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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Third meeting
Rome, 20–23 March 2007
Item 4 (c) of the provisional agenda*
Policy guidance and working procedures related to the work of the Chemical Review Committee: bridging information

Bridging information

Note by the Secretariat

A. Background

1. At its first meeting, the Chemical Review Committee considered a working paper on bridging information that would be used by the Committee to judge the acceptability of a notification where the notifying country had used a risk evaluation from another country or international body. As noted in paragraphs 33–35 of the report of that meeting (UNEP/FAO/RC/CRC.1/28), the Committee adopted the paper on the understanding that it would be applied on a case-by-case basis and that it would be developed further in the light of future experience.

2. At its third meeting, the Conference of the Parties to the Rotterdam Convention considered the issue of risk evaluations carried out under other multilateral environmental agreements and their relevance to candidate chemicals under the Rotterdam Convention. During those discussions, several representatives pointed out that the current guidelines on

* UNEP/FAO/RC/CRC.3/1

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bridging information would need to be developed further in order to accommodate the consideration of global risk evaluations as experience was gained. As noted in paragraphs 63–66 of the report of that meeting (UNEP/FAO/RC/COP.3/26), in the light of the views expressed, the Conference endorsed the approach recommended in the Secretariat's note (UNEP/FAO/RC/COP.3/10), including its stipulation that, in order to satisfy criterion (b) (iii) of Annex II to the Rotterdam Convention, bridging information providing evidence of the prevailing conditions in the notifying country would have to be submitted.

3. The annex to the present note contains a revised version of the working paper on bridging information that was adopted by the Committee at its first meeting. The paper contains some proposed amendments that aim to define more precisely the sort of information that should be provided by notifying Parties in support of global risk evaluations in order that the Committee may determine whether criterion (b) (iii) of Annex II has been met. The annex has not been formally edited.

B. Proposed action by the Committee

4. The Committee may wish to consider the working paper on bridging information, as amended, and propose further revisions as may be necessary as experience is gained in reviewing notifications of final regulatory actions and associated supporting documentation relevant to global risk evaluations.

Annex

Introduction

1. Risk or hazard evaluations and exposure assessments 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 and exposure assessments 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 (b) (iii) 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.

- **NEW 7(D)** Information is required describing direct exposure to a chemical and any adverse effects resulting from that exposure. Thus a description of the incident should be provided which may include, for example, the extent or number of casualties, its circumstances and a description of the signs, symptoms and/or effects;
- Actual or measured exposure
- Expected or anticipated exposure

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

(a) How does the presence of a chemical lead to human and environmental (actual or expected) exposure? Actual exposure can be directly measured. Expected exposure can be estimated.

(b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical.

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.

- **NEW 13** Information is required describing direct exposure to a chemical and any adverse effects resulting from that exposure. Thus a description of the incident should be provided which may include, for example, the extent or number of casualties, its circumstances and a description of the signs, symptoms and/or effects;
- Actual or measured exposure
- Expected or anticipated exposure

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

(a) How does the presence of a chemical lead to human and environmental (actual or expected) exposure? Actual exposure can be directly measured. Expected exposure can be estimated.

(b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical.