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OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE

ISSUES ASSOCIATED WITH THE IMPLEMENTATION OF THE OPERATIONAL PROCEDURES:

INFORMATION TO BE CONTAINED IN THE SUPPORTING DOCUMENTATION PROVIDED BY A NOTIFYING COUNTRY USING A RISK EVALUATION FROM ANOTHER COUNTRY IN SUPPORT OF THEIR 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 "bridging" information to be contained in the supporting documentation provided by a notifying country using a risk evaluation from another country in support of its final regulatory action.

2. The present note divided into two chapters. Chapter one, entitled points to consider, provides a context for the review of this issue by the Committee while Chapter two, entitled possible elements, includes an initial list of elements for the Committee to consider in developing the guidelines.

Background

3. At its third session the Interim Chemical Review Committee identified a range of issues concerning the compatibility of current regulatory practices with the requirements of the interim prior informed consent procedure.

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4. One particular issue arose in considering a notification of final regulatory action from a country which had taken as its risk evaluation that submitted by the European Community. The ability of this risk evaluation to meet the criterion stipulated in paragraph (b) (iii) of annex II on "prevailing conditions", was questioned. The Committee agreed that the Intergovernmental Negotiating Committee (INC) 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 could be allowed to accept information from neighbouring and other countries that had identical or similar conditions in relation to the use of pesticides.

5. In its consideration of this issue the ninth session of the INC recognized the right of any country to take domestic regulation action regarding use of chemicals and recalled that that action must be notified under the terms of the Convention.

6. It further noted that, in the absence of documentation detailing how the risk evaluation used from another country related to conditions prevalent in the notifying country, such an action would not be considered as meeting the criteria of Annex II of the Convention.

7. Finally the INC stressed that, even when hazard or risk evaluation information was taken from another country, supporting documentation would be expected to demonstrate that conditions in that country were similar and comparable to those in the notifying country. The supporting documentation could include "bridging" information on, among others 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 Committee to judge whether conditions were comparable. Further, the sufficiency and acceptability of that information would have to be determined by the Committee on a case-by-case basis.

8. The INC requested the Interim Chemical Review Committee to develop guidelines on the scope of "bridging" information to be contained in the supporting documentation provided by the notifying country, for review at its tenth session.

A. Points to consider

9. The ability of the Interim Chemical Review Committee to determine if a submitted notification meets the criteria in annex II of the Convention is to a large extent determined by the level of detail in the supporting documentation provided by the notifying country.

10. In order for the Committee to establish that a final regulatory action was taken as a consequence of a risk evaluation, a notifying country is to provide documentation that demonstrates that such actions were based on a risk evaluation involving conditions prevailing within that country.

11. A risk evaluation consists of two key elements an evaluation of hazard and of exposure. The hazard component reflects the inherent toxicity of the chemical and is to a large extent generic in that such evaluations from international sources (e.g. WHO/IPCS or IARC etc.) or national governments (e.g. United States Environmental Protection Agency or European Community) may be used by countries in support of their national regulatory actions. The exposure component is different in that it is uniquely determined by the conditions under which the chemical is used in a country.

12. Where a notifying country has adopted a risk evaluation from another country, the supporting documentation submitted to the Committee must demonstrate that the conditions prevailing in the notifying country (e.g. those that determine the level of exposure) are comparable to those in the country that undertook the original risk evaluation. This additional or bridging information should include a comparison of the how the chemical was used in the two countries. For example:

(i) it is anticipated that a risk evaluation based on the use of a pesticide in fruit orchards in one country might be applicable to a similar application to tree fruit in a second country while extrapolation to cover a post harvest application might not be acceptable.

(ii) a risk evaluation in a develop country which concludes that a chemical can only be used under very stringent conditions that minimize occupational exposure e.g. full body protective clothing, respirators, closed system mixing and loading etc., might be applicable to a second country where it can be demonstrated that such protective equipment or clothing is not available such that the risks to workers would be unacceptable.

13. The Committee will need to evaluate the submitted information an a case-by-case basis in order to determine whether it meets the criteria of Annex II.

B. Possible Elements

14. The type of information needed to facilitate a comparison of the conditions of use and hence the exposure scenario between the notifying country and the country that completed the referenced risk evaluation for a pesticide have been listed below. These points would also be extrapolated to a comparison of the uses and potential exposures for an industrial chemical.

15. These elements have been proposed assuming that the principal exposure scenario results from occupational use of the chemical, there may be further or different points to consider for situations where exposure is through the ambient environment or diet.

16. Information to facilitate a comparison of occupational exposure:

(i) the form in which the chemical was used

- formulation type:
  - liquid, powdered, granular etc
  - concentration of active ingredient(s)

(ii) how the chemical is used in both countries

- use pattern:
  - crops treated
  - 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 other ?
- if applied in the field
  climatic conditions, comparability between the two countries

(iii) risk reduction measures - relevance of restrictions/precautions on use in the country that undertook the risk evaluation, for example:

- 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
- effects on non-target organisms

- buffer zones to protect sensitive areas such as water bodies or species habitats, are they enforceable in the notifying country