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INTERGOVERNMENTAL NEGOTIATING COMMITTEE FOR AN
INTERNATIONAL LEGALLY BINDING INSTRUMENT FOR
THE APPLICATION OF THE PRIOR INFORMED CONSENT
PROCEDURE FOR CERTAIN HAZARDOUS CHEMICALS AND
PESTICIDES IN INTERNATIONAL TRADE

Tenth session

Geneva, 17-21 November 2003

Item 4 (e) (iii) of the provisional agenda*

**Implementation of the interim prior informed consent procedure:
Issues arising out of the fourth session of the Interim Chemical Review Committee**

**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**

Note by the secretariat

Introduction

1. The Intergovernmental Negotiating Committee at its ninth session requested the Interim Chemical Review Committee to develop guidelines on the scope of the “bridging” 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.
2. Annexed to the present note is a working paper developed by the fourth session of the Interim Chemical Review Committee in response to the aforementioned request of the Intergovernmental Negotiating Committee at its ninth session.

* UNEP/FAO/PIC/INC.10/1.

A. Background

3. At the third session of the Interim Chemical Review Committee, in considering a notification of final regulatory action from a country that had taken as its risk evaluation that submitted by the European Community, the issue arose of whether that risk evaluation met the criterion stipulated in subparagraph (b) (iii) of Annex II, on “prevailing conditions”. The Committee agreed that the Intergovernmental Negotiating Committee should be asked to provide guidance on how to determine when countries should provide their own risk evaluations for their own prevailing conditions and, conversely, under what conditions the Committee was allowed to accept information from neighbouring and other countries that had identical or similar conditions in relation to the use of pesticides.
4. In its consideration of the issue, the Intergovernmental Negotiating Committee at its ninth session recognized the right of any country to take domestic regulatory action regarding use of chemicals and recalled that such action must be notified under the terms of the Convention.
5. It noted also that, in the absence of documentation detailing how the risk evaluation from another country related to conditions prevalent in the notifying country, such regulatory action would not be considered as meeting the criteria of Annex II of the Convention.
6. At its ninth session, the Intergovernmental Negotiating Committee stressed that, when hazard or risk evaluation information from another country was used, supporting documentation would be expected to demonstrate that conditions in that other country were similar and comparable to those in the notifying country. The supporting documentation could include “bridging” information on, among other things, a comparison of uses, conditions of use, physical and climatic conditions and risk-reduction measures. The level of detail of that information should be sufficient to enable the Interim Chemical Review Committee to judge whether conditions were indeed comparable. Also, the sufficiency and acceptability of the information must be determined by the Interim Chemical Review Committee on a case-by-case basis.
7. The Intergovernmental Negotiating Committee requested the Interim Chemical Review Committee to develop guidelines for review at its tenth session on the scope of “bridging” information to be contained in the supporting documentation provided by the notifying country.
8. At its fourth session, the Interim Chemical Review Committee had before it a note by the Secretariat (UNEP/FAO/PIC/ICRC.4/8) on the issue which set out points to consider and possible elements that might be included in the requested guidelines. Representatives noted that the bridging information must be detailed and science-based, setting out the national conditions of use and describing precisely what was being compared and how. One representative cautioned that the requirements for bridging information should not be more demanding than those for the submission of a normal notification. It was stressed that, where a country opted to use a risk evaluation from another country and supply bridging information, its notification of final regulatory action would be examined by the Committee on a case-by-case basis.
9. At its fourth session, Interim Chemical Review Committee approved the working paper, as orally amended, for transmission to the Intergovernmental Negotiating Committee at its tenth session, with the understanding that the paper would be updated in the light of actual experience in its use.

B. Possible action by the intergovernmental negotiating committee

10. The Intergovernmental Negotiating Committee is invited to take note of the working paper reproduced in annex to the present note.

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.
