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INTERIM CHEMICAL REVIEW COMMITTEE

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OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE -
REPORT OF THE WORK OF TASK GROUP 3A AND 3B ON FORMATS FOR DECISION
GUIDANCE DOCUMENTS ON BANNED AND SEVERELY RESTRICTED CHEMICALS
AND SEVERELY HAZARDOUS PESTICIDE FORMULATIONS

Note by the secretariat

1. The Interim Chemical Review Committee, at its first session, reviewed its operational procedures. The Committee identified four priority tasks and decided to set up a task group for each of them to work intersessionally. Task group 3 was charged with the following: to develop standard formats for decision guidance documents reflecting the needs of countries with respect to import decisions based on the information provided in the notification of final regulatory action (annex I and annex IV of the Rotterdam Convention). The work was divided between two sub-groups 3A and 3B.

2. Annexed to this note is the report of task group 3 (sub-groups 3A and 3B) submitted to the secretariat. The report provides brief background information on the objective and composition of the task group and information on how the work of the two sub-groups was organized. Finally, in sections E and F, respectively, the report identifies issues for consideration by the Interim Chemical Review Committee and provides specific recommendations on how the Committee might proceed.

* UNEP/FAO/PIC/ICRC.2/1.

Annex

**REPORT ON THE WORK OF TASK GROUPS 3A AND 3B:
FORMATS FOR DECISION GUIDANCE DOCUMENTS ON BANNED AND SEVERELY
RESTRICTED CHEMICALS AND SEVERELY HAZARDOUS PESTICIDE FORMULATIONS**

A. OBJECTIVES OF THE TASK GROUP

1. The objectives of task group 3A and 3B, established at the first session of the Interim Chemical Review Committee, are :
 - (a) for task group 3A - to develop formats for decision guidance documents for banned and severely restricted pesticides and industrial chemicals, based on format of the notification which collected the information (annex I of the Convention); and
 - (b) for task group 3B - to develop formats for decision guidance documents for severely hazardous pesticide formulations, based on format of the proposal which collected the information (annex IV of the Convention).

B. COMPOSITION OF THE TASK GROUP

2. The members of task group 3A, assigned at the first session of the Interim Chemical Review Committee, were:

Secretariat (lead)	Marc Debois
Reiner Arndt	Karel Gijsbertsen
Cathleen Barnes	Masayuki Ikeda
	Dudley Achu Sama

3. The members of task group 3B, assigned at the first session of the Interim Chemical Review Committee, were:

Secretariat (lead)	Bill Murray
Azhari Omer Abdelbagi	Fatoumata Jallow Ndoeye
Mohamed Ammati	Sandra de Souza Hacon
Cathleen Barnes	Ravinandan Sibartie
Mercedes Bolaños Granda	Kasumbogo Untung
Ian Coleman	Dudley Achu Sama
Marc Debois	
Mohamed El Zarka	NGOs:
Masayuki Ikeda	GCPF (Jakob Brassel)
Julio Monreal	IUF (Peter Hurst)

C. BACKGROUND

4. The Rotterdam Convention, in line with Article 7, requires that, once the Chemical Review Committee has decided to recommend a chemical for listing in annex III of the Convention, it prepare a draft decision guidance document. The decision guidance document should, at a minimum, be based on the information specified in annex I, or, as the case may be, annex IV, and include information on uses of the chemical in a category other than the category for which the final regulatory action applies.
5. The Interim Chemical Review Committee, at its first session, developed a process for the drafting of decision guidance documents that included a mechanism for collecting and disseminating comments

received as they are developed. In developing this process it was clear that the information contained in a decision guidance document and its format should as far as possible be standardised. A consistent format would facilitate the development of the decision guidance document in line with the information listed in annex I of the Convention and its use by designated national authorities (DNAs) when making import decisions.

6. Task group 3 was created with the mandate to develop standard formats for decision guidance documents reflecting the needs of countries with respect to import decisions based on the information provided in the notification of regulatory action (annex I and annex IV of the Convention).

D. ORGANIZATION OF THE WORK

7. The work of task group 3 was divided between two subgroups. A work plan for task group 3A – on the format for decision guidance document for banned or severely restricted pesticides or industrial chemicals - was circulated on 12 June 2000 and adopted by task group 3A without any changes. A number of background documents were circulated with the work plan, including: relevant parts of the Convention (text and annexes), existing format of decision guidance documents and examples of published decision guidance documents, format of OECD monographs, and excerpts from the reports of earlier meetings of the FAO/UNEP Joint Group of Experts on PIC, under the original PIC procedure. No additional background documents were suggested by members of the task group.

8. Members of task group 3A suggested that the format for existing decision guidance documents for banned or severely restricted chemicals was an acceptable template on which to base their discussions. Two task group members provided the secretariat with very detailed comments and suggested changes (additions/deletions) to be made to the current format. The final proposal of task group 3A for a template of a decision guidance document for a banned or severely restricted chemical is attached to this report (Appendix I).

9. A work plan for task group 3B – on the format for a decision guidance document for severely hazardous pesticide formulations - was circulated on 11 August 2000 and adopted by task group 3B without any changes. A number of background documents were circulated with the work plan: - relevant parts of the Convention (text and annexes), existing format of a decision guidance document for severely hazardous pesticide formulations, and examples of published decision guidance documents.

10. Members of task group 3B suggested that the format for the existing decision guidance documents for severely hazardous pesticide formulations was an acceptable template on which to base their discussions. However, task group members also pointed out that the result of the work of task group 2, on the development of an incident report form and associated guidance on the submission of proposals for severely hazardous pesticide formulations, could constitute a basis to revisit the current format. The information contained in the proposals from task group 2 would be a key component of the development of decision guidance documents for severely hazardous pesticide formulations.

11. These approaches were discussed at an informal meeting with the task group members attending the seventh session of the Intergovernmental Negotiating Committee (Geneva, November 2000) and endorsed by the bureau of the Interim Chemical Review Committee. The relevant status reports for task groups 3A and 3B were circulated to all task group members for information in early November 2000.

E. ISSUES TO CONSIDER

12. The decision guidance document for a chemical subject to the PIC procedure serves the purpose:
- to inform each Party of the health and/or environmental reasons why certain Parties took final regulatory actions to ban or severely restrict the chemical, or of the reasons why a Party proposed the chemical as a severely hazardous pesticide formulation;
 - to provide each Party with additional relevant information; and
 - to enable each Party to take a decision regarding future import of this chemical/severely hazardous pesticide formulation into the territory of the Party.
13. Task group 3A has captured the points that need to be considered in reviewing the current format of a decision guidance document quite clearly. However, further discussion is necessary regarding the purpose of the decision guidance document, on how it is used by DNAs and the role of the Committee in its development. The results of the discussion within task group 1 suggest that there is a need for a thorough discussion on the relationship between the information provided in the notification of final regulatory action (including supporting documentation) and the development of the decision guidance document.
14. It needs to be clear that the basic information contained in the decision guidance document on hazard and risk must be directly linked to the notification and supporting documentation provided by the notifying Parties. The document must reflect the basis for the decisions on the part of the notifying Parties; it is not a scientific treatise of the chemical. For example, it is possible to envisage a situation where a decision guidance document would have little or no information on environmental effects, as the notified regulatory action focussed on human health concerns. The reverse would hold true for a chemical on which the notified regulatory actions are based on environmental concerns; the decision guidance document would contain limited/minimal information on human health effects. This is a basic point that needs to be clear to the Committee members when drafting decision guidance documents.
15. Once the link between notifications and decision guidance document has been established, the next step is to review the current content of existing decision guidance documents against the information that will reliably be available to the Committee. The level of detail will be an issue that can only be effectively addressed once the incoming information from the notifications is better understood and the basic content of the decision guidance document agreed.
16. A further point that needs to be addressed by the Committee concerns the fact that as the decision guidance documents are to be widely distributed for comment, it must be clear where and to what extent these comments can be incorporated. For example, as the risk evaluation comes from the Parties that have taken the regulatory actions the text of the evaluation could not be significantly changed; clarified perhaps, but not changed. If this point is not clear to the Committee, it will put itself in the impossible position of having to contend with widely varying documentation, submitted by outside interest groups, both supporting and refuting the notifying Party's regulatory decision. For this reason the comments that could most profitably be solicited would relate to any further information that would assist DNAs in making import decisions, including: information on alternative chemicals or agricultural/industrial processes, additional trade names, other sources/manufacturers of the chemical, etc.
17. The decision guidance document is to provide information to a DNA regarding the basis for the final regulatory actions through which the chemical entered the PIC procedure. As it is the DNA that provides the import response based on the decision guidance document, any proposed changes in content or level of detail would need to be developed in cooperation with them.

F. RECOMMENDATION TO THE INTERIM CHEMICAL REVIEW COMMITTEE

18. As a first step towards developing a final format of a decision guidance document for banned or severely restricted chemicals, the Interim Chemical Review Committee should review Annex I and Annex II of the Convention in order to build a common understanding of the basic information available for drafting these documents. This should result from the work underway in task group 1. Once this link between notifications and decision guidance documents has been established, the next step would be to review the current content of the decision guidance documents against the information that will reliably be available to the Committee through the notifications of final regulatory action forwarded to it by the secretariat.

19. Similarly, the work of task group 2 on the incident report form and developing guidance on submitting proposals for severely hazardous pesticide formulations is a key contribution to deliberations on the content and format of decision guidance documents on severely hazardous pesticide formulations. The next step for task group 3B is thus dependent on the results of the work of task group 2. The goal would be to ensure that as far as possible the information provided through the incident report form and that requested in parts 2 and 3, annex IV of the Convention, is an adequate basis for developing a decision guidance document for severely hazardous pesticide formulations.

20. A further point that will need to be addressed concerns the fact that as a decision guidance document will be distributed for comment to all Parties and observers, the Committee must ensure that there is a clear understanding to what extent the comments provided can be incorporated.

21. The Interim Chemical Review Committee should, at its next session:

- (a) further consider the purpose of a decision guidance document, how they are used by DNAs and the information available to the Committee on which to develop a decision guidance document;
- (b) review the content of the decision guidance document against the information available (the output of task group 1 and task group 2);
- (c) consider how the available information might be best presented in a decision guidance document, in order to facilitate the development of such documents by the Committee and their use by DNAs; and
- (d) consider how to handle comments on draft decision guidance documents.

22. Possible outcomes of the discussion could be:

- (a) a clear understanding of the purpose of a decision guidance document including how they are used by DNAs;
- (b) a clear understanding of the information that will be available to the Committee in line with the obligations of the Convention (Articles 5 and 6 and Annexes I and IV) and how this will form the basic content of a decision guidance document;
- (c) a proposal on how to further develop relevant formats for decision guidance documents to facilitate their development by the Committee and use by DNAs; and
- (d) a description of appropriate operational procedures for handling comments on draft decision guidance documents.

Appendix I

PIC – Decision guidance document for a banned or severely restricted chemical

Xxxx Xxxx

Published:

- Common name
- Other names/
synonyms
- CAS-No.(s)
- Harmonized System
Customs Code
- Category
- Use(s)
- Trade names
- Formulation types
- Basic manufacturers

Reasons for inclusion in the PIC procedure

Xxxx Xxxx is included in the PIC procedure as a [pesticide] [and/or] [industrial chemical]. It is included in the procedure on the basis of the final regulatory actions reported by a number of Governments.

Final regulatory action: (see Annex 2 for details)

Summary report to include:

- effective date(s) and category(ies) to which ban or severe restriction applies
- Reason(s) for each type of final regulatory action

Hazards and risks to human health and/or the environment

WHO	
EPA	
EU	
IARC	
OECD	

Risk Evaluation

Results, methodology applied, documentation used:

Protective measures that have been applied concerning the chemical

Protective measures applied

Measures to reduce exposure

Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard class:

Packing:

Alternatives and Socio-economic effects

Substances (chemical and trade name(s)) and/or management methods (for risk reduction)

- impacts on costs, trade, accident cases(present and future)

It is essential that before a country considers substituting any reported alternatives, it ensures that the use is relevant to its national needs.

Waste management

Storage/ reuse/ recovery/ disposal

It should be noted that the methods recommended in literature are often not suitable in a specific country. High temperature incinerators may not be available. Consideration should be given to the use of alternative destruction technologies.

First aid

Exposure limits

	Type of limit	Value national / international
Food (Country A)		
Air		
Soil		
...Food... (Country B)		
...Air...		
...Soil...		
Workplace		

Annexes

- Annex 1 **Further information on the substance**
- Annex 2 **Details on Final regulatory action**
- Annex 3 **Address of designated national authorities**
- Annex 4 **References**

Annex 1 - Further information on the substance

1 Physico-Chemical properties

- 1.1 Identity
- 1.2 Formula
 - Chemical name
 - Chemical type
- 1.3 Solubility
 - logP_{ow}
- 1.4 Vapour pressure
- 1.5 Melting point
- 1.6 Reactivity

2 Toxicological properties

2.1 General

- 2.1.1 Mode of action
- 2.1.2 Uptake
- 2.1.3 Metabolism

2.2 Effects on human health

- 2.2.1 Acute toxicity
 - Symptoms of poisoning
- 2.2.2 Chronic toxicity (including sub-chronic toxicity)
- 2.2.3 Epidemiological studies

2.3 Toxicity studies with laboratory animals and *in vitro* systems

- 2.3.1 Toxicity after single dose (Acute toxicity)
 - Oral
 - Dermal
 - Inhalation
 - Irritation

- 2.3.2 Effects after short-term exposure
- 2.3.3 Effects after long-term exposure
- 2.3.4 Effects on reproduction
- 2.3.5 Mutagenicity
- 2.3.6 Carcinogenicity

3 Exposure

- 3.1 Environment
 - 3.1.1 Food
 - 3.1.2 Air
 - 3.1.3 Water
- 3.2 Occupational
- 3.3 Accidental poisoning

4 Effects on the environment

- 4.1 Fate
 - 4.1.1 Biotic and abiotic degradation
 - 4.1.2 Bioconcentration
 - 4.1.3 Distribution in air, water and soil
- 4.2 Ecotoxicity
 - 4.2.1 Fish
 - 4.2.2 Aquatic invertebrates
 - 4.2.3 Algae
 - 4.2.4 Birds
 - 4.2.5 Bees
 - 4.2.6 Terrestrial plants
 - 4.2.7 Others (e.g. soil dwelling organ.)

Annex 2 - Details on final regulatory actions reported**Country Name**

1. Effective date(s) of entry into force of actions
2. Succinct details of the final regulatory action(s)
3. Reasons for action
4. Basis for inclusion into Annex III
 - 4.1. Risk evaluation
 - 4.2 Criteria used
 - 4.3 Relevance to other States and Region
5. Alternatives
6. Waste management

Annex 3 – Address of designated national authorities

Country Name

Name(s) of DNA(s), official contact address

CP DNA Industrial Chemicals and Pesticides

P DNA Pesticides

C DNA Industrial Chemicals

Annex 4 – References

Regulatory control action

Statistics on trade during the last 12 months

Documentation used for risk evaluation

Documentation used for Accident reporting and Poison Management
