GENERAL PRESENTATION OF THE PIC PROCEDURE IN THE ROTTERDAM CONVENTION

Note by the secretariat

1. The purpose of this note is to present to the Interim Chemical Review Committee the context within which its work will be performed. The first section provides a description of the new prior informed consent (PIC) procedure. The second section describes some aspects of the process for selecting chemicals for inclusion under the original PIC procedure that might be relevant for the Committee’s consideration of the draft decision guidance documents referred to the Committee by the Intergovernmental Negotiating Committee at its sixth session.

I. NEW, INTERIM PIC PROCEDURE

A. Mandate

2. The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (hereinafter referred to as the “Convention”) was adopted by a Conference of Plenipotentiaries (hereinafter referred to as the “Conference”) on 10 September 1998. The Conference considered that, pending the entry into
force of the Convention, interim arrangements were required to continue to operate a voluntary procedure, in order to protect human health and the environment from certain hazardous chemicals and pesticides.

3. The Conference thus decided, in a resolution on interim arrangements adopted on 11 September 1998, that the original PIC procedure contained in the Amended London Guidelines for the Exchange of Information on Chemicals in International Trade and the Code of Conduct on the Distribution and Use of Pesticides would be changed to an interim PIC procedure, in order to bring it in line with the procedure established by the Convention, with effect from 11 September 1998. This interim PIC procedure is to be implemented on a voluntary basis by participating States until a date to be specified by the Conference of the Parties at its first meeting.

B. Intergovernmental Negotiating Committee

4. The Conference requested the Intergovernmental Negotiating Committee to oversee the operation of the interim PIC procedure during the period between the date on which the Convention is opened for signature and the date of the opening of the first meeting of the Conference of the Parties.

C. Interim secretariat for the Rotterdam Convention

5. The Conference requested the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nation (FAO) to provide secretariat services during the interim period. An interim secretariat has been established for this purpose. The Convention stipulates, in article 19, that following its entry into force, the secretariat functions will be performed jointly by the Executive Director of UNEP and the Director-General of FAO.

D. Interim Chemical Review Committee

6. The Conference invited the Intergovernmental Negotiating Committee to establish an interim subsidiary body to discharge the functions entrusted to the Chemical Review Committee to be established under article 18, paragraph 6, of the Convention. Accordingly, the Intergovernmental Negotiating Committee established an Interim Chemical Review Committee at its sixth session in July 1999 to perform these functions, in particular under articles 5, 6 and 7, during the interim period. The Intergovernmental Negotiating Committee also decided on the Interim Committee’s composition, on the basis of equitable geographical distribution, including ensuring a balance between developed and developing Parties. The criteria to be applied in the Interim Committee’s decision-making are defined in annexes II and IV of the Convention, and voting rules are set out in article 18. The participation of observers is to be governed by the rules of procedure of the Intergovernmental Negotiating Committee.
E. Flow charts describing the PIC procedure

7. Annex I contains five flow charts which have been developed to illustrate the operative articles 4-12 of the Convention. First, a "Summary chart - information exchange and the PIC procedure" shows the main steps or phases described in articles 5-12. Thereafter "Flow chart I - information exchange procedure", "Flow chart II - prior informed consent procedure", "Flow chart III - prior informed consent procedure - continued" and "Flow chart IV - Export notification" present in more detail the various actions expected of Parties, the secretariat, the Conference of the Parties and the Chemical Review Committee in order to make the procedure work, including the export notification procedure under article 12.

F. Implementation of the interim PIC procedure

8. The following description of the interim PIC procedure is based on the procedure laid down in the Convention, and reference is made to the specific text of each article that applies. It should be noted, however, that in the text and flow charts that follow, for the implementation of the interim PIC procedure:

   (a) A "Party" should be understood to mean any State or regional economic integration organization having nominated a designated national authority or authorities for the purpose of participating in the interim PIC procedure;

   (b) The "Conference of the Parties" should be understood to refer to the Intergovernmental Negotiating Committee, which was authorized by the Conference of Plenipotentiaries to oversee the operation of the interim PIC procedure;

   (c) The "Chemical Review Committee" or "Committee" should be understood to mean the Interim Chemical Review Committee, which was established by the Intergovernmental Negotiating Committee at its sixth session to perform the functions assigned to the Chemical Review Committee in the Convention;

   (d) The "PIC procedure" should be understood to mean the interim PIC procedure;

   (e) "Annex III" of the Convention should be understood to mean a list of chemicals currently subject to the interim PIC procedure.

G. Designated national authorities

9. Article 4 of the Convention requires each Party to designate one or more national authorities to act on its behalf in the performance of the administrative functions required by the Convention. The article also stipulates that each Party shall seek to ensure that the authority has sufficient resources to perform its tasks effectively.

H. Types of chemicals included in the interim PIC procedure

10. Under article 3, the scope of the Convention is limited to banned or severely restricted chemicals and severely hazardous pesticide formulations. The Convention defines these chemicals as follows in article 2:
(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. 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;

(b) "Severely restricted chemical" means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or 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;

(c) "Severely hazardous pesticide formulation" means a chemical formulated for pesticidal use that produces severe health or environmental effects observable within a short period of time after single or multiple exposure, under conditions of use.

11. The Convention does not apply to narcotic drugs and psychotropic substances, radioactive materials, wastes, chemical weapons, pharmaceuticals, including human and veterinary drugs, chemicals used as food additives, food, and chemicals in quantities not likely to affect human health or the environment, provided they are imported for the purpose of research or analysis or by an individual for his or her own personal use in quantities reasonable for such use.

1. Banned or severely restricted chemicals

12. Article 5 of the Convention describes means of identifying banned or severely restricted chemicals to be included in the procedure. The underlying principle for the identification of these chemicals is that they are identified for inclusion on the basis of government actions, i.e. national risk evaluations and risk reduction actions (to ban or severely restrict a chemical) as reported to the secretariat. Parties are to notify the secretariat in writing of all final regulatory actions taken to ban or severely restrict a chemical, as soon as possible and no later than 90 days after the final regulatory action has taken effect. Annex I of the Convention lists the information to be provided. The secretariat has developed a specific form to assist designated national authorities in reporting such actions.

13. The secretariat is to verify whether all the information required according to annex I has been provided in each notification received. If all information requirements are fulfilled, the secretariat will circulate a summary of the notification to all Parties. If the notification does not contain all information required, the Party is informed accordingly. A synopsis of the notifications received, including summaries of those

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notifications that contained all the information required by annex I and an indication of those that did not, is published twice a year (in June and December) in the PIC Circular.

14. When the secretariat has received at least one notification from each of two PIC regions that it has verified as meeting the information requirements of annex I, it will forward the information to the Chemical Review Committee. The Committee will then review the submitted information and, by applying the criteria set out in annex II of the Convention, make a recommendation to the Conference of the Parties on whether the chemical should be made subject to the PIC procedure.

2. Severely hazardous pesticide formulations

15. Article 6 of the Convention describes means of identifying severely hazardous pesticide formulations to be included in the procedure. A developing country or a country with an economy in transition that is experiencing problems caused by a severely hazardous pesticide formulation under conditions of use in its territory may propose the inclusion of the formulation in the PIC procedure. Annex IV, part 1, of the Convention lists the information to be provided in each proposal. The secretariat has developed a specific form to assist designated national authorities in making such proposals.

16. The secretariat is to verify whether all the information required according to annex IV, part 1, has been provided. If all information requirements are fulfilled, the secretariat will circulate a summary of the proposal to all Parties. Such summaries are published twice a year (in June and December) in the PIC Circular. If the proposal does not contain all information required, the Party is informed accordingly.

17. In addition, the secretariat will collect additional information regarding the proposal, as listed in annex IV, part 2, of the Convention, from States, other Parties, international organizations, non-governmental organizations and other sources.

18. Once all the information, as listed in annex IV, parts 1 and 2, is available, the secretariat will forward the information to the Chemical Review Committee. The Committee will then review the submitted information and, by applying the criteria set out in annex IV, part 3, of the Convention, make a recommendation to the Conference of the Parties on whether the pesticide formulation in question should be made subject to the PIC procedure.

H. Selecting chemicals to be included in the interim PIC procedure

19. Article 7 describes the decision-making process for including chemicals in the PIC procedure. For each chemical or pesticide formulation the Chemical Review Committee decides to recommend for inclusion, it is charged with drafting a decision guidance document, to be forwarded to the Conference of the Parties together with the recommendation. Article 18, paragraph 6 (c), requires the Committee to do its utmost to make its recommendations by consensus. If all efforts at consensus have been exhausted, and no consensus reached, the recommendations are as a last resort to be adopted by a two-thirds majority vote of the members present and voting.

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20. When the recommendation with the draft decision guidance document is forwarded to the Conference of the Parties, the Conference decides whether the chemical should be made subject to the PIC procedure and, if so, approves the draft decision guidance document. In accordance with article 22, paragraph 5 (b), the Conference’s decision must be taken by consensus. When the decision to include a chemical in the PIC procedure has been taken and the related draft decision guidance document has been approved by the Conference of the Parties, the secretariat disseminates the decision and the approved decision guidance document to all Parties.

I. Removing chemicals from the original PIC procedure

21. It is recognized that cases might arise where new scientific evidence is brought forward demonstrating that the health or environmental concerns that originally led to a chemical’s inclusion in the PIC procedure can no longer be substantiated. A process for removing chemicals from the listing in annex III is described in article 9.

22. Any Party can submit to the secretariat information which was not available at the time of the decision to list a chemical in annex III and which indicates that its listing may no longer be justified in the light of the relevant criteria in annex II or IV. The secretariat must forward this information to the Chemical Review Committee, which must review the submitted information and, after applying the same criteria that are used to decide on inclusion of a chemical, make a recommendation to the Conference of the Parties on whether the chemical in question should be removed from the PIC procedure. From this point onwards the process is parallel to the process for selecting chemicals described in articles 5, 6 and 7.

23. The Conference of Plenipotentiaries decided, in paragraph 8 of the resolution on interim arrangements, that during the interim period the Intergovernmental Negotiating Committee should decide on the inclusion of any additional chemicals under the interim PIC procedure in accordance with the provisions of articles 5, 6, 7 and 22 of the Convention. The Intergovernmental Negotiating Committee, at its sixth session, did not include the removal of chemicals from the listing in annex III (under article 9 of the Convention) in the mandate of the Interim Chemical Review Committee.

J. Obligations in relation to imports

24. Once a chemical has been included in the PIC procedure, the decision guidance document is distributed to designated national authorities, which are requested to transmit to the secretariat, within nine months of the distribution of the decision guidance document, a response regarding the future import of the chemical.

25. Such a response may consist of a final decision to consent to import, not to consent to import or to consent to import only under certain conditions. If a Party cannot reach a final decision within the time given, it can, however, provide an interim response, which may include:
(a) An interim decision consenting to import with or without specified conditions, or not consenting to import during the interim period;

(b) A statement that a final decision is under active consideration;

(c) A request to the secretariat, or to the Party that notified the final regulatory action, for further information;

(d) A request to the secretariat for assistance in evaluating the chemical.

26. If the interim response does not include a decision regarding import, it is considered as an interim response that does not contain an interim decision. The response given must relate to the category or categories specified for the chemical in annex III.

27. The secretariat has developed a specific form to assist designated national authorities in providing such responses. The secretariat compiles the responses and circulates them to all designated national authorities twice a year (in June and December) in the PIC Circular.

28. Each Party is required to make its import responses available to those concerned within its jurisdiction, in accordance with its legislative or administrative measures. A Party that takes a decision not to consent to the import of a chemical or to consent to its import only under specified conditions must, if it has not already done so, simultaneously prohibit or make subject to the same conditions any import of the chemical from any source as well as domestic production of the chemical for domestic use. This rule is intended to ensure non-discrimination between external and internal sources of the chemical.

K. Obligations in relation to exports

29. Each Party must then take appropriate legislative or administrative measures to communicate the import responses in the PIC Circular to those concerned within its jurisdiction and to ensure that exporters within its jurisdiction comply with the decisions in each response no later than six months after the date on which the secretariat first publishes the decision in the PIC Circular.

30. Each Party must also advise and assist importing Parties, upon request and as appropriate, to obtain further information to help them to provide a response regarding import for chemicals subject to the PIC procedure and to strengthen their capacities and capabilities to manage chemicals safely during their life cycle.

31. Finally, each Party must ensure that no chemical subject to the PIC procedure is exported from its territory to any importing Party that, in exceptional circumstances, has failed to transmit a response or has transmitted an interim response that does not contain an interim decision, unless:

(a) It is a chemical that, at the time of import, is registered as a chemical in the importing Party; or
(b) It is a chemical for which evidence exists that it has previously been used in, or imported into, the importing Party and in relation to which no regulatory action to prohibit its use has been taken; or

(c) Explicit consent to the import has been sought and received by the exporter through a designated national authority of the importing Party. The importing Party must respond to such a request within 60 days and must promptly notify the secretariat of its decision.

32. The above obligations of each Party apply with effect from the expiration of a period of six months from the date on which the secretariat first informs the Parties, through the PIC Circular, that a Party has failed to transmit a response or has transmitted an interim response that does not contain an interim decision, and shall apply for one year.

L. Additional information exchange on chemicals in international trade

33. In addition to the PIC procedure, the Convention also contains three articles intended to facilitate the exchange of information on chemicals between Parties. The export notification procedure outlined in article 12 is intended to inform authorities in importing countries that a chemical which has been banned or severely restricted in the country of export is being, or will be, sent to their country. Thus, the obligation for export notification may encompass chemicals other than those subject to the PIC procedure.

34. Annex V of the Convention stipulates the information to be provided in the export notification. The notification must be provided for the chemical prior to the first export following adoption of the corresponding final regulatory action. Thereafter, the notification must be repeated before the first export in any calendar year. The requirement to notify before export may be waived by the designated national authority of the importing Party. An updated export notification must also be provided in the event of the adoption of a final regulatory action that results in a major change concerning the ban or severe restriction of that chemical.

35. The importing Party is required to acknowledge receipt of the first export notification received. If the exporting Party does not receive acknowledgement within 30 days, it must submit a second notification and make reasonable efforts to ensure that the importing Party receives it.

36. This export notification is not an obligation tied to the export of any chemical subject to the PIC procedure. A Party has the obligation to provide an export notification for all chemicals it has banned or severely restricted, whether the chemicals are subject to the PIC procedure or not. The obligation to provide an export notification to a specific country for a chemical that is subject to the PIC procedure, however, ceases if the importing Party has provided an import response for the chemical and the other Parties have been informed about the response through the PIC Circular.

37. In addition, the Convention contains provisions on information to
accompany exported chemicals (article 13) and information exchange (article 14). These are, however, not reflected in the annexed flow charts.

II. ORIGINAL PIC PROCEDURE

38. The original PIC procedure was changed, from 11 September 1998, to bring it into line with the new procedure established by the Convention. As such, the original procedure is no longer of direct relevance to the work of the Interim Chemical Review Committee. However, at its sixth session the Intergovernmental Negotiating Committee requested the Interim Committee to review draft decision guidance documents for four chemicals which had been identified for inclusion under the original PIC procedure and had been included by the Conference in the interim PIC procedure, but for which draft decision guidance documents had not yet been circulated (see UNEP/FAO/PIC/ICRC.1/4 and Adds.1-4).

39. As background information for item 6 of the provisional agenda (Consideration of draft decision guidance documents referred to the Interim Chemical Review Committee by the Intergovernmental Negotiating Committee), it may be useful to provide a short description of how these four chemicals were identified for inclusion in the original PIC procedure. The FAO/UNEP Joint Group of Experts on Prior Informed Consent, at its eighth meeting in March 1995, considered a list of chemicals that had been notified as banned or severely restricted at that time. The Group applied a set of selection criteria to this list, with the aim of assigning priority to chemicals for inclusion. It recommended the inclusion of 12 banned or severely restricted pesticides and 5 acutely hazardous pesticide formulations in the original PIC procedure. All of these, with the exception of bromacil, ethylene dichloride, ethylene oxide and maleic hydrazide, are now subject to the interim PIC procedure. Ethylene dichloride, ethylene oxide and maleic hydrazide were recommended for inclusion on the basis of the fact that these pesticides had been notified as banned or severely restricted in more than five countries before 1 January 1992. Bromacil was recommended for inclusion as it had been notified as banned or severely restricted in at least one country after 1 January 1992.

40. Finally, annex II provides the historical background and describes in more detail some of the criteria applied when selecting chemicals for inclusion in the original PIC procedure that might be relevant to the Interim Committee’s work.

1. See annex II, paragraph 5.
STEP 1
• Notification of final regulatory action to ban or severely restrict a chemical
• Proposal on severely hazardous pesticide formulation causing problems under conditions of use

STEP 2
• Decision to make a chemical subject to PIC and list in Annex III
• Dissemination of a Decision Guidance Document to all Parties

STEP 3
• Importing country responds regarding future import of each PIC chemical
• Dissemination of responses received to all Parties

STEP 4
• Follow-up on importing Party responsibilities
• Follow-up on exporting Party responsibilities
FLOW CHART I - INFORMATION EXCHANGE

STEP 0 - Final regulatory action to ban or severely restrict

Party adopts final regulatory action

The ban/severe restriction complies with definitions in article 2?

STEP 0 - Experience of problem under conditions of use

Party that is a developing country or a country with economy in transition experiences problems caused by a severely hazardous pesticide formulation under conditions of use in its territory

STEP 1 - Notification of final regulatory action to ban or severely restrict

At date of entry into force for each Party Requirements in Annex I

Notify to secretariat all final regulatory actions in effect, if not submitted earlier under the voluntary PIC procedure

STEP 1 - Severely hazardous pesticide formulation

Propose to Secretariat that the formulation is listed in Annex III

As soon as possible and no later than 6 months after receipt Requirements in Part I of Annex IV

STEP 1 - Severely hazardous pesticide formulation

Secretariat has verified whether proposal contains information required in part 1 of Annex IV

Secretariat collects additional information given in Part 2 of Annex IV

STEP 1 - Severely hazardous pesticide formulation

Go to Flowchart II

STEP 1 - Severely hazardous pesticide formulation

If notification contains information required, Secretariat forwards summary of the information received to all Parties

Secretariat sends synopsis of information received, including information on those notifications which do not contain all information required in Annex I

SECRETARIAT

STEP 0 - Final regulatory action to ban or severely restrict

Art. 5.2

Notify to secretariat all final regulatory actions in effect, if not submitted earlier under the voluntary PIC procedure

STEP 0 - Final regulatory action to ban or severely restrict

Art. 5.1

Provide notification of final regulatory action to Secretariat

STEP 0 - Final regulatory action to ban or severely restrict

Art. 5.3

Secretariat has verified whether notification contains information required in Annex I

STEP 1 - Notification of final regulatory action to ban or severely restrict

Secretariat informs Party if notification does not contain information required

STEP 1 - Severely hazardous pesticide formulation

Secretariat has verified whether proposal contains information required in Annex IV

STEP 1 - Severely hazardous pesticide formulation

Secretariat informs Party if proposal does not contain information required

STEP 1 - Severely hazardous pesticide formulation

Go to Flowchart II

STEP 1 - Severely hazardous pesticide formulation

If notification contains information required, Secretariat forwards summary of the information received to all Parties

Secretariat sends synopsis of information received, including information on those notifications which do not contain all information required in Annex I

STEP 1 - Severely hazardous pesticide formulation

If notification contains information required, Secretariat forwards summary of the information received to all Parties
FLOW CHART II - PRIOR INFORMED CONSENT PROCEDURE

STEP 2(1) - Decision to list a chemical in Annex III and dissemination of a DGD

- At least one notification from each of two PIC regions
  - Secretariat forwards proposal or notifications to Chemical Review Committee

- Criteria in part 3 of Annex IV
  - Chemical Review Committee reviews information and recommends whether the chemical or formulation should be listed in Annex III

- For each chemical it has decided to recommend for listing in Annex III, the Chemical Review Committee prepares a draft DGD

- Based on the information contained in Annex I, or, as the case may be, Annex IV
  - Chemical Review Committee forwards draft DGD and recommendation on listing to COP

- COP approves DGD and decides on listing of chemical

- COP (at 1st meeting) decides on listing in Annex III of any chemical included in the voluntary PIC procedure, which at that time is not already listed in Annex III, provided all requirements for listing in Annex III have been fulfilled

- From Flow chart I

STEP 2(2) - Decision to remove a chemical from Annex III and dissemination of a revised DGD

- Party submits information not available at the time of decision to list a chemical in Annex III, which indicates that its listing may no longer be justified

- Secretariat forwards information to Chemical Review Committee

- Criteria in part 3 of Annex IV
  - Chemical Review Committee reviews information and recommends whether the chemical should be removed from Annex III.

- For each chemical it has decided to recommend for removal from Annex III, the Chemical Review Committee prepares a revised draft DGD

- Chemical Review Committee forwards draft revised DGD and recommendation on removal to COP

- COP approves revised DGD and decides on removal of chemical

- Secretariat communicates decision and approved or revised DGD to all Parties

- Go to flow chart III
FLOW CHART III - PRIOR INFORMED CONSENT PROCEDURE - continued

From Flow chart II

Art. 7.3/9.4
Secretariat communicates decision and approved or revised DGD to all Parties

STEP 3 - Response concerning future import and dissemination of responses to all Parties

Art. 10.2
Take decision on future import

NO
As soon as possible and no later than 9 months of dispatch of DGD

YES

Art. 10.2/10.4/10.5
Provide response concerning future import to Secretariat

No later than date of entry into force for each Party

Art. 10.3
After 9 months - failed to transmit decision to Secretariat

Secretariat submits written request for Party to provide a response and, where appropriate, helps Party to provide response within time period specified in last part of art. 11.2

Art. 10.7
Transmit import responses for all chemicals listed in Annex III, if not provided earlier under the voluntary PIC procedure

Art. 10.10
Provide response concerning future import to Secretariat

Every 6 months

Secretariat informs all Parties of responses received, including failure to provide a response

STEP 4 - Follow-up on exporting Party responsibilities

Applies 6 months from date on which Secretariat first informed Parties of failure to transmit response

Art. 11.2
Exporting Parties comply with article 11.2

1 year

Art. 11.1(b)
Exporting Parties comply with decision in each response

Secretariat submits written request for Party to provide a response and, where appropriate, helps Party to provide response within time period specified in last part of art. 11.2

No later than 6 months after date on which Secretariat first informed Parties of response

Art. 11.2
Article 11.2 ceases to apply

Article 11.2 says -

Each Party shall ensure that a chemical listed in Annex III is not exported from its territory to any importing Party that in exceptional circumstances has failed to transmit a response or has transmitted an interim response that does not contain an interim decision, unless:

(a) It is a chemical that, at the time of importation, is registered as a chemical in the importing Party; or

(b) It is a chemical for which evidence exists that it has previously been used in, or imported into, the importing Party and in relation to which no regulatory action to prohibit its use has been taken; or

(c) Explicit consent to the importation has been sought and received by the exporter through a designated national authority of the importing Party. The importing Party shall respond to such request within 60 days and shall promptly notify the Secretariat of its decision.
FLOW CHART IV - EXPORT NOTIFICATION

STEP 0: Final regulatory action to ban or severely restrict

Party takes regulatory action

Ban/severe restriction complies with definitions in art. 27?

STEP 1(1) - Notification of final regulatory action to ban or severely restrict

Prior to first export after adoption of the regulatory action

Requirements in Annex V

STEP 1(2) - Export Notification for chemical banned or severely restricted in its territory

Art. 12.3

Provide updated export notification after adopting action that results in major change in original ban or severe restriction

Art. 12.1 & 12.5

Provide Export notification to the importing Party

Obligation to notify ends when response regarding import has been distributed according to Art. 10.10.

Resubmit export notification if receipt not acknowledged by importing Party within 30 days of dispatch of first notification

Within 30 days

Party considers need for action

YES

NO

Party can wait for possible future DGD

YES

Party takes regulatory action

See Flowchart I
Annex II

ORIGINAL PIC PROCEDURE

A. Historical background

1. The growth in world trade in chemicals during the 1960s and 1970s led to increasing concern about the risks associated with their use, particularly in developing countries, which frequently did not have the necessary expertise or infrastructure to ensure their safe use. This concern led to the development of the International Code of Conduct on the Distribution and Use of Pesticides by the Food and Agriculture Organization of the United Nations (FAO) and the London Guidelines for the Exchange of Information on Chemicals in International Trade by the United Nations Environment Programme (UNEP). The FAO Code of Conduct was adopted by the FAO Conference in 1985, and the London Guidelines were adopted by the UNEP Governing Council in 1987.

2. Both the Code of Conduct and the London Guidelines included provisions aimed at making existing information about hazardous chemicals more freely available, thus permitting competent authorities in countries to assess the risks associated with use of chemicals under their own conditions of use. The first of these provisions concerned information exchange on chemicals in international trade. The second provision, known as prior informed consent (PIC), was added to both instruments in 1989 to help control imports of unwanted chemicals that had been banned or severely restricted in order to protect human health or the environment.

3. Although the two instruments were developed in different forums, they were compatible and could be implemented jointly. FAO and UNEP therefore agreed to share operational responsibility for the implementation of the procedure and to jointly manage common elements, through the establishment of the FAO/UNEP Joint Programme for the operation of prior informed consent. This original PIC procedure was operated from 1989 until 11 September 1998, when the Conference of Plenipotentiaries agreed to change the procedure to bring it in line with the procedure established by the Convention, during the interim period before the Convention entered into force.

B. FAO/UNEP secretariat on implementation of the PIC procedure

4. FAO and UNEP were responsible for the operation of the Joint Programme for the operation of prior informed consent. The Plant Protection Service of FAO was the lead office for pesticides. In UNEP, the Chemicals Unit was the lead office for industrial and consumer chemicals. A “Guidance for Governments” document was developed by the secretariat to provide information and guidance on the operational details of the original PIC procedure.

C. FAO/UNEP Joint Group of Experts on PIC

5. As the London Guidelines and the Code of Conduct provided limited
detail on the operational aspects of the procedure, an FAO/UNEP Joint Group of Experts on PIC was established to provide guidance to the secretariat on a range of issues linked to the operational details of the procedure. The Joint Group of Experts also made recommendations on the inclusion of chemicals in the procedure.

6. The Group held eight meetings following its establishment in December 1989. It consisted of 10 members - 5 selected by UNEP, with expertise in industrial and consumer chemicals, and 5 by FAO, with expertise in pesticides. The members were selected on the basis of their experience and the principle of fair geographical distribution. Participation included experts from Canada, Colombia, Ecuador, Ireland, Malaysia, the Netherlands, the Philippines, Sri Lanka, Turkey, the United Kingdom, the United Republic of Tanzania and the United States. The participants were invited in their individual capacities, not as representatives of national governments. In addition, non-governmental organizations and intergovernmental organizations participated as observers. Participation of non-governmental organizations was limited to four organizations - two international industry groups and two public interest groups. Normally, up to 20 participants would attend the meetings.

D. Types of chemicals included in the original PIC procedure

7. In the original PIC procedure, any pesticide or industrial or consumer chemical banned for health or environmental reasons could be considered a candidate for inclusion in PIC. In addition, acutely toxic pesticide formulations which presented a hazard under conditions of use in developing countries could be included. Pharmaceuticals, radioactive materials and food additives were excluded, and there was also an exclusion for small quantities of chemicals used for research purposes and some other small-volume uses.

8. No experience was built up under the original PIC procedure with consumer chemicals. There was no precise definition of what a consumer chemical was, and especially not of the relationship between consumer chemicals and products which contain chemicals. Examples that could illustrate this “grey zone” are the prohibition of or setting of maximum levels of lead and mercury content in paints, and the prohibition or limitation of additives in fuel.

1. Chemicals which were banned or severely restricted for health or environmental reasons by final governmental regulatory action

9. As in the new PIC procedure, the underlying criterion in determining whether chemicals in this category were to be made subject to the original PIC procedure was whether they had been subject to government actions. Specific criteria were developed to define the type of national control actions that would be considered relevant to the original PIC procedure,
but no additional assessment of the scientific basis of the national control actions was carried out by the FAO/UNEP secretariat.

10. As part of the information exchange procedure, participating countries provided information to the FAO/UNEP secretariat, in the form of a Notification of Control Action, on regulatory control actions taken to ban or severely restrict chemicals at the national level. This information was sent to and compiled by the secretariat and circulated to designated national authorities in participating countries. Circulating a compilation of notified control actions was intended to make competent authorities aware of the regulatory actions in other participating countries and provide information on the reasoning behind the actions that were taken, and also to serve as the primary means for identifying banned or severely restricted chemicals to be included in the original PIC procedure.

11. Certain problems arose in applying the criteria from the Guidance for Governments document concerning whether a reported ban or severe restriction was considered to be relevant to the original PIC procedure. One problem involved determining what constituted an acceptable “health or environmental” reason. It was not clear how environmental effects were included in the criteria as given in the Guidance for Governments document. Despite the fact that the procedure covered actions taken “for health or environmental reasons”, the examples given in the document of control actions that qualified made little reference to environmental concerns. It was also difficult to interpret how acute toxicity considerations were to be included. The criteria, compiled in 1990 on the basis of discussions and meeting reports when the original PIC procedure was developed, were limited to a list of examples of acceptable control actions. There was no clear indication of why certain other aspects had been excluded from being acceptable.

(a) Definition of “banned or severely restricted”

12. The definitions of “banned” and “severely restricted” as given in the Amended London Guidelines and the International Code of Conduct were very similar to those that apply for the new PIC procedure. The definitions, however, caused a number of problems in the operation of the original PIC procedure. The definition of “severely restricted”, for example, did not provide any indication of what could be considered as “virtually all uses prohibited nationally”. The Joint Group of Experts indicated that a control action could be considered as a severe restriction provided the remaining allowed uses were only minor. However, it was not clear whether the determination of “major” or “minor” should be judged on a quantitative basis (quantity used, number/types of uses limited), or on the importance of the use to the local economy, reduced exposure potential, obtained risk reduction, etc.

(b) Notification of control action to ban or severely restrict a chemical

13. All participating countries were requested, when joining the procedure, to provide a national inventory of all pesticides and industrial and consumer chemicals currently subject to bans or severe restrictions. Of the 155
countries participating in the original PIC procedure, 57 responded to this request. When the original PIC procedure was designed, governments emphasized that it was important that each notification should contain sufficient information to judge whether the control action complied with the criteria for bans and severe restrictions under the procedure. Despite this, in all cases, it was necessary to seek clarification from the designated national authorities. In reviewing the submitted notifications, the following problems were frequently encountered:

(a) Insufficient information to judge whether remaining uses constituted only a minor part of previous/possible uses (in quantity or risk reduction) and therefore constituted a severely restricted use;

(b) Insufficient information to judge whether the reasons for the control action complied with the criteria given in the Guidance for Governments document;

(c) Often incomplete notifications, lacking information on remaining uses allowed, reference to national documents, effective date or reasons for the control action, etc.

14. In addition, the criteria used by countries to notify FAO and UNEP about control actions on chemicals were not consistent. In a number of cases there were significant differences, since the reported basis for bans or severe restrictions lay in national laws, which differ greatly among countries. In this regard, some countries had extensive data requirements and demanded rigorous analysis before they took such regulatory decisions; others had more limited review and assessment procedures.

(c) Selecting banned or severely restricted chemicals for inclusion in the original PIC procedure

15. As countries provided notifications of banned or severely restricted chemicals, the FAO/UNEP secretariat verified that the reported control actions complied with the definitions and criteria described before. However, a large number of chemicals had already been banned or severely restricted prior to the adoption of the original PIC procedure, so the Amended London Guidelines and the Code of Conduct, and later also the Joint Group of Experts, made some recommendations as to how all these chemicals were to be introduced into the procedure.

16. Any chemical banned or severely restricted in at least one country after 1 January 1992 was eligible for inclusion. In the case of chemicals banned or severely restricted prior to that date, those for which control actions had been taken in five or more countries were also eligible. Priority was to be given to those pesticides/chemicals that were still in trade and, thereafter, to those being phased out. Pesticides/chemicals that were known to be no longer on the market would not be considered. Eventually, any chemical banned or severely restricted in one or more countries was to be included.

17. Concern was expressed about including in the original PIC procedure those chemicals that had been banned or severely restricted in only one country, when the country might not have undertaken a complete scientific analysis before taking the action, or when the reasons for the control action were peculiar to
the country taking the action. However, within the original procedure, no assessment of the scientific basis of the reported national control actions was to take place.

2. Acutely hazardous pesticide formulations which had not been banned or severely restricted in any country for health or environmental reasons, but which were causing problems under conditions of use found in developing countries.

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18. It was recognized by Governments, when developing the original PIC procedure, that if chemicals were selected only from among those that had been banned or severely restricted, pesticides that presented a hazard under conditions of use in developing countries would not necessarily be included. The Amended London Guidelines and the FAO guidelines for the operation of PIC made specific reference to the need for an expert group to consider the problem of acutely hazardous pesticide formulations to determine whether there was a need for a list of such products to supplement the chemicals which were already subject to the original PIC procedure.

19. Consistently with the philosophy of prior informed consent, participating countries would be provided with information on these pesticide formulations to enable them to make informed decisions, based on an evaluation of the potential risks, concerning whether they wished to receive shipments. The FAO/UNEP Joint Group of Experts on PIC proposed that candidates for this group of pesticides should include pesticide formulations likely to cause problems under conditions of use in developing countries and pesticides whose active ingredients are in the World Health Organization (WHO) Class IA list of pesticides and whose typical formulations also fall into WHO Class IA. This, however, resulted in a list of several hundred candidate formulations, so additional criteria needed to be developed.

(a) Selecting acutely hazardous pesticide formulations for inclusion in the original PIC procedure

20. Ideally, pesticide formulations that cause problems under conditions of use in developing countries should have been identified on the basis of documented reports of adverse effects. However, experience showed that this was problematic, since most developing countries did not have established systems for documenting and reporting such incidents. The Joint Group of Experts concluded that it was not reasonable to assume safe use of these formulations solely on the basis of an absence of data from developing countries.

21. Further efforts to identify specific candidates included several approaches. Reviewing of data on poisoning incidents and adverse effects documented in industrialized countries could be used to supplement any

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2. WHO Recommended Classification of Pesticides by Hazards and Guidelines to Classification 1994 (WHO/PCS/94.2).
information available from developing countries. The rationale was that if, despite their relatively greater ability to impose and enforce safety precautions, industrialized countries continued to experience problems, developing countries would be likely to have even greater difficulties.

22. A second approach considered by the Joint Group of Experts as a supplement to reported incidents in developing countries was a “grading point system”, which the group developed over its first eight meetings. However, this system, which assigned points for a defined set of questions relating to potential hazards in use, relied on much subjective information and was very difficult to validate.

23. As a third approach, the Joint Group of Experts agreed to consider whether the existence of handling restrictions in industrialized countries could serve as an additional mechanism for “flagging” candidates for chemicals likely to cause problems under the conditions of use in developing countries. However, the pilot project initiated by the Group to develop inventories of handling restrictions in selected countries made little progress. The initial idea was to compare these inventories and identify formulations subject to handling restrictions designed to minimize occupational exposure in more than one country. The principal advantage of this approach was to put greater emphasis on the regulatory actions of industrialized countries. The feasibility of this third approach was, however, not further considered.

24. It was recognized that each of these approaches would miss some pesticides that were likely to pose problems in developing countries. However, it was thought that, collectively, they could be used to supplement information available from developing countries and to “flag” pesticide formulations likely to be of concern. The advantages to considering a multifaceted approach to identifying hazardous pesticide formulations included the following:

(a) The responsibility to prove that a product may be used safely was devolved on the manufacturer, rather than the developing country having to prove that the product presented a problem;

(b) A compound or formulation became a candidate for the original PIC procedure as a result of a government action, which was also the underlying principle governing the inclusion of banned or severely restricted chemicals in the procedure.

(b) Acutely hazardous pesticide formulations included in the original PIC procedure

25. The FAO/UNEP Joint Group of Experts, at its fifth meeting in October 1992, considered 10 pesticide active ingredients whose formulations had been identified as potentially causing problems under conditions of use in developing countries. During the meeting representatives of public interest groups and industry associations made presentations regarding the pesticide formulations under discussion. In closed session, the Joint Group of Experts applied a “grading point system” to each formulation considered, and on this basis recommended certain formulations of five pesticide active ingredients for inclusion in the original PIC procedure. These pesticide formulations are included in annex III of the Convention, and are thus also subject to the interim PIC procedure.