, while the precise dates for the intervening work, particularly that relating to the Bureau, would likely need to be reviewed on an annual basis in consultation between the secretariat and the Chair of the CRC. Requesting supporting documentation on an ongoing basis should allow some greater flexibility in the interim dates between the deadline for the eligibility of notifications for consideration by the CRC and the date of dispatch of the meeting documents.

Based on the steps in the process for preparing documents and the time required for each step, the following timeline is proposed:

15 August – 8 weeks before cut-off for the submission of supporting documentation

- Deadline for the receipt and review of notifications for candidate chemicals in order that they may be scheduled for review by the CRC. Notifications submitted after this date will be eligible for review by the CRC at a subsequent meeting.
- Letters to notifying countries to submit supporting documentation for candidate chemicals if they have not already done so. Information submitted in response to these letters may need translation.
- The request for supporting documentation on an ongoing basis may allow for the preparation of the information for review by the Bureau at an earlier date.

Not later than 15 October – 2 weeks before finalization of documents for the next meeting of the CRC

- Deadline for the submission of supporting documentation for candidate chemicals scheduled for review by the CRC.
- Focussed summaries and supporting documentation will be sent for translation as received if necessary.
- Commencement of initial assessment of the candidate chemicals scheduled for review by the CRC

Not later than 1 November – 6 weeks before dispatch of documents for the next meeting of the CRC

- All meeting documents are submitted to Conference Services for finalization. Some, such as notifications and supporting documentation, require only a cover page and should be processed quickly.
- The initial assessment of the candidate chemicals prepared by the secretariat is sent to the Bureau for review and amendment as appropriate within 2 to 4 weeks. The minimum time available would be two weeks, depending on the potential number of candidates for which supporting documentation is pending. The request for supporting documentation on an ongoing basis may allow for a longer time for review by the Bureau.

1 December – minimum 8 weeks before CRC meets

- All documents are sent to CRC members by courier and posted on the Convention website.
- CRC members are invited to form intersessional task groups on priority chemicals based on the recommendations contained in the report of the Bureau.
- Task group reports are circulated 1 to 2 weeks prior to the CRC meeting and finalized immediately prior to the meeting.

IV. **Trade restrictions under other multilateral environmental agreements**

The controls on trade imposed under the Stockholm Convention on Persistent Organic Pollutants and the Montreal Protocol on Substances that Deplete the Ozone Layer and raised the question of whether, in considering candidate chemicals for listing in Annex III to the Rotterdam Convention, the Chemical Review Committee should give a lower priority to chemicals which were already included in either of those agreements.

COP3 endorsed the approach, that in the interest of facilitating the work of the Committee, lower priority should be given to chemicals already included in other multilateral environmental agreements. On the other hand, chemicals under consideration for inclusion in such agreements or newly included but subject to lengthy phase-out periods would be treated in the usual way.

Preparation and use of focused summary

Introduction

Designated national authorities (DNAs) are invited to submit focused summaries of the information used in support of regulatory actions when providing supporting documentation for review by the CRC. The use of a focused summary by the Committee is not intended to establish a new obligation for DNAs but remains a voluntary action aimed at facilitating the work of the Committee.

The working paper on the preparation and use of focused summary was originally developed by the interim CRC. It was adopted by the first session of the CRC, as amended, and noted by the second session of the COP.

Preparation and use of focused summaries

A. Purpose of focused summaries

1. Focused summaries are important tools in facilitating the work of the Chemical Review Committee in reviewing notifications of final regulatory actions for banned or severely restricted chemicals which are candidates for inclusion in Annex III of the Convention.

2. Focused summaries should summarize the notification of final regulatory action while ensuring that an adequate level of detail is provided so that the basis for the regulatory action is clearly presented. They should demonstrate how the notification fulfils the criteria in Annex II of the Convention by providing a summary of key decisions and key findings, with references to the associated documents.

3. Designated national authorities (DNAs) are invited to submit focused summaries of the information used in support of regulatory actions when providing supporting documentation for review by the Chemical Review Committee. The use of a focused summary by the Committee is not intended to establish a new obligation for DNAs but remains a voluntary action aimed at facilitating the work of the Committee. Focused summaries should also assist DNAs in putting together a notification of final regulatory action for banned or severely restricted chemicals.

4. The format and content of focused summaries are flexible. They should focus on the information which a Government has considered in support of its final regulatory action. Documentation already produced and published by national Governments may be adequate as focused summaries. Focused summaries should be as informative and as short as possible; depending on the nature of the notification, they could be in the order of 10 pages in length. In situations where the supporting documentation is not available in English, the focused summary would be that part of the documentation which is translated into that language. It should be noted, however that the focused summary is not intended to replace supporting documentation, and the supporting documentation should still be provided.

B. Outline or key headings to include in a focused summary

B1. Introduction

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

(a) The events that led to the final regulatory action;

(b) The significance of the regulatory action, e.g., one use or many uses, level or degree of exposure;

(c) An overview of the regulatory system of the notifying country, if relevant;

(d) The scope of the regulatory action: a precise description of the chemicals subject to the regulatory action.

B2. Risk evaluation

6. This section should contain evidence, as available, that a risk evaluation was carried out under the prevailing conditions of the notifying country. It should confirm that the criteria in Annex II, subparagraph (b), have been met. It may include:

(a) Key findings of the national risk evaluation;

(b) Key data reviews consulted together with a brief description;

(c) Reference to national studies, e.g. toxicological and ecotoxicity studies;

(d) A summary of actual or potential human exposure and/or environmental fate.

C. Risk reduction and relevance to other States

7. This section should contain evidence that the control action is of relevance to other States. It may include information on the following:

(a) Estimates of the quantity of chemicals used, or imported/exported, at the time of the regulatory action and, if possible, information on ongoing trade;

(b) Relevance of the control action to other States, i.e., those with similar conditions of use;

(c) Comments on the typical use of the chemical in the notifying country, with comments on possible misuse if appropriate.

D. Worked example of a focused summary: monocrotophos

1. Introduction

8. This section should provide a brief statement or summary of the final regulatory action and the reasons for the action taken (e.g., occupational health concerns, environmental concerns). It may include:

(a) The events that led to the final regulatory action:

The registration of monocrotophos and all products was withdrawn as the result of a review of monocrotophos conducted by the Australian National Registration Authority for Agricultural and Veterinary Chemicals (NRA) and its advisory agencies.

(b) Exposure:

From 9 December 1999, the Australian registration of monocrotophos was cancelled by the NRA. The NRA's decision cancels the registrations and all relevant approvals, and halts further imports. Use of monocrotophos will be phased out over a year to allow current stocks of monocrotophos to be used up. This was seen as the lowest-risk option for disposing of existing stocks of monocrotophos, in the light of risks associated with product recall, storage and disposal. It also allows users time to change over to other pesticides. Wholesale supply of products to cease by 30 June 2000; retail sale to cease by 31 December 2000; and all minimum recommended levels will be withdrawn from 30 June 2002.

(c) An overview of the regulatory system of the notifying country, if relevant

The NRA is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals. The NRA's Existing Chemicals Review Programme (ECRP) systematically examines agricultural and veterinary chemicals registered in the past to determine whether they continue to meet current standards for registration. Chemicals for review are chosen according to predetermined, publicly available selection criteria. The review's findings are based on information collected from a variety of sources, including data packages and information submitted by registrants, information submitted by members of the public, questionnaires sent to key user/industry groups and Government organizations, and literature searches.

(d) Scope of the regulatory action: a precise description of the chemicals subject to the regulatory action:

Australia has withdrawn registration for monocrotophos and all products with a phase-out period of one year, ending 30 June 2002 for existing stocks. The Australian MRLs for monocrotophos are to be withdrawn on 30 June 2002.

2. Risk evaluation

9. This section should contain evidence, as available, that a risk evaluation was carried out under the prevailing conditions of the notifying country. It should confirm that criteria in Annex II, subparagraph (b) have been met. It may include:

(a) Key findings of the national risk evaluation

Australia's risk evaluation took into account toxicology and public health; occupational health and safety; environmental impact; trade impact; and availability of lower-risk alternatives. The review concluded that continued use of monocrotophos would pose an unacceptably high risk to workers, to wildlife, especially avian and aquatic species, and to trade. The environmental risk of monocrotophos use is primarily through exposure of non-target species. Monocrotophos is very highly toxic to birds exposed on an acute oral and subacute dietary basis. Monocrotophos was determined to be the cause of mortality or was strongly implicated in a large number of bird-kill incidents affecting a wide variety of avian species. Monocrotophos posed serious risks to birds even when application was performed in a manner consistent with label directions. Monocrotophos is also highly toxic to freshwater invertebrates. The human health risk arises because monocrotophos is a potent cholinesterase inhibitor and applicators and workers are potentially at risk of acutely toxic effects. In laboratory studies on rats and rabbits, monocrotophos was found to induce maternal toxicity and developmentally toxic effects (runting), but no major teratological abnormalities, at low doses.

(b) Key data reviews consulted together with a brief description:

FAO/WHO, 1995. Pesticide Residues in Food – 1995 evaluations. Part II - Toxicological and Environmental. Joint Meeting on Pesticide Residues (JMPR); WHO Geneva WHO/PCS/96.48.

FAO/WHO, 1993. Pesticide Residues in Food – 1993; Report, Joint Meeting on Pesticide Residues (JMPR); FAO Plant Production and Protection Paper 122.

FAO/WHO, 1995. Pesticide Residues in Food – 1995; Report, Joint Meeting on Pesticide Residues (JMPR); FAO Plant Production and Protection Paper 133.

WHO/PCS/96.3. World Health Organization, IPCS, Geneva.

USEPA, 1985. Guidance for the re-registration of manufacturing use and certain end use pesticide products containing monocrotophos. USEPA, Washington, D.C. (Sept. 1985).

USEPA, 1985. Pesticide fact sheet No 72: Monocrotophos. USEPA, Washington D.C.

(c) Reference to national studies, e.g. toxicological and ecotoxicity studies:

The NRA review of monocrotophos, January 2000. NRA Review Series 00.1. National Registration Authority for Agricultural and Veterinary Chemicals (http://www.nra.gov.au/chemrev/chemrev.shtml).

National Registration Authority for Agricultural and Veterinary Chemicals (NRA) Board Resolution 793, Action 99-77a, 9 December, 1999.

(d) Summary of actual or potential human exposure and/or environmental fate:

Human exposure assessment

10. General public: The only exposure path relevant to the general public was considered to be food. An estimate of monocrotophos intake was derived from the Australian Market Basket Survey. This procedure is based on measured monocrotophos residues found in food surveys rather than assuming that the pesticide is present at the maximum residue limit (MRL). In 1994, the estimated intake in the group with the highest consumption of monocrotophos residues (toddlers aged two) was 7.2 ng/kg bw/day which accounts for less than 3 per cent of the acceptable daily intake (ADI).

11. Workers: In accordance with internationally accepted practice, the occupational risk assessment was based on hazard characterization and worker exposure. The latter took into consideration the mixing, loading and application activities involved in the use of the pesticide. However, there were no measured worker exposure studies for mixing, loading or application of monocrotophos and therefore, the United Kingdom Prediction Operator Exposure Model (UKPOEM) was used to estimate exposure, from which margins of exposure (MOE) for the Australian use pattern were determined wherever possible.

12. The conclusions of the occupational health and safety assessment were that:

- High-volume air-blast spraying of fruit and vegetables posed a high and unacceptable risk for workers applying monocrotophos, even if mixer/loader exposure was eliminated.
- High-volume and low-volume boom-spraying on flowers, tomatoes, French beans and maize are not supported as the risk is unacceptable.
- Ground-spraying on broadacre crops is not supported as the risk is unacceptable.
- Aerial spraying is the only application method which was supported because of the comparatively minimal likely exposure to users.

Environmental exposure assessment

13. Australia's environmental assessment calculations using standard methodology showed that there was a high risk to birds from the use of monocrotophos when avian food items were sprayed. There was also a high aquatic risk to sensitive invertebrates from spray drift at all application rates, except for boom-spray applications at 140 g a.i/ha, where, provided suitable measures to reduce spray drift are in place, the risk is moderate. The risk to bees and other non-target insects was high. There is also a potentially high risk to aquatic organisms from runoff if rain occurs within days of application.

3. Risk reduction and relevance to other States

14. This section should contain evidence that the control action is of relevance to other States. It may include information on the following:

(a) Estimates of the quantity of chemicals used, or imported/exported, at the time of the regulatory action and, if possible, information on ongoing trade

No information

(b) Relevance of the control action to other States, i.e. those with similar conditions of use

The restriction of use of monocrotophos should be considered by all States because of the high risk associated with all uses but particularly ground spraying, of monocrotophos even when rigorous occupational health and safety practices are employed. The Australian review identified risks to users, trade and the environment and especially to avian and aquatic species.

Alternatives: The following alternatives are considered to pose lower risks to workers and the environment. World Health Organization hazard classifications are provided as an aid to the

consideration of relative risks. The classifications are for active constituents. Actual hazard depends on formulations.

Moderately hazardous: chlorpyrifos, diazinon; dimethoate; fenitrothion.

Slightly hazardous: azamethiphos; malathion.

(c) Comments on the typical use of the chemical the notifying country, with comments on possible misuse if appropriate

15. Typical and supported uses of monocrotophos were: aerial application to bananas, potatoes, and broadacre crops including tobacco, cereals, wheat, oilseeds and cotton; high-volume air-blast spraying of fruit and vegetables; high-volume and low-volume boom-spraying on flowers, tomatoes, French beans and maize; ground spraying on broadacre crops. After the NRA review, aerial spraying was the only application method which was supported because of the comparatively minimal likely exposure to users.

Policy guidance on contaminants

Introduction

The interim CRC had encountered difficulties with the issue and the Intergovernmental Negotiation Committee (INC) at its seventh session adopted a policy on contaminants.

The Chemical Review Committee at its first session took note of the policy with the understanding that further discussion on the issue would be deferred until such time as a notification relating to a contaminant was placed before the Committee.

Policy guidance on contaminants

Note by the Secretariat

1. In its review of maleic hydrazide, the interim Chemical Review Committee was requested to consider the overall policy issues related to adding chemicals to Annex III of the Convention on the basis of control actions related to contaminants within the substance rather than the substance itself. At its first session, the interim Chemical Review Committee recommended that the Negotiating Committee should adopt a policy on contaminants (UNEP/FAO/PIC/ICRC.1/6, annex I, section E).

2. At its seventh session, the Intergovernmental Negotiating Committee adopted the recommendation of the interim Chemical Review Committee that a "policy on contaminants would include final regulatory actions to ban a pesticide that had been taken by at least two countries in two PIC regions on the basis of a contamination contained in that substance, where the notifications also met the requirements of Annexes I and II of the Convention". The Negotiating Committee adopted this recommendation at its seventh session as decision INC-7/4 (FAO/UNEP/PIC/INC.7/15, annex I).

3. At its first meeting, the Conference of the Parties agreed to forward this policy to the first meeting of the Chemical Review Committee for its considerations.

4. The Committee may wish to note this policy and defer detailed discussion of this policy relating to contaminants until the Committee is confronted by such a situation.

Working paper on the application of criterion (d) of Annex II

Introduction

In considering a notification of final regulatory action from Thailand regarding the chemical endosulfan, the Chemical Review Committee at its second session extensively discussed the term “misuse” as used in Annexes II and IV of the Convention. To capture the Committee’s discussion, and to clarify the matter for future meetings, a working paper on the issue of misuse was prepared and forwarded to the COP. It was understood that future notifications relating to “misuse” should be considered on a case-by- case basis and the working paper should evolve as further experience was gained.

The COP at its third session agreed that the CRC would continue to consider notifications involving misuse on a case-by-case basis. A legal opinion to clarify the meaning of “intentional misuse” as requested by COP3 will be attached to the paper as soon as available.

Working paper on the application of criterion (d) of Annex II

1. At the second meeting of the Chemical Review Committee, the experts considered a notification of a severely restricted chemical, where unapproved use was described as "misuse". The notification was found to meet criteria (a)–(c) of Annex II. During the discussion, however, the question arose as to the application of the term "intentional misuse" as set forth in criterion (d) of Annex II

2. Annex II of the Convention sets out criteria for listing banned or severely restricted chemicals in Annex III, and states that, in reviewing the notifications forwarded to it, the Chemical Review Committee shall:

(a) Confirm that the final regulatory action has been taken to protect human health or the environment;

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation;

(c) Consider whether the final regulatory action provides a sufficient decrease in the quantity of the chemical used or the number of its uses;

(d) Take into account, that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

3. In the course of the discussion the Committee noted that there were varying views on what constituted misuse, as compared to common and recognized patterns of use of pesticides, largely as a result of the varying levels of controls over pesticide uses that existed under different regulatory systems. It was noted that, in developed countries, "common use" might be considered equivalent to the legal use, in other words, those uses listed on the product label. In countries with a less developed regulatory structure, however, the degree to which the pesticides were regulated and the role of the label in the national regulatory process varied widely, such that the difference between what constituted common use or misuse practices could be difficult to define.

4. The Committee also noted that pesticides were frequently used for suicide and for the intentional poisoning of fish and that such a use could be qualified as an "intentional" misuse.

5. In taking its decision the Committee noted that the case under consideration was the first notification where a final regulatory action had been taken to combat an environmental or health risk, as a result of a common and recognized pattern of crop protection use that was described as a misuse. While the Committee took into account criterion (d) of Annex II, in this particular case, the notification clearly met criteria (a)–(c), and in particular criterion (b) (iii). It was clear that intentional misuse was not the only reason proposed for listing the chemical in Annex III.

6. The Committee felt that future notifications of this kind relating to "misuse" should be considered on a case-by-case basis and the working paper should evolve as further experience was gained. It was agreed to inform the Conference of the Parties of the further development of the present working paper.

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