



United Nations
Environment Programme

Food and Agriculture Organization
of the United Nations

Distr.
GENERAL

UNEP/FAO/PIC/INC.9/9
6 June 2002

ORIGINAL: ENGLISH

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

Ninth session

Bonn, 30 September-4 October 2002

Item 4 (e) of the provisional agenda*

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

Issues to consider in ensuring consistency between the scope of reported national regulatory
actions and the inclusion of the chemical in the interim prior informed consent procedure

Note by the secretariat

Annexed to the present note is an issue paper on ensuring consistency between the scope of reported national regulatory actions and the inclusion of the chemical in the interim prior informed consent procedure, 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).

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

Annex

Issues to consider in ensuring consistency between the scope of reported national regulatory actions and the inclusion of the chemical in the interim prior informed consent procedure

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

1. The Interim Chemical Review Committee held its third session at Geneva from 17-21 February 2002. It 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 focuses on those issues related to the scope of submitted regulatory actions and how chemicals included in the interim prior informed consent (PIC) procedure might be best described. The purpose of the paper is to set out these issues and possible options for the consideration of the Negotiating Committee at its ninth session. The second set of issues relates to determining whether a regulatory action has been taken as a consequence of a risk evaluation relevant to the prevailing conditions in the notifying country. A discussion on those issues may be found in document UNEP/FAO/PIC/INC.9/8.

Introduction

2. At its third session, the Interim Chemical Review Committee considered notifications of final regulatory action for banned chemicals and the first proposal to include a severely hazardous pesticide formulation. In applying the requirements of the Convention as detailed in articles 5 and 6 and annexes II and IV, two sets of issues arose. The first involves including in the interim PIC procedure substances not specifically identified in notifications of final regulatory actions. The second is composed of a set of related issues on how the scope of the chemicals included in the interim PIC procedure might be best described. This includes the implications of including specific formulations such as Granox TBC and Spinox T with identified percentages of the active ingredients in the interim PIC procedure, as well as the intent of the Review Committee at its third session that the individual forms of asbestos should be listed in such a way that countries could take import decisions for each individual form. The Review Committee considered it important that the issues that arose in those discussions should be clearly defined and forwarded to the ninth session of 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.

I. BACKGROUND

4. A chemical enters the interim PIC procedure on the basis of final regulatory actions or proposals for severely hazardous pesticide formulations submitted by Parties. Articles 5 and 6 set out the procedures and annexes I and IV the information requirements that are the basis for the identification of candidate chemicals for inclusion in the Convention. Article 7 requires that when Parties have decided to include a chemical in the PIC procedure they also approve the draft decision guidance document. The decision guidance document must be based on and reflect the submitted notifications of the final regulatory action to ban or severely restrict a chemical or proposals for severely hazardous pesticide formulations.

5. The Interim Chemical Review Committee, at its second session, considered the possible inconsistent use of chemical abstract numbers and chemical descriptions in annex III of the Convention. It was noted that notifications generally apply to an active ingredient and may or may not include reference to specific derivatives (salts/esters) or isomeric forms of that active ingredient. It was also noted that it was not clear to what extent regulatory authorities characterize the chemicals subject to their regulatory actions or the use

made of Chemical Abstract Service (CAS) numbers in recording/reporting these actions, and that it would seem that the description of the individual chemicals and the corresponding CAS numbers may not have been applied in a consistent, unambiguous manner to chemicals subject to the interim PIC procedure (see UNEP/FAO/PIC/ICRC.2/10).

6. The Review Committee concluded that in submitting notifications of final regulatory actions countries must describe a chemical accurately by name and CAS number. The Review Committee also agreed to apply four scenarios as the basis for developing further recommendations for future inclusion of chemicals in the interim PIC procedure (see UNEP/FAO/PIC/ICRC.2/11).

7. The notifications for DNOC considered by the third session of the Review Committee banned all uses of plant protection products containing DNOC. The CAS number referred to in the notifications was for DNOC only, while it may also be used as different salts, which have different CAS numbers. Whereas it may be clear that the DNOC component of the compound had been the basis for the toxicological assessment, for the purposes of the interim PIC procedure all the forms must be specified, and it was agreed that further clarification must be sought from the notifying authorities as to the precise scope of their regulatory actions. That information would be reflected in the draft decision guidance document. It was also agreed that the Intergovernmental Negotiating Committee should be asked for guidance on including in the interim PIC procedure substances not specifically identified in notifications (UNEP/FAO/PIC/INC.9/6, para. 58).

8. As a result of the discussion of the proposals for inclusion of the severely hazardous pesticide formulations Spinox T and Granox TBC, several members of the Review Committee expressed concern over the implications of including a single specific formulation with identified percentages of the active ingredients in the interim PIC procedure. It was felt that further guidance from the Intergovernmental Negotiating Committee was necessary to determine how such listings should be considered in the future. The secretariat was requested to examine the implications of this and prepare an issue paper outlining the discussion and reviewing the consequences of such listings for consideration by the Intergovernmental Negotiating Committee at its ninth session (UNEP/FAO/PIC/INC.9/6, para. 82).

9. Similarly, the Review Committee agreed that, in recommending that the various forms of asbestos become subject to the interim PIC procedure, it was their intent that the forms should be listed in such a way that countries could take import decisions for each individual form. The Review Committee also agreed that the exact approach for listing might best be left to the Intergovernmental Negotiating Committee (UNEP/FAO/PIC/INC.9/6, para. 72).

10. Finally, the Review Committee agreed to forward the draft decision guidance document on monocrotophos to the Intergovernmental Negotiating Committee with a recommendation that monocrotophos be included in the interim PIC procedure and the decision guidance document adopted. If the Negotiating Committee decides to include monocrotophos in the interim PIC procedure, the possible implications for those specific formulations that are already included might need to be considered.

11. To facilitate the review of these issues by the Intergovernmental Negotiating Committee, they have been grouped under two separate headings. The first concerns including in the interim PIC procedure substances not specifically identified in notifications of final regulatory actions or proposals for severely hazardous pesticide formulations. The second considers how best to describe the chemicals included in the interim PIC procedure. The specific issues are presented in chapter II below using the chemicals considered by the Interim Chemical Review Committee at its third session as examples.

II. ISSUES, POSSIBLE OPTIONS AND POINTS TO CONSIDER

Issue 1: Including in the interim PIC procedure substances not specifically identified in notifications of final regulatory actions or proposals for severely hazardous pesticide formulationsA. DNOC

12. The notifications of final regulatory actions submitted to the Interim Chemical Review Committee banned all uses of plant protection products containing DNOC. The CAS number referenced in the individual notifications was for DNOC only. DNOC may also be used as different salts that have different CAS numbers. Both of the notifications considered by the Review Committee referred to DNOC as a common name with the CAS number for DNOC. In both cases only the ammonium salt had been permitted for use prior to the ban. Further information on the scope of the regulatory actions confirmed that the final regulatory actions applied to all derivatives of DNOC. No products containing DNOC in any form were permitted for use by the authorities submitting the notifications of final regulatory actions.

13. According to article 5 and the information requirements of annex I, the chemical proposed for inclusion in the interim PIC procedure is that described in the notifications of final regulatory action.

Options

(A) Only DNOC and the one salt (ammonium salt) referenced in both notifications would be subject to the interim PIC procedure. Other salts would not be included as they were not explicitly referenced in the notifications considered to meet the requirements of the Convention;

(B) As the intended scope of the submitted regulatory actions was to cover all forms of DNOC, all products containing any or all salts could be considered subject to the interim PIC procedure, even though the individual salts were not explicitly referenced in each of the notifications.

Points to consider

14. Under option A, a subset of DNOC products (DNOC and its ammonium salt) would be subject to the interim PIC procedure. Products containing other salts of DNOC that were also determined to be subject to the notified bans would not be included.

15. Under option B, all products containing DNOC (DNOC and all salts) would be subject to the interim PIC procedure. This may be seen as expanding the scope of the chemical included in the interim PIC procedure beyond those compounds explicitly identified in the submitted notifications.

16. The same situation exists for other compounds that, like DNOC, are or may be marketed as a range of derivatives (salts or esters) with comparable toxicological profiles as well as compounds that exist in different mixtures of stereo isomeric forms.

B. Granox TBC and Spinox T

17. The Interim Chemical Review Committee considered the first proposal for the inclusion in the PIC procedure of a severely hazardous pesticide formulation. In reviewing the supporting documentation, there was concern that the onset of symptoms was not consistent with carbamate intoxication, given that it appeared that the majority of symptoms, including fatalities, occurred 45 to 120 days after the first exposure. However, it was recognized that this may be an artefact of the way in which the data were reported and probably reflected the time from when users first started applying the formulation, rather than the time between the last exposure and the onset of symptoms. It was also noted that symptoms reported did not reflect the full range of those typically associated with cholinesterase inhibition. For carbamates, such symptoms as miosis and excess salivation are typically of short duration. Given that the data were collected some time after exposure, those symptoms would not be expected to be observed. In addition, it was noted

that the forms used to collect the data may have influenced the symptoms reported, since it did not list the full range of symptoms representative of cholinesterase inhibition. The reported respiratory problems were considered to be indicative of lung oedema, normally a symptom of severe carbamate poisoning, and possibly a precondition to the reported limb oedemas.

18. It was agreed that the overall weight of evidence clearly indicated that the use of the formulations in accordance with common and recognized patterns of use within Senegal resulted in the reported incidents.

19. The Review Committee agreed to recommend to the Negotiating Committee that the specific formulation (containing 15 per cent thiram, 7 per cent benomyl and 10 per cent carbofuran) reported to cause problems under conditions of use in the proposing country, be included in the interim PIC procedure.

20. In making this recommendation, several members of the Review Committee expressed concern over the implications of listing a single specific formulation with identified percentages of the active ingredients in the interim PIC procedure and requested guidance from the Intergovernmental Negotiating Committee. The concerns were based on the fact that any changes in the specified percentages of any one of the active ingredients would effectively remove such formulations from the scope of the interim PIC procedure, even though they might represent the same or possibly a greater level of hazard under the conditions of use in developing countries or countries with economies in transition. Similarly, other powdered formulations with one different active ingredient (captafol instead of thiram) used in Burkina Faso and the Gambia would not be included.

21. In view of the fact that the adverse effects observed were indicative of carbamate poisoning, that Germany and the United States of America confirmed the need to use special and protective apparel during the use of carbofuran, and that for the 24 countries and the European Union that submitted information for the consideration of the Committee there were no reported registrations or uses of powdered formulations of carbofuran, consideration might be given to including powdered formulations of carbofuran in the interim PIC procedure. This would serve to focus on the likely source of the adverse effects and assist developing countries to manage better the risks associated with the use of powdered formulations of carbofuran.

22. According to article 6 and the information requirements in part 1 of annex IV, the formulation considered for inclusion in the interim PIC procedure is that described in the submitted proposal.

Options

- (A) Only those formulations containing the level of active ingredients identified in the submitted proposal (15 per cent thiram, 7 per cent benomyl and 10 per cent carbofuran) be considered subject to the interim PIC procedure;
- (B) As it may be reasonable to conclude that other formulations containing this combination of active ingredients at the same level or above those in the formulation identified in the proposals would represent a comparable or greater hazard, such formulations should automatically also be considered subject to the interim PIC procedure;
- (C) As it may be reasonable to conclude that powdered formulations containing carbofuran at the same level (10 per cent) or above that in the formulation identified in the proposals would represent a comparable or greater hazard, consideration could be given to including such powdered formulations of carbofuran in the interim PIC procedure.

Points to consider

23. Under option A, only the specific formulation explicitly identified in a submitted proposal would be subject to the interim PIC procedure. All other formulations where there was even a minor change in the level of any one of the active ingredients would not be included, even though they might represent a

comparable or greater hazard to human health or the environment. This would parallel the manner in which formulations for methyl-parathion are listed in annex III.

24. Under option B, all formulations containing this combination of active ingredients, with one or more of the active ingredients at or above the specified concentrations, would be subject to the interim PIC procedure. In this way, formulations that might reasonably be expected to represent a comparable or greater hazard to human health or the environment would be included. This would parallel the manner in which formulations for monocrotophos, methamidophos and phosphamidon are listed in annex III.

25. Option C, while including formulations that might reasonably be expected to represent a comparable or greater hazard to human health, would substantially broaden the scope of the formulations subject to the interim PIC procedure beyond those identified in the submitted proposal.

26. It is conceivable that a situation could arise where an active ingredient was included in a range of individual formulations that are subject to the interim PIC procedure. Each specific formulation would require a separate decision guidance document and import response in line with article 10 of the Convention. The practical problems at the national level associated with the enforcement of these import decisions involving different concentrations of an active ingredient in the different formulations, as well as at the level of the secretariat in tracking compliance, might benefit from further consideration.

Issue 2: Identification of chemicals to be included in the interim PIC procedure

27. The decisions on the scope of the individual chemicals subject to the interim PIC procedure will determine how they are to be described. According to article 7, the adoption of the decision guidance document forms a part of the decision to include a chemical in the interim PIC procedure. The decision guidance document should then clearly identify the chemical(s) subject to the interim PIC procedure as described in the supporting notifications of regulatory action or the proposals for severely hazardous pesticide formulations. Articles 10 and 11 set out the obligations of countries with respect to the import and export of chemicals respectively and refer specifically to the chemicals listed in annex III. This suggests that, in order to facilitate implementation of the interim PIC procedure and avoid possible disputes based on a differential understanding of what chemicals are included, chemicals subject to the interim PIC procedure must be described as explicitly and unambiguously as possible.

28. The Review Committee, at its second session, considered the possible inconsistent use of chemical abstract numbers and chemical descriptions in annex III of the Convention. It would seem that the description of the individual chemicals and the corresponding CAS numbers may not always have been applied in a consistent, unambiguous manner. While the listings of chemicals in this annex can only be amended by the Conference of the Parties, it is possible for the Intergovernmental Negotiating Committee to interpret the chemicals listed in annex III for the purpose of the interim PIC procedure. It is important that, as additional chemicals are included in the interim PIC procedure, they should be described as clearly and unambiguously as possible. The decisions taken on how best to describe these additions to the interim PIC procedure may have implications for the interpretation of at least some of the chemicals presently listed in annex III under the interim PIC procedure.

A. DNOC

29. The decision on the range of DNOC-containing products to be included in the interim PIC procedure will determine how they are to be described.

Options

- (A) If the decision is to limit inclusion to DNOC itself and a single salt, then the individual chemicals might be listed along with the relevant CAS number in order to avoid confusion with other salts that may not be subject to the interim PIC procedure;

(B) If it is decided to include all salts of DNOC in the interim PIC procedure then either all individual salts and their associated CAS numbers might be explicitly listed; or it could be decided to list “DNOC and its salts” along with the CAS number for the free acid, with the individual salts and associated CAS numbers specified in the decision guidance document.

B. Granox TBC and Spinox T

30. The decision on the range of related formulations containing the identified active ingredients (thiram, benomyl and carbofuran) to include in the interim PIC procedure will determine how they are to be described.

Options

(A) If the decision is to include only the specific formulations included in the submitted proposal then the precise percentages of the individual active ingredients should be listed, along with the specific CAS numbers of the individual active ingredients;

(B) If the decision is to include all formulations containing the active ingredients at or above the precise percentage then they should be appropriately listed, along with the specific CAS numbers of the individual active ingredients;

(C) If a decision is taken to include powdered formulations of carbofuran it would be logical to list those containing carbofuran at greater than or equal to 10 per cent active ingredient, along with the CAS number for carbofuran.

C. Asbestos

31. At its third session the Interim Chemical Review Committee recommended that amphibole forms of asbestos (crocidolite, amosite, actinolite, anthophyllite and tremolite) and chrysotile should be subject to the interim PIC procedure. At present, crocidolite is already included in the interim PIC procedure. In making the various forms of asbestos subject to the interim PIC procedure, it was the intent of the Review Committee that the forms should be listed in such a way that countries could take import decisions for the individual forms.

Option

Should the Intergovernmental Negotiating Committee decide to include the additional forms of asbestos in the interim PIC procedure, then it would seem logical to list the six forms of asbestos subject to the interim PIC procedure individually along with their associated CAS numbers.

D. Monocrotophos

32. The Intergovernmental Negotiating Committee is to consider a new decision guidance document, based on notifications of final regulatory action to ban the chemical from two countries. This new decision guidance document will thus cover all formulations of monocrotophos. At present, certain monocrotophos formulations (soluble liquid formulations of monocrotophos that exceed 600 g active ingredient per litre) are subject to the interim PIC procedure.

33. Should monocrotophos become subject to the interim PIC procedure, according to article 10, countries would be required to make separate import decisions for all forms of monocrotophos as well as soluble liquid formulations of monocrotophos that exceed 600 g active ingredient per litre.

Options

- (A) For the interim period, it could be decided to retain separate decision guidance documents and lists of import responses for monocrotophos and for the specific liquid formulations identified;
- (B) For the interim period, the Intergovernmental Negotiating Committee may wish to consider an interpretation of the chemicals subject to the interim PIC procedure whereby an import response on monocrotophos would, unless stated otherwise, be considered also to apply to the specific formulations.

Points to consider

- 34. If the Intergovernmental Negotiating Committee decides to include monocrotophos in the interim PIC procedure then there will be two different decision guidance documents and two sets of potentially contradictory import responses, one for all formulations of monocrotophos, and one for soluble liquid formulations that exceed 600 g active ingredient per litre. This could lead to potential confusion on the part of countries in the implementation of the interim PIC procedure.
- 35. In the second instance, should the Negotiating Committee issue the proposed interpretation, countries could be invited to submit a single decision regarding future imports of monocrotophos that would be considered to apply to all forms of monocrotophos including soluble liquid formulations that exceed 600 g active ingredient per litre, unless explicitly exempted in the submitted import response.

III. CONSIDERATIONS IN EVALUATING THE PROPOSED OPTIONS

- 36. The decision guidance document should set out the scope of the chemicals subject to the interim PIC procedure. However, it would facilitate implementation of the interim PIC procedure if the full scope of the chemicals subject to the procedure were also clearly identifiable from a single list that did not require interested parties to refer to the decision guidance documents.
- 37. The Intergovernmental Negotiating Committee should adopt a consistent approach to the identification of the chemicals subject to the interim PIC procedure in order to avoid a situation where future decisions might result in differential interpretations of the scope of the chemicals subject to the interim PIC procedure.

IV. POSSIBLE ACTION BY THE INTERGOVERNMENTAL NEGOTIATING COMMITTEE

- 38. The Negotiating Committee may wish to review the issues and proposed options as the basis for providing the requested guidance to the Interim Chemical Review Committee.
- 39. The Committee may also wish to:
 - (a) Respond to the specific requests for guidance from the Interim Chemical Review Committee as set out in chapter II of the present document;
 - (b) Recommend to Governments that precise chemical descriptions and relevant CAS numbers for all of the chemicals subject to a final regulatory action be clearly presented in the notifications of final regulatory actions submitted to the secretariat;
 - (c) Decide that the Interim Chemical Review Committee, in making recommendations to the Intergovernmental Negotiating Committee for the inclusion of chemicals in the interim PIC procedure, should provide a clear and unambiguous description of the chemicals covered by the recommendation including a specific description of any relevant derivatives as well as associated CAS numbers;

(d) Request the Review Committee to review where differences in interpretation of the scope of the chemicals subject to the interim PIC procedure may arise and make a recommendation to the Negotiating Committee at its next session on how countries might interpret these chemical descriptions.
