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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
First meeting
Geneva, 11–18 February 2005
Item 6 (b) (ii) of the provisional agenda*

Operational procedures for the Chemical Review Committee: working procedures and policy guidance forwarded from the Conference of the Parties: policy guidance: bridging information

Policy guidance: bridging information

Note by the secretariat

1. At its ninth session, the Intergovernmental Negotiating Committee was requested to provide guidance on two distinct issues under the issue of compatibility: whether preventive regulatory actions on pesticides met the definition of a ban under article 2 of the Convention and the relationship of such regulatory action to the criteria in Annex II, and how to determine when countries should provide supporting risk evaluations based on conditions prevailing in their country (UNEP/FAO/PIC/INC.9/8).

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

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2. Noting that article 2 did not rule out preventive action, even if a chemical was not proposed for use in the notifying country, the Interim Negotiating Committee agreed that the definition of a banned chemical in that article included preventive regulatory actions taken to protect human health or the environment from chemicals that might not have been proposed for use in the notifying country (UNEP/FAO/PIC/INC.9/21, para. 69).

3. At its ninth session, the Interim Negotiating Committee requested the interim Chemical Review Committee to develop guidelines on the scope of such bridging information to be contained in the supporting documentation provided by the notifying country, for review by the Intergovernmental Interim Negotiating Committee at its tenth session (ibid., para. 74).

4. At its fourth session, the interim Chemical Review Committee considered a working paper on adapting risk evaluations, prepared on the basis of a note submitted by the secretariat (UNEP/FAO/PIC/ICRC.4/8). The Committee approved the working paper, as orally amended, for transmission to the Interim Negotiating Committee at its tenth session, on the understanding that the paper would be updated in the light of actual experience of its use. The Committee requested the Interim Negotiating Committee to take note of the working paper and to invite countries to make practical use of it (see UNEP/FAO/PIC/ICRC.4/18, para. 52).

5. At the tenth session of the Interim Negotiating Committee, representatives expressed support for the use of the guidelines prepared by the interim Chemical Review Committee on the scope of the bridging information to be provided by a notifying country using a risk evaluation from another country in support of final regulatory action (UNEP/FAO/PIC/INC.10/14). The Interim Negotiating Committee noted that the guidelines would be applied flexibly and that all countries could base domestic regulatory action on whatever information they wished (UNEP/FAO/PIC/INC.10/24, para. 82). The guidelines as noted by the Negotiating Committee at its tenth session were posted on the Rotterdam Convention web site.

6. At its first meeting, the Conference of the Parties agreed to forward the paper on the scope of the bridging information to be provided by a notifying country using a risk evaluation from another country in support of final regulatory action to the Chemical Review Committee for consideration at its first meeting. The paper is annexed to the present note.

7. The Committee is invited to review the paper and consider its adoption as part of the policy guidance for the Committee.

Annex

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 Interim 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 Interim 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 Interim 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.