Handbook

of working procedures and policy guidance for the Chemical Review Committee

October 2014

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

Preface

1. The Chemical Review Committee has adopted several papers on working procedures and policy guidance covering a broad range of issues related to its work, some of which it has subsequently revised. The papers are intended to facilitate the Committee's work and to help ensure consistency and transparency. The compilation of the on working procedures and policy guidance has been made available as information document at each Committee's meeting.

2. At its ninth meeting, the Committee agreed that the Secretariat should compile the current version of the Committee's working procedures and policy guidance in the form of an e-handbook for possible publication on the Convention website. The aim of the exercise was to improve the readability and accessibility of the procedures and guidance.

3. The working procedures and policy guidance contained in the present e-handbook may be revised in the light of experience acquired as necessary.

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1 Working procedures

1.1 Process for drafting decision-guidance documents and accompanying explanatory notes

Reference: Annex to decision RC-2/2, amended by decision RC-6/3

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. Further amendments were adopted by the sixth session of the COP in its Decision RC-6/3.

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 (in the six official languages of the United Nations) and the tabular summary of comments will be distributed as a meeting document for discussion at a Chemical Review Committee meeting 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.

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

Reference: UNEP/FAO/RC/CRC.3/5

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.

Purpose

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 banned or severely restricted chemicals in accordance with Article 5 of the Rotterdam Convention.

This working paper is intended:

(a) To clarify the purpose of each section of the decision guidance document;

(b) To characterize the information to be included;

(c) 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 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 for both industrial chemicals and pesticides 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 (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.

(a) 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.

(b) 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.

(c) 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 on-going 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:

(a) Under trade names:

(b) This is an indicative list of trade names. It is not intended to be exhaustive.

(c) 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.

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

(b) 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.

Example: *[Chemical X]* is included in the PIC procedure as a pesticide. It is has been listed on the basis of the final regulatory actions to severely restrict its use, notified by *[Country 1]*, and to ban its use, notified by *[Country 2]*.

No final regulatory actions relating to industrial chemical uses have been notified.

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).

(a) The text should reflect the reasoning used by the regulatory authority to underpin the national regulatory action(s) – for example, as presented in national law, regulation, gazette, legal journal, code.

(b) Specific reference to the relevant directive or regulation for the reported regulatory action(s) should be included in annex 2.

(c) The reason(s) stated should set the stage for the subsequent description of the underlying risk evaluation.

National authorities should 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).

(a) 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.

(b) 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) A **ban** in the regulated category of use eliminates all exposure (occupational or environmental); and

(b) 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 on the *regulatory* measures taken to **ban** or **severely restrict** the chemical and associated products.

(a) 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

(b) 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 Organization or International Standards Organization.

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.

(a) 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.

(b) 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) and organic strategies as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through National IPM focal points, the FAO, IFOAM (International Federation of Organic Movements) 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 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 organizations 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.

(a) This section should focus on internationally recognized standards such as IARC, WHO/IPCS classification systems.

(i) 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.

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

(b) The US EPA and European Union classification systems have been included as they are widely used by many countries as a reference.

(c) 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:

<table>
<tr><th colspan="4">4. Hazards and Risks to human health and the environment</th></tr>
<tr><td colspan="4">4.1 Hazard Classification</td></tr>
<tr><td rowspan="4">WHO / IPCS</td><td>Technical product
a.i.:</td><td colspan="2">Insert classification e.g. Class Ia (extremely hazardous)
Classification based on oral or dermal toxicity in rats $LD_{50:}$ (WHO reference)</td></tr>
<tr><td>Formulations</td><td>a.i. (%)</td><td>Hazard class</td></tr>
<tr><td>Liquid</td><td></td><td></td></tr>
<tr><td>Solid</td><td></td><td></td></tr>
<tr><td>IARC</td><td colspan="3">Group 3: the agent is not classified as to its carcinogenicity to humans. (IARC reference)</td></tr>
<tr><td>European Union</td><td colspan="3">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)</td></tr>
<tr><td>US EPA</td><td colspan="3">Toxicity Class I (formulation) (EPA reference)</td></tr>
</table>

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.

(a) This section should focus on those exposure limits that are internationally recognized, *e.g.*, Codex levels in food, WHO drinking water guidelines, etc.

(b) All references should include the date when they were established and the date of any subsequent

review by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), etc.

(c) 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 (*i.e.* 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.

(a) Reference should be generic and include the most recent WHO/IPCS recommendation.

(b) It should note any aspects specific to the chemical cited in the decision guidance document.

(c) 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.

(a) This section should include references to appropriate internationally recognized guidelines such as those developed by FAO for pesticides.

(b) 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.

(c) 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 contains information submitted by the notifying countries based on the national assessments which were used to support the reported final regulatory action. 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.

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 of the substance and/or product(s) 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 principal headings in this annex generally reflect those used by OECD countries and the European Union in their monographs. This approach will assist all countries, especially developing countries, which may have used an OECD/European Union monograph as the basis for the risk 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.

(a) 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).

(b) 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.)

(c) 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:

(a) 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.

(b) 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.

(c) 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

2.1. General information

This section should provide brief information on the mode of action, symptoms of poisonings and on absorption, distribution, excretion and metabolism in mammals. It can be retrieved from the notifications as well as from internationally recognized sources such as the Pesticide Manual or WHO/IPCS/JMPR/IARC evaluations.

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.

(a) 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.

(b) 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).

(a) 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. The following is an example for a reference list:

Regulatory actions

Decision by the Norwegian Agricultural Inspection Service (NAIS) 22.10.2002 (200200430 IP/hmo).

Supporting documentation provided by *Country X*

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

Supporting documentation provided by *Country Y*

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)*

Others

WHO (2003): Health Risk of Persistent Organic Pollutants from Long-Range Transboundary Air Pollution.

Relevant guidelines and reference documents

FAO/WHO Food Standards (2010). CODEX Alimentarius.

FAO (2006) Framework of FAO Guidelines on Pesticide Management in support of the Code of Conduct. http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Guidelines/Framework.htm

Appendix I: Standard Core Set of Abbreviations[1]

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
µm	micrometre
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
cc	cubic centimetre
cm	centimetre
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50%
EC	European Community
EC_{50}	median effective concentration
ED_{50}	median effective dose
EEC	European Economic Community
EHC	Environmental Health Criteria
EU	European Union
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}	median inhibitory concentration
ILO	International Labour Organisation
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
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

[1] This core list should serve as the basis for DGDs for industrial chemicals, pesticides and severely hazardous pesticide formulations. It should be augmented by abbreviations used in the individual DGDs relevant to the chemical(s) in question.

Definitions and spelling should, as far as practicable, follow the IUPAC glossary of terms in toxicology and the IUPAC glossary of terms relating to pesticides in their current editions.

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.

STANDARD CORE SET OF ABBREVIATIONS	
	Residues)
k	kilo- (x 1000)
kg	kilogram
Koc	soil organic partition coefficient
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	lowest-observed-effect level
m	metre
m.p.	melting point
mg	milligram
ml	millilitre
mPa	millipascal
MRL	maximum residue limit
MTD	maximum tolerated dose
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
Pow	octanol-water partition coefficient, also referred to as Kow
PPE	personal protective equipment
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	standard(ized) mortality ratio
STEL	short-term exposure limit
TER	toxicity exposure ratio
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
w/w	weight for weight
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)

2.2.2. 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 and bioaccumulation

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
- Other

4.2.2. Aquatic species

- Fish
- Invertebrates
- Algal species
- Aquatic plants
- Other

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.

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

Reference: UNEP/FAO/RC/CRC.8/11

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. 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 revised following the seventh session of the CRC and adopted by its eighth session with the understanding that it would continue to evolve in the light of future experience.

Purpose

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.

This working paper is intended:

(a) To clarify the purpose of each section of the decision guidance document

(b) To characterize the information to be included

(c) 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.

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

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.*

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 formulation 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.

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 (see annex IV for further details on the active ingredient(s))

Purpose: To provide an unequivocal identification of the pesticide formulation(s) subject to the PIC procedure.

This basic information on the formulation should be obtained directly from part A of the submitted severely hazardous pesticide formulation report form.

This section should include as much information as possible on the composition of the formulation:

Required information:

(a) type of formulation (for example, suspension concentrate);

(b) names and concentration of each active ingredient;

(c) CAS number of each active ingredient.

Recommended information:

(a) name(s) or trade name(s) of the severely hazardous pesticide formulation;

(b) molecular formula(s) of each active ingredient;

(c) chemical structure(s) of each active ingredient;

(d) name(s) of the manufacturer(s).

2. Reason for inclusion in the PIC procedure

Purpose: To provide a generic statement that clearly identifies the 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.

Example: The formulation [*name of the formulation*] (*name(s) of active ingredient(s), relative concentration(s), type of formulation*) is listed in Annex III of the Rotterdam Convention in the category of severely hazardous pesticide formulations. This formulation was found to cause [*human health and/or environmental*] problems under conditions of use in [*Country which had submitted the proposal*], consistent with the provisions of article 6 and Annex IV of the Convention.

The rationale developed by the Chemical Review Committee at its *XXXth* session in support of their recommendation to include such formulations in the PIC procedure may be found in annex I to this document.

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.

Example: There may be other formulations marketed under the names of [XXX of YYY] containing different combinations of these or other active ingredients. It is only those [*formulation type*] formulations containing the above noted combination of active ingredients at or above the specified concentrations that are subject to the PIC procedure.

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

Purpose: To provide a clear description of how the formulation is typically used in the reporting country. It should include a description of the 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.

The 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 of the Convention.

3.1 Permitted uses of the formulation

(a) What it is used for - space fumigation, seed treatment, crops treated etc.

(b) Application method – how it is used

(c) Pests controlled

(d) Timing, rate and frequency of application

3.2 Restrictions in handling or use

Such information is relevant to worker exposure and/or environmental exposure. Information on restrictions in handling or use may be derived from the product label or from part A of the submitted incident report form.

Where applicable, the information could be grouped under the following headings, personal protection, equipment, storage, and disposal.

3.3 Availability/applicability of protective clothing

Information on proposed protective clothing may be derived from the label. Information on the availability of protective clothing in the reporting country may be derived from the incident report form and/or from additional information collected by the secretariat in line with part 2 of Annex IV of the Convention.

3.4 Actual uses

This section should provide information on how the formulation is/was used in the reporting country in practice (if such information is available), *i.e.* the types of crops treated, applications, methods, types of pests controlled, timing, rate and frequency of application, and if the use differs from the officially permitted uses.

This information may be derived from the incident report form and/or from additional information collected by the secretariat in line with part 2 of Annex IV of the Convention.

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 II and, if feasible, the safety data sheets in annex III.

4.1 Description of the incident

A summary of key points could include the following:

(a) Where the incident occurred

(b) Main activity at the time of exposure

(c) Application method

(d) Route of exposure

(e) Conditions of use when the incident occurred, e.g. prevailing climatic conditions, use of protective clothing

4.2 Description of the adverse effects

Summary of key points described in the incident report form (annex II)

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 safety data sheet included in annex III. Reference to the WHO classification may be helpful (see section 6).

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

Summary of information in the incident report form (annex II)

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: To provide an internationally recognized baseline from which countries can better understand the potential concerns with the formulations in question relative to others that they might be using.

The content of this section should be 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 most recent edition of the WHO *recommended classification of pesticides by hazard* (http://www.who.int/ipcs/publications/pesticides_hazard/en) should be used as the primary reference for oral LD50 values. Where several LD50 values for other routes of exposure, e.g. dermal, have been published, the lowest deemed reliable is used (and referenced). This is in line with the approach used by WHO in compiling the oral LD50 values.

Where a formulation consists of more than one active ingredient, the fact that the calculated hazard classification cannot account for possible synergistic effects or the potentiation of toxicity as a result of interaction among the active ingredients should be noted.

7. Alternative pest-control practices

Purpose: To provide countries with brief information on alternatives that have been identified by the country submitting the proposal, or other sources.

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.

Example: 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) and organic strategies as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through national IPM focal points, the FAO, IFOAM (International Federation of Organic Movements) 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.

Annex 1. Rationale for the recommendation by the Chemical Review Committee to include the severely hazardous formulation in the PIC procedure

This section contains the rationale prepared in support of the recommendation of 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. The original wording of the rationale should be kept.

Annex 2. Information on reported incident from incident report

This annex should include specific information submitted by the notifying country:

(a) Name of the country

(b) Designated national authority contact information

(c) Summary of completed incident report form(s) (e.g., part B for human health-related incidents).

Annex 3. 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 according to GHS (http://www.unece.org > transports > legal instruments > GHS >… Annex 4) contain the following key headings:

1. Chemical product identification and company identification
2. Hazard identification
3. Composition of and other information on ingredients
4. First aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls and personal measures
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

Other 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.

References to manufacturers' safety data sheets for the formulation may also be part of this annex.

Annex 4. Further information on the pesticide active ingredient(s)

The content of this annex should be based on the information specified by Annex IV of the Convention, which has been available to the CRC. Some generic information may also be taken from international reviews such as those of WHO/IPCS/JMPR/IARC, where available and considered relevant.

Purpose: To provide an overall summary of information on the **pesticide active ingredient**, including physico-chemical, toxicological and ecotoxicological properties.
Whenever such information was available to the CRC that reviewed the proposal, data on the **formulation** should be added, as a separate section of this annex.

The decision guidance document is not intended to be a scientific treatise on a chemical. The emphasis should be on the concerns that related to the incident reports. For example, if the incidents are related to

occupational exposure, this annex section should focus on human health effects rather than environmental aspects.

Annex IV may follow a similar structure as annex I of the DGDs in accordance with article 5 of the Rotterdam Convention, focusing on hazard information of the substance.

References should be given for the individual end points / sections.

Annex 5. References

This annex should include 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.

Examples: British Crop Production Council (2009_2010). E-Pesticide Manual, Version 5.0.1, 2010, 15th edition.

IPCS (2009) International Programme on Chemical Safety, Poisons Information Monograph 399, Paraquat. Available at http://www.inchem.org/documents/pims/chemical/pim399.htm

WHO, 2010. The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2009. Available at: http://www.who.int/ipcs/publications/pesticides_hazard/en/

A full set of the information regarding [*name of formulation*] that was available to the *XXX*th Session of the Chemical Review Committee may be found in the following documents which are available on the Rotterdam Convention Website www.pic.int:

UNEP/FAO/RC/CRCX/1

UNEP/FAO/RC/CRCX/1.Add1

Appendix. Standard core set of abbreviations[2]

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
µm	micrometre
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
cc	cubic centimetre
cm	centimetre
DNA	deoxyribose nucleic acid
DT_{50}	dissipation time 50%
EC	European Community
EC_{50}	median effective concentration
ED_{50}	median effective dose
EEC	European Economic Community
EHC	Environmental Health Criteria
EU	European Union
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}	median inhibitory concentration
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
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)

[2] This core list should serve as the basis for DGDs for industrial chemicals, pesticides and severely hazardous pesticide formulations. It should be augmented by abbreviations used in the individual DGDs relevant to the chemical(s) in question.

Definitions and spelling should, as far as practicable, follow the IUPAC glossary of terms in toxicology and the IUPAC glossary of terms relating to pesticides in their current editions. 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.

STANDARD CORE SET OF ABBREVIATIONS	
k	kilo- (x 1000)
kg	kilogram
Koc	soil organic partition coefficient.
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	Lowest-observed-effect level
m	metre
m.p.	melting point
mg	milligram
ml	millilitre
mPa	millipascal
MRL	maximum residue limit
MTD	Maximum Tolerated Dose
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
Pow	octanol-water partition coefficient, also referred to as Kow
PPE	personal protective equipment
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	standard(ized) mortality ratio
STEL	short-term exposure limit
TER	toxicity exposure ratio
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
w/w	weight for weight
WHO	World Health Organization
wt	weight

1.4 Process for determining evidence of ongoing international trade

Reference: UNEP/FAO/RC/CRC.1/28, annex III

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.

1.5 Common and recognized patterns of use of severely hazardous pesticide formulations

Reference: UNEP/FAO/RC/CRC.1/9

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.

Purpose

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.

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

Reference: UNEP/FAO/RC/CRC.2/6

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.

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 September) and the cut-off date for the eligibility of notifications for consideration by the CRC (15 May) 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 May – 8 weeks before cut-off for the submission of supporting documentation

(a) 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.

(b) 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.

(c) 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 July – 2 weeks before finalization of documents for the next meeting of the CRC

(a) Deadline for the submission of supporting documentation for candidate chemicals scheduled for review by the CRC.

(b) Focussed summaries and supporting documentation will be sent for translation as received if necessary.

(c) Commencement of initial assessment of the candidate chemicals scheduled for review by the CRC

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

(a) 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.

(b) 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 September – minimum 8 weeks before CRC meets

(a) All documents are sent to CRC members by courier and posted on the Convention website.

(b) CRC members are invited to form intersessional task groups on priority chemicals based on the recommendations contained in the report of the Bureau.

(c) 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).

1.7 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

Reference: UNEP/FAO/RC/CRC.7/3

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. This process called for the creation of Task Groups by the CRC that would work intersessionally to undertake a preliminary review of the chemicals scheduled for consideration by the CRC.

This document has been developed to guide the operation of intersessional Task Groups in the review of chemicals for which notifications of final regulatory actions to ban or severely restrict their use have been submitted by Parties in at least two PIC regions in line with Article 5 of the Convention. It briefly explains the role of the Task Groups, how they operate and the structure, content and level of detail needed in preparing a report of the outcome of their preliminary review to the full Committee.

This working paper was adopted by the CRC at its seventh session and will continue to evolve based on the experience gained.

Membership and composition of intersessional Task Groups

For each chemical scheduled for review by the CRC, an intersessional Task Group is established by the Secretariat in consultation with the Bureau. Task Groups consist of one to two coordinators and a representative group of members of the CRC. All members of the CRC are expected to participate in the work of at least one Task Group. Members may participate in as many Task Groups as they wish by simply informing the Task Group Coordinator(s) and the Secretariat of their interest.

Role of intersessional Task Groups

It is not feasible for the CRC to initiate a detailed review of each chemical in the time available at its annual meeting. The role of an intersessional Task Group is to undertake a preliminary review of the documentation available in support of the individual candidate chemicals in the light of the information requirements and criteria set out in Annexes I and II of the Convention respectively. The preliminary review by the Task Group is intended to facilitate the work of the Committee by ensuring that for each of the chemicals scheduled for consideration by the Committee a detailed review of the notifications and supporting documentation has been undertaken. The work of the intersessional Task Group does not replace the requirement for each of the candidate chemicals to be considered by the full Committee.

For each chemical a Task Group will prepare a report which includes their assessment of whether the individual notifications and supporting documentation meet the requirements of the Convention. It is essential that the report provides sufficient detail in order that the full Committee can understand the reasoning behind the conclusions of the Task Group with respect to the individual requirements. The analysis of the individual notifications as amended by the CRC will form part of the report of the meeting. In undertaking the preliminary review, the Task Group should consider the policy guidance and working procedures developed to guide the work of the CRC.

It should be noted that the work of Task Groups is not to initiate a debate on whether or not there is agreement with the national regulatory action, but rather whether the regulatory action meets the requirements set out in Annex I and the criteria set out in Annex II of the Convention. It is also not the aim of the Task Group to discuss whether or not there is agreement with the outcome of the risk evaluation performed by the notifying Party in support of the national decision.

Operation of intersessional Task Groups

Prior to a CRC meeting

Approximately two months prior to the CRC meeting the notifications and supporting documentation for all of the chemicals scheduled for review by the CRC are posted on the Rotterdam Convention website (www.pic.int). At the same time Task Groups are created.

Individual Task Group members are expected to review the notifications and supporting documentation in detail, complete the analysis table (a template[3] is provided by the Secretariat) with the required information and send the file to the Task Group Coordinator within two weeks upon receipt of the notifications and supporting documentation. The partly completed analysis table will serve as a means for each Task Group member to become familiar with the information in the notifications and supporting documentation. Task Group Coordinators are to prepare the first draft of the report of the preliminary review of a chemical and take the lead in initiating and mediating discussions among the Task Group members. All Task Group members are expected to contribute to the further development of the draft report of the preliminary review and to play a role in the discussions at the CRC meeting.

The Task Group Coordinator will circulate the draft report of the preliminary review to all Task Group members by e-mail for comment four weeks prior to the CRC meeting. Each Task Group member should review and provide comments on the draft report to the coordinator within 2 weeks. Communication among members of the Task Group during the intersessional period is critical. Most Task Group discussion take place by e-mail and conference calls are recommended, where possible. Task Group members should ensure that all other members in the group are copied on e-mail correspondence. Task Group Coordinators will finalize the draft report taking into account the inputs from Task Group members. The draft Task Group report will be posted on the Convention website (www.pic.int) two weeks before the CRC meeting. Comments from CRC members and observers will be collected by the Secretariat and made available at the Task Group meeting.

Members of the intersessional Task Groups will have the opportunity for a face to face meeting to review and finalise the draft report immediately prior to the CRC meeting. The Task Group meeting is open to all members and observers. The final report of the Task Group will be made available to the full Committee as a Conference Room Paper (CRP).

During the CRC meeting

Task Group members should be prepared to respond to any questions that may be raised by Committee members regarding the preliminary review of the chemical. Following consideration of the results of the Task Group reports, the Committee will discuss and decide whether the individual notifications meet the requirements of the Convention. Where the notification is found to meet the requirements of the Convention the analysis will be the basis for the rationale prepared by the CRC which will be annexed to the report of the meeting. Where there are two notifications from two PIC regions that meet the requirements of the Convention the Committee will prepare a recommendation to the COP to list the chemical in Annex III of the Convention along with the rationale supporting this recommendation.

Undertaking the preliminary review by an intersessional Task Group

It is recommended that the intersessional Task Group follow a two-step process in undertaking the preliminary review to facilitate the review and preparation of the draft report. The first step is to systematically review and organise the information available to the Committee for each chemical according to the criteria of Annex II of the Convention. The second is to prepare a detailed analysis of this information that addresses each of the criteria in Annex II of the Convention.

The analysis forms the main body of the Task Group report and should explain the basis for the Task Group conclusions as to whether the individual criteria of Annex II have been satisfied or not. The analysis should also highlight those areas that the Task Group considers need particular attention by the CRC.

Step 1 - Organize information

In order to facilitate a structured review of the information provided to Task Groups, an analysis table (a template is provided by the Secretariat) and brief guidance on its completion has been developed to assist in summarizing the information in the notifications and supporting documentation. The analysis table set out the individual elements for the information requirements and criteria contained in Annexes I and II of the Convention, respectively.

The analysis table is to be completed for each notification. The completed tables will serve as a means to locate in the supporting documentation specific information relevant to the individual elements of Annexes I and II. The completed tables will facilitate the preparation of the analysis by the Task Group Coordinators and its subsequent review by Task Group members and the full Committee.

Prior to completing the analysis tables, it is recommended that the Task Groups familiarise themselves with the associated guidance. The following are contained in the analysis table template:

Guidance for completing individual country templates: Guidance on how to complete the individual sections of the templates for each notification.

[3] These analysis table templates are designed to facilitate the work of the Task Groups to organize the information contained in the notifications and supporting documentation, but are not to take the place of Task Group reports or to be appended to the Task Group reports.

Summary report: A summary of the information provided in the individual notifications. This report is automatically generated from the information inserted in the templates prepared for each country's notification.

Country templates: Set out the individual elements of Annexes I and II of the Convention, completed templates facilitate the identification of where in the supporting documentation information relevant to the individual elements might be found.

Step 2 – Analysis of information available for individual notifications

Based on the information available to the Committee in the notifications and supporting documentation, the Task Group should, for each notification, establish whether or not the individual criteria of Annex II have been met. For each notification a detailed analysis, addressing the individual criteria in Annex II of the Convention should be prepared, that clearly states whether the information available is sufficient to satisfy these criteria, and if so, how. The analysis should explain the conclusions for the individual criteria in sufficient detail that members of the Task Group and of the full Committee can understand how the conclusion was reached.

Based on the information in the notification and supporting documentation, the analysis should thus include information such as:

(a) a review of the scope of the regulatory action, precise identity of the chemical(s) concerned, ban versus severe restriction, etc.;

(b) the reason for which the action was taken, including highlights of the supporting risk evaluation;

(c) a conclusion as to whether the notification meets the individual criteria in Annex II and the associated analysis that was the basis for this conclusion.

The systematic review and analysis of the information available to support individual notifications and preparation of a detailed analysis is the primary function of the intersessional Task Groups and is key to the successful operation of the CRC. Where a notification is determined by the Committee to meet the requirements of the Convention, the analysis will form the basis for the preparation of the rationale which will be included in the report of the meeting. Where there are two notifications from two PIC regions for the same chemical that are found to meet the requirements of the Convention and which the Committee decides to recommend to the Conference of the Parties that it be listed in Annex III the individual rationale will accompany the recommendation.

Task Group Reports

The Task Group report should include a cover page that sets out the names of the Task Group members, a list of the information available to the Task Group for each notification, a brief summary of the principal conclusions clearly stating which, if any, of the notifications meet the criteria of Annex II. It should also as appropriate highlight those elements in the notifications for which particular consideration/scrutiny by the Committee is recommended.

The main body of the report should consist of the detailed analysis outlining, for each notification, whether or not the criteria contained in Annex II of the Convention have been met. An overall conclusion as to whether or not to recommend inclusion of the chemical in Annex III of the Convention should be made.

The completed tables do not need to be annexed to the final version of the Task Group report as the text of the report summarizes the information and conclusions of the Task Group. An example of a completed Task Group report, which can also be used as an outline for a Task Group report, is provided in an annex to this document.

Annex to the guidance

Example of a completed Task Group report

Rotterdam Convention
CRCx Meeting: Geneva/Rome, dd/mm/yyyy
Report of the Task Group on Chemical X

Task Group members

(to be updated at Sunday pre-meeting)

Chair:

Members:

Observers:

Secretariat:

Information available to the Task Group

(List documents)

1. Introduction

Example:

Two notifications on Chemical X from Country 1 and Country 2 have been verified by the Secretariat as containing the information requirements of Annex I of the Rotterdam Convention. These two notifications underwent a preliminary review by the Secretariat and Bureau, who evaluated whether or not the notifications appeared to meet the requirements of the Convention. The notifications, supporting documentation and results of the preliminary review were made available to the Chemical Review Committee for their consideration (document UNEP/FAO/RC/CRCx/x).

The purpose of this report is to present the Task Group's analysis of the notifications and supporting documentation and to put forward recommendations for the consideration of the Committee.

The report contains an overall analysis, along with a recommendation to the Committee. The report draws its conclusions based on the information provided in the notifications of the two Parties, and an analysis of the compatibility of each notification with the requirements of Annex I and the criteria of Annex II.

2. Analysis of the notification from Country 1

(to be prepared for each individual notification)

2.1 Scope of the notified regulatory action

Example:

The notified regulatory action relates to chemical X and the pesticidal use of the chemical as XXX. The decision made was to severely restrict the uses of chemical X.

The notification was found to comply with the information requirements of Annex I.

The following table and analysis sets out how the notification from country 1 meets the criteria of Annex II (see annex for cross reference to detailed information in the notification and supporting documentation).

Criteria	***Country 1***
(a)	*Met/Not Met**
*(b)***	*Met/Not Met*
(b)(i)	*Met/Not Met*
(b)(ii)	*Met/Not Met*
(b)(iii)	*Met/Not Met*
(c)(i)	*Met/Not Met*
(c)(ii)	*Met/Not Met*
(c)(iii)	*Met/Not Met*
(c)(iv)	*Met/Not Met*
(d)	*Met/Not Met*

** insert "no agreement" if no agreement within the task group has been reached*

*** this extra line has been inserted to indicate whether the entire criterion (b) has been met. The whole criterion has only been met if all of the sub-criteria have been met.*

2.2 Compatibility with the criteria of Annex II (a)

Example:

The regulatory action was taken to protect human health and the environment. Chemical X has been used as XXX. The notification describes the specific risks and outlines that a severe restriction of Chemical X use significantly reduces the exposure of aquatic organisms. ***(include reference to where the information is contained in the notification and/or supporting documentation)***

2.3 Compatibility with the criteria of Annex II (b)

In this section, the report needs to outline the information used to establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation must be based on a review of scientific data in the context of the conditions prevailing in the Party in question. The documentation provided must demonstrate that this is the case and information should be included in the report.

For each of the headings below, please state whether the information available is sufficient to satisfy the criteria and provide the reasoning for how this conclusion was reached, including references to the relevant information in the notification and/or supporting documentation.

i) Data had been generated according to scientifically recognized methods

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

Example of i) and ii):

Country 1 undertook research studies prior to the regulatory action and published the results in an internationally peer reviewed scientific journal: Review of the Persistence, Bioaccumulation, and Toxicity of Country X in Aquatic environments in relation to Country 1's toxic substances management policy, (Reference: R. James Maguire, Water Qual. Res. J. Canada, 2000, volume 35 (4), 633-679. See table 5, page 662, for a list of studies that were undertaken.) A detailed review conducted by the government of country 1 concluded that chemical X is extremely toxic to aquatic organisms, and is sufficiently persistent and bioaccumulative to warrant virtual elimination from the environment in the country.

iii) Final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action

Example:

The exposure was based on measured concentrations of chemical X in seawater in country 1. Chemical X compounds were reported to partition the aquatic environment, being more persistent in sediment than in water. Seawater and sediment samples taken in 1994 exceeded acute and chronic toxicity, and chronic toxicity thresholds, respectively. In marine sediments, chemical X was found more frequent in 1994 than a decade earlier, despite initial regulatory control actions taken. Due to the chemical characteristics of long persistence in sediment, chemical X concentrations in marine sediments are expected to exceed chronic toxicity thresholds for years to come.

The risk evaluation took into account these exposure data and the ecotoxicological endpoints for Chemical X and the result was an unacceptable risk to aquatic organisms as fish, molluscs and other invertebrates. High concentrations of chemical X in sediments caused high frequency of imposex (imposition of male characteristics on female organisms) on molluscs.

Accordingly, the risk evaluation clearly took into account the conditions prevailing in country 1 and it is concluded that criterion Annex II (b) has been met.

2.4 Compatibility with the criteria of Annex II (c)

Consider whether the final regulatory action provides a sufficiently broad basis to merit the 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

Example:

The final regulatory action prohibited uses of chemical X as antifouling paints for ships which was the main use of chemical X, therefore led to a significant decrease in the quantity of the chemical use, while the use of chemical X in material and wood preservatives remain allowed and do not reflect a major use pattern in country 1 compared to use in antifouling paints (Reference: Focused summary; Introduction, paragraph b, last sentence).

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

Example:

It is expected that since the regulatory action will remove this source of chemical X to the aquatic environment, this led to a significant reduction of risk to the environment. Although persistence in the marine environment at some locations will maintain elevated levels for some time, removing this source of input will allow recovery to occur (Reference: Page 7 of notification, last paragraph of 2.4.2).

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

Example:

Chemical X in antifouling paints used on ship hulls could cause risk in the aquatic environment wherever such ship may travel, and therefore the relevance of the final regulatory action is not limited to country 1. (reference)

iv) Whether there is evidence of ongoing international trade in the chemical (this information may be found in the notification or obtained, when available, through the Secretariat)

Example:

There is evidence of ongoing international trade, country 1 had provided estimated quantity of the chemical imported and exported.

Accordingly there is sufficient information to conclude that criterion Annex II c has been met.

2.5 Compatibility with the criteria of Annex II (d)

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

(If yes, reference should be provided)

Example:

There is no indication in the notification that concerns for intentional misuse prompted the regulatory action.

3. Analysis of the notification from Country 2

(to be prepared with the same information as provided above for Country 1)

4. Conclusion

Example:

The task group concluded that the notification of final regulatory action of country 1 met the information requirements of Annex I and the criteria set out in Annex II of the Convention.

The task group also concluded that the notification of final regulatory action of country 2 met the information requirements of Annex I and the criteria set out in Annex II of the Convention.

5. Recommendation

Example:

Consequently, the Task Group recommends that the Chemical Review Committee conclude that the above discussed notifications from country 1 and 2 have met the criteria set out in Annex I and Annex II of the Convention.

6. Points to be considered by the CRC

(This section should highlight those elements in the notifications for which particular consideration or scrutiny by the Committee is recommended, as appropriate)

Example:

The task group noted that three compounds of chemical X were referenced in the notification from country 1, while that from country 2 referenced seven compounds.

2 Policy guidance

2.1 Preparation and use of focused summaries

Reference: UNEP/FAO/RC/CRC.1/28, annex IV

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.

A. Purpose of focused summaries

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.

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.

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.

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

1. Introduction

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.

2. Risk evaluation

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

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

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 relevan:

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

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:

(i) Human exposure assessment

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).

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.

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

a. 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.

b. High-volume and low-volume boom-spraying on flowers, tomatoes, French beans and maize are not supported as the risk is unacceptable.

c. Ground-spraying on broadacre crops is not supported as the risk is unacceptable.

d. Aerial spraying is the only application method which was supported because of the comparatively minimal likely exposure to users.

(ii) Environmental exposure assessment

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

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.

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.

2.2 Bridging Information

Reference: UNEP/FAO/RC/CRC.3/4

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.

Introduction

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.

1. 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.

2. 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.

3. 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.

4. 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.

5. 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

6. 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:

a. Liquid, powdered, granular and so on;

b. 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:

a. Type of use (agricultural pesticide, non-agricultural pesticide, use as disinfectants, vector control, wood preservatives)

b. Rate, frequency and period of application

c. Method of application (spray, drip, dip)

d. Application equipment (back pack sprayer, air blast sprayer etc.)

e. Greenhouse, field application, post-harvest, other

f. 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:

a. Requirement for protective clothing, whether it is typically available and/or feasible in the country reporting the regulatory action

b. Special application equipment, whether it is typically available and/or feasible in the country reporting the regulatory action

c. Occupational exposure limit.

7. 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:

a. Liquid, powdered, granular, etc.

b. 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:

a. Rate and frequency of application

b. Method of application (spray, drip, dip, etc.)

c. Application equipment (back pack sprayer, air blast sprayer, etc.)

d. 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:

a. 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

8. 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:

(a) Workers

(b) General population

(c) End users

(d) Others (for example specific subgroups of the population such as children, pregnant women or the elderly)

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

(a) Soil, air, water

(b) Habitat

(c) Wildlife.

10. 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.

11. 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:

(i) Formulation type (where appropriate)

(ii) Concentration of the chemical

(iii) Contaminants.

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

(i) What are the key factors affecting release?

a. Open or closed

b. Waste water treatment (if relevant)

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

a. Exposure limits

b. 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?

12. 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, e.g. by using models.

(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.

2.3 Contaminants

Reference: UNEP/FAO/RC/CRC.1/12

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

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).

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).

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.

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.

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

Reference: working paper on the application of criterion (d) of Annex II : UNEP/FAO/RC/COP.3/7, annex IV; legal opinion: UNEP/FAO/RC/CRC.3/INF/7; supplementary legal opinion: UNEP/FAO/RC/CRC.6/10 and Corr.1

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.

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 was made available to the Committee in document UNEP/FAO/RC/CRC.3/INF/7.

Subsequently, at its fourth meeting, the Conference of the Parties, by its decision RC-4/6, requested parties and interested observers to provide to the Secretariat their considered views on the application of criterion (d) and requested the Secretariat to provide those views to the United Nations Environment Programme legal office for it to review its previous advice to the Chemical Review Committee contained in document UNEP/FAO/RC/CRC.3/INF/7 regarding clarification of the meaning of the term "intentional misuse" and the application of criterion (d), and to provide further advice, when completed, to the Chemical Review Committee.

Consequently, the UNEP legal office, having received from the Secretariat the views submitted by a number of Parties and interested observers on this matter in accordance with the decision, reviewed its previous legal opinion provided to the CRC at its third meeting. On the basis of this review, the UNEP legal office concluded that its legal opinion provided to the CRC at its third meeting should be maintained, but it might be necessary to further clarify certain issues which provided the underlining basis to form the previous legal opinion but might not be explicit. The supplementary legal opinion should be read together with the previous legal opinion. It does not supersede or replace the previous legal opinion, but merely to complement it. The supplementary legal opinion produced by the UNEP legal office pursuant to that request was submitted to the Chemical Review Committee at its sixth meeting in documents UNEP/FAO/RC/CRC.6/10 and Corr.1.

Both the original and supplementary legal opinions, as submitted to the Committee at its third and sixth meetings, respectively, have been reproduced in the annex to this working paper.

Introduction

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" would usually be consistent with 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.

Annex to the working paper

Legal opinion on intentional misuse and the application of criterion (d) of Annex II

Legal opinion on intentional misuse, as submitted to the Chemical Review Committee at its third meeting (UNEP/FAO/RC/CRC.3/INF/7)

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:

(a) 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.

(b) 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"**:

(a) 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

(b) 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) 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:

(a) 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

(b) 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:

(a) 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

(b) 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).

Supplementary legal opinion concerning the clarification of the meaning of "intentional misuse" and the application of criterion (d) in Annex II of the Convention, as submitted to the Chemical Review Committee at its sixth meeting (UNEP/FAO/RC/CRC.6/10 and Corr.1)

A. Basis for interpretation

1. The Vienna Convention on the Law of Treaties codifies internationally recognized norms and practices regarding treaties which are applicable to the Rotterdam Convention. The Vienna Convention, in Articles 31, sets out general rule of interpretation. In accordance with its paragraph 1 "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose." As specified in its paragraph 2, the context for the purpose of the interpretation of a treaty shall comprise the text, including its preamble and annexes, and also any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty as well as any instrument which was made by one or more parties in connexion with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty. Together with the context, in accordance with its paragraph 3, the following must be taken into account: any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; any relevant rules of international law applicable in the relations between the parties. In accordance with its paragraph 4, "[a] special meaning shall be given to a term if it is established that the parties so intended." Furthermore, the Vienna Convention, in its Article 32, envisages supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31 leaves the meaning ambiguous or obscure or leads to a result which is manifestly absurd or unreasonable.

B. Objective of the Rotterdam Convention

2. As stated in its Article 1, the objective of the Rotterdam Convention is "to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision making process on their import and export and by disseminating these decisions to Parties."

3. In concluding the Rotterdam Convention, as stated in its preamble, the Parties are "[a]ware of the harmful impact on human health and the environment from certain hazardous chemicals and pesticides in international trade," and "[d]etermined to protect human health, including the health of consumers and workers, and the environment against potentially harmful impacts from certain hazardous chemicals and pesticides in international trade."

4. The above objective and the fundamental intent of the Parties to protect human health and the environment from potential harm of certain hazardous chemicals and pesticides in international trade provide the foundation upon which the provisions of the Convention as contained in its various articles and annexes ought to be understood and interpreted.

C. Circumstances and particular requirements of developing countries and countries with economies in transition

5. In concluding the Rotterdam Convention, the Parties, as stated in the preamble, took into account "the circumstances and particular requirements of developing countries and countries with economies in transition, in particular the need to strengthen national capabilities and capacities for the management of chemicals, including transfer of technology, providing financial and technical assistance and promoting cooperation among the Parties". In addition to the specific provisions to address problems and special needs of developing countries and countries with economies in transition, such as the procedures governing severely hazardous pesticide formulation (Article 6) and technical assistance (Article 16) , the circumstances and particular requirements of developing countries and countries with economies in transition need to be taken into account in the application of the provisions contained in the text and annexes of the Convention, where relevant.

6. In this context, the CRC, when it considers the final regulatory action notified by Parties in accordance with criteria set out in Annex II, is required to give consideration to the circumstances and particular requirements of developing countries and countries with economies in transition, including when it considers the conditions prevailing in the Party in question in connection with its action required under Annex II. This might have direct bearing on

consideration of what might constitute "use" or "misuse" or "intentional misuse", and the application of the criterion contained in paragraph (d) of Annex II. As stated in the previous legal opinion, 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 in a developing country or country with economies in transition, if the person believes that he/she is using the chemical in a manner as designed for its use due to its common use in his/her community, 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, or simply believes that common use of a chemical in his/her community is legitimate use because of illiteracy or lack of understandable means for communicating the legitimate use.

D. Application of criteria in Annex II

7. 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. These actions are to: (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; and (c) consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III. In accordance with criterion (d), the CRC is to take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III. The CRC, while considering those criteria, is required to bear in mind the objective and the fundamental intent of the Parties to protect human health and the environment from potential harm of certain hazardous chemicals in international trade.

8. It should be noted that the criteria contained in paragraphs (a), (b) and (c) require the CRC to confirm, establish or consider relevant facts with regard to the final regulatory action notified by Parties. On the other hand, the criterion contained in paragraph (d) requires the CRC to remain conscious of the condition that intentional misuse is not in itself an adequate reason to list a chemical in Annex III. Given the text of Annex II, and by reading it in ordinary meaning to the respective terms in this context, and in light of the objective of the Convention, and subject to the meaning of "use" of a chemical for its purpose, in the event where the criteria under paragraphs (a), (b) and (c) are met, it appears that the criterion contained in paragraph (d) cease to take effect. On the other hand, where those criteria in paragraphs (a), (b) and (c) are not met, and the only the reason for the final regulatory action in question is "intentional misuse" as such, the criterion in paragraph (d) would take effect. With this background, the previous legal opinion stated as follows:

> "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."

9. Furthermore, in considering the above, it should be recalled that as defined in Article 2, the Convention refers to the categories of use of a chemical consisting of pesticide (including severely hazardous pesticides formulation) and industrial. Therefore, where provisions of the Convention refer to "use" of a chemical, it should be understood to mean either the use of the chemical as a pesticide or an industrial chemical. Given this overall context, for the purpose of the Convention:

(a) "misuse" referred to in paragraph (d) of Annex II is understood to mean a use not as pesticide or industrial chemical;

(b) a chemical used as a pesticide or industrial chemical should not be considered to constitute "misuse".

2.5 Working paper on the application of criteria (b) of Annex II

Reference: UNEP/FAO/RC/CRC.8/10

The purpose of this paper is to assist the Chemical Review Committee (CRC) in judging whether a notification of final regulatory action meets criteria (b) of Annex II of the Convention.

Introduction

Annex II of the Convention sets out the criteria for listing banned or severely restricted chemicals in Annex III of the Convention. Paragraph (b) 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 notification of final regulatory action and supporting documentation are to be reviewed by the Committee.

This working paper was originally developed by the Committee at its first meeting. The guidance was amended to include further examples based on the experience gained at subsequent 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.

This most recent version was adopted by the eighth session of the CRC with the understanding that it would continue to evolve in the light of future experience.

The present working paper is divided into three chapters:

(a) Chapter I – background - outlines 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.

(b) Chapter II - application of criteria (b) (i) and (b) (ii) - provides guidance aimed at improving consistency in applying criteria (b) (i) and (b) (ii) in the analysis of the notifications.

(c) Chapter III - application of criterion (b) (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.

Chapter I - Background

1. 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 notifications of final regulatory action are submitted using a form which was developed in order to provide a standardized format for reporting national final regulatory actions. The form is based on the information requirements of Annex I.

2. In order to decide whether a chemical can be recommended for inclusion in Annex III, the Committee reviews the information contained in the notification of final regulatory action and accompanying supporting documentation in the light of the criteria in Annex II of the Convention.,

3. 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.

4. Under the Rotterdam Convention, it is generally agreed that a risk evaluation is neither hazard assessment nor risk assessment but something in between (UNEP/FAO/RC/CRC1/13). Risk evaluation comprises information on hazard and exposure. This means that risk evaluation is an evaluation of intrinsic toxicological and ecotoxicological properties and actual or expected relevant exposure, which may include information on actual incidents. In notifications of final regulatory actions to ban or severely restrict a chemical:

(a) Information on hazard is generally based on internationally accepted toxicological or ecotoxicological data, which are considered not to be area-/ country-/ location-specific;

(b) Information on exposure is to be related to the prevailing conditions of use in the notifying Party.

5. Therefore, the Committee is to establish that a risk evaluation considering the conditions in the Party has been undertaken and has resulted in the final regulatory action that has been notified. The Committee considers each of the three criteria in paragraph (b) one by one with regard to how the information provided in the notification and supporting documentation demonstrates that all criteria ((b) (i), (b) (ii) and (b) (iii)) are met.

6. This stepwise approach should assist the Committee in analysing the information provided by the notifying Party in order to reach an overall conclusion as to whether the entire criterion (b) is met. This can only be the case if all sub-criteria have been met.

Chapter II - Application of criteria (b) (i) and (b) (ii) of Annex II

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

8. 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 ecotoxicological properties.

9. In submitted notifications, this includes lists of physico-chemical parameters such as melting and boiling points or lists of toxicological or ecotoxicological endpoints including LD_{50} and LC_{50} data for a range of laboratory animals, birds and fish. In many countries this information is not generated nationally, but may be found in a range of internationally recognized sources.[4] Information referenced from such sources is considered to have met criteria (b) (i) and (b) (ii) for information set out in Paragraph 1 of Annex I.

10. At its third meeting, the Conference of the Parties endorsed the approach recommended by the Secretariat, 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), as long as the Committee can establish that a risk evaluation considering the conditions in the Party has been undertaken.[5]

11. 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.

12. 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 information on hazard from internationally recognized reference sources as well as information on actual or anticipated/estimated exposure under the prevailing conditions in the notifying country.

13. In order to establish whether criteria (b) (i) and (b) (ii) of Annex II have been completely met, information on hazard as well as on exposure should be considered.

14. Information on hazard 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 been generated according to scientifically recognized methods and data reviews have been performed and documented according to generally recognized scientific principles and procedures. Information on exposure relevant to prevailing conditions in

[4] 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), Draft Assessment Reports from the EU as well as data from decision-guidance documents. More detailed data may be found in internationally recognized data bases (EU, EPA, IUPAC, IUCLID, etc.).

[5] Paragraph 66 of UNEP/FAO/RC/COP.3/26

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.

15. 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 for information on hazard and exposure 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 (b) (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 were 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 (b) (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 Convention or the Montreal Protocol. Other documents, such as national or regional assessments, would need to be examined on a case-by-case basis.

- Criteria (b) (i) and (ii) would only be met if the CRC could verify that the data referenced were reviewed in the context of the conditions prevailing in the notifying Party.

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.
- Criteria (b) (i) and (ii) would only be met if the CRC could establish on a case-by-case basis whether the data provided were reviewed in the context of the conditions prevailing in the notifying Party.

Chapter III - Application of criterion (b) (iii)

16. 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[6]. 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.

17. 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.[7]

18. 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.

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

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

19. 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.

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

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 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 use of models, *e. g.* to calculate anticipated exposure levels of humans and/or the environment, is an internationally recognized scientific practice, which is frequently applied as part of risk evaluations.

For acutely toxic pesticides or industrial chemicals, the description of the prevailing conditions in the notifying country 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.

The guidance that has been developed on common and recognized patterns of use of severely hazardous pesticide formulations (UNEP/FAO/RC/CRC. 6/INF/3) may also be relevant to certain elements of expected or anticipated exposure.

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, paragraph 10).

   a. 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. Consequently, the Chemical Review Committee at its first session decided that 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 Union.

(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, paragraphs 25-26).

   a. 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 1b, 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 risk as a

consequence of the use of the chemical in the notifying country may be sufficient. Data on actual, measured exposure "field measurements" in the notifying country are not mandatory.

a. Specific example to be identified

(iv) Use of risk evaluations from other countries or international bodies together with bridging information on anticipated exposure in the notifying country. An example is the Jamaican notification for aldicarb (UNEP/FAO/RC/CRC.4/10).

a. Jamaica carried out a risk evaluation using results of studies conducted by the United States and the International Programme on Chemical Safety (IPCS) to compare the worker exposure and leaching conditions with the conditions of use in Jamaica. This evaluation in Jamaica considered oral, dermal and inhalation toxicity for rats, rabbit and birds and WHO classification. Studies showed that the use of the product without protective clothing presented risks to farmers. Small-scale farmers in Jamaica do not have access to protective clothing as confirmed through a survey conducted in Jamaica. Furthermore, the hot tropical climatic conditions make wearing protective clothing uncomfortable. Therefore, the risks for small-scale farmers in Jamaica were considered unacceptable.

b. Leaching of aldicarb to ground water was considered possible in Jamaica due to its solubility in water and the presence of underground rivers in limestone areas across Jamaica where much of the farming is done. The risk evaluation considered the conditions under which water was contaminated by aldicarb in the United States and found that the same could occur in limestone areas in Jamaica. Even with the application of strong enforcement measures under conditions that were less susceptible to pollution than island ecologies like Jamaica, this did not prevent water contamination in the United States. The evaluation concluded that adults and children might be exposed to high levels of aldicarb due to water pollution combined with contamination of food.

c. The Chemical Review Committee at its fourth session concluded that the supporting documentation showed that the final regulatory action had been based on a risk evaluation involving the prevailing conditions of exposure within Jamaica.

(v) A risk evaluation has been made, but no consensus could be reached that prevailing conditions in the notifying country have been adequately taken into consideration. A case example is the notification for paraquat from Sweden (CRC.5/8 and addenda; CRC.6/9, Add. 1-4)

a. Prior to the decision to ban paraquat in 1982, Sweden undertook a risk evaluation based on a dossier on the toxicological profile of paraquat, which also contained information on poisoning cases worldwide. The regulatory authority had concluded that mechanical failure of spraying equipment or protective clothing could lead to excessive and potentially fatal exposure of workers. Since no antidote or remedial cure exits, the risk was considered unacceptable. Environmental concerns (persistence in soil) were mentioned as an additional reason for the ban.

b. However, no bridging information between the worldwide poisoning cases and the conditions in Sweden had been provided. The Chemical Review Committee at its sixth session thus concluded that criterion (b) of Annex II had not been met.

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, paragraph 3).

a. 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 Chemical Review Committee at its

first session 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, paragraph 3).

a. The Chemical Review Committee confirmed at its second session that Thailand had severely restricted endosulfan, as commonly used in Thailand, by banning emulsifiable 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 also 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. The use of models, *e. g.* to calculate anticipated exposure levels of humans and/or the environment, is an internationally recognized scientific practice, which is frequently applied as part of risk evaluations.

For both pesticides and industrial chemicals, the description of the prevailing conditions in the notifying country could include information on 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.6/INF/3) may be relevant to certain elements of expected or anticipated exposure.

Examples

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

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

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. Consequently, the Chemical Review Committee decided at its first session that the EC 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 Union.

b. Endosulfan - Netherlands notification (UNEP/FAC/RC/CRC.2/20 annex II, paragraph 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 LC_{50} for fish (0.00017 mg/l) results in a risk quotient of 82, which was considered unacceptable.

c. Dicofol – Netherlands notification (UNEP/FAO/RC/CRC.2/20 annex III, paragraphs 1 and 2)

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 were 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 was deemed unacceptable. 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. Therefore, the Chemical Review Committee agreed at its second session that 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.

d. Azinphos methyl – Norway notification (UNEP/FAO/RC/CRC.6/16, annex II, paragraphs 8-11)

The notification from Norway demonstrated that the final regulatory action had been based on a comparison of ecotoxicological endpoints (no observed effect concentrations (NOECs) for fish and other aquatic organisms, derived from ecotoxicological tests and a microcosm study) with predicted environmental concentrations (PECs) in surface water. These PECs were determined using a standard calculation method taking into account the application rate in Norway, as well as a 30 meter buffer zone. The PEC thus calculated was 1.53 µg/L. When this was compared to the NOEC of 0.32 µg/L established from the microcosm study, the ratio of 5 indicated that the predicted concentration in surface water is 5 times higher than an acceptable concentration for the protection of aquatic species and was thus deemed unacceptable. This conclusion was also supported by actual concentrations from a monitoring programme in Norway, in which the detected concentrations in surface water were twice as high as the acceptable concentration for the protection of aquatic species. The Chemical Review Committee agreed at its sixth session that the notification from Norway met all the criteria in Annex II to the Convention

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).

a. Endosulfan – Jordan notification (UNEP/FAO/PIC/ICRC5/15, paragraphs 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[8] 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:

a. 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. At its second session, the Chemical Review Committee concluded that the final regulatory action had been based on chemical-specific risk evaluations, taking into account the conditions of exposure within Canada.

(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

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

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-B. There may also be effects on terrestrial plants, aquatic ecosystems and climate.

A case example includes the following:

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

(b) Canada banned carbon tetrachloride based on a conclusion that it had 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).

(c) *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.

(d) Specific example to be identified.