UNITED NATIONS

PIC

United Nations Environment Programme

Food and Agriculture Organization of the United Nations

Distr.
GENERAL

UNEP/FAO/PIC/ICRC.4/6
12 December 2002

ENGLISH ONLY

Interim Chemical Review Committee
Fourth session
Rome, 3 – 7 March 2003
Item 4 (b) (i) of the provisional agenda*

OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE

ISSUES ASSOCIATED WITH THE IMPLEMENTATION OF THE OPERATIONAL PROCEDURES:

DRAFT WORKING PAPER ON PREPARING INTERNAL PROPOSALS AND DECISION GUIDANCE DOCUMENTS FOR BANNED OR SEVERELY RESTRICTED CHEMICALS

Note by the secretariat

1. At its second session, the Interim Chemical Review Committee (ICRC) adopted a working paper on preparing internal proposals and decision guidance documents on banned or severely restricted chemicals with the understanding that it would be updated in the light of experience gained in its implementation.

2. The working paper was used by the drafting groups on DNOC and asbestos established at the third session of the ICRC. Comments provided by the co-chairs and members of the drafting groups have been used to revise the working paper and as the basis for a brief list of issues to consider by the Committee in reviewing the amended document.

3. Annexed to this note is a revised version of the working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals and a brief list of issues for the Committee to consider in its review.

* UNEP/FAO/PIC/ICRC.4/1.

Annex

Issues to consider:

1. Need for a separate working paper for the development of decision guidance documents on industrial chemicals.

2. Abbreviations list – should it contain just the abbreviations in the particular DGD or should a standard list be developed and built on as necessary? - many abbreviations may be specific to industrial or pesticide chemicals.

- The present practice is to use a standard list of abbreviations amended as necessary to reflect additional or unique abbreviations in a given decision guidance document.
- It may be that separate list of abbreviations should be developed for decision guidance documents for pesticides and industrial chemicals.

3. More guidance is needed on the amount of detail required e.g. in giving information on Dangerous Goods classification.

4. Occupational exposure standards will often be more relevant to industrial chemicals than any other exposure standard and should be included in decision guidance documents for industrial chemicals. The problem of different methods of calculation could be overcome by explanation accompanying the values. Work may be needed to identify internationally accepted occupational exposure limits.

- This issue was discussed at ICRC-3, no internationally accepted occupational exposure limits were identified.

5. In drafting the decision guidance document on monocrotophos it was agreed that references in annex 1 would be made to the primary source e.g. the government or international evaluation document rather than individual articles/documents included therein. The approach taken in the asbestos DGD is somewhere in between in that the individual articles are referenced in the text as being cited in the international evaluation (EHC document). These individual articles are the included in the list of references.

- It may be that clear guidance on a consistent way in which to include/cite references should be incorporated into the working paper.

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

UNEP

WORKING PAPER ON PREPARING INTERNAL PROPOSALS AND DECISION GUIDANCE DOCUMENTS FOR BANNED OR SEVERELY RESTRICTED CHEMICALS

Purpose: This working paper is to serve as guidance to drafting groups in the preparation of decision guidance documents for further consideration by the Interim Chemical Review Committee (ICRC). It is designed:

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

1. Identification and uses

Purpose: To provide an unequivocal identification of the chemical that is to be 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 the generic and, as far as possible, all other forms of a chemical covered in the underlying notifications of final regulatory action should be included here. The scope of the chemical identified in this section of the DGD (chemical desription and associated CAS numbers) must be consistent with the recommendation by the Interim Chemical Review Committee for inclusion of the chemical in the PIC procedure (listing in Annex III of the Convention).

Notes: Updated or additional information on trade names, formulation types and basic manufacturers for products moving in international trade will be sought from Committee members and other interested parties during the consultation phases.

The list of trade names, formulation types and manufacturers should be comprehensive and 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 should only be completed where a chemical has been subjected to a severe restriction and the notifying country or countries has or have allowed continued use of the chemical and associated products.

Purpose: To provide information about *non-regulatory* measures (including technical and field-level arrangements) 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.

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. Such 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 and used in workshops.

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 ensures that the use is relevant to its national needs and the anticipated local conditions of use.

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.

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.

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.

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*.

4.4 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: While 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.

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.

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. Additional evaluations or reviews on the chemical from other sources can be submitted by governments to the secretariat for posting on the Rotterdam Convention website.

The principal headings in this annex section 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 2.2.8 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 the appendix 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, where the re situation may arise where has been an evaluation of n accepted internation the chemical at the international level e.g. by the OECD, WHO/IPCS or IARC has that reached conclusions that differ from those of the findings of the notifying parties.

- 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 2.2.8 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..

Specific comments - *for details of proposed subheadings, see the appendix below*

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.

- 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 Interim 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.

List References under headings as appropriate:

Regulatory actions

Documents used in risk evaluation

Documents used for accident reporting and poison management

Appendix II

Headings and list of information points that could be included under each

1. Physico-chemical properties

2. Toxicological properties

2.1. General

2.1.1. Mode of action

2.1.2. Symptoms of poisoning

2.1.3. Absorption, distribution, excretion and metabolism in mammals

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

2.2 Toxicology studies

2.2.1 Acute toxicity

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

2.2.2 Short term toxicity

- Target/critical effect
- Oral
- Dermal
- Inhalation

2.2.3 Genotoxicity (including mutagenicity)

2.2.4 Long term toxicity and carcinogenicity

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

2.2.5 Effects on reproduction

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

2.2.6 Neurotoxicity/delayed neurotoxicity

- Acute neurotoxicity

- Subchronic neurotoxicity

Special studies (where available)

- could include human immunotoxicity studies

2.2.7 Summary of mammalian toxicity and overall evaluation
- include summary of key findings of relevant international reviews e.g. WHO/IPCS/IARC evaluations

3. Human exposure/risk evaluation

3.1 Food

3.2 Air

3.3 Water

3.4 Occupational

3.5 Medical data contributing to regulatory decision – could include:
- Report on medical surveillance on manufacturing plant personnel
- Report on clinical cases and poisoning incidents
- Observations on exposure of the general population and epidemiological studies

4. Environmental fate and effects

4.1 Fate

4.1.1 Soil
- 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
