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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Second meeting
Geneva, 13–17 February 2006
Item 4 of the provisional agenda*
Operational procedures for the Chemical Review Committee

Working procedures and policy guidance for the Chemical Review Committee

Note by the secretariat

1. At its 1st meeting in February 2005, the Chemical Review Committee adopted a number of working papers on policy guidance and working procedures covering a broad range of issues related to the work of the Committee. Subsequently, at its second meeting, from 27–30 September 2005, the Conference of the Parties adopted decision RC-2/2 on the process for drafting decision-guidance documents and took note of the working papers on the preparation and use of focused summaries and on the process for determining ongoing trade in chemicals.

2. Those documents are intended to facilitate the work of the Committee and help ensure consistency and transparency. They will be revised, if necessary, in the light of experience. They were originally developed during the interim prior informed consent procedure.

3. The annex to the present note contains the working procedures and policy guidance documents for the Chemical Review Committee. They have not been formally edited.

* UNEP/FAO/RC/CRC.2/1.

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Annex

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Working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals - Adopted by CRC1

Working procedure: process for drafting decision-guidance documents and accompanying explanatory notes

A. Process for drafting decision-guidance documents

Flow chart

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

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

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

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

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

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

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

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

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

UNEP/FAO/CRC1/ working procedures: preparing internal proposals and DGD for BSRC

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* Numbers refer to steps in the flow chart.

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

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

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

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

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

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

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

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

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

* Numbers refer to steps in the flow chart.

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

Introduction/Purpose

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

This working paper is intended:

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

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

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

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

General guidance

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

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

A standard list of "core" ***abbreviations*** have been prepared based on experience in drafting decision guidance documents to date. It is intended that this core list serve as the basis for decision guidance documents for both industrial chemicals and pesticides and that it be augmented by abbreviations used in the individual decision guidance documents relevant to the chemical(s) in question. This core list of abbreviations is appended to this working paper (appendix 1). As a general rule it is preferable that acronyms used only once in the text be spelled out rather than included in the list of abbreviations.

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

Working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals - Adopted by CRC1

1. Identification and uses

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

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

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

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

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

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

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

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

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

2. Reasons for inclusion in the PIC procedure

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

- References to any previous *listing(s)* under the PIC procedure should also be included, where relevant.
- For dual-use chemicals, it will also be important to note when the PIC obligations do not apply to the use category that was not regulated.

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

List notifying countries alphabetically.

2.1 Final regulatory action

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

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

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

2.2 Risk evaluation

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

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

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

3. Protective measures that have been applied concerning the chemical

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

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

3.1 Regulatory measures to reduce exposure

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

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

3.2 Other measures to reduce exposure

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

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

Working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals - Adopted by CRC1

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

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

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

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

3.3 Alternatives

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

It is not be feasible for the decision guidance document to contain a comprehensive list of specific pest crop complexes and recommended pesticides or non-chemical alternatives, particularly for pesticides that have a broad spectrum of activity. As the available alternatives are constantly evolving, identifying sources of information is likely to be more useful and more reliable than a list of specific recommendations.

- Notifying countries may provide information about chemical and non-chemical alternatives that are being used within their jurisdictions. Detailed information can be included in annex 2.
- Information from sources other than the notifying country might be referenced here with details on where the information might be found provided to DNAs through the PIC Circular and the Rotterdam Convention website (see following note)

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

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

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

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

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

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

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

3.4 Social and economic effects

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

Note: Most countries do not undertake rigorous social and economic studies that are relevant beyond their own jurisdictions, but they may provide information on alternatives when a country took an action to restrict a chemical.

This information is optional. When reported, there will need to be a caveat that countries consider the results of this information in the context of their own national conditions.

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

4.1 Hazard Classification

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

- This section should focus on internationally recognized standards such as IARC, WHO/IPCS classification systems.
- The US EPA and European Community classification systems have been included as they are widely used by many countries as a reference.
- All references should include the date when they were established.

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

An example of the classifications is provided:

Hazards and risks to human health and/or the environment	
IARC	
European Community	

4.2 Exposure limits

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

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

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

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

4.3 Packaging and labelling

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

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

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

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

4.4 First aid

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

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

Notes: For chemicals that are not acutely toxic, this section may not be relevant and could be completed with the statement "*not applicable to this chemical*"

Recognizing that a range of first-aid treatments may be available, this section should include a generic statement on the need for caution and should remind parties of the need to ensure that this information is in compliance with any national standards that may exist.

4.5 Waste management

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

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

Annex 1

Further information on the chemical

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

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

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

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

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

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

General comments

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

The level of detail will be a function of the information that is available and will need to be determined on a case-by-case basis. As a guiding principle, however, the focus should be on those end points that were the basis for the risk evaluation underlying the notified final regulatory action. For example, in those instances where a chemical was found to be a reproductive toxin and this was the basis for the regulatory action, greater detail would be expected on the supporting studies e.g. NOEL/NOAEL/LOEL, than on end points for which the results may have been negative (i.e., simply stating “was not carcinogenic”). In the case of universally recognized regulatory guidelines or limits such as the acceptable daily intake (ADI) or acute reference dose (ARfD), details on the supporting studies on which they are based should be included.

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

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

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

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

Where information from an international evaluation such as an IPCS Environmental Health Criteria document is included, the reference in the text should be to this document, rather than to the individual articles quoted therein.

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

1. Physico-chemical properties

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

2. Toxicological properties

2.2 Toxicity studies

This section lays out the toxicological profile of the chemical as assessed by the notifying countries at the time of their final regulatory actions(s). It should also include a comparative summary of any IPCS/WHO international evaluations, such as those of WHO/ IPCS/JMPR, where they are available and considered relevant. This summary should be included in section 2.2.7 Summary of mammalian toxicity and overall evaluation.

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

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

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

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

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

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

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

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

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

5. Environmental exposure/risk evaluation

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

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

Annex 2 Details on final regulatory actions reported

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

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

Annex 3 Addresses of designated national authorities

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

Annex 4 References

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

List References under headings as appropriate:

Regulatory actions

Documents used in risk evaluation

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

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

Documents used for accident reporting and poison management

Appendix I. Standard Core Set of Abbreviations

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
µg	Microgram
µm	Micrometre
ArfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
ADP	adenosine diphosphate
ATP	adenosine triphosphate
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CA	Chemicals Association
cc	Cubic centimetre
CHO	Chinese hamster ovary
cm	centimetre
DNA	Deoxyribose Nucleic Acid
E.C.	European Community
EC_{50}	Effect concentration, 50%
ED_{50}	Effect dose, 50%
EEC	European Economic Community
EHC	Environmental Health Criteria
FAO	Food and Agriculture Organization of the United Nations
g	Gram
h	hour
ha	Hectare
i.m.	intramuscular
i.p.	intraperitoneal
IARC	international Agency for Research on Cancer
IC_{50}	inhibition concentration, 50%;
ILO	international Labour Organisation
IPCS	international Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	Kilo- (x 1000)
kg	Kilogram
Koc	organic carbon-water partition coefficient
l	Litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LD_{LO}	lowest lethal dose
LOEL	lowest observed effect level
m	Metre
m.p.	melting point
mg	Milligram
ml	Millilitre
mPa	MilliPascal
MTD	maximum tolerated dose
ng	Nanogram
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
PCM	Phase contrast microscopy
Pow	octanol-water partition coefficient
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other

STANDARD CORE SET OF ABBREVIATIONS	
	contexts the terms mg/kg or mg/l are used).
RfD	reference dose for chronic oral exposure (comparable to ADI)
SMR	standardized mortality ratio
STEL	short term exposure limit
TLV	threshold limit value
TWA	time weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	Ultraviolet
VOC	volatile organic compound
WHO	World Health Organization
wt	Weight

Appendix 2

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

1. Physico-chemical properties

2. Toxicological properties

2.1. General

2.1.1. Mode of action

2.1.2. Symptoms of poisoning

2.1.3. Absorption, distribution, excretion and metabolism in mammals

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

2.2 Toxicology studies

2.2.1 Acute toxicity

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

2.3.2 Short term toxicity

- Target/critical effect
- Oral
- Dermal
- Inhalation

2.2.3 Genotoxicity (including mutagenicity)

2.2.4 Long term toxicity and carcinogenicity

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

2.2.5 Effects on reproduction

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

2.2.6 Neurotoxicity/delayed neurotoxicity

- Acute neurotoxicity
- Subchronic neurotoxicity

Special studies (where available)

- could include human immunotoxicity studies

UNEP/FAO/CRC1/ working procedures: preparing internal proposals and DGD for BSRC

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

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

4.1.2 Water

- Route and rate of degradation

4.1.3 Air

- Fate and behaviour

4.1.4 Bioconcentration

4.1.5 Persistence

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

- Acute toxicity mammals
- Acute toxicity birds
- Dietary toxicity birds
- Reproductive toxicity birds

4.2.2 Aquatic species

- Fish
- Invertebrates
- Algal species
- Aquatic plants

4.2.3 Honey bees and other arthropods

4.2.4 Earthworms

4.2.5 Soil microorganisms

4.2.6 Terrestrial plants

5 Environmental exposure/risk evaluation

Specific reference as appropriate to the following

5.1 Terrestrial vertebrates

- Mammals/birds

5.2 Aquatic species

- Fish/invertebrates/algal species/aquatic plants

5.3 Honey bees

- Other arthropods

5.4 Earthworms

5.5 Soil microorganisms

5.6 Summary – overall risk evaluation

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

Introduction/purpose

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

2. This working paper is intended:

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

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

General guidance

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

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

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

1. Identification

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

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

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

2. Reason for inclusion in the PIC procedure

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

Generic text may include:

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

- (name active ingredient(s) and relative concentrations, and specific formulation(s))
- This severely hazardous pesticide formulation is subject to the Rotterdam Convention as it was found to cause problems under conditions of use in line with Article 6 and Annex IV of the Convention.

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

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

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

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

- This is a key section of the decision guidance document as it will help countries that use the formulation to determine how closely the reported incident reflects their own patterns of use. This would be useful information to countries when making import decisions.
- This information should be available to the drafting group from the incident report form on severely hazardous pesticide formulations and/or from additional information collected by the secretariat in line with part 2 of Annex IV.

3.1 Permitted uses of the formulation

- Space fumigation, seed treatment, crops treated etc.
- Application method – how it is used
- Pests controlled
- Rate and frequency of application

3.2 Restrictions in handling or use

- Relevant to worker exposure or environmental exposure

3.3 Availability/applicability of protective clothing

3.4 Actual uses

- Description of how the formulation is typically used, e.g. crops treated, pests controlled, application methods, rate and frequency of application etc., particularly where such use differs from the officially permitted uses.

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

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

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

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

- Where the incident occurred
- Main activity at the time of exposure
- Application method
- Route of exposure
- Conditions of use when the incident occurred, e.g. prevailing climatic conditions

4.2 Description of the adverse effects

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

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

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

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

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

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

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

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

6. WHO hazard classification of the formulation

Purpose: This section should provide an internationally recognized baseline from which countries can better understand the potential concerns with the formulations in question relative to others that they may be using

- This should be calculated based on the best available information. The values and possible hazard classification should be based on the principal routes of exposure (e.g. dermal, oral) and presented in tabular format.
- The WHO recommended classification of pesticides by hazard should be used as the primary reference for oral LD_{50} values. Where several LD_{50} values for other routes of exposure, e.g. dermal, have been published, the lowest deemed reliable is used (and referenced). This is in line with the approach used by WHO in compiling the oral LD_{50} values.
- Where a formulation consists of more than one active ingredient, the fact that the calculated hazard classification cannot account for possible synergistic effects or the potentiation of toxicity as a result of interaction among the active ingredients should be noted.

7. Alternative pest-control practices

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

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

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

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

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

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

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

It is essential that before a country considers substituting alternatives for a given formulation, it ensures that the use is relevant to its national needs and the anticipated local conditions of use.

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

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

Annex II Information on reported incident from incident report

This should include specific information submitted by the notifying country:

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

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

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

Safety data sheets typically contain the following key headings:

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

Other examples of readily available information that might be used to complete this annex include the IPCS International Chemicals Safety Cards, summaries from environmental health criteria documents etc. These documents are freely accessible at www.inchem.org.

Annex III Summary of toxicological properties

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

For mammalian toxicological end points, the primary data generated for a pesticide formulation are limited to a set of six acute toxicity studies. The most common and those that might be expected to be available for a given formulation are the following:

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

Where there is a risk or hazard evaluation on the formulation either from a national Government or an international source it may be summarized here.

- Where this information is not available for a given formulation, consideration should be given to including:
    - The material safety data sheet (MSDS) for the formulation;
    - A reference to the risk or hazard information in annex II on the active ingredient(s) from an internationally recognized source such as the INCHEM database, the EXTOXNET Profile, IPCS International Chemical Safety Cards, summaries from environmental health criteria documents etc.

Appendix. Standard core set of abbreviations

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

Pow	octanol-water partition coefficient
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used).
RfD	reference dose for chronic oral exposure (comparable to ADI)
SMR	standardized mortality ratio
STEL	short term exposure limit
TLV	threshold limit value
TWA	time weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VOC	volatile organic compound
WHO	World Health Organization
wt	weight

Process for determining evidence of ongoing trade Noted by COP2 – Adopted by CRC 1

Working procedure: process for determining evidence of ongoing trade

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

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

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

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

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

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

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

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

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

Working procedure: common and recognized patterns of use of severely hazardous pesticide formulation

Note by the Secretariat

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

A. Background

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

(a) Reliability of the evidence indicating that use of the formulation in accordance with common or recognized practices within the proposing party, resulted in the reported incidents;

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

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

B. Defining the Problem

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

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

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

C. Issues to Consider

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

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

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

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

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

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

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

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

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

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

(b) What uses are permitted?

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

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

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

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

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

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

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

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

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

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

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

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

17. Given the difficulty in collecting information on the use of individual pesticide formulations a different approach may be warranted. This could include a combination of information specific to the pesticide or formulation in question (that included in parts 1 and 2 of Annex IV), as well as more generic information on pesticide use in countries that could be made available to the Committee. This could involve consideration of at least three elements:

(a) Inherent toxicity of the active ingredient or formulation;

(b) Conditions of registration (e.g., the need for personal protective equipment) for the active ingredient and the same or similar formulations in countries with more developed regulatory infrastructure;

(c) Information on how pesticides are commonly used in developing countries or countries with economies in transition. This latter information would not have to be country-specific, it might be based on information on common agricultural practices associated with certain commodities, or how pesticides are generally applied in such countries, e.g., the use of backpack sprayers, accessibility to personal protective equipment.

D. Next Steps

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

Policy guidance: preparation and use of focused summaries

A. Purpose of focused summaries

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

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

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

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

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

B1. Introduction

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

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

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

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

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

B2. Risk evaluation

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

(a) Key findings of the national risk evaluation;

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

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

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

C. Risk reduction and relevance to other States

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

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

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

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

D. Worked example of a focused summary: monocrotophos

1. Introduction

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

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

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

(b) Exposure:

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

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

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

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

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

2. Risk evaluation

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

(a) Key findings of the national risk evaluation

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

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

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

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

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

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

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

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

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

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

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

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

Human exposure assessment

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

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

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

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

Environmental exposure assessment

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

3. Risk reduction and relevance to other States

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

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

No information

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

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

Alternatives: The following alternatives are considered to pose lower risks to workers and the environment. World Health Organization hazard classifications are provided as an aid to the consideration of relative risks. The classifications are for active constituents. Actual hazard depends on formulations.

Moderately hazardous: chlorpyrifos, diazinon; dimethoate; fenitrothion.

Slightly hazardous: azamethiphos; malathion.

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

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

Policy guidance: bridging information

Introduction

1. Risk or hazard evaluations completed in one country may be used by another country in support of its notification of final regulatory action submitted in accordance with Article 5 of the Rotterdam Convention. 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 are similar to and compatible with those in the notifying country. 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.

2. 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 for this notification to be a trigger for further consideration under the Convention.

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

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 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 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 could include:

(a) The form in which the chemical was used in both countries;

(i) Formulation type:

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

(ii) Contaminants

(b) How the chemical is used in both countries:

(i) Use pattern:

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

(ii) If applied in the field: climatic conditions, comparability between the countries

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

(i) Human health effects:

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

7. Information to facilitate a comparison of environmental exposure:

(a) The form in which the chemical was used in both countries:

(i) Formulation type:

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

(ii) Contaminants

(b) How the chemical is used in both countries:

(i) Use pattern:

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

(ii) If applied in the field, environmental conditions such as climatic conditions, soil type and non-target organisms; comparability between the two countries

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

(i) Effects on non-target organisms:

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

(ii) Other environmental effects.

B. Industrial chemicals

8. Information to facilitate a comparison of human exposure could include information on:

- Workers
- General population
- End users
- Others

9. Information to facilitate a comparison of environmental exposure:

- Soil, air, water
- Habitat
- Wildlife.

10. Description of the sequence(s) of events leading to exposure:

(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 (if relevant);

(c) Patterns of use (if relevant): 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 (if relevant): e.g., disposal of chemical on land leads to ground water contamination.

11. Description of the key factors affecting the chain of events leading to exposure:

(a) The form in which the chemical was used in both countries:

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

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

(i) What are the key factors affecting release?

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

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

- Exposure limits
- Protective equipment.

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

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

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

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

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

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

12. Any other relevant information demonstrating similarity in conditions, e.g. incident reports, monitoring data.

Policy guidance: contaminants

Note by the Secretariat

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

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

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

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

Policy Guidance: Risk Evaluation in the Context of the Rotterdam Convention

Explanatory note on criterion (b) (iii) of Annex II of the Rotterdam Convention

A. Background

1. In assessing notifications of banned and severely restricted chemicals used in a notifying country under article 5, problems arose with the application of the term "risk evaluation".

2. Annex II of the Convention sets out the criteria for listing banned or severely restricted chemicals in Annex III. Paragraph (b) of Annex II states that, in reviewing the notifications forwarded to it, the Chemical Review Committee shall "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 conditions prevailing in the Party in question."

3. The report of the fifth session of the Intergovernmental Negotiating Committee states:

"The term 'risk evaluation' used in Annex I and Annex II is understood by the Intergovernmental Negotiating Committee to be not a risk assessment, but rather an evaluation of intrinsic toxicological and ecotoxicological properties and actual or expected relevant exposure, including actual incidents and scientific evidence of hazard."

4. To clarify the issue it may be helpful also to consider the work of the Organisation for Economic Cooperation and Development (OECD) and the World Health Organization (WHO) in developing definitions of risk assessment and hazard assessment.[1]

5. It was noted that consideration of the term risk evaluation by the Chemical Review Committee is in the context of the Rotterdam Convention and is not to be confused with definitions developed by OECD, WHO or other bodies.

[1] The following examples might be considered:

"*Risk assessment*: A process intended to calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system.

"The risk assessment process includes four steps: hazard identification, hazard characterization (related term: dose-response assessment), exposure assessment, and risk characterization. It is the first component in a risk analysis process;

"*Hazard assessment*: A process designed to determine the possible adverse effects of an agent or a situation to which an organism, system, or sub-population could be exposed.

"The process includes hazard identification and hazard characterization. The process focuses on the hazard in contrast to risk assessment where exposure assessment is a distinct additional step."

Source: Alphabetical list of selected generic terms in hazard and risk assessment and their definitions (OECD/IPCS/WHO).

B. Risk evaluation in the context of the Rotterdam Convention

6. Risk evaluation is neither hazard assessment nor risk assessment, but something in between. Risk evaluation considers information on hazard and exposure. In notifications of final regulatory actions to ban or severely restrict a chemical:

(a) Information on hazard assessment is normally based on internationally accepted toxicological or ecotoxicological data;
(b) Information on exposure is to be related to the prevailing conditions of use in the notifying country.

7. For a better understanding of the minimum information on exposure that might be required by the Chemical Review Committee in reviewing risk evaluations, it was considered useful to develop some examples as a means of defining the minimum requirements for information regarding exposure. Any additional information will facilitate decision-making by the Chemical Review Committee. For the first two examples, where reported incidents occur in a country other than the country submitting the notification of final regulatory action the relevance to the notifying country should be described[2].

8. The Chemical Review Committee will consider each notification on a case-by-case basis. The use of this guidance is intended to be interpreted flexibly.

Example 1: Incidents involving direct exposure by humans

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

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

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

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

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

(a) How does the presence of the chemical lead to human and environmental (actual or expected) exposure? Actual exposure can be directly measured. Expected exposure can be estimated, possible factors… [*to be developed if necessary*]

(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.

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[2] Information to be contained in the supporting documentation provided by a notifying country using a risk evaluation from another country in support of final regulatory action (UNEP/FAO/INC.10/14).