UNITED NATIONS

RC

UNEP/FAO/RC/CRC.4/INF/3

Distr.: General
9 January 2008

English only

United Nations Environment Programme

Food and Agriculture Organization of the United Nations

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Fourth meeting
Geneva, 10–13 March 2008
Item 4 of the provisional agenda*

Introduction to the operation of the Chemical Review Committee

Working procedures and policy guidance for the Chemical Review Committee

Note by the Secretariat

1. 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.

2. 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 contained in document UNEP/FAO/RC/CRC.1/10 and the working procedures for determining existing trade in chemicals outlined in document UNEP/FAO/RC/CRC.1/8.

3. At its third meeting, in October 2006, 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 outlined in document UNEP/FAO/RC/CRC.2/6. It considered the working paper on the application of criterion (d) of Annex II contained in document 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 trade restrictions under other multilateral environment agreements set out in document UNEP/FAO/RC/COP.3/9 and the policy guidance on risk evaluations under other multilateral environment agreements and their relevance to candidate chemicals set out in document UNEP/FAO/RC/COP.3/10.

4. At the third meeting of the Chemical Review Committee, three documents were further considered: a document on bridging information (UNEP/FAO/RC/CRC.3/4), a working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals (UNEP/FAO/RC/CRC.3/5), and a working paper on the application of criteria (b) (i), (b) (ii) and

* UNEP/FAO/RC/CRC.4/1.

(b) (iii) of Annex II of the Rotterdam Convention (UNEP/FAO/RC/CRC.3/6). These three documents, which have been amended to reflect the comments made at the meeting, were adopted by the Committee.

5. 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.

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

Annex

Working Procedures and Policy Guidance for the Chemical Review Committee

(Revised 2007)

Table of Contents

Working procedures:

Process for drafting decision-guidance documents and accompanying explanatory notes

Introduction

The purpose of the document is to guide the work of the Chemical Review Committee (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.

This process for drafting decision-guidance documents and the accompanying explanatory notes was developed by the interim CRC. The first session of the CRC reviewed and 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-2/2.

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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)

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

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

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.

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

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.

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.

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.

* Numbers refer to steps in the flow chart.

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

(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 procedures:

Working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals

Introduction

This document provides guidance to intersessional Drafting Groups of the Chemical Review Committee (CRC) in the preparation of decision guidance documents for banned or severely restricted chemicals. 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 adopted at the first session of the CRC. Subsequent sessions of the CRC have reviewed and amended this working paper based on the experience gained in drafting decision guidance documents. This most recent version was adopted by the third session of the CRC with the understanding that it would continue to evolve in the light of future experience.

Working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals

Introduction/Purpose

This working paper is to serve as guidance to drafting groups established by the Chemical Review Committee (CRC) for the preparation of decision guidance documents for banned or severely restricted chemicals in accordance with Article 5 of the Rotterdam Convention.

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

This working paper is expected to evolve as further experience is gained in the preparation of decision guidance documents. It is to be used by drafting groups preparing decision guidance documents for both pesticides and industrial chemicals. In this version of the working paper those sections which are potentially different for industrial chemicals and pesticides have been highlighted. If required, future versions of the working paper may be split into two separate working documents, one for pesticides and one for industrial chemicals.

A separate working paper has been developed for the preparation of decision guidance documents for severely hazardous pesticide formulations in accordance with Article 6 of the Rotterdam Convention.

In order to further facilitate the work of the drafting groups an electronic template of a draft decision guidance document has been prepared as a companion document to this working paper.

General guidance

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. This text provides a brief summary of the process through which the individual decision guidance document was developed and includes three separate sections an introduction, purpose and disclaimer.

In cases where a decision guidance document includes more than one chemical (e.g. asbestos), a table of contents will facilitate the use of the document. Similarly the insertion of footers identifying the chemical should be included on each page.

A standard list of “core” abbreviations have been prepared based on experience in drafting decision guidance documents to date. It is intended that this core list serve as the basis for decision guidance documents for both industrial chemicals and pesticides and that it 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 (appendix 1). As a general rule it is preferable that acronyms used only once in the text be spelled out rather than included in the list of abbreviations.

In preparing a decision guidance document, it may be that not all sections are relevant to the chemical under consideration. It is preferable, in this 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 had considered that section.

1. Identification and uses

Purpose: To provide an unequivocal identification of the chemical subject to the PIC procedure and its use as either a pesticide or an industrial chemical, or both.

- This basic information should be obtainable from the submitted notifications and the supporting material available to the Committee prior to its decision to develop a decision guidance document.

- CAS numbers for all forms of the chemical covered in the relevant notifications of final regulatory action should be included here. The scope of the chemical identified in this section (chemical description and associated CAS numbers) must be consistent with the recommendation by the Chemical Review Committee (CRC) for inclusion of the chemical in Annex III of the Convention. Should additional CAS numbers be found during the development of the decision guidance document, they should be brought to the attention of the CRC. If they do not broaden the scope of the original notification, they could be included here.

- Chemical structural formula should be included if practicable. Structural formula may be found in standard references documents on pesticides e.g. The Pesticide Manual.

Notes: Updated or additional information on trade names, formulation types and basic manufacturers for products moving in international trade may be identified through the responses to the call for information on ongoing manufacture, use and trade of the chemical.

The list of trade names, formulation types and manufacturers should, where possible, distinguish old products from those that are known to be moving in international trade.

It is clear that a list of both manufacturers and trade names will be constantly changing, for this reason a generic disclaimer along the following lines should be considered:

Under trade names:
This is an indicative list of trade names. It is not intended to be exhaustive.

Under basic manufacturers:
This is an indicative list of current and former manufacturers of XXX. It is not intended to be exhaustive.

In accordance with article 7, when a chemical may be used as both a pesticide and an industrial chemical (a dual-use chemical), the decision guidance document should provide information on uses in both categories. A statement on "reported use in X category" or "no reported uses in X category" should be given (where X is either an industrial chemical for a pesticide decision guidance document or a pesticide for an industrial chemical).

2. Reasons for inclusion in the PIC procedure

Purpose: To provide a generic statement that clearly identifies the use category (pesticide or industrial chemical) and whether the chemical is subject to a **ban** or **severe restriction** in the notifying countries.

- References to any previous *listing(s)* under the PIC procedure should also be included, where relevant.

- For dual-use chemicals, it will also be important to note when the PIC obligations do not apply to the use category that was not regulated.

Note: It is hoped that generic text will develop as new decision guidance documents are developed and language becomes more familiar.

List notifying countries alphabetically.

2.1 Final regulatory action

Purpose: To provide a brief statement/summary of the final regulatory action(s) as reported by the notifying countries and the reasons for the actions taken (e.g., occupational health concerns, environmental concerns).

- The text should reflect that used by the regulatory authority to underpin the national regulatory action(s) – for example, as presented in national law, regulation, gazette, legal journal, code.
- Specific reference to the relevant directive or regulation for the reported regulatory action(s) should be included in annex 2.
- The reason(s) stated should set the stage for the subsequent description of the underlying risk evaluation.

National authorities should take care to ensure that any technical legal references, if they are used, are accurate.

2.2 Risk evaluation

Purpose: To provide a brief summary (no more than 1-2 pages) highlighting the key reported finding(s) of the national risk evaluation(s) that led to the regulatory action(s).

- The text should reflect the reason(s) identified in the final regulatory action(s) by the notifying countries and include information on the uses that were permitted prior to the regulatory action.
- In the interests of brevity, the text may include references to Convention Annexes I and II for additional details.

Note: Depending on the chemical and the finding(s) of the national risk evaluations, this section may provide information on an individual country basis, or, where there are multiple country notifications based on common human health or environmental concerns, the information may be summarized and combined. It would also be useful to highlight the differences in regulatory actions, if they are not already obvious.

3. Protective measures that have been applied concerning the chemical

Purpose: To highlight measures taken to reduce exposure, in the first instance through *regulatory* controls or measures and secondly through *other* measures (administrative, non legal/voluntary codes of practice, field practice, etc) recalling that:

- a **ban** in the regulated category of use eliminates all exposure (occupational or environmental); and
- a **severe restriction** in the regulated category of use allows continued use in a manner that reduces risk to an “acceptable” level.

3.1 Regulatory measures to reduce exposure

Purpose: To provide information about the *regulatory* measures taken to **ban** or **severely restrict** the chemical and associated products.

- for **bans**, the risk has been eliminated and therefore a simple explanation of the risk management strategy to deal with existing stocks may be enough; and
- for **severe restrictions**, briefly describe the *regulatory* measures taken/set in place to reduce the risk to acceptable levels - e.g. by restricting access to trained/certified applicators or requiring purchasers to be licensed.

3.2 Other measures to reduce exposure

This section is primarily intended for additional information from the notifying country(ies) on chemicals that have been severely restricted e.g. chemicals where for which virtually all use has been prohibited.

For most banned chemicals this section would not be completed. The exception is where there was relevant chemical specific information from either the notifying country or international sources on possible risk mitigation measures.

Purpose: To provide information about *non-regulatory* measures (including technical and field-level arrangements) for severely restricted chemicals taken/set in place to reduce exposure and ensure that risk remains at an acceptable level for the uses that are permitted to continue. Information could include, for example changing the type of formulation or application equipment used, specifying the personal protective equipment or clothing required.

Where available, information from the notifying country or international sources of information on chemical specific risk mitigation measures may also be referenced. Examples may include publications from the International Labour Organisation or International Standards Organisation.

It is not intended that generic information on handling hazardous chemicals would be included in this section.

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

3.3 Alternatives

Purpose: To provide countries with brief information about alternatives that have been identified by the notifying country or countries and others where available.

It is 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 pesticides 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.

- Notifying countries may provide information about chemical and non-chemical alternatives that are being used within their jurisdictions. Detailed information can be included in annex 2.

- Information from sources other than the notifying country might be referenced here with details on where the information might be found provided to DNAs through the PIC Circular and the Rotterdam Convention website (see following note)

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

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

The following is an example of standard text for this section related to ***pesticides.***

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

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

It is essential that before a country considers substituting alternatives, it ensure that the use is relevant to its national needs and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

For ***industrial chemicals,*** the final paragraph above should be used, to indicate the need to consider the hazards associated with possible alternatives. National alternatives should be included, and if international organisations have discussed alternatives in reviews etc. this information could also be included.

3.4 Social and economic effects

This section would only be completed where Notifying Countries have undertaken specific studies of the social and economic effects related to their final regulatory action(s) and wish to report on their findings.

Note: Most countries do not undertake rigorous social and economic studies that are relevant beyond their own jurisdictions, but they may provide information on alternatives when a country took an action to restrict a chemical.
This information is optional. When reported, there will need to be a caveat that countries consider the results of this information in the context of their own national conditions.

4. Hazards and risks to human health and/or the environment

4.1 Hazard Classification

Purpose: To provide a brief summary of internationally recognized classifications applied to the chemical(s) for which the decision guidance document has been prepared.

- This section should focus on internationally recognized standards such as IARC, WHO/IPCS classification systems.
    - The standard reference for LD_{50} values is the most recent edition of the WHO/IPCS publication, *Recommended classification of pesticides by hazard*

and guidelines to classification. The WHO classification schemes for pesticides as well as its formulations are based on oral or dermal toxicity. According to the WHO guideline, the route which indicate greater hazard would be chosen for its classification.

- As far as possible, information on the WHO hazard classification of liquid and solid formulations should be included.

- The US EPA and European Community classification systems have been included as they are widely used by many countries as a reference.
- All references should include the date when they were established.

Note: It is not intended that national standards be included here, notifying countries should include their national classification schemes in Annex 2.

The following is an example of how this information might be presented:

4. Hazards and Risks to human health and the environment			
4.1 Hazard Classification			
WHO / IPCS	Technical product a.i.:	Insert classification e.g. Class Ia (extremely hazardous) Classification based on oral or dermal toxicity in rats $LD_{50:}$ (WHO reference)	
	Formulations	a.i. (%)	Hazard class
	Liquid		
	Solid		
IARC	Group 3: the agent is not classified as to its carcinogenicity to humans. (IARC reference)		
European Community	Classification of the active substance is (Commission Directive reference): T (toxic) Xi (Irritant) N (dangerous for the environment) R 24/25 (Toxic in contact with skin/ if swallowed) R 36 (Irritating to eyes) R 50/53 (Very toxic to aquatic organisms / may cause long-term adverse effects in the aquatic environment)		
US EPA	Toxicity Class I (formulation) (EPA reference)		

4.2 Exposure limits

Purpose: To provide a brief summary of internationally recognized exposure limits as applied to the chemical(s) subject to the decision guidance document.

- This section should focus on those exposure limits that are internationally recognized, e.g., Codex levels in food, WHO drinking water guidelines, etc.
- All references should include the date when they were established and date of any subsequent review by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), etc.
- It is not intended to capture occupational exposure limits such as Threshold Limit Values (TLVs) for pesticides largely because of the widely differing ways in which they may be calculated

Note: It is not intended that national standards be included here as their applicability to other countries is limited without a good understanding of how the limits were derived. Notifying countries could include them in Annex 2 if they feel it is appropriate and necessary.

If no international exposure limits are available, the words 'not applicable for this chemical' could be inserted.

4.3 Packaging and labelling

Purpose: To provide a quick reference to existing standards for packaging and labelling of the chemical.

This section should focus on internationally recognized classifications established by the United Nations Committee of Experts on the Transport of Dangerous Goods, and on the Globally Harmonized System of Classification and Labelling of Chemicals (if used), the International Maritime Dangerous Goods Code, etc., along with relevant explanatory text if applicable (ie for specific requirements).

Note: In the case of pesticides, this section should include a generic statement on the availability of further specific guidance on appropriate symbols and label statements for individual pesticides and formulations in the FAO *Guidelines on Good Labelling Practice for Pesticides*.

4.3 Packaging and labelling	
The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:	
Hazard Class and Packing Group:	
International Maritime Dangerous Goods (IMDG) Code	
Transport Emergency Card	

4.4 First aid

Purpose: To provide a quick reference to internationally recognized information on the treatment of chemical poisoning (pesticides and industrial chemicals) available at the time of publication of the decision guidance document.

- The reference should as far as possible be generic and include the most recent WHO/IPCS recommendation.
- It should note any aspects specific to the chemical cited in the decision guidance document.
- A reference to the WHO website for other relevant information might also be included www.inchem.org

Notes: For chemicals that are not acutely toxic, this section may not be relevant and could be completed with the statement "*not applicable to this chemical*"
Recognizing that a range of first-aid treatments may be available, this section should include a generic statement on the need for caution and should remind parties of the need to ensure that this information is in compliance with any national standards that may exist.

4.5 Waste management

Purpose: To ensure that countries are aware of the need for appropriate management of wastes and to provide references to relevant guidance and other sources of information.

- This section should include references to appropriate internationally recognized guidelines such as those developed by FAO for pesticides.
- Particular attention should be drawn to the relevant terms of international agreements – the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal.
- Notifying countries may wish to note specific actions taken to avoid the creation of stockpiles, including arrangements to permit use of existing stocks during a phase-out period.

Annex 1

Further information on the chemical

Annex 1 includes information submitted by the notifying countries based on the their national assessments which were used to support the reported final regulatory action.

Purpose: To provide an overall summary of information on the chemical for which the reported regulatory action(s) have been taken, including physico-chemical properties and the results of toxicological and ecotoxicity studies. The decision guidance document is not intended to be a scientific treatise on a chemical. The emphasis should be on the concerns that formed the basis of the reported final regulatory action(s). For example, if the sole basis of the reported regulatory action(s) is unacceptable occupational exposure, this annex section should focus on human health effects rather than environmental aspects.

The results of international reviews such as those of WHO/IPCS/JMPR/IARC should also be included in this section where available and considered relevant.

Subsequent evaluations or reviews of the chemical from Parties, other than those that submitted the notifications of final regulatory actions may be submitted to the secretariat for posting on the Rotterdam Convention website.

The principal headings in this annex generally reflect those used by OECD countries and the European Community in their monographs. This approach will assist all countries, especially developing countries, that may have used an OECD/European Community monograph as the basis for the hazard evaluation supporting their final regulatory action(s). The generic headings and general guidance on content should facilitate consistency in the format and content of decision guidance documents.

- The introduction to the annex should describe its content. This should include reference to any relevant international reviews (e.g. those of OECD, IPCS/WHO or IARC) and how this information has been incorporated into the document. For example whether or not the results of an international assessment (toxicological or ecotoxicological) are substantively different from those of the notifying countries should be noted. In the case of mammalian toxicity a summary of the two evaluations highlighting the similarities or differences as appropriate may be included in section 2.2.7 of this annex (see below).
- The level of detail within the subheadings may be adjusted to accommodate the information used to support the notified regulatory action and available to the drafting group. (See appendix 2 to the present note for a list of the headings and subheadings and an indication of the points that may be included under each.)
- Specific sections on *exposure/risk evaluation* have been included for both **human health** and environmental **fate and effects**. These sections should include specific information from notifying countries on the basis for their final regulatory action.

General comments

Tabular summaries of information should be used wherever possible; this should not, however, be at the expense of a clearly stated analysis that explains how the data were used in the risk evaluation that formed the basis for the reported regulatory action.

The level of detail will be a function of the information that is available and will need to be determined on a case-by-case basis. As a guiding principle, however, the focus should be on those end points that were the basis for the risk evaluation underlying the notified final regulatory action. For example, in those instances where a chemical was found to be a reproductive toxin and this was the basis for the regulatory action, greater detail would be expected on the supporting studies e.g. NOEL/NOAEL/LOEL, than on end

points for which the results may have been negative (i.e., simply stating "was not carcinogenic"). In the case of universally recognized regulatory guidelines or limits such as the acceptable daily intake (ADI) or acute reference dose (ARfD), details on the supporting studies on which they are based should be included.

LD_{50} and LC_{50} data can vary widely for a chemical. In order to avoid apparent discrepancies in the information reported, it may be better to report a range of values wherever possible, particularly where the results from more than one source are combined.

In reporting toxicity data reference should be made to the duration of exposure for all studies reported, including acute toxicity studies, where it is available or known.

In some cases, the notifying parties may reach different conclusions on individual end points related to human health or the environment. Furthermore, the situation may arise where there has been an evaluation of the chemical at the international level e.g. by the OECD, WHO/IPCS or IARC that has reached conclusions that differ from those of the findings of the notifying parties. In such cases the following approaches should be considered:

- It is intended that these differences be clearly indicated in the decision guidance document, where they concern "pivotal end points" within the risk evaluation, that is those end points upon which the final regulatory action was based.
- Where there are differences in interpretation of data concerning specific end points, but the differences do not affect the outcome of the final regulatory action or the conclusions of the international review, the degree to which these details will be reflected in the decision guidance document will need to be considered on a case-by-case basis.
- Section 2.2.7 Summary of mammalian toxicity and overall evaluation – this section provides an opportunity to summarize the conclusions of the toxicological evaluations from the notifying countries as well as any relevant international reviews e.g. WHO/IPCS/IARC..

Where information from an international evaluation such as an IPCS Environmental Health Criteria document is included, the reference in the text should be to this document, rather than to the individual papers quoted therein. Where information from the risk evaluations by the notifying Parties is included, it is sufficient if this source is indicated, rather than the specific studies or reviews referred to.

Specific comments - *details of proposed subheading may be found in appendix 2*

1. Physico-chemical properties

This section characterizes the chemical, based on national evaluations and recognized information sources e.g. *Pesticides Manual, A World Compendium* (Crop Protection Publications - ISBN 0 948404 79 5)

2. Toxicological properties

2.2 Toxicity studies

This section lays out the toxicological profile of the chemical as assessed by the notifying countries at the time of their final regulatory actions(s). It should also include a comparative summary of any IPCS/WHO international evaluations, such as those of WHO/ IPCS/JMPR, where they are available and considered relevant. This summary

should be included in section 2.2.7 Summary of mammalian toxicity and overall evaluation.

In the interests of brevity, where multiple studies for the same end point exist, the drafting group should report in a summary form, rather than report on each individual study. The level of detail will need to be considered on a case-by-case basis. It is generally accepted that where a review document has been used as the source of the information, the review document is cited rather than the individual studies.

- Under the heading **Summary of mammalian toxicity and overall evaluation (section 2.2.7)**, the drafting group should provide a concise summary of key end points, in order to facilitate comparisons among different evaluations and to improve understanding of those end points considered in the human exposure/risk evaluation section (see the preceding section on **General comments**).

3. ***Human exposure/risk evaluation***

This section highlights in greater detail those human exposure and risk factors that led to the regulatory control action(s), focusing on the major exposure routes (i.e. food, air, water and occupation).

- Information concerning epidemiological studies or poisoning incidents that were considered by the notifying country in taking the reported regulatory action could be inserted under the subheading **Medical data** (section 3.5).

Note: Where the reported regulatory actions are based on environmental effects, it is anticipated that this section of the decision guidance document would be minimal.

4. ***Environmental fate and effects***

This section provides information on the environmental fate characteristics (**Fate**, section 4.1) of the chemical and the results of ecotoxicity studies (**Effects on non-target organisms**, section 4.2).

Note: Specific subheadings for the parameters of persistence and bio-concentration have been included to facilitate the identification of chemicals with the characteristics of persistent organic pollutants (POPs).

5. Environmental exposure/risk evaluation

This section highlights in greater detail those environmental fate factors that led to the regulatory control action(s) and should include a summary of the overall risk evaluation.

Note: Where the reported regulatory actions are based on human health concerns (e.g., risks to workers), it is anticipated that this section of the decision guidance document would be minimal.

Annex 2 Details on final regulatory actions reported

Annex 2 reports expand upon the information presented regarding the final regulatory action(s) of each notifying country.

This annex should reflect the information provided in the notification of regulatory action form and presented to the Chemical Review Committee for review. The annex represents an opportunity for notifying countries to provide increased detail on aspects of the regulatory decision that they may wish to include.

Annex 3 Addresses of designated national authorities

This annex should provide detailed information on how to contact the designated national authorities of the notifying countries, including the name of a contact person; mailing address; telephone, fax and telex numbers; and email address.

Annex 4 References

This annex includes a list of the sources of information cited in the decision guidance document. Where information from a review document has been used, the reference should be to the review document, rather than to the individual papers within the review. Original papers should only be cited where they have been considered individually, rather than as a component of the review.

List References under headings as appropriate:

Regulatory actions
Documents used in risk evaluation

Environmental Health Criteria No. 165: Inorganic Lead. IPCS/WHO 1995 (*an example of a review document)*

Sebastien P, Begin R, & Masse S (1990) Mass number and size of lung fibres in the pathogenesis of asbestosis in sheep. Int J Exp Pathol, 71: 1-10. *(individual paper cited if the original paper was used in the preparation of the DGD)*

Appendix I. 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 triphosphate
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CA	Chemicals Association
cc	cubic centimetre
CHO	Chinese hamster ovary
cm	centimetre
DNA	deoxyribonucleic acid
E.C.	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 Organisation
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)

STANDARD CORE SET OF ABBREVIATIONS

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, also referred to a P or Kow
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

Appendix 2

Headings for Annex I and a list of information points that could be included under each

1. Physico-chemical properties

2. Toxicological properties

2.1. General

2.1.1. Mode of action

2.1.2. Symptoms of poisoning

2.1.3. Absorption, distribution, excretion and metabolism in mammals

- Rate and extent of absorption
- Distribution
- Potential for accumulation
- Rate and extent of excretion
- Metabolism in animals
- Toxicologically significant compounds (animals, plants and environment)

2.2 Toxicology studies

2.2.1 Acute toxicity

- Rat LD_{50} oral
- Rat LD_{50} dermal
- Rat LC_{50} inhalation
- Skin irritation
- Eye irritation
- Skin sensitization (test method used and result)

2.3.2 Short term toxicity

- Target/critical effect
- Oral
- Dermal
- Inhalation

2.2.3 Genotoxicity (including mutagenicity)

2.2.4 Long term toxicity and carcinogenicity

- Target/critical effect
- Relevant NOAEL/NOEL
- Carcinogenicity

2.2.5 Effects on reproduction

- Reproduction target/critical effect
- Lowest relevant reproductive NOAEL/NOEL
- Developmental target/critical effect
- Lowest relevant developmental NOAEL / NOEL

2.2.6 Neurotoxicity/delayed neurotoxicity

- Acute neurotoxicity
- Subchronic neurotoxicity

Special studies (where available)

- could include human immunotoxicity studies

2.2.7 Summary of mammalian toxicity and overall evaluation

- include summary of key findings of relevant international reviews e.g. WHO/IPCS/IARC evaluations

3. Human exposure/risk evaluation

3.1 Food

3.2 Air

3.3 Water

3.4 Occupational

3.5 Medical data contributing to regulatory decision – could include:

- Report on medical surveillance on manufacturing plant personnel
- Report on clinical cases and poisoning incidents
- Observations on exposure of the general population and epidemiological studies

4. Environmental fate and effects

4.1 Fate

4.1.1 Soil

- Field dissipation
- Aerobic and anaerobic degradation
- Rate of degradation
- Adsorption/desorption
- Mobility

4.1.2 Water

- Route and rate of degradation

4.1.3 Air

- Fate and behaviour

4.1.4 Bioconcentration

4.1.5 Persistence

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

- Acute/chronic toxicity mammals
- Acute/chronic toxicity birds
- Dietary toxicity birds
- Reproductive toxicity birds

4.2.2 Aquatic species

- Fish
- Invertebrates
- Algal species
- Aquatic plants

4.2.3 Honey bees and other arthropods

4.2.4 Earthworms

4.2.5 Soil microorganisms

4.2.6 Terrestrial plants

5 Environmental exposure/risk evaluation

Specific reference as appropriate to the following

5.1 Terrestrial vertebrates

- Mammals/birds

5.2 Aquatic species

- Fish/invertebrates/algal species/aquatic plants

5.3 Honey bees

- Other arthropods

5.4 Earthworms

5.5 Soil microorganisms

5.6 Summary – overall risk evaluation

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

Introduction

This document provides guidance to intersessional 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 adopted at the first session of the CRC.

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

Working procedures:

Process for determining evidence of ongoing international trade

Introduction

This paper describes the process followed by the Secretariat in determining ongoing international trade in a chemical scheduled for review by the Chemical Review Committee (CRC)..

The criteria for listing banned or severely restricted chemicals in Annex III of the Convention are set out in Annex II. Criterion (c) (iv) requires that the CRC consider "*whether there is evidence of ongoing international trade in the chemical*". In order to ensure that such information is available to the CRC the Secretariat, once it receives a second notification of final regulatory action for a chemical, initiates the collection of information on the international trade in that chemical.

This process, originally developed by the interim CRC, was adopted by the CRC at its first session. The Conference of the Parties 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 international 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

Working procedures:

Common and recognized patterns of use of severely hazardous pesticide formulations

Introduction

This paper was developed to facilitate the work of the Chemical Review Committee (CRC) when considering proposals for severely hazardous pesticide formulations. It sets out issues to consider in characterizing common and recognized patterns of use of pesticides in developing countries and countries with economy in transition and how relevant information might be collected by the Secretariat.

This proposal, originally developed by the interim CRC, was adopted by the CRC at its first session, with the understanding it would continue to evolve 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

Working procedures:

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

Introduction

This document describes a procedure for dealing with notifications of final regulatory action with the objective of improving the efficiency of the operation of the Chemical Review Committee (CRC). 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. It was used as the basis for preparing for the third session of the CRC which agreed that the process did not require any amendment and could be used by the bureau in preparing for the Committee's fourth meeting. During the discussion of this issue at the third meeting of the Conference of the Parties (COP), the procedures met with general approval and were noted by the Conference.

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 inter-sessional work including the setting of priorities and deadlines (UNEP/FAO/RC/CRC.1/28 paragraphs 122-125)..

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.

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 along with a request to submit the supporting documentation referenced in their notifications and if possible a focussed summary. 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 secretariat, working with the Bureau, undertakes 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.

Intersessional task groups will be established 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, will 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 will form part of the report of the meeting. The lead experts for individual chemicals will 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.

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

The CRC 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 regarding the summer holiday period in southern countries, dispatch of the documents for the CRC earlier in December rather than later was preferred.

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) are more or less fixed, while the precise dates for the intervening work, particularly that relating to the Bureau, will 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 allows 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 has been developed:

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**

In the light of the controls on trade imposed under the Stockholm Convention on Persistent Organic Pollutants and the Montreal Protocol on Substances that Deplete the Ozone Layer, the question was raised 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.

The third meeting of the Conference of the Parties endorsed this 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 (UNEP/FAO/RC.COP.3/26 paragraph 62).

Working procedures:

Guidance to intersessional Task Groups on reviewing notifications of final regulatory actions and supporting documentation for chemicals scheduled for consideration by the Chemical Review Committee

Introduction

This document describes the process for the operation of the intersessional Task Groups established to undertake the initial review of chemicals scheduled for consideration by the Chemical Review Committee (CRC).

The process for drafting decision guidance documents, set out in Decision RC.2/2, provides for the creation of Task Groups to work intersessionally. This paper was developed to provide guidance to the intersessional Task Groups in reviewing candidate chemicals. An initial draft of this paper, considered by the third meeting of the CRC was amended to reflect the Committee's comments with the understanding that it was a work in progress that could be further amended in the light of experience gained.

Guidance to intersessional Task Groups on reviewing notifications of final regulatory actions and supporting documentation for chemicals scheduled for consideration by the Chemical Review Committee

Background

The Conference of the Parties at its second meeting (COP.2) adopted, in decision RC.2/2, a process for the preparation of decision guidance documents by the Chemical Review Committee pursuant to Article 7 (see Appendix I). Subsequently, as a means of promoting efficiency in the intersessional work of the CRC, a procedure for the preliminary review of notifications was adopted by the Committee at its second meeting and endorsed by its third meeting (UNEP/FAO/RC/CRC.3/1 paragraph 34). During the discussion of this issue at COP.3, the procedures met with general approval and were noted by the Conference (UNEP/FAO/RC/COP.3/26 paragraph 46). The procedure for the preliminary review of notifications can be found in the compilation of policy guidance and working procedures related to the work of the CRC available on the Convention website or upon request from the Convention Secretariat.

Decision RC.2/2 provides for the creation of Task Groups to work intersessionally. The procedure for the preliminary review of notifications provides further guidance on the steps and timelines for intersessional work of the Committee and priority setting. Based on this initial review, the Task Group review will recommend whether or not the chemical should be included in Annex III of the Convention. The report of the intersessional Task Group is presented to the full Committee and serves as the basis for its consideration of the candidate chemical.

Role of an Intersessional Task Group

For each chemical scheduled for review by the CRC an intersessional Task Group (TG) composed of one or two coordinators and a representative group of members of the Committee will be proposed by the Secretariat in consultation with the Bureau. Once a TG is established, all CRC members will be informed by e-mail of its composition and of the designation of coordinators. Members are free to participate in as many TG as they wish and need simply inform the TG coordinator and the Secretariat of their interest.

The role of the intersessional TG is to undertake an initial review of the notifications and supporting documentation for a chemical in the light of the information requirements and criteria set out in Annexes I and II of the Convention, respectively. In undertaking this review, the members of the TG should consider the relevant working papers and policy guidance developed to direct the work of the Committee. This initial review will facilitate the work of the Committee by ensuring that there is a clear understanding of the scope of the regulatory action, and whether or not the criteria in Annex II of the Rotterdam Convention have been met (see Appendix II).

The compilation of the policy guidance and working procedures related to the work of the CRC is available on the Convention website, or upon request from the Convention Secretariat, and will be made available to all members of the CRC together with the notifications and supporting documentation for candidate chemicals.

The TG will present to the Committee their assessment of whether the individual notifications and supporting documentation meet the requirements of the Convention.

The report should include:

1. a review of the scope of the control action (precise identity of the chemical(s) concerned, ban versus severe restriction, etc.);
2. the reason for which the action was taken, including highlights of the supporting risk evaluation;

3. a brief assessment or analysis of whether the individual notifications meet the criteria in Annex II, which would serve as the basis for a rationale setting out how the notifications and the supporting documentation meet the requirements of the Convention.

It is important that the reports provide sufficient detail in order for the full Committee to understand the reasoning behind the rationale. Where notifications are found not to meet the criteria of Annex II, a brief statement on which criteria were met and which were not would also facilitate the work of the Committee and should be incorporated in the TG report.

Based on this initial review, the CRC will make a recommendation as to whether or not the chemical should be included in Annex III of the Convention.

Operation of Intersessional Task Groups.

The notifications and supporting documentation for all of the chemicals scheduled for review by the CRC are sent to all Committee members. The TGs are created to ensure that certain members of the CRC have undertaken a detailed review of the information available to the Committee and that these members will be prepared to lead the discussion on these chemicals during the meeting. All CRC members will be expected to participate in the work of one or more TGs.

Communication among members of the TG during the intersessional period is critical. TG coordinators are expected to take the lead in reviewing the documentation and in drafting the report. The draft report is then circulated to all TG members for comment prior to the CRC meeting. Individual TG members are therefore expected to review the notifications, supporting documentation and the draft report prepared by the co-ordinator(s). The report should clearly explain the basis for the conclusions of the TG on whether the individual criteria have or have not been met. The report can also be used to highlight those aspects of the notifications to which the TG considers the CRC should pay particular attention. The members of the intersessional TGs will have the opportunity to meet to review the draft report and discuss any comments immediately prior to the CRC meeting.

At the CRC meeting, TG members should be prepared to respond to any questions that may be raised at the meeting or provide clarifications regarding their review of the chemical. Following consideration of the results of the TG report, the Committee will decide whether to make a recommendation to include the chemical in Annex III of the Convention and develop an internal proposal for a decision guidance document. Where it is determined that a notification meets the requirements of the Convention, a rationale explaining how the criteria have been met is prepared and included in the report of the meeting.

It should be noted that the work of the TGs is not to initiate a debate on whether or not there is agreement with the national decision, but rather whether the regulatory action meets the requirements set out in Annexes I and II of the Convention. It is not the aim of these discussions to agree on the outcome of the risk evaluation performed by the notifying Party in support of the national decision.

Getting Started

In order to facilitate the work of the TGs, the CRC has developed a template (in the form of an Excel spreadsheet) and associated guidance. The individual entries in the template reflect the information requirements and criteria contained in Annexes I and II of the Convention, respectively. The template facilitates a structured review of the information and should be completed for each of the notifications of final regulatory action submitted to the Committee. The “Comments” field provides an opportunity to briefly explain the basis for the conclusion of whether or not the individual criteria have been met. The statements in the “Comments” field provide a basis for the one to two - page analysis/summary which explains the underlying reasoning for the intersessional review findings and together with the completed templates, form the basis for the TG report.

The summaries of the key elements of the notifications contained in TG reports should be sufficiently detailed and clearly document why criteria were considered to have been met or not. It is the responsibility of the TG co-coordinator(s) to ensure that the necessary explanatory comments are included in the designated column in the template.

The template for summarizing the information in the notifications and supporting documentation is in three formats:

Guidance template: This template includes guidance on how to complete the individual sections;

Country templates: Individual tables which are to be completed for each notification relevant to Annexes I and II of the Convention;

Summary report: A summary of the information provided in the individual notifications. This template is automatically completed from the information inserted in the individual country templates for the individual notifications.

Prior to completing the country templates it is recommended that users – in particular the TG coordinators - first read the information included in the guidance template. The user should then complete the country templates for the individual notifications. The summary report is automatically created from the information inserted in the individual country templates for the individual notifications. The template and the associated guidance will be improved over time and modified as necessary, based on experience gained in their use.

An electronic "interactive" version of the full sets of templates, as well as hardcopies, will be provided to all CRC members together with the notifications and supporting documentation for candidate chemicals. A copy of the worked example is appended to this working paper (Appendix III).

Task Group Reports

The report of the TG should consist of:

1. the completed templates for each notification and supporting documentation in the light of the requirements of the Convention;
2. a one to two-page analysis/summary briefly reviewing the requirements of the Convention and whether or not the criteria have been met. This analysis/summary should include a clear conclusion as to whether or not to recommend inclusion of the chemical in Annex III of the Convention.

As noted previously, TG coordinators are to prepare a draft report and circulate it to TG members for comment prior to the CRC meeting. The report can be used to highlight those aspects of the notifications to which the TG considers the CRC should pay particular attention. Members of the intersessional TGs will have the opportunity to meet to review the draft report and discuss any comments immediately prior to the CRC. An example of a completed TG Report is annexed to this document (Appendix III). An electronic version of the template will be made available to all CRC members together with the notifications and supporting documentation for candidate chemicals.

Appendix I: Excerpt from decision RC-2/2 on the process for drafting decision guidance documents

Appendix II: Criteria from Annex II of the Convention

Appendix III: Worked example of task group report

Appendix I

Excerpt from decision RC-2/2 on the process for the preparation of draft decision-guidance documents

The Conference of the Parties

Decides that the preparation of decision-guidance documents by the Chemical Review Committee pursuant to Article 7 of the Convention shall follow the process set out in the flow chart and explanatory notes contained in the annex to the present decision.

Annex to decision RC-2/2

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)

↓ ↓

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

↓

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

↓

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.

↓

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

↓

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.

↓

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.

↓

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.

* Numbers refer to steps in the flow chart.

Appendix II

Text of Annex II of the Rotterdam Convention

Criteria for listing banned or severely restricted chemicals in Annex III

In reviewing the notifications forwarded by the Secretariat pursuant to paragraph 5 of Article 5, the Chemical Review Committee shall:

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

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

(iv) Whether there is evidence of ongoing international trade in the chemical;

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

Appendix III

WORKED EXAMPLE OF COMPLETED TASK GROUP REPORT

Rotterdam Convention

CRC Meeting : Geneva, 13 -17 February 2006

Report of the Task Group on Tributyltin compounds (TBT)

Task Group members

Chair: K. Berend
L. Juergensen
L. Attias
N. Nudelman
B. Hitzfeld
H. Chin Sue
H. Mahmud
H. Al-Hasani

Observers: C. Barnes
J. Foley
P. Rumsby

Secretariat: G. Wyrwal

Information available to the Task Group

UNEP/FAO/RC/CRC.1/28 (paragraphs 103 to 107)
UNEP/FAO/RC/CRC.2/11
UNEP/FAO/RC/CRC.2/11/Add.1
UNEP/FAO/RC/CRC.2/11/Add.2
UNEP/FAO/RC/CRC.2/11
UNEP/FAO/RC/CRC.2/INF/2

Introduction

- A new notification from Canada was available to the Committee together with supporting documentation. This notification has undergone a preliminary review by the secretariat and the Bureau, who concluded that it appeared to meet all the criteria of Annex II (document UNEP/FAO/RC/CRC.2/9 refers).

- Notifications from the European Community (EC), Japan and the Republic of Korea had been previously considered by the Chemical Review Committee at its first meeting (CRC 1), which had concluded that the only notification that met all the Annex II criteria was that from the EC.

- The purpose of this report is to present the task group's analysis of the notifications of the EC and Canada and the supporting documentation and to put forward recommendations for the Committee's consideration.

- The report is based on the annexed Excel spreadsheet analysing the notifications of the EC and Canada, which includes a summary of the information provided in the notification (Article 5) and an analysis of compatibility with the requirements of Annex I and Annex II.

- The report contains an overall analysis, together with a recommendation to the committee.

Analysis

Both of the notified regulatory actions relate to all tributyltin (TBT) compounds and the use of these compounds in anti-fouling paints was the main concern. As such this biocidal use was regarded as falling within the pesticides category under the Convention. In both regulatory actions, the decision made was to ban the use of TBT compounds in anti-fouling paints, while allowing some other minor uses to remain. Both regulatory actions therefore constitute severe restrictions.

Both notifications were found to comply with the information requirements of Annex I. Although the EC notification lacks an assessment of socioeconomic effects of the regulatory action, and the notification from Canada does not contain any information about estimated levels of production, import, export and use of the TBT compounds, such information is non-mandatory.

The following table set out how the notifications from the EC and Canada meet the criteria of Annex II (see annex for more details).

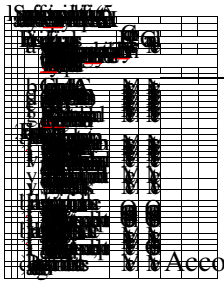
Criteria/country	European Community	Canada
(a)	Met	Met
(b)(i)	Met	Met
(b)(ii)	Met	Met
(b)(iii)	Met	Met
(c)(i)	Met	Met
(c)(ii)	Met	Met
(c)(iii)	Met	Met
(c)(iv)	Met	Met
(d)	Met	Met

The EC's notified regulatory action was taken to protect both human health and the environment while the Canadian regulatory action was to protect the environment alone. Although there is no precise information available concerning the quantities of TBT compounds used in antifouling paints versus other uses, it is generally understood that antifouling paints were the predominant use of these compounds. Both notifications describe the specific risks and outline significant reductions in exposure that will result from the severe restriction of use. Both notifications are based on risk evaluations taking into account local exposure scenarios and monitoring. The risk evaluations and the data upon which they are based are to recognised scientific standards and principles.

The considerations that led to the regulatory actions are generally applicable and are not specific to a limited geographical area or to other specific circumstances. Both Parties have provided some evidence of ongoing international trade (criterion (c) (iv)). Moreover this has been confirmed by observers (see document UNEP/FAO/RC/CRC.2/INF/2). Furthermore there is no evidence in any of the notifications that concerns for intentional misuse prompted the regulatory actions.

Conclusion

The notifications of regulatory action from the European Community and Canada meet all the requirements of Annex II.



Recommendation

Accordingly, the Task Group suggests that the CRC should decide to recommend to the COP that tributyltin compounds should be included in Annex III to the Convention.

		d)	**Other relevant information**						
			i	Socio-economic effects	Open	Met			
			ii	Alternatives and their risks	Met	Met			
	CONCLUSION: COMPLETENESS OF INFO REQUIRED UNDER ART 5 AND IN ANNEX I				EC	Canada			
					Met	Met			
	Summary and analysis of hazard- and risk evaluations compared to requirements in <u>annex II</u>								
					Country:				
					EC	Canada			
			II(a)	**Was regulatory action taken to protect health or the environment**	Met	Met			
		5	**Establish that the final regulatory action has been taken as a consequence of a risk evaluation**						
			II(b)(i)	Data have been generated according to scientifically recognised methods	Met	Met			
			II(b)(ii)	Data reviews have been performed and documented according to generally recognised scientific principles and procedures	Met	Met			
			II(b)(iii)	The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action	Met	Met			
		6	**Consider whether the final regulatory action provides a sufficiently broad basis to permit listing af the chemical in Annex III by taking into account:**						
			II(c)(i)	Whether the action led, or would be expected to lead to a significant decrease in the quantity of the chemical used or the number of its uses	Met	Met			
			II(c)(ii)	Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human or the environment of the Party that submitted the notification	Met	Met			
			II(c)(iii)	Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances	Met	Met			
			II(c)(iv)	Whether there is evidence of ongoing international trade in the chemical	Met	Met			
		7	**II(d)**	**Was concern about intentional misuse the reason for the regulatory action?**	Met	Met			

		CONCLUSION: COMPLETENESS OF INFO REQUIRED UNDER ART 5 AND IN ANNEX II	EC	Canada			

							Country 1 =
	I	**Summary of information provided in notification (art 5)**					**EC**
		and analysis of its compability with requirements in annex I					
Ref. in Noitif.		**1**	**Properties, identification and uses**				Met / Not met / Open
1.1			**1**	a	Common name	All tri-organostannic compounds, in particular Tributyltin (TBT) compounds including Tributyltin oxide ((Bis(tributyltin) oxide)	Met
1.2			**1**	b	Chemical name (IUPAC)	Yes	Met
1.3			**1**	c	Trade names and preparations	Yes	Met
1.4			**1**	d	Code numbers (CAS and others)	Tributyltin oxide 56-35-9; Tributyltin benzoate 4342-36-3; Tributyltin chloride 1461-22-9; Tributyltin fluoride 1983-10-4; Tributyltin linoleate 24124-25-2; Tributyltin methacrylate 2155-70-6; Tributyltin naphthenate 85409-17-2.	Met
1.6			**1**	e	Classification	UN Hazard Class (Pack Group) 6.1 (II). Severe marine pollutant. T; R25, 48/23/25 Xn R21 Xi R36/38. R50-53	Met
1.7			**1**	f	Use	Pesticide - Non-agricultural pesticide with biocidal action. Most common - marine antifouling agents or industrial water treatment. TBTO effective against barnacles (most important fouling organism). Used as wood preservatives. Industrial - Auxiliary agent in intermediate synthesis in Pharmaceutical industry, modification of synthetic rubber and in some drugs	Met
1.8			**1**	g	Physico-chemical, toxicological and ecotoxicological inforrmation	Physicochemical Properties - Formulae for all main forms of Tributyl tin listed together with information on Molecular weight, Appearance, Tin content, Melting point, Boiling point, Decomposition, Relative density, Vapour pressure, Solubility in water and organic solvent and Partition coefficient. Information applying to TBTO is reported as this is the main chemical form found in fouling paints and is hydrolysed to TBT in the water column. Data on other forms of TBT are found in the supporting documentation. Toxicological Information - TBT is absorbed through the gut and rapidly distributed in tissues (mainly liver and kidneys). It is of moderate to low acute toxicity (range of LD50s). It is a skin and eye irritant with skin dermatitis at TBT concentrations greater than 0.01%. There is no evidence of mutagenic potential and there is insufficient evidence to suggest that TBTO is a possible carcinogen. TBTO is not considered to be a teratogen. Main toxic effects are on the immune system and the ADI is based	Met
		2	**Final regulatory actions**				
			a)	**Information specific to regulatory action**			
2.2.1				i	Summary of the final regulatory action	Banned from Jan 2003 - tri-organostannic compounds banned in all paints and products to prevent fouling of water craft, equipment for fishing or shellfish farming, totally or submerged appliances or equipment and in industrial water treatment.	Met

2.2.2				ii	Ref to regulatory document	Commission Directive 2002/62/EC of 2 July 2002 adapting to technical progress for the 9th time Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (organostannic compounds). Other relevant regulatory actions: Council Directive 89/677/EEC (Dec 1989), Commission Directive 1999/51/EC (May 1999).	Met
2.2.3				iii	Date of entry into force	12 July 2002. Member States required to adopt and publish provisions necessary to comply with this Directive by 21 October 2002 at latest and apply measures from 1 January 2003.	Met
2.3				iv	Was action taken on the basis of hazard or risk evaluation,- Referece to relevant documentation.	Yes Independent Risk Assessment for EC (1998) reviewed by Scientific Committee for Toxicity, Ecotoxicity and the Environment (CSTEE) of EC (1998) and developments agreed at IMO International Convention on the Control of Harmful Anti-fouling Systems (2001)	Met
2.4				v	reason for acton relevant to human health or the environment	Both human health and the environment	Met
2.4.1 **2.4.2**				vi	Summary of hazards and risks	Human Health - 1) Unacceptable health risks in the exposure to atmospheric TBT during transfer of ingredients to the mixing vessel during anti-fouling paint manufacture. 2) ingestion of contaminated food (e.g. mussels) where TBT concentration is high. Environment - Unacceptable environmental risks in the following areas: release to surface water from manufacture of TBTO and TBT self-polishing co-polymer paints; release to surface water from dockyard procedures; release to surface water from use of TBT on ships in marine, brackish or freshwater environment. While risk from manufacture may be controlled, releases from ships are difficult to control even when levels are reduced to the minimum to maintain antifouling efficiency, the amount released from a large ship is considerable.	Met
			b)	**Final regulatory action for <u>industrial</u> use**			
2.5.1				i	Prohibited uses	Not relevant	Open
2.5.1				ii	Allowed uses	Not relevant	Open
2.5.3				iii	Estimaion of quantities produced, imported, exported and used	Not relevant	Open
			b)	**Final regulatory action for <u>pesticide</u> use**			
2.5.2				i	Prohibited uses	Tri-organostannic compounds may not be placed on the market for 1) use as substances and constituents of preparations when acting as biocides in free association paints: or 2) used as substances and constituents acting as biocides to prevent fouling by microorganisms, plants or animals, of all watercraft, fishing or shellfish farming appliances or any totally or partially submerged appliance or equipment: 3) may not be used as substances and constituents of preparations intended for use in the treatment of industrial waters.	Met
2.5.2				ii	Allowed uses	All uses, including use as a preservative for wood, not covered by Directive 2002/62/EC remain allowed.	Met
2.5.3				iii	Estimaion of quantities produced, imported, exported and used	Produced 3000KT/y; Imported 30 KT/y; Exported 1700 KT/y; Used 1330 KT/y (EU apparent consumption 1996) TBTO data.	Met

2.6			**c)**	**Relevance of action to other states and regions**		Protection of the aquatic environment and human health	Met
			d)	**Other relevantinformation**			
2.7.1				i	Socio-economic effects	No information	Open
2.7.2				ii	Alternatives and their risks	Alternative tin-free antifoulant systems available (copper acrylate and other copper systems, booster and non- booster, non-stick biocide-free products) and others still under development (natural product extracts e.g. sponge). Toxicity and environmental impact of alternatives being assessed. Without anti-fouling fuel consumption of ships may increase by 50%. Performance of most alternatives lower and price higher than TBT.	Met
		COMPLETENESS OF INFO REQUIRED					
		UNDER ART 5 AND IN ANNEX I					Met

	II	**Summary and comparision of the hazard and risk evaluations performed by the notifying countries: human health and or environment**					**EC**
			3	**Summary of hazards and risks to human HEALTH**			
					Hazard identification to human health	Skin and eye irritation. Main toxic effects are on the immune system and the ADI is based on this effect with lowest value of 0.3 microgrammes/kg bw/day.	
					Reference(s):	Risk Assessment for European Commission (1998), ' Assessment of the risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use'; IPCS (1990) Environmental Health Criteria No. 116 Tributyltin compounds; Opinion of Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the 1998 Report (1998). These documents contain detailed assessment and identification of the hazards of TBT.	
					Evaluation of risk to human health	1) Unacceptable health risks in the exposure to atmospheric TBT during transfer of ingredients to the mixing vessel during anti-fouling paint manufacture. 2) ingestion of contaminated food (e.g. mussels) where TBT concentration is high.	
					Reference(s):	Risk Assessment for European Commission (1998), ' Assessment of the risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use'; Opinion of Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the 1998 Report (1998). These documents contain a detailed risk assessment of TBT including regional exposure details.	
			4	**Summary of hazards and risks to ENVIRONMENT**			
					Hazard identification to environment	TBTO is strongly absorbed to sediment and the principal degradation pathway is biodegradation to dibutyltin and monobutyltin and eventually to tin oxide. TBTO is highly acutely toxic to molluscs, fish and bacteria. It is highly chronically toxic to daphnia and other effects include imposex on dogwhelk (TBTO <1 ng/l) and other species and effects on shell development of the Pacific oyster at concentrations <1 ng/l. TBT log Pow >3 and may bioaccumulate.	
					Reference(s):	Risk Assessment for European Commission (1998), ' Assessment of the risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use'; IPCS (1990) Environmental Health Criteria No 116 Tributyltin compounds (This document contains detailed assessment and identification of the hazards of TBT to the environment)	
					Evaluation of risk to environment	Unacceptable environmental risks in the following areas: release to surface water from manufacture of TBTO and TBT self-polishing co-polymer paints; release to surface water from dockyard procedures; release to surface water from use of TBT on ships in marine, brackish or freshwater environment. While risk from manufacture may be controlled, releases from ships are difficult to control even when levels are reduced to the minimum to maintain antifouling efficiency, the amount released from a large ship is considerable.	
					Reference(s):	Risk Assessment for European Commission (1998), ' Assessment of the risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use'; IPCS (1990) Environmental Health Criteria No 116 Tributyltin compounds; Opinion of Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the 1998 Report (1998).	

	III	**Analysis of compability with the criteria laid down in Annex II**					**EC**
				II(a)	**Was regulatory action taken to protect health or the environment**	Both	Met
			5	**Establish that the final regulatory action has been taken as a consequence of a risk evaluation**			
				II(b)(i)	Data have been generated according to scientifically recognised methods	The hazard data were generated according to scientifically recognised methods from peer-reviewed literature and tests conducted to internationally recognised methods	Met
				II(b)(ii)	Data reviews have been performed and documented according to generally recognised scientific principles and procedures	The main reviews were conducted by IPCS (WHO, UNEP, ILO) and an independent review commissioned by EC together with an assessment by EC's CSTEE of independent experts. These reviews were conducted according to recognised scientific principles by experts in the field.	Met
				II(b)(iii)	The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action	The independent Risk Assessment takes into account the exposure conditions within the European Union and including exposure scenarios e.g EU dockyards	Met
			6	**Consider whether the final regulatory action provides a sufficiently broad basis to permit listing af the chemical in Annex III by taking into account:**			
				II(c)(i)	Whether the action led, or would be expected to lead to a significant decrease in the quantity of the chemical used or the number of its uses	A ban on TBT in anti-fouling paint which is a major use would significantly decrease the quantity of the chemicals used.	Met
				II(c)(ii)	Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human or the environment of the Party that submitted the notification	Reduction of the levels of exposure from the application of TBT-based paint in dockyards, and reduced levels of indirect exposure through contaminated food. This regulatory action is expected to significantly reduce input of TBT to the aquatic environment. The timescale over which effects would be seen is likely to be biphasic: initially a significant drop in water concentrations resulting in reduced risk for exposed environments. However, residual concentrations of TBT in water would remain for some time after the ban with continual release from ship hulls and TBT reservoirs accumulating in sediment of contaminated areas. Considering the long halflife of TBT degradation, it is likely that TBT will remain in the water column and sediment for up to 20 years after cessation of TBT input to the environment. These residual concentrations should not present a risk to population sustainability.	Met

				II(c)(iii)	Indicate whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances	Protection of the aqueous environment and human health would extend to other states and region as the release of TBT from anti-fouling paint on ship hulls takes place world-wide.	Met
				II(c)(iv)	Whether there is evidence of ongoing international trade in the chemical	Other biocidal uses remain allowed in the EC. Evidence of exports provided to TG	Met
			7	**II(d)**	Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III	The regulatory action was based not on illegal misuse but on the effects of legitimate use of TBT anti-fouling paints.	Met
					REMARKS:		

							Country 2 =
	I	**Summary of information provided in notification (art 5)**					**Canada**
		and analysis of its compability with requirements in annex I					
Ref. in Noitif.		**1**	**Properties, identification and uses**				Met / Not met / Open
1.1		1	a	Common name	Tributyltin compounds		Met
1.2		1	b	Chemical name (IUPAC)	Yes , Tributyltin oxide, Tributyltin fluoride, Tributyltin methacrylate IUPAC and CAS Nos.		Met
1.3		1	c	Trade names and preparations	Yes		Met
1.4		1	d	Code numbers (CAS and others)	Tributyltin oxide 56-35-9; Tributyltin fluoride 1983-10-4; Tributyltin methacrylate 2155-70-6		Met
1.6		1	e	Classification	UN Hazard Class 6.1 Pack Group II. T; R25-48/23/25 Xn R21 Xi R36/38. US EPA PC Code 083001		Met
1.7		1	f	Use	Pesticide - TBT compounds used in non-agricultural biocide pest control products, most commonly, anti-fouling paint for ship hulls. Continue to be used in material and wood presatives, and as a slimicide		Met
1.8		1	g	Physico-chemical, toxicological and ecotoxicological inforrmation	Physicochmeical Properties - TBTO information on Molecular weight and formula, Boiling point, Melting point, Relative density, Vapour pressure, Flash point, Solubility in water and Octanol/water Partition coefficient. Information applying to TBTO is reported as this is the main chemical form found in fouling paints. Toxicological Information - Review focussed on environmental risk so exhaustive review of human health effects not undertaken. Moderate to high oral toxicity in laboratory animals - effects on blood lipids, endocrine system, liver, spleen and transient deficits in brain development. Dermal toxicity is low but very hazardous as inhaled aerosol with lung irritation and oedema. Severe irritation to skin and eyes but not a skin sensitizer.. Main toxic effects on immune system. Limited carcinogenicity data suggesting increased endocrine tumours at high doses but no genotoxic potential. No effect on reproductive parameters in rat multigenerational study.Occupational exposure to TBT results in irritation		Met
		2	**Final regulatory actions**				
			a)	**Information specific to regulatory action**			
2.2.1				i	Summary of the final regulatory action	Registration of all tri-N-butyltin-based TBT antifouling paints and their associated registered concentrates and active ingredients, were phased out during 2002. The registrant agreed to conduct a recall of any unsold product to ensure that there was no product in the channel of trade after January 1, 2003.	Met
2.2.2				ii	Ref to regulatory document	Pest Management Regulatory Agency Special Review Decision: Tributyltin Anti-fouling Paints for Ship Hulls (SRD2002-01)	Met
2.2.3				iii	Date of entry into force	October 31, 2002	Met

2.3				iv	Was action taken on the basis of hazard or risk evaluation,- Reference to relevant documentation.	Yes - Pest Management Regulatory Agency Special Review Decision: Tributyltin Anti-fouling Paints for Ship Hulls (SRD2002-01); Review of the Persistence, Bioaccumulation, and Toxicity of Tributyltin in Aquatic Environments in Relation to Canada's Toxic Substances Management Policy, R. James Maguire, Water Qual. Res. Canada, 2000, volume 35, No. 4, 633-679.	Met
2.4				v	reason for action relevant to human health or the environment	Environment	Met
2.4.1 **2.4.2**				vi	Summary of hazards and risks	TBT is an exclusively anthropogenic chemical which is extremely toxic to aquatic organisms and is sufficiently persistent and bioaccumulative to warrant virtual elimination from Canadian environment. Regulatory control of anti-fouling paints prior to 1999 had not eliminated problem (monitored by imposex on molluscs). Continued use of TBT in anti-fouling paints posed unacceptable risk to Canadian waters based on PBT. Owing to long persistence in sediment, TBT sediment concentrations may exceed chronic thresholds for years to come	
			b)	**Final regulatory action for <u>industrial</u> use**			
2.5.1				i	Prohibited uses	Not relevant	Open
2.5.1				ii	Allowed uses	Not relevant	Open
2.5.3				iii	Estimation of quantities produced, imported, exported and used	Not relevant	Open
			b)	**Final regulatory action for <u>pesticide</u> use**			
2.5.2				i	Prohibited uses	All formulations of anti-fouling paint containing tributyltin compounds are prohibited from import, sale or use in Canada.	Met
2.5.2				ii	Allowed uses	Formulations for pest control uses in the following categories are still allowed - material preservative, wood preservative, slimicide	Met
2.5.3				iii	Estimation of quantities produced, imported, exported and used	Not available	Open
2.6			**c)**	**Relevance of action to other states and regions**		TBT anti-fouling paints can cause harm to the environment. Preventing use on ships' hulls therefore protects the aquatic environment wherever the ship may travel.	Met
			d)	**Other relevant information**			
2.7.1				i	Socio-economic effects	Organotin anti-fouling paints registered for number of different types of ships, with 3 paints, 3 concentrations and active ingredient, Tributyltin methacrylate. Information suggests that adequate alternative paints are available.	Met
2.7.2				ii	Alternatives and their risks	Since 1989, several non-TBT anti-fouling paints with copper have been evaluated and registered for use in Canada. More than 50 copper-based anti-fouling paints registered for use. Two copper thiocyanate paints are suitable for application to ships with aluminium hulls.	Met

		COMPLETENESS OF INFO REQUIRED UNDER ART 5 AND IN ANNEX I	Met
	II	**Summary and comparision of the hazard and risk evaluations performed by the notifying countries: human health and or environment**	**Canada**
	3	**Summary of hazards and risks to human HEALTH**	
		Hazard identification to human health	Regulatory action not relevant to human health
		Reference(s):	IPCS (1990) Environmental Health Criteria No 116 Tributyltin compounds
		Evaluation of risk to human health	Regulatory action not relevant to human health
		Reference(s):	IPCS (1990) Environmental Health Criteria No 116 Tributyltin compounds
	4	**Summary of hazards and risks to ENVIRONMENT**	
		Hazard identification to environment	TBT is exclusively anthropogenic and is extremely toxic to aquatic organisms and is sufficiently persistent and bioaccumulative to warrant virtual elimination from Canadian environment.
		Reference(s):	Pest Management Regulatory Agency Special Review Decision: Tributyltin Anti-fouling Paints for Ship Hulls (SRD2002-01); Review of the Persistence, Bioaccumulation, and Toxicity of Tributyltin in Aquatic Environments in Relation to Canada's Toxic Substances Management Policy, R. James Maguire, water Qual. Res. Canada, 2000, volume 35, No. 4, 633-679.
		Evaluation of risk to environment	Regulatory control of anti-fouling paints prior to 1999 had not eliminated problem; monitored by imposex on molluscs. Continued use of TBT in anti-fouling paints posed unacceptable risk to Canadian waters based on PBT. Owing to long persistence in sediment, TBT sediment concentrations may exceed chronic thresholds for years to come
		Reference(s):	Pest Management Regulatory Agency Special Review Decision: Tributyltin Anti-fouling Paints for Ship Hulls (SRD2002-01); Review of the Persistence, Bioaccumulation, and Toxicity of Tributyltin in Aquatic Environments in Relation to Canada's Toxic Substances Management Policy, R. James Maguire, water Qual. Res. Canada, 2000, volume 35, No. 4, 633-679.

	III	**Analysis of copability with the criteria laid down in Annex II**				Canada	
				II(a)	**Was regulatory action taken to protect health or the environment**	Regulatory action was taken to protect the Environment	Met
			5	**Establish that the final regulatory action has been taken as a consequence of a risk evaluation**			
				II(b)(i)	Data have been generated according to scientifically recognised methods	The data stated in the reviews upon which the hazard identification and risk assessment have been based on recognised testing methods or peer-reviewed literature (Environment Canada and Health Canada/Pest Management Regulatory Agency)	Met
				II(b)(ii)	Data reviews have been performed and documented according to generally recognised scientific principles and procedures	The reviews for physicochemical data are published by the WHO UNEP and ILO and are based on scientifically recognised testing methods and peer-reviewed literature. The environmental risk evaluation has been carried out by Canadian authorities according to recognised scientific principles and procedures. (Environment Canada and Health Canada/Pest Management Regulatory Agency)	Met
				II(b)(iii)	The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action	The risk evaluation was based on both hazard (toxicity to aquatic organisms) and exposure (presence in freshwater and marine systems at levels that cause toxicity to aquatic organisms) and therefore meets the criteria for a risk evaluation in the context of the Rotterdam Convention. Details were provided in the supporting documentation. It is noted that exposure in the environment was measured by using a biomarker of exposure (imposex in molluscs).	Met
			6	**Consider whether the final regulatory action provides a sufficiently broad basis to permit listing af the chemical in Annex III by taking into account:**			
				II(c)(i)	Wethether the action led, or would be expected to lead to a significant decrease in the quantity of the chemical used or the number of its uses	Banning of TBT anti-fouling paints will remove the source of TBT to aquatic environments. TBT is likely to remain elevated in the marine environment for some time due to its persistence, however, removing the source of input will allow recovery.	Met
				II(c)(ii)	Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human or the environment of the Party that submitted the notification	Banning of TBT anti-fouling paints will lead to a reduction in risk over time. TBT is likely to remain elevated in the marine environment for some time due to persistence, however, removing the source of input will allow recovery.	Met

				II(c)(iii)	Indicate whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances	The environmental concerns are generally applicable, and would be relevant whenever the TBT is used as an anti-fouling paint on ship hulls. TBT anti-fouling paint on ships poses a risk wherever the ship may travel. It is noted that previous severe restrictions of TBT use as an anti-fouling paint did not sufficiently reduce inputs into marine sysytems, as toxicity to aquatic organisms continued, therefore TBT was banned.	Met
				II(c)(iv)	Whether there is evidence of ongoing international trade in the chemical	Registration for other pesticide products containing TBT compounds remain registered. Active ingredients are imported into China.	Met
			7	**II(d)**	**Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III**	The risk evaluation and regulatory action are not based on the intentional misuse of TBT but on the effects of the TBT compounds based on normal use as an anti-fouling paint for ship hulls..	Met

Policy guidance:

Preparation and use of focused summaries

Introduction

This paper describes the content of a focussed summary that is to be submitted by a Party in support of their notification of final regulatory action to ban or severely restrict a chemical scheduled for consideration by the Chemical Review Committee (CRC).

Parties are encouraged to prepare a focussed summary when supporting documentation for a notification is either very voluminous or is available in a language other than English. The use of a focused summary by the CRC is not intended to establish a new obligation for designated national authorities (DNAs) but remains a voluntary action aimed at facilitating the work of the Committee.

This working paper, originally developed by the interim CRC, was adopted by the CRC at its first session as amended and noted by the second session of the Conference of the Parties. The Conference also agreed to encourage Parties to prepare focused summaries in accordance with this guidance.

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:

Bridging Information

Introduction

The purpose of this paper is to assist the Chemical Review Committee (CRC) in judging the acceptability of a notification of final regulatory action, with respect to criterion (b) (iii) of Annex II, where the notifying Party has used a risk evaluation from another country or international body as the basis for its national decision.

At its third meeting, the Conference of the Parties agreed that, in order to satisfy criterion (b) (iii) of Annex II to the Rotterdam Convention, bridging information providing evidence of the prevailing conditions in the notifying country would have to be submitted. It was further agreed that the working paper on bridging information would need to be developed further in order to accommodate the consideration of global risk evaluations as experience was gained.

At its first meeting, the CRC considered an initial draft of this working paper which was further discussed and amended at its third meeting.

Bridging Information

Introduction

1. When examining notifications made in accordance with Article 5 of the Rotterdam Convention, the Chemical Review Committee must establish whether criteria b (i), b (ii) and b (iii) of Annex II have been met. The *working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II* includes practical examples where the Committee has determined that these criteria have been met. Meeting criterion (b) (iii), i.e. that a final regulatory action was based on a risk evaluation involving prevailing conditions within the party taking the action, has proven particularly difficult. Other than conducting risk evaluations by themselves, notifying countries may use risk evaluations and/or exposure assessments completed in another country or from an international risk evaluation. When submitting actual or estimated exposure to also ensure that 2b(i) has bee met.

2. This document provides guidance on the sort of information that will need to be considered by the Chemical Review Committee in determining that the conditions in the country which completed the original risk evaluation and exposure assessments or risk evaluations carried out under other international agreements or conventions, such as the Montreal Protocol on substances that deplete the ozone layer or the Stockholm Convention on Persistent Organic Pollutants (POPs) are similar to and compatible with those prevailing in the notifying country.

3. For those countries whose national regulatory programmes require the use of risk evaluations but which lack the capacity and resources to perform such evaluations, these guidelines may also be of interest.

4. It is important to note that when a Party submits a notification of final regulatory action, the risk evaluation and the "bridging" information must be sufficient to fulfil the criteria in Annex II (b) (iii) for this notification to be a trigger for further consideration under the Convention.

5. The use of these guidelines is intended to be voluntary. They should be interpreted flexibly.

6. The Chemical Review Committee will consider such bridging information on a case-by-case basis. In reviewing the information, the Committee will apply the following principles:

(a) Exposure or potential exposure is a key element;

(b) The information should be science-based, on the best available knowledge;

(c) The information should also be sufficiently detailed to enable the Chemical Review Committee to make an assessment.

7. The following elements, if relevant for the final regulatory decision, should be considered in comparing the exposure scenario in the country that completed the original risk evaluation or the relevance of the exposure scenarios considered in the international risk evaluation to the conditions prevailing in the notifying country that has used that risk evaluation in support of its notification of final regulatory action. They address both human health and environmental exposure.

A. Pesticides

8. Information to facilitate a comparison of human exposure between countries or to demonstrate relevance of an international risk evaluation could include:

(a) The form in which the chemical was used in both countries or a comparison of the form in which the chemical is used in the notifying country to those which were considered in the international evaluation;

(i) Formulation type:

- Liquid, powdered, granular and so on;
- Concentration of active ingredient(s);

(ii) Contaminants:

(b) How the chemical is used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation;

(i) Use pattern:

- Type of use (agricultural pesticide, non-agricultural pesticide, use as disinfectants, vector control, wood preservatives)
- Rate, frequency and period of application
- Method of application (spray, drip, dip)
- Application equipment (back pack sprayer, air blast sprayer etc.)
- Greenhouse, field application, post-harvest, other
- Storage conditions

(ii) If applied in the field: climatic or geographic conditions, comparability between the countries or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes, or chemicals with persistent, bioaccumulating and toxic properties such as POPs, or chemicals derived from certain heavy metals such as mercury might pose problems for human health in the notifying country, e.g. via the food chain)

(c) Risk mitigation measures in both countries - relevance of restrictions/precautions on use in the country that undertook the risk evaluation or relevance of recommended risk mitigation measures from international evaluations, such as:

(i) Human health effects:

- Requirement for protective clothing, whether it is typically available and/or feasible in the country reporting the regulatory action
- Special application equipment, whether it is typically available and/or feasible in the country reporting the regulatory action
- Occupational exposure limit.

9. Information to facilitate a comparison of environmental exposure:

(a) The form in which the chemical was used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation:

(i) Formulation type:

- Liquid, powdered, granular, etc.
- Concentration of active ingredient(s)

(ii) Contaminants

(b) How the chemical is used in both countries or a comparison of the use conditions in the notifying country to those which use forms were considered in the international evaluation:

(i) Use pattern:

- Rate and frequency of application
- Method of application (spray, drip, dip, etc.)
- Application equipment (back pack sprayer, air blast sprayer, etc.)
- Greenhouse, field application, post-harvest, etc.

(ii) If applied in the field, environmental conditions such as climatic conditions, soil type and non-target organisms; comparability between the two countries or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes or chemicals with persistent, bioaccumulating and toxic properties such as POPs, or chemicals derived from certain heavy metals such as mercury might pose problems in the environment of the notifying country)

(c) Risk mitigation measures - relevance of restrictions/precautions on use in the country that undertook the risk evaluation or relevance of recommended risk mitigation measures from international evaluations, such as:

(i) Effects on non-target organisms:

- Buffer zones to protect sensitive areas such as water bodies or species habitats; whether such zones are enforceable in the notifying country

(ii) Other environmental effects.

The description of indirect exposure via the environment should address the following:

(a) How the presence of a chemical in the environment, results in (actual or potential) exposure of humans or organisms in the environment. Actual exposure can be directly measured. Potential exposure can be estimated.

(b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical.

B. Industrial chemicals

10. Information to facilitate a comparison of human exposure between countries or to demonstrate relevance of conditions considered in an international risk evaluation could include information on:

- Workers
- General population
- End users
- Others (for example specific subgroups of the population such as children, pregnant women or the elderly)

11. Information to facilitate a comparison of environmental exposure between countries or to demonstrate relevance of conditions considered in an international risk evaluation:

- Soil, air, water
- Habitat
- Wildlife.

12. Description of events leading to exposure either as described in the notification of another country or in the international evaluation such as one or several of the following examples:

(a) Production process: e.g., where releases to air during production or processing of the chemical leads to general population exposure;

(b) Patterns of storage and distribution;

(c) Patterns of use: e.g., where the product is used on fabric, consumers are subjected to dermal exposure from clothing made from the treated fabric;

(d) Patterns of disposal: e.g., disposal of chemical on land leads to ground water contamination.

13. Description of the key factors, such as one or several of the following examples, affecting the chain of events leading to exposure:

(a) The form in which the chemical was used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation:

- Formulation type (where appropriate)
- Concentration of the chemical
- Contaminants.

(b) If release is associated with the production process, description of the production process:

(i) What are the key factors affecting release?

- Open or closed
- Waste water treatment (if relevant)

(ii) What options exist for controlling release or exposure?

- Exposure limits
- Protective equipment.

(c) If release is associated with storage and distribution, description of the storage and distribution process:

(i) What are the key factors affecting release?
(ii) What options exist for controlling release or exposure?

(d) If release is associated with use, description of use:

(i) What are the key factors affecting release?
(ii) What options exist for controlling release or exposure?

(iii) Hazard communication

(e) If release is associated with disposal, description of the disposal process:

(i) What are the key factors affecting release?
(ii) What options exist for controlling release or exposure?

Any other relevant information demonstrating similarity in conditions as described by another notifying country, e.g. incident reports, monitoring data, or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes or chemicals with persistent, bioaccumulating and toxic properties such as POPs, or certain heavy metals such as mercury or their compounds might pose problems to human health (e.g. via the food chain) or in the environment of the notifying country).

The description of indirect exposure via the environment should address the following:

(a) How the presence of a chemical in the environment results in (actual or potential) exposure of humans or organisms in the environment. Actual exposure can be directly measured. Potential exposure can be estimated.

(b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical.

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Policy guidance:

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.

Policy guidance:

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

Introduction

The purpose of this paper is to assist the Chemical Review Committee (CRC) in judging the acceptability of a notification of final regulatory action with respect to criterion (d) of Annex II.

The Chemical Review Committee (CRC) at its second session extensively discussed the term "intentional misuse" as included 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 intentional misuse was prepared and forwarded to the third meeting of the Conference of the Parties (COP). It was understood that future notifications relating to "intentional 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 COP.3, has been appended to the working paper developed by the CRC.

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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Legal opinion on intentional misuse

Note by the Secretariat

At its third meeting, the Conference of the Parties agreed that the Chemical Review Committee would continue to consider notifications involving intentional misuse on a case-by-case basis but that a legal opinion from the United Nations Environment Programme (UNEP) legal office to clarify the meaning of "intentional misuse" should be obtained and made available to the Committee in order to inform future discussions. The legal opinion of the UNEP legal office on "intentional misuse" may be found below:

Intentional misuse

Issue: With regard to the application of criterion (d) of Annex II, there is the need to clarify the meaning of "intentional misuse", which is also referred to in Part 3, criterion (e) of Annex IV.

Legal opinion:

Under Annex II, the CRC is required to undertake actions listed in paragraphs (a) to (d) of Annex II in reviewing the notifications forwarded by the Secretariat pursuant to paragraph 5 of Article 5. In other words, at its deliberations on the notifications, the CRC needs to examine them on the basis of all the criteria listed in Annex II.

Regarding criterion (d) of Annex II, the following may be observed:

- It does not exclude the possibility that a banned chemical, which might have satisfied the criteria (a) to (c) of Annex II, might be intentionally misused. In this case, the incidents of intentional misuse associated with the chemical should not be construed to disqualify that chemical for listing in Annex III.

- On the other hand, if intentional misuse is the sole reason for the final regulatory action on the chemical and criteria (a)-(c) are not satisfied, it might be considered that there is no adequate reason for listing the chemical in Annex III.

Regarding the question of "intentional misuse" of a chemical, the following should be considered:

Meaning of **"misuse"**:

- Where a law or regulation governing the use of the chemical exists in a country, the chemical is used for the purposes not permitted under the law or regulation; or
- The chemical is used in a manner not intended or reasonably foreseeable by the manufacturer of the chemical, irrespective of whether there is a law or regulation governing the use of the chemical in the country.

Meaning of "**intentional**":

- A person who uses the chemical is in the state of mind in which he/she seeks to accomplish certain results (i.e. the act is to be done or omitted) through a course of action. In other words, he/she desires to cause consequences of his/her act or he/she believes consequences are substantially certain to result by using the chemical.

With regard to **"intentional misuse**":

For a person to commit “intentional misuse” of the chemical, the following conditions should be met:

- The person knows the legitimate use of the chemical, as permitted under the relevant law or regulation, or otherwise as specified in the label or other means of communication accompanying the chemical; and
- The person purposefully uses the chemical in contravention of the legitimate use of the chemical, with the knowledge or belief that such illegitimate use of the chemical will cause the result that he/she so desires.

Even when the chemical is “misused” in a strict sense, it may not constitute the act of “intentional misuse” of the chemical by a person, given the prevailing circumstances, if:

- The person believes that he/she is using the chemical in a manner as designed for its use (e.g. as many people use the chemical in his/her community and no one has been punished for using it) ; or
- The person does not have specific knowledge concerning the law or regulation governing the chemical or the use for which the chemical is designed, and therefore he/she is not able to ascertain its legitimate use (e.g. illiteracy, lack of understandable means for communicating the legitimate use).

Policy guidance:

Working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II

Introduction

The purpose of this paper is to assist the Chemical Review Committee (CRC) in judging the acceptability of a notification of final regulatory action with respect to criteria (b) (i) (b) (ii) and (b) (iii) of Annex II.

The criteria for listing banned or severely restricted chemicals in Annex III of the Convention are set out in Annex II of the Convention. Paragraph 3 of Annex II requires that the CRC "*establish that the final regulatory action has been taken as a consequence of a risk evaluation.*" It further states that "*the evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question*" and lists three criteria (b (i) to (iii)) against which the supporting documentation is to be reviewed by the Committee.

This working paper, originally considered at the second meeting of the CRC, was developed based on the findings of two task groups established by the Committee at its first meeting. The guidance was amended with further examples included based on the experience gained at the second and third meetings of the CRC and guidance provided by the third meeting of the Conference of the Parties. The guidance will continue to evolve in the light of future experience.

Risk evaluation: working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II

Introduction

1. The present working paper is divided into three chapters: chapter I provides a brief background on the relationship between the information requirements for notifications submitted under Article 5 of the Convention and the criteria set out in Annex II of the Convention for listing banned or severely restricted chemicals in Annex III of the Convention; chapter II provides guidance aimed at eliminating ambiguity and improving consistency in referring to criteria (b) (i) and (b) (ii) in the analysis of the notifications; chapter III provides an initial list of examples as a basis for further guidance to the Chemical Review Committee in defining minimum requirements for information on the exposure component of a risk evaluation. This list will be expanded on an ongoing basis as further practical experience is gained in reviewing candidate chemicals.

I. Background

2. Annex I of the Convention sets out the information requirements relevant to a notification of final regulatory action submitted under Article 5 of the Convention. The information requirements of Annex I were the basis for the notification of regulatory action form which was developed to provide a standardized format for reporting national final regulatory actions.

3. The information contained in the notification of final regulatory action and accompanying supporting documentation are considered by the Committee in the light of the criteria for the inclusion of chemicals in Annex III of the Convention set out in Annex II of the Convention.

4. Annex II states:

> "In reviewing the notifications forwarded by the Secretariat pursuant to paragraph 5 of Article 5, the Chemical Review Committee shall:
>
> . . .
>
> (b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:
>
> (i) Data have been generated according to scientifically recognized methods;
> (ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
> (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action.

II. Application of criteria (b) (i) and (b) (ii)

5. Criteria (b) (i) and (b) (ii) are particularly relevant to two specific paragraphs of the information requirements listed in Annex I.

6. Paragraph 1 of Annex I sets out the information on the properties, identification and uses of a substance, including recognized names of the substance, relevant code numbers and hazard classification, as well as physico-chemical, toxicological and eco-toxicological properties.

7. In submitted notifications, this includes lists of physicochemical parameters such as melting and boiling points or lists of toxicological or eco-toxicological endpoints including, LD50 and LC50 data for a range of laboratory animals, birds and fish. In most countries this information is

not generated nationally, but may be found in a range of internationally recognized sources[1]. Information referenced from such sources is considered to have met criteria (b) (i) and (b) (ii).

8. At its third meeting, the Conference of the Parties endorsed the approach recommended in the secretariat's note, namely that the Committee should consider risk evaluations under the Montreal Protocol and the Stockholm Convention as adequate support for meeting criteria (b) (i) and (b) (ii). [2]

9. Paragraph 2 (a) of Annex I sets out specific information to be provided that describes the final regulatory action to ban or severely restrict the chemical. This includes information on the risk or hazard evaluation upon which the regulatory decision was based, reasons for the regulatory action relevant to human health or the environment, a summary of the hazards and risks presented by the chemical and the expected effect of the final regulatory action.

10. In notifications, this information is generally in the form of a short written statement which briefly explains the risk or hazard evaluation on which the national regulatory action was based and a reference to the relevant documentation. The supporting documentation prepared by the country submitting the notification, including a focused summary, generally provides more detailed information regarding the basis for the regulatory action. The risk or hazard evaluation may include a combination of hazard information from internationally recognized reference sources as well as information on exposure under the prevailing conditions in the notifying country.

11. On the one hand, hazard information is not for the most part generated nationally, but is drawn from a range of internationally recognized sources, and information from such sources is generally considered to have met criteria (b) (i) and (b) (ii). On the other hand, information on exposure relevant to prevailing conditions in the notifying country is largely generated at the national level, and whether or not this information meets criteria (b) (i) and (b) (ii) will need to be considered on a case-by-case basis.

12. There are four basic scenarios relevant to a consideration of criteria (b) (i) and (b) (ii) of Annex II and the information requirements of Annex I. A description of the scenarios and how criteria (b) (i) and (b) (ii) might apply to each follows:

Scenario 1: Data are not provided and there is no reference to a source of data in the notification or in the supporting documentation.

- Criteria (b) (i) and (b) (ii) would not be met.

Scenario 2: Data are provided but the source of the data is not referenced in the notification or in the supporting documentation.

- Criteria (b) (i) and (ii) would not be met as it would not be possible to verify that the data have been generated according to scientific principles and procedures or that the data reviews have been performed and documented according to generally recognized scientific principles and procedures.

Scenario 3: Data are not provided but there is a reference to a source of data in the notification or in the supporting documentation.

- Criteria (b) (i) and (ii) would be met where the notifying country merely references a source document, without drawing out the specific information which they have used to make their decision, provided that the reference is to an internationally recognized source including a risk evaluation undertaken under the Stockholm

[1] Internationally recognized sources include the Pesticide Manual, documents generated by the Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), the International Agency for Research on Cancer (IARC) and the United Nations Environment Programme (UNEP) as well as data from decision-guidance documents.

2 Paragraph 66 UNEP/FAO/RC/COP.3.26

Convention or the Montreal Protocol. Other documents, such as national or regional assessments, would need to be examined on a case-by-case basis.

Scenario 4: Data are provided and the source of the data is referenced in the notification or in the supporting documentation.

- Criteria (b) (i) and (b) (ii) would be met, provided that the data are from an internationally recognized source including a risk evaluation undertaken under the Stockholm Convention or the Montreal Protocol. Other documents, such as national or regional assessments, would need to be examined on a case–by-case basis.

III. Application of criterion (b) (iii)

13. At its first meeting, the Committee decided to accept the policy guidance on risk evaluation in the context of the Rotterdam Convention contained in document UNEP/FAO/RC/CRC.1/13 as a work in progress and to amend it as necessary in the light of further experience[3]. In order to facilitate the work of the Committee in reviewing risk evaluations, the guidance set out some examples as a means of defining the minimum requirements for information regarding exposure.

14. At its second meeting, the Committee considered a working paper which had been developed by the Secretariat based on the work of the task groups established at the first meeting of the Committee (UNEP/FAO/RC/CRC.2/7). The meeting commended the secretariat on the paper which they said provided very useful guidance to the Committee. It was proposed that further examples identified during that meeting would be included in subsequent revisions of the document [4]

15. At its third meeting, the Conference of the Parties endorsed the approach recommended in the secretariat's note, namely that in order for criterion (b) (iii) to be met, bridging information providing evidence of the prevailing conditions in the notifying country would need to be submitted. [5]

16. The examples listed here are intended to serve as guidance to the Committee on how to document or explain the exposure component of a risk evaluation in order to facilitate its work and to help ensure transparency and consistency.

17. It is understood that the Committee will consider notifications on a case-by-case basis and that this list of examples will be expanded or refined as experience is gained in reviewing notifications in support of candidate chemicals. This guidance is intended to be interpreted flexibly.

Example 1: Incidents involving direct exposure of humans

Information is required describing direct exposure to a chemical and any adverse effects resulting from that exposure. Thus a description of the incident should be provided which may include, for example, the extent or number of casualties, its circumstances and a description of the signs, symptoms and/or effects.

a) Actual or measured exposure

[3] Report of the Chemical Review Committee on the work of its first meeting UNEP/FAO/RC/CRC.1/28, para. 39.

[4] Report of the Chemical Review Committee on the work of its second meeting UNEP/FAO/RC/CRC.2/20, paras 32-36).

5 Paragraph 66 UNEP/FAO/RC/COP.3.26

This is based on a situation in which a country has taken a national regulatory action based on a risk evaluation which includes an assessment of exposure based on empirical or measured levels of a chemical that reflect the prevailing conditions in the notifying country.

Example

i) The regulatory action on DNOC notified by Peru and considered at the third session of the Interim Chemical Review Committee (ICRC) was based on hazard data supplemented by a study of poisoning incidents in the country. ICRC concluded that, taken together, the material demonstrated that there had been a risk evaluation that took into account prevailing conditions in that country (UNEP/FAO/PIC/ICRC.3/19, annex II).

b) Expected or anticipated exposure

This is based on the concept that a country can notify a national regulatory action that is based on expected exposure. Such exposure information might be developed based on modelling data generated by international organizations or other Governments and adapted to the anticipated exposure and prevailing conditions in the notifying country.

The guidance that has been developed on common and recognized patterns of use of severely hazardous pesticide formulations (UNEP/FAO/RC/CRC.9) may be relevant to certain elements of this discussion.

For acutely toxic pesticides or industrial chemicals, this could include information on the availability and common use of protective equipment or poisoning scenarios (if relevant and available), a description of how a chemical was used –or a description of the conditions of storage, transport or disposal and potential exposures in each scenario.

Examples

i) Comparison of mammalian and environmental toxicity data with anticipated exposure levels generated using models. A case example is the European Union notification regarding methyl parathion (UNEP/FAO/RC/CRC.1/28, annex V, para. 10).

   - The notification and supporting documentation showed that the final regulatory action had been based on a chemical-specific risk evaluation taking into account the conditions of exposure within the European Community. The risk evaluation of the pesticidal uses of methyl parathion concluded that, on the basis of the results of several exposure models, there were unacceptable risks to workers and non-target organisms (insects, birds, aquatic organisms and mammals) due to the acute and chronic toxic effects of methyl parathion.

ii) For non-threshold carcinogens, there may be a national policy that no exposure is acceptable. Thus, a description of the anticipated use of the chemical may be sufficient, with no specific information on exposure needed. A case example is the Canadian notification of bis (chloromethyl) ether (UNEP/FAO/RC/CRC.1/28, annex V, paras. 25-26).

   - Canada concluded that bis (chloromethyl) ether was a non-threshold carcinogen in humans. As a result it was understood that there is some probability of adverse effect at any level of exposure. Although levels at the time of the regulatory action did not pose a threat to human health, the regulatory action was put in place as a precautionary measure to protect the health of Canadians. This approach is consistent with the objective that exposure to non-threshold carcinogens be reduced wherever possible, and obviates the need to establish an arbitrary de minimis level of risk. Based on this, the Chemical Review Committee at its first session concluded that the supporting documentation showed that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within Canada.

iii) Pesticides with defined hazard classifications, e.g., WHO hazard classification 1a or 1 b, may be subject to national policy that they not be registered based on the understanding that the prevailing conditions of use in a country will result in unacceptable risk to workers or the environment. In such a case, a description of the anticipated use of the chemical may be sufficient, with no specific information on exposure needed.

- Specific example to be identified

Example 2: Incidents involving direct exposure of the environment (wildlife, livestock, etc.)

Information is required describing the direct exposure to the chemical and the adverse effects resulting from that exposure. Thus, a description of the incident should be provided, which may include, for example, the extent or number of casualties, its circumstances and a description of its effects.

a) Actual or measured exposure

For both pesticides and industrial chemicals this could include a description of how a chemical was used and or a description of the conditions of storage, transport or disposal and potential environmental exposures in each scenario.

Examples

i) Comparison of toxicity data for fish and monitoring data (measured exposures in surface water). A case example is the notification by the Netherlands regarding methyl bromide (UNEP/FAO/RC/CRC.1/28, annex V, para. 3).

- The risk evaluation of the Netherlands focused on the behaviour and effects of methyl bromide in air, groundwater and surface water. The estimated concentration in groundwater amounted to approximately 100 µg/L, based on a soil degradation half-life of about 15 days and a sorption constant of about 2.5 L/kg. The measured concentrations in surface water amounted to approximately 9 mg/L, which resulted in the expectation of a very high risk for fish (LC_{50} (96h) 3.9 mg/L). The Committee agreed that the evaluation of the risks to aquatic organisms met the requirements of the criterion with respect to the prevailing conditions of use in the Netherlands.

ii) Comparison of toxicity data for fish and observation of effects on non-target organisms including fish and other aquatic organisms following application of endosulfan to rice paddies in Thailand for the control of golden apple snail. (UNEP/FAO/RC/CRC.2/20, Annex II, para 3).

- The Committee confirmed that Thailand had severely restricted endosulfan, as commonly used in Thailand, by banning emusifiable concentrate and granular formulations, whereas the use of capsulate formulation remained registered. This decision was based on a national risk evaluation as follows: a survey in five provinces to assess the use of endosulfan for golden apple snail control in paddy fields showed that approximately 94 per cent of farmers used pesticides and that, of those, 60–76 per cent used endosulfan. There were no measured concentrations of endosulfan in the treated paddies however the death of fish and other aquatic organisms was reported in every province and emulsifiable concentrate (EC) and granule (GR) formulations were known to be very toxic to fish and aquatic organisms.

b) Expected or anticipated exposure

This is based on the concept that a country can notify a national regulatory action that is based on expected exposure. Such exposure information might be developed based on modelling data that

is generated by international organizations or other Governments and adapted to the anticipated exposure and prevailing conditions in the notifying country.

For both pesticides and industrial chemicals, this could include a description of how a chemical was used, or a description of the conditions of storage, transport or disposal and potential environmental exposures in each scenario.

The guidance developed on common and recognized patterns of use of severely hazardous pesticide formulations (UNEP/FAO/RC/CRC.9) may be relevant to certain elements of this discussion.

Examples

i) Comparison of mammalian and environmental toxicity data with anticipated exposure levels generated using models. Case examples include the following:

- Methyl-parathion - European Union (EU) notification (UNEP/FAO/RC/CRC.1/28, annex V, para. 10)

The EU notification demonstrated that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within the European Community. The risk evaluation of the pesticidal uses of methyl parathion concluded that, on the basis of the results of several exposure models, there were unacceptable risks to workers and non-target organisms (insects, birds, aquatic organisms and mammals) due to the acute and chronic toxic effects of methyl parathion.

- Endosulfan - Netherlands notification (UNEP/FAC/RC/CRC.2/20 annex II, para 2).

The Netherlands notification banned all uses of endosulfan on basis of a national risk evaluation. It was found that application of endosulfan according to good agriculture practice would result in surface water concentrations that would significantly affect aquatic organisms (especially fish). Emission of endosulfan to surface water will occur as a result of spraying drift during application. The surface water concentration of endosulfan during application was estimated with a dispersion model. Assuming a drift emission factor of 10 per cent, an endosulfan concentration of 0.014 mg/l was calculated. A comparison of this concentration with the lowest LC50 for fish (0.00017 mg/l) results in a risk quotient of 82, which was considered unacceptable.

- Dicofol – Netherlands notification (UNEP/FAO/RC/CRC.2/20 annex III paras 1 and 2)

The notification demonstrated that the final regulatory action had been based on estimated concentrations of the chemical in the environment taking into account the prevailing conditions in the Netherlands. The risk evaluation concluded that, on the basis of the results of modelled exposure there were unacceptable risks to non-target organisms (predatory birds feeding on fish) due to persistence and bioaccumulation of dicofol

.Dicofol is a persistent chemical. Laboratory experiments found the chemical to be highly accumulative (bioconcentration factor (BCF) of about 10,000), a property that might lead to effects via the food chain (secondary poisoning). In addition, further experiments revealed effects on the reproduction of owls and pigeons where eggshell thinning at a concentration of 3 mg/kg feed was demonstrated. Modelling estimations indicated that application (according to good agriculture practice) of dicofol would lead to exposure of fish-eating birds. Based on the BCF there is an estimation of about 30 mg/kg feed, assuming a diet of 100 per cent contaminated fish to be eaten by predatory birds. Concentration in fish and predatory birds may reach levels as a result of continuous build-up in the tissues which lead to significant adverse effects. This is clearly deemed unacceptable.

Example 3: Indirect exposure via the environment (air, water, soil)

The description of indirect exposure via the environment should address the following:

(a) How the presence of a chemical in the environment results in human and environmental (actual or expected) exposure. Actual exposure can be directly measured. Expected exposure can be estimated.

(b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical, would facilitate the work of the Committee.

Examples

i) The presence of a chemical in the environment in itself is not sufficient to meet criteria b (iii).

- Endosulfan – Jordan notification (UNEP/FAO/PIC/ICRC5/15, paras. 39–41)

Jordan had banned endosulfan because it was persistent in the environment and residues had been found in soil. The decision to ban endosulfan had been based on research findings pointing to the chemical's carcinogenic properties and statements that it was found in groundwater. Information available to the Committee (monitoring data) indicated the presence of endosulfan in the soil, but no residues of endosulfan had been reported in groundwater in Jordan. At its fifth session, the Interim Chemical Review Committee concluded that it was not clear that presence in the soil would lead to human or environmental exposure.

ii) Some chemicals have characteristics that allow them to bioconcentrate or biomagnify[6] to levels that cause toxic effects. A regulatory action may have been taken as a precautionary measure to reduce or eliminate future risks to humans or wildlife. There may be special concerns with endangered species (environmental risk) or human subpopulations with high consumption of sea food and other traditional food (health risk). Thus, information about the persistence, biomagnification/bioconcentration and toxic properties of the chemical together with a description of the use, releases and anticipated exposure to the chemical could be the basis of the decision. A case example includes the following:

- Mirex – Canadian Notification (UNEP/FAO/RC/CRC.2/20, annex III D)

Canada banned mirex because it is persistent, bioaccumulative and subject to transboundary movement. The decision to ban mirex was based on the fact that it has been demonstrated to cause cancer in laboratory animals and it is possibly carcinogenic in humans. Mirex contaminates several ecosystems in Canada. Human dietary exposure to mirex is generally low with the possible exception of the group dependant on a diet of fish or fish feeding birds from Lake Ontario and the St Lawrence River and of hunters eating game birds**.**

iii) Indirect exposure may also be considered to include indirect effects that result from the action of a chemical on another system. Such actions may in turn have direct and indirect impacts for example the direct impact of increased ultraviolet radiation on the notifying Party or an indirect impact as a result of the general effects associated with the release to the environment of a chemical that contributes to the depletion of the ozone layer.

Ozone depletion:

Direct effects: The direct impact to the environment by a chemical that depletes the ozone layer could include the resultant increase in exposure to the damaging effects of UV radiation. The extent of the effect on individual countries would vary with their geographical location, as certain areas of the globe (such as polar regions) are more affected by ozone depletion. For example ozone levels in equatorial regions have remained relatively stable, both throughout different seasons within a year and from year to year, while higher latitudes have demonstrated significant seasonal variations associated with the spring formation of 'ozone holes' over the poles. Human exposure to UV-B depends upon not only an individual's location (latitude and altitude) but also the duration and timing of outdoor activities (time of day, season of the year) and precautionary behaviour (use of sunscreen, sunglasses and protective clothing). An individual's skin colour and age can influence the occurrence and severity of some of the health effects from exposure to UV-

[6] Bioaccumulation is considered as a broader term covering both processes.

B. There may also be effects on terrestrial plants, aquatic ecosystems and climate. A case example includes the following:

- Carbon tetrachloride - Canadian notification (UNEP/FAO/RC/CRC.1/28, annex V, paras. 31–32).

Canada banned carbon tetrachloride based on a conclusion that it had an ozone-depleting potential and created indirect hazards via the environment. In the Canadian Arctic, UV levels can increase substantially from season to season, owing to the hole in the ozone layer, which is caused by ozone-depleting substances such as carbon tetrachloride. In the light of that, the Chemical Review Committee at its first session concluded that the final regulatory action had been taken as a consequence of a risk evaluation. Other supporting documentation showed that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within Canada (UNEP/FAO/RC/CRC.1/28, annex V, section E).

Indirect effects: There are complex links between changes in the ozone layer and climate change effects. Ozone-depleting substances may act as greenhouse gases and may therefore contribute to global warming, while it is not clear what effect actual depletions in the ozone layer may have on climate change. Releases of ozone-depleting substances may be considered to have a global effect and a Party may make statements relating to these effects as supporting information for its decision to ban the chemical.

- Specific example to be identified

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