UNITED NATIONS

RC

UNEP/FAO/RC/CRC.1/13

Distr.: General
10 December 2004

English only

United Nations Environment Programme

Food and Agriculture Organization of the United Nations

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) (iv) 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: risk evaluation in the context of the Rotterdam Convention

Policy guidance: risk evaluation in the context of the Rotterdam Convention

Note by the secretariat

1. At its fifth session, the interim Chemical Review Committee developed an explanatory note on criterion (b) (iii) of Annex II of the Rotterdam Convention UNEP/FAO/PIC/ICRC.5/15, annex II).

2. At its eleventh session, the Intergovernmental Negotiating Committee, agreed to forward this note to the first meeting of the Conference of the Parties for consideration at its first meeting, along with other working procedures and policy guidance developed by the interim Chemical Review Committee.

3. At its first meeting, the Conference of the Parties agreed to forward the explanatory note on risk evaluation in the context of the Rotterdam Convention to the Chemical Review Committee for consideration at its first meeting. The explanatory note is annexed to the present note.

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

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

Annex

Explanatory note on criterion (b) (iii) of Annex II of the Rotterdam Convention

A. Background

1. In assessing notifications of banned and severely restricted chemicals used in a notifying country under article 5, problems arose with the application of the term "risk evaluation".

2. Annex II of the Convention sets out the criteria for listing banned or severely restricted chemicals in Annex III. Paragraph (b) of Annex II states that, in reviewing the notifications forwarded to it, the Chemical Review Committee shall "Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of conditions prevailing in the Party in question."

3. The report of the fifth session of the Intergovernmental Negotiating Committee states:

> "The term 'risk evaluation' used in Annex I and Annex II is understood by the Intergovernmental Negotiating Committee to be not a risk assessment, but rather an evaluation of intrinsic toxicological and ecotoxicological properties and actual or expected relevant exposure, including actual incidents and scientific evidence of hazard."

4. To clarify the issue it may be helpful also to consider the work of the Organisation for Economic Cooperation and Development (OECD) and the World Health Organization (WHO) in developing definitions of risk assessment and hazard assessment.[1]

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[1] The following examples might be considered:

"*Risk assessment*: A process intended to calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system.

"The risk assessment process includes four steps: hazard identification, hazard characterization (related term: dose-response assessment), exposure assessment, and risk characterization. It is the first component in a risk analysis process;

"*Hazard assessment*: A process designed to determine the possible adverse effects of an agent or a situation to which an organism, system, or sub-population could be exposed.

"The process includes hazard identification and hazard characterization. The process focuses on the hazard in contrast to risk assessment where exposure assessment is a distinct additional step."

Source: Alphabetical list of selected generic terms in hazard and risk assessment and their definitions (OECD/IPCS/WHO).

5. It was noted that consideration of the term risk evaluation by the Interim Chemical Review Committee is in the context of the Rotterdam Convention and is not to be confused with definitions developed by OECD, WHO or other bodies.

B. Risk evaluation in the context of the Rotterdam Convention

6. Risk evaluation is neither hazard assessment nor risk assessment, but something in between. Risk evaluation considers information on hazard and exposure. In notifications of final regulatory actions to ban or severely restrict a chemical:

(a) Information on hazard assessment is normally based on internationally accepted toxicological or ecotoxicological data;
(b) Information on exposure is to be related to the prevailing conditions of use in the notifying country.

7. For a better understanding of the minimum information on exposure that might be required by the Interim Chemical Review Committee in reviewing risk evaluations, it was considered useful to develop some examples as a means of defining the minimum requirements for information regarding exposure. Any additional information will facilitate decision-making by the Interim Chemical Review Committee. For the first two examples, where reported incidents occur in a country other than the country submitting the notification of final regulatory action the relevance to the notifying country should be described[2].

8. The Interim Chemical Review Committee will consider each notification on a case-by-case basis. The use of this guidance is intended to be interpreted flexibly.

Example 1: Incidents involving direct exposure by humans

9. Information is required describing the direct exposure to the chemical and the adverse effects resulting from that exposure. For example, a description of the incident should be provided, which may include the extent or number of casualties, its circumstances and a description of the signs, symptoms and/or effects.

Example 2: Incidents involving direct exposure by the environment (wildlife, livestock etc.)

10. Information is required describing the direct exposure to the chemical and the adverse effects resulting from that exposure. For example, a description of the incident should be provided, which may include the extent or number of casualties, its circumstances and a description of the effects.

Example 3: Indirect exposure via the environment (air, water, soil)

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

(a) How does the presence of the chemical lead to human and environmental (actual or expected) exposure? Actual exposure can be directly measured. Expected exposure can be estimated, possible factors… [*to be developed if necessary*]

[2] Information to be contained in the supporting documentation provided by a notifying country using a risk evaluation from another country in support of final regulatory action (UNEP/FAO/INC.10/14).

(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, would facilitate the work of the Committee.