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INTERIM CHEMICAL REVIEW COMMITTEE

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Item 5 (b) (ii) of the provisional agenda*

OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE

ISSUES ASSOCIATED WITH THE IMPLEMENTATION OF THE OPERATIONAL
PROCEDURES: REPORT OF THE DRAFTING GROUP ON MONOCROTOPHOS

DRAFT WORKING PAPER ON PREPARING INTERNAL PROPOSALS
AND DECISION GUIDANCE DOCUMENTS

Note by the secretariat

1. At its second session, the Interim Chemical Review Committee established an intersessional drafting group on monocrotophos, entrusted with preparing a draft decision guidance document in line with the process adopted by the Intergovernmental Negotiating Committee at its seventh session (decision INC-7/6).
2. Annexed to the present note is the report of the drafting group as submitted to the secretariat. The report provides brief background information on the objective and composition of the drafting group and information on how its work was organized. In addition to the decision guidance document on monocrotophos a working paper was also developed based on lessons learnt. The working paper is proposed as a possible basis for guidance on the development of decision guidance documents for future drafting groups. A copy of the working paper is appended to the report of the drafting group.
3. The draft decision guidance document on monocrotophos is available to the Committee in a separate meeting document UNEP/FAO/PIC/ICRC.3/18 and will be considered under agenda item 6 (c), "Consideration of draft decision guidance documents".

* UNEP/FAO/PIC/ICRC.3/1.

Annex

REPORT ON THE WORK OF THE DRAFTING GROUP ON MONOCROTOPHOS

A. Objectives of the drafting group

1. The objective of drafting group on monocrotophos, established at the second session of the Interim Chemical Review Committee, was to produce a draft decision guidance document for monocrotophos.

B. Composition of the drafting group

2. The members of drafting group on monocrotophos, assigned at the second session of the Interim Chemical Review Committee, were:

Co-chairs: Tamás Kömives
André Mayne

Members: Azhari Omer Abdelbagi
Dudley Achu Sama
Reiner Arndt
Marc Debois
Masayuki Ikeda
Ravinandan Sibartie
Janet Taylor
Beverley Wood

Secretariat

C. Background

3. Article 5, paragraphs 5 and 6, requires that the secretariat, when it has received at least one notification from two prior informed consent (PIC) regions regarding a particular chemical that it has verified meet the requirements of annex I, forward these notifications to the Interim Chemical Review Committee. Notifications from Australia and Hungary on the pesticide monocrotophos were forwarded to members of the Committee prior to its second session.

4. The Committee reviewed the two notifications, including the supporting documentation referred to therein, and, taking into account each of the specific requirements set out in annex II of the Convention, concluded that the requirements of that annex had been met.

5. Accordingly, the Committee agreed to recommend to the Intergovernmental Negotiating Committee that monocrotophos become subject to the interim PIC procedure and agreed to establish an intersessional drafting group with the mandate to produce a draft decision guidance document (UNEP/FAO/ICRC.2/11).

6. In line with the process for developing decision guidance documents adopted by the Intergovernmental Negotiating Committee at its seventh session (decision INC-7/6), a schedule for the preparation of the draft decision guidance document was agreed. The goal was to have a draft available for consideration by the Committee at its third session in March 2002.

D. Organization of work

7. The co-chairs of the drafting group prepared an internal proposal document, based on the submitted notifications and supporting documentation and in consultation with the secretariat. A working paper was also developed on the lessons learnt in drafting the initial proposal. The working paper is proposed to serve as the basis for guidance on the development of internal proposals and decision guidance documents for

future drafting groups. It provides a better understanding of the rationale for the information contained in the different sections of the initial proposal and where there are opportunities for adding or citing further information. The internal proposal and a draft working paper were circulated to members of the task group for comment in mid-June. The documents were duly modified in the light of the comments received.

8. The initial proposal on monocrotophos and the working paper were circulated to all members of the Committee and observers to the second session of the Committee, a total of 34 countries, on 22 July 2001. Responses were received from five countries: China, Samoa, the Sudan, Saudi Arabia and the United States of America, and from the European Commission.

9. The initial proposal on monocrotophos and the working paper were duly amended in the light of the comments received. A status report on the work of the task group, including a compilation of the comments, issues identified for further consideration, the amended initial proposal and the working paper, were circulated to drafting group members 17 October 2001. This status report and the list of issues identified form the basis for the present report to the Committee. Copies of all of the comments received will be available to the Committee at its third session.

E. Issues to consider

10. It is of crucial importance to develop a decision guidance document that reflects the information available to the Committee and that provides sufficient detail, so that designated national authorities can understand the basis for the reported regulatory actions and make an appropriate decision on future imports. In developing the decision guidance document on monocrotophos and the working paper a number of issues were identified. In many instances they have been addressed in the revisions to the documents. In order to facilitate discussion by the Committee, outstanding issues have been sorted into the following topics.

(a) Decision guidance documents are developed on the basis of information provided through a range of sources, including national and international assessments. As a result there is bound to be a range of terminology and reporting styles used in the supporting documents available to the drafting groups. It is important to ensure a level of consistency among decision guidance documents, to facilitate their use by designated national authorities without interpreting the risk evaluation information available, e.g., Latin names and alternatives;

(b) A consistent approach to the use of Chemical Abstracts Service (CAS) numbers in drafting decision guidance documents needs to be developed. The CAS numbers reported in the decision guidance document reflect the scope of the chemical subject to the interim PIC procedure. It is therefore essential that the CAS numbers in the decision guidance document accurately reflect the scope of the regulatory action reported by the designated national authority and not simply be a list of all CAS numbers that may have been assigned to various isomeric forms and mixtures of the chemical. It is unclear to what extent and how countries use CAS numbers in defining the scope of their regulatory actions.

11. The task group agreed that the working paper would provide useful guidance to future drafting groups in preparing decision guidance documents, recognizing that each will need to be considered on a case-by-case basis, particularly with respect to the appropriate level of detail in Annex I. It was also agreed that the working paper would continue to evolve as further experience is gained and that it might also be a useful tool in the training workshops on the Rotterdam Convention. The current draft of the working paper is appended to this report.

F. Recommendation to the Interim Chemical Review Committee

12. At its next session, the Interim Chemical Review Committee might wish to consider the following measures:

(a) Reviewing the outcome of the work of the drafting group, with particular focus on the draft working paper;

(b) Reviewing the issues, with a view to considering and proposing possible ways in which they might be addressed;

(c) Considering the need to revise the working paper as experience is gained in its implementation.

13. Possible outcomes of the discussion could be:

(a) Adoption of the working paper, as revised by the Committee as draft guidance for drafting groups in preparing internal proposals and decision guidance documents;

(b) Reassessment of the working paper by the Committee, once experience is gained in its implementation.

Appendix I

Working paper on the content of a decision guidance document for a banned or severely restricted chemical

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.

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.

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.

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).

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.

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.

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.

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.

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.

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.

Alternatives

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

- 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.
- 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 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.

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.

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.

Hazards and risks to human health and/or the environment

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.
- Notifying countries have the option to include their own national classification schemes here or in Annex 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.

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.

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*.

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.

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.

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 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 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 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 section should focus on human health effects rather than environmental aspects.

The principal headings in this 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 level of detail within the subheadings may be adjusted to accommodate the information 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. 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 end points 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.

LD₅₀ and LC₅₀ 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 there has been an accepted international review of the chemical, the findings of that review may differ from 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.

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 international evaluations, such as those of WHO/IPCS/JMPR, where they are available and considered relevant.

- 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.

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 LD₅₀ oral
- Rat LD₅₀ dermal
- Rat LC₅₀ 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

2.2.7 Summary of mammalian toxicity and overall evaluation

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
