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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

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Item 4 (e) of the provisional agenda\*

IMPLEMENTATION OF THE INTERIM PRIOR INFORMED CONSENT PROCEDURE:  
ISSUES ARISING OUT OF THE THIRD SESSION OF THE INTERIM  
CHEMICAL REVIEW COMMITTEE

Issues to consider in establishing whether a final regulatory action has been taken as a  
consequence of a risk evaluation relevant to the conditions within the reporting party in line with the criteria  
of annex II to the Convention

Note by the secretariat

Annexed to the present note is an issue paper prepared in cooperation with Mr. Reiner Arndt, Chair  
of the Interim Chemical Review Committee, as requested by that Committee at its third session  
(17-21 February 2002).

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\* UNEP/FAO/PIC/INC.9/1.

## Annex

### Issues to consider in establishing whether a final regulatory action has been taken as a consequence of a risk evaluation relevant to the conditions within the reporting party in line with the criteria of annex II to the Convention

#### Paper prepared in cooperation with the Chair of the Interim Chemical Review Committee

1. The Interim Chemical Review Committee at its third session, held at Geneva from 17 to 21 February 2002, identified a series of issues related to the application of the provisions of the Convention for which guidance was requested from the Intergovernmental Negotiating Committee. These issues have been divided into two papers for consideration by the Negotiating Committee. The present paper outlines the issues concerned with establishing whether a regulatory action has been taken as a consequence of a risk evaluation relevant to the prevailing conditions in the notifying country. An initial draft of the paper was sent to the members of the Review Committee for comment. Comments were received from the European Commission and Samoa. The second set of issues concerns the scope of regulatory actions and the identification of chemicals included in the interim prior informed consent (PIC) procedure and may be found in document UNEP/FAO/PIC/INC.9/9.

### Introduction

2. At its third session the Interim Chemical Review Committee considered notifications of final regulatory actions for candidate chemicals for inclusion in the interim PIC procedure. In applying the requirements of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade to these notifications as detailed in article 5 and annexes I and II, there were two distinct sets of issues that the Review Committee had to consider. The first related to the question of whether preventive regulatory actions on pesticides met the definition of a ban under article 2, and more generally the relationship of such regulatory actions to the criteria in annex II. The second was how to determine when countries should provide their own risk evaluations for the conditions prevailing in their country and, conversely, under what conditions the Review 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. Recognizing that the outcome of these deliberations could set a precedent in the consideration of further chemicals and the importance of a consistent process of decision-making, and to ensure transparency in its operation, the Review Committee considered it important that the issues that arose in these discussions should be clearly defined and forwarded to the Intergovernmental Negotiating Committee for consideration and guidance.

3. The present paper summarizes the relevant provisions of the Convention and sets out the issues as identified at the third session of the Interim Chemical Review Committee, where possible illustrated with representative examples. The definitions of a banned chemical and a final regulatory action may be found in article 2 of the Convention, while the criteria for inclusion of banned or severely restricted chemicals are listed in annex II. For ease of reference, the relevant excerpts from the definitions in article 2, as well as the text of annex II, may be found in appendices I and II below.

## I. BACKGROUND

4. Article 5 of the Convention, "Procedures for banned or severely restricted chemicals", sets out the obligations regarding the identification and evaluation of candidate chemicals that have been banned or severely restricted in a participating country. Notifications forwarded by the secretariat to the Interim Chemical Review Committee have been found to meet the information requirements of annex I to the Convention. The Review Committee reviews these notifications in accordance with the criteria set out in annex II and recommends to the Intergovernmental Negotiating Committee whether the chemical should be included in the interim PIC procedure.

5. One of the notifications of final regulatory actions considered by the Interim Chemical Review Committee at its third session was from a country where the chemical in question had never been used or proposed for use. A representative of that country clarified that the country banned such chemicals as a matter of policy based on a defined set of criteria. In particular, pesticides that were included in hazard classification categories 1a and 1b of the World Health Organization (WHO) would not be permitted for use. The Review Committee questioned whether such preventive regulatory actions on pesticides met the definition of a ban under article 2 and, more generally, the relationship of such preventive actions for chemicals never used in a country to the annex II criteria. It was agreed to refer these questions to the Intergovernmental Negotiating Committee for guidance (UNEP/FAO/PIC/INC.9/6, annex, paras. 59-62).
6. A further issue arose when it was stated in another notification that the country had taken as its risk evaluation that submitted by the European Community. The question of the criterion stipulated in paragraph (b) (iii) of annex II on “prevailing conditions”, therefore arose and it was 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 Interim Chemical Review 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 (*Ibid.*, para. 63).
7. In applying the criteria in annex II, the Review Committee considered that the provisions of paragraphs (a) and (b) thereof, specifically the obligation to confirm and establish certain aspects of the notifications, were required and had to be satisfied in order for a banned chemical to be recommended for inclusion in the Convention. However, as paragraphs (c) and (d) of annex II reflect information that is to be considered or taken into account in reviewing submitted notifications, the Review Committee agreed that such information, whilst highly desirable, was not required to be present in each and every notification for a particular chemical.
8. In its deliberations, the Review Committee noted the importance of distinguishing between the sovereign right of a country to determine the acceptable level of risk as the basis for national regulatory decision-making versus what is required as the basis for international action according to the requirements of the Rotterdam Convention. It was also noted that all notifications of national regulatory actions to ban or severely restrict a chemical submitted to the secretariat are included in the PIC Circular and posted on the Rotterdam Convention web site and as such represent an important contribution to information exchange.

## II. ISSUES

### Issue 1. Whether preventive regulatory actions for pesticides meet the definition of a ban under article 2

9. Article 2 of the Convention contains two definitions that are relevant to this discussion (see appendix I below). First, the definition of a banned chemical in article 2 (b) is independent of whether or not the chemical has been used in the country taking the action. The first sentence states that a “banned chemical means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment.” The definition then specifically mentions that this includes “a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process...” This provision identifies certain types of preventive regulatory action but does not necessarily exclude others. Secondly, the definition of final regulatory action in article 2 (e) is independent of the basis for the regulatory action. In both instances, the definitions may apply to regulatory actions on chemicals regardless of whether or not the chemical was used in the country at the time of the regulatory action.
10. The Intergovernmental Negotiating Committee may wish to consider whether the definition of a banned chemical in article 2 of the Convention should include “preventive” regulatory actions, taken to protect human health or the environment, for chemicals that may not have been proposed for use in the notifying country.

Issue 2. Relationship of final regulatory actions for chemicals never used in a country to the criteria in annex II

11. From its deliberations, the Interim Chemical Review Committee identified two types of regulatory actions for chemicals never used in a country, distinguished by whether or not the chemical had been proposed for use in the notifying country.
12. Scenario 1: A country notifies a final regulatory action to ban a chemical that has been refused approval for first-time use or withdrawn from further consideration in the domestic approval process, in order to protect human health or the environment.
13. In order to meet the criteria in annex II, particularly paragraph (b), the notification and supporting documentation would need to demonstrate that the regulatory action was taken as a consequence of a risk evaluation of the proposed uses, based on a review of scientific data in the context of the prevailing conditions in the notifying country.
14. The Intergovernmental Negotiating Committee may wish to consider:
  - (a) Whether the availability of the supporting documentation relevant to a consideration of the criteria in annex II will be determined by the extent to which such final regulatory actions are based on a premarket evaluation of the risks associated with the proposed uses under the prevailing conditions in the notifying country;
  - (b) Whether the extent to which a notification and supporting documentation for specific chemicals are found to meet the criteria in annex II, particularly paragraph (b), would need to be considered on a case-by-case basis.
15. Scenario 2: A country notifies a final regulatory action to ban a chemical that has not been proposed for use in that country.
16. Such preventive regulatory actions may reflect national policies with respect to hazardous chemicals based on a range of both technical and socio-political considerations. For example, one of the notifications reviewed by the Interim Chemical Review Committee was found to be the result of a general policy decision for chemicals based on the following criteria: (a) they had an oral LD<sub>50</sub> of < 30mg/kg body weight, that is, were very hazardous; (b) they showed chronic toxicity, such as carcinogenicity; (c) they were persistent; (d) they underwent bioaccumulation; (e) they caused damage to certain indicator species; (f) they contained contaminants with the foregoing characteristics; (g) residues were frequently found in exported products; (h) they had been banned in other countries; and (i) there were alternatives of proven lower toxicity. That country also noted that no pesticides that were within WHO hazard classification categories 1a or 1b would be permitted for use.
17. The Review Committee could not reach a consensus on whether final regulatory decisions based on such general policies would meet the criteria of annex II. A primary concern was the extent to which such regulatory actions met the criteria in paragraph (b) of annex II, particularly for a risk evaluation involving the conditions prevailing in the notifying country.
18. The Intergovernmental Negotiating Committee is asked to consider:
  - (a) Whether, as a general rule, final regulatory actions to ban chemicals not proposed for use in a country as part of a general policy on hazardous chemicals would be expected to meet the criteria in annex II;

(b) Whether such notifications would need to be supplemented by chemical-specific supporting documentation that would allow the Interim Chemical Review Committee to establish that the final regulatory action was taken as a consequence of a risk evaluation of the anticipated or likely uses of the chemical in the notifying country based on a review of scientific data in the context of the conditions prevailing in that country as per the criteria in annex II;

(c) Whether the extent to which the notification and supporting documentation are found to meet the criteria in annex II, particularly paragraph (b), would need to be considered on a case-by-case basis.

Issue 3. How to determine when countries should provide their own risk evaluations for the conditions prevailing in their country and, conversely, under what conditions the Review 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

19. The requirement that a regulatory action should be taken as a consequence of a documented risk evaluation and based on a review of scientific data in the context of the conditions prevailing in the notifying country is provided in annex II to the Convention. The challenge is how to determine what constitutes an acceptable risk evaluation and the relevant documentation required in support of the submitted notification in the context of annex II.

20. The range of abilities among countries in undertaking risk evaluations in support of final regulatory actions varies widely. They may be characterized into three main scenarios, as detailed below:

(a) In countries with well-established regulatory infrastructures there has been a trend towards increasingly detailed risk evaluations as a key component of regulatory decision-making. These evaluations are generally well documented and would be available to the Interim Chemical Review Committee for review in support of submitted notifications. Such risk evaluations would be expected to meet the requirements of annex II;

(b) Some countries make use of information from a range of sources in making a regulatory decision. For example, one of the notifications of final regulatory action submitted to the Interim Chemical Review Committee was based on a risk evaluation developed using a hazard evaluation from the United States of America Environmental Protection Agency in combination with basic information on exposure under conditions of use in the notifying country. The resulting risk evaluation reflected the conditions prevailing within that country and was found to meet the requirements of annex II.

(c) Some countries may adopt the regulatory decisions of other countries as the basis for their national decisions. For example one of the notifications of final regulatory action submitted to the Interim Chemical Review Committee was based on the regulatory action in a neighbouring country with the statement that the conditions of use were similar. There was no supporting documentation outlining the relevance of the underlying risk evaluation of the neighbouring country to the uses in the notifying country. In this instance the Committee did not consider that the notification met the criteria of annex II.

21. The Intergovernmental Negotiating Committee may wish to consider:

(a) Whether for the first two scenarios, in paragraph 18 (a) and (b) above, the submitted notifications of final regulatory action might be expected to include detailed information on the risk evaluation relating to the prevailing conditions in the notifying country and that such information might be considered on a case-by-case basis as to whether or not they met the criteria in annex II;

(b) Whether in the third scenario, in paragraph 18 (c) above, the ability of a submitted notification to satisfy the criteria in annex II will be a function of the supporting documentation provided by the notifying country. Specifically that:

- (i) The supporting documentation would need to demonstrate that the prevailing conditions in the notifying country are comparable to those in the country that undertook the risk evaluation in order that might be considered to meet the criteria in annex II;
  - (ii) The “bridging information” should include a comparison of the uses of the chemical in the two countries, the general conditions of use, etc.;
  - (iii) The acceptability of the submitted information would need to be determined on a case-by-case basis.
- (c) Whether or not in the absence of documentation that demonstrates how the referenced risk evaluation relates to the prevailing conditions in the notifying country it is expected that such notifications of final regulatory action would meet the criteria of annex II.

Appendix IExcerpt from article 2 of the Rotterdam Convention

"For the purposes of this Convention:

...

"(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

...

(e) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical;

..."

Appendix II

Annex II of the Rotterdam Convention

Criteria for listing banned or severely restricted chemicals in annex III

In reviewing the notifications forwarded by the Secretariat pursuant to paragraph 5 of Article 5, the Chemical Review Committee shall:

- (a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;
- (b) 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 the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:
  - (i) Data have been generated according to scientifically recognized methods;
  - (ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
  - (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;
- (c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:
  - (i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;
  - (ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;
  - (iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;
  - (iv) Whether there is evidence of ongoing international trade in the chemical;
- (d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

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