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**Rotterdam Convention on the Prior
Informed Consent Procedure for Certain
Hazardous Chemicals and Pesticides in
International Trade**

Conference of the Parties

First meeting

Geneva, 20–24 September 2004

Item 9 (b) of the provisional agenda*

**Matters recommended by the Intergovernmental Negotiating Committee
for action by the Conference of the Parties at its first meeting:
Operational procedures for the Chemical Review Committee**

**Working procedures and guidance for the consideration of
the Chemical Review Committee**

Note by the secretariat

1. At its seventh session, the 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 considered the issues associated with the discontinuation of the interim prior informed consent (PIC) procedure. In its decision INC-7/7, the Committee requested the secretariat to prepare a paper on the issues associated with the discontinuation of the interim PIC procedure, setting out the options and their consequences, advantages and disadvantages in relation to the PIC procedure (annex I, UNEP/FAO/PIC/INC.7/15).

* UNEP/FAO/RC/COP.1/1.

2. At its eighth session, the Negotiating Committee considered the note prepared by the secretariat on issues associated with the discontinuation of the prior informed consent (PIC) procedure (UNEP/FAO/PIC/INC.8/16). The Negotiating Committee took note of the report of the working group established to consider this topic and agreed to continue its examination of the issue at its ninth session.
3. At its ninth session the Negotiating Committee considered a note prepared by the secretariat to facilitate follow-up to the work accomplished by the working group (UNEP/FAO/PIC/INC.9/18). The Negotiating Committee made progress in its examination of these issues and adopted recommendations to the first meeting of the Conference of the Parties (UNEP/FAO/PIC/INC.9/21, annex III).
4. The present note has been prepared in response to the proposal of the working group that procedures established under the interim PIC procedure be adopted under the Convention PIC procedure.

Introduction

5. Five sessions of the interim Chemical Review Committee were convened between February 1999 and February 2004. In reviewing individual chemicals, the Committee gained substantial practical experience that has been captured in a range of operational procedures, working papers and policy guidance. In some cases this experience has formed the basis for decisions by the Negotiating Committee while in others it was simply noted by that Committee.
6. The working group established by the Negotiating Committee to consider the issues associated with the discontinuation of the interim PIC procedure recommended that the procedures established under the interim PIC procedure be adopted for the Convention PIC procedure, with the understanding that they would continue to evolve as experience was gained in their implementation (UNEP/FAO/PIC/INC.9/18, annex I, para. 42).
7. The present paper comprises the following three chapters: I – “Working papers and guidelines”, which identifies the key working papers and guidelines developed by the interim Chemical Review Committee; II – “Policy guidance”, which sets out more policy-related issues considered by the interim Chemical Review Committee; and III - “Suggested action by the Conference of the Parties”, in which the Conference of the Parties is invited to consider forwarding this documentation to the Chemical Review Committee at its first meeting, for consideration and possible adoption.

I. Working papers and guidelines

A. Process for drafting decision guidance documents

8. At its first meeting, the interim Chemical Review Committee developed a flow chart of the process and explanatory notes for drafting decision guidance documents for banned and severely restricted chemicals and severely hazardous pesticide formulations (UNEP/FAO/PIC/ICRC.1/6, annex IV). The process was adopted by the Negotiating Committee at its seventh session by decision INC-7/6 and formed the basis for the work of the Committee in developing decision guidance documents for chemicals included in the interim PIC procedure, at its four subsequent sessions (UNEP/FAO/PIC/INC.7/15, annex I).

B. Working paper on preparing internal proposals and decision guidance documents for banned and severely restricted chemicals

9. A working paper on preparing decision guidance documents for banned or severely restricted chemicals, originally developed by the interim Chemical Review Committee at its third session, was used by inter-sessional drafting groups in preparing decision guidance documents for chemicals that were considered at the Committee’s fourth and fifth sessions. The working paper was revised at each session of the interim Chemical Review Committee in the light of the experience of the inter-sessional drafting

groups and discussion within the full Committee. It was emphasized that the working paper was a work in progress and could be further modified on the basis of additional experience.

10. At its tenth session, the Negotiating Committee noted the revision of the working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals by the interim Chemical Review Committee at its fourth session (UNEP/FAO/PIC/INC.10/24, para. 87).

11. At its fifth session, the interim Chemical Review Committee considered a revision of the working paper based on the further experience of the inter-sessional drafting groups on parathion, tetraethyl and tetramethyl lead (UNEP/FAO./PIC/ICRC.5/6). The document was further revised by the Committee and the amended version posted on the Rotterdam Convention web site.

12. The working paper sets out the format and content for a decision guidance document for banned or severely restricted chemicals. The Committee agreed to refer the paper to the Conference of the Parties for consideration at its first meeting, in order that the chemical review committee set up by the Conference of the Parties might consider it as part of procedures to be used by it in developing its own procedures for preparing decision guidance documents (UNEP/FAO/PIC/ICRC.5/15, para. 30).

C. Working paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations

13. A working paper on preparing decision guidance documents for severely hazardous pesticide formulations, originally considered by the interim Chemical Review Committee at its third session was used by an inter-sessional drafting group in preparing a decision guidance document considered at the fourth session of the interim Chemical Review Committee (UNEP/FAO/PIC/ICRC.4/7). It was agreed that the co-chairs of the drafting group would work inter-sessionally to develop a further draft of the working paper (UNEP/FAO/PIC/ICRC.4/18, para. 34).

14. At its fifth session, the interim Chemical Review Committee considered a revision of the working paper (UNEP/FAO./PIC/ICRC.5/7). The document was further revised by the Committee and the amended version posted on the Rotterdam Convention web site.

15. The working paper sets out the format and content for a decision guidance document for severely hazardous pesticide formulations. The Committee agreed to refer the paper to the Conference of the Parties for consideration at its first meeting, in order that the chemical review committee set up by the Conference of the Parties might consider it as part of procedures to be used by it in developing its own procedures for preparing decision guidance documents (UNEP/FAO/PIC/ICRC.5/15, para. 30).

D. Severely hazardous pesticide incident report forms

16. To assist countries in implementing article 6 of the Convention, the interim Chemical Review Committee, working with the secretariat and a range of experts in the field, developed an incident report form and instructions to facilitate the collection and submission of information on hazardous pesticide formulations based on human health incidents and on environmental incidents. The forms have been developed for use at the field level and consist of a series of closed questions – a checklist – that captures the basic information needed, with options for including additional information where available.

17. The Intergovernmental Negotiating Committee, in decision INC-7/3 approved the development of the form and instructions (UNEP/FAO/PIC/INC.7/15, annex I). At its third and fourth sessions, the interim Chemical Review Committee finalized the human health incident and environmental incident forms respectively on the understanding that they would be amended in the light of experience (UNEP/FAO/PIC/ICRC.3/19, paras. 30–32, and UNEP/FAO/PIC/ICRC.4/18, paras. 28–32).

18. At its ninth session, the Intergovernmental Negotiating Committee was invited to note the adoption of the health incident report form and guidance by the interim Chemical Review Committee (UNEP/FAO/PIC/INC.9/7, paras. 10–13). At its tenth session, the Negotiating Committee noted the adoption of the revised environmental incident form by the interim Chemical Review Committee at its fourth session (UNEP/FAO/PIC/INC10/24, para. 86).

19. The health incident form and the environmental incident form were sent to all designated national authorities and also to a broad range of intergovernmental and non-governmental organizations and bilateral and multilateral aid agencies in June 2002 and June 2003 respectively. The forms and instructions were also posted on the Rotterdam Convention website.

E. Determination of ongoing trade in chemicals

20. At its second session, the interim Chemical Review Committee agreed that, when forwarding notifications for review, the secretariat should initiate collection of information on international trade in the chemical concerned (UNEP/FAO/PIC/ICRC.2/11, para. 28 (e)). At its third session, the interim Chemical Review Committee reviewed a proposal on the process for the determination of ongoing trade in chemicals, as set out in document UNEP/FAO/PIC/ICRC.3/12. The Committee agreed to follow those guidelines (UNEP/FAO/PIC/ICRC.3/19, para. 48) and they were used for candidate chemicals considered by the interim Chemical Review Committee at its fourth and fifth sessions. The guidelines, as agreed by the interim Chemical Review Committee at its third session, were posted on the Rotterdam Convention web site.

21. At its ninth session, the Intergovernmental Negotiating Committee was invited to note the process adopted by the interim Chemical Review Committee at its third session (UNEP/FAO/PIC/INC.9/7, para. 23).

F. Common and recognized patterns of use of severely hazardous pesticide formulations

22. At its third session, the interim Chemical Review Committee had before it the first proposal for inclusion of a severely hazardous pesticide formulation. One of the criteria to be determined was whether the pesticide had been handled in a manner that was consistent with common and recognized patterns of use in the country submitting the proposal. The difficulty of collecting information on incidents in developing countries and countries with economies in transition was acknowledged (UNEP/FAO/PIC/ICRC.3/19, para. 49). The interim Chemical Review Committee reviewed and agreed to use the guidelines proposed in document UNEP/FAO/PIC/ICRC.3/13 as a basis on which to characterize common recognized patterns of use and to collect the information identified on a case-by-case basis (UNEP/FAO/PIC/ICRC.3/19, para. 51).

23. At its ninth session, the Intergovernmental Negotiating Committee was invited to note the guidelines adopted by the interim Chemical Review Committee (UNEP/FAO/PIC/INC.9/7, para. 25). The guidelines, as agreed by the interim Chemical Review Committee at its third session, were posted on the Rotterdam Convention web site.

II. Policy guidance

A. Focused summaries

24. At its second session, the interim Chemical Review Committee recommended that, before the Secretariat forwarded verified notifications for review, the designated national authority should, if possible, submit a focused summary of the information used in support of the regulatory action, and cited in the notification of final regulatory action, for use by Committee (UNEP/FAO/PIC/ICRC.2/11, para. 28).

25. The interim Chemical Review Committee further considered this issue at its third and fourth sessions. A draft working paper and a worked example of a focused summary were available to Committee at its fourth session (UNEP/FAO/PIC/ICRC.4/5). The Committee agreed that focused summaries were complementary to the process of regulatory action and would facilitate its work and approved the working paper on the preparation and use of focused summaries, as amended, for transmission to the Intergovernmental Negotiating Committee at its tenth session (UNEP/FAO/PIC/ICRC.4/18, para. 47).

26. At its tenth session the Negotiating Committee took note of the working paper on the preparation and use of focused summaries prepared by the interim Chemical Review Committee (UNEP/FAO/PIC/INC.10/15) and invited designated national authorities to prepare focused summaries, on a voluntary basis, using the information at their disposal (UNEP/FAO/PIC/INC.10/24, para. 85). The process, as noted by the Negotiating Committee at its tenth session, was posted on the Rotterdam Convention web site.

B. Compatibility of current regulatory practice with the notification requirement

27. At its ninth session, the Intergovernmental Negotiating Committee was requested to provide guidance on two distinct issues under the issue of compatibility: whether preventive regulatory actions on pesticides met the definition of a ban under article 2 and the relationship of such regulatory action to the criteria in Annex II, and the concerns that countries should provide supporting risk evaluations based on conditions prevailing in their country (UNEP/FAO/PIC/INC.9/8).

28. Noting that article 2 did not rule out preventive action, even if a chemical was not proposed for use in the notifying country, the Negotiating Committee agreed that the definition of a banned chemical in that article included preventive regulatory actions taken to protect human health or the environment from chemicals that might not have been proposed for use in the notifying country (UNEP/FAO/PIC/INC.9/21, para. 69).

29. At its ninth session, the Negotiating Committee requested the interim Chemical Review Committee to develop guidelines on the scope of such bridging information to be contained in the supporting documentation provided by the notifying country, for review by the Intergovernmental Negotiating Committee at its tenth session (*ibid.*, para. 74).

30. At its fourth session, the interim Chemical Review Committee considered a working paper on adapting risk evaluations, prepared on the basis of a note submitted by the secretariat (UNEP/FAO/PIC/ICRC.4/8). The Committee approved the working paper, as orally amended, for transmission to the Negotiating Committee at its tenth session, with the understanding that the paper would be updated in the light of actual experience of its use. The Committee requested the Negotiating Committee to take note of the working paper and to invite countries to make practical use of it (see UNEP/FAO/PIC/ICRC.4/18, para. 52).

31. At the tenth session of the Negotiating Committee, representatives expressed support for the use of the guidelines prepared by the interim Chemical Review Committee on the scope of the bridging information to be provided by a notifying country using a risk evaluation from another country in support of final regulatory action (UNEP/FAO/PIC/INC.10/14). The Negotiating Committee noted that the guidelines would be applied flexibly and that all countries could base domestic regulatory action on whatever information they wished (UNEP/FAO/PIC/INC.10/24 paragraph 82). The guidelines as noted by the tenth session of the Negotiating Committee was posted on the Rotterdam Convention web site.

C. Contaminants

32. In its review of maleic hydrazide, the interim Chemical Review Committee was requested to consider the overall policy issues related to adding chemicals to Annex III of the Convention on the basis of control actions related to contaminants within the substance rather than the substance itself.

33. At its first session, the interim Chemical Review Committee recommended that the Negotiating Committee should adopt a policy on contaminants which would include final regulatory actions to ban a pesticide that had been taken by at least two countries in two PIC regions on the basis of a contamination contained in that substance, where the notifications also met the requirements of Annexes I and II of the Convention (UNEP/FAO/PIC/ICRC.1/6, annex I, section E). The Negotiating Committee adopted the recommendation at its seventh session as decision INC-7/4 (FAO/UNEP/PIC/INC.7/15, annex I).

III. Suggested action by the Conference of the Parties

34. The Conference of the Parties is invited to request the secretariat to forward the working papers, guidelines and policy guidance referred to in sections II and III of the present note, to the Chemical Review Committee at its first meeting, for consideration and possible adoption.
