

## Organization and targets of the prior informed consent notification scheme.

### Part I. Development and implementation

William James MURRAY

*Plant Protection Service, Plant Production and Protection Division,  
Food and Agriculture Organization of the United Nations, Rome, Italy*

**Summary.** - The concern about the trade in chemicals has led to the development and adoption 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). Both codes are voluntary, are addressed largely to governments and industry, and incorporate both practical guidelines and ethical considerations. To ensure the implementation of this principle a prior informed consent (PIC) procedure has been established, which operates in addition to the broader information exchange and export notification provisions. The goal of PIC is to create an international system whereby participating importing countries will obtain information concerning chemicals whose use has been banned or severely restricted in other countries, decide whether to allow, restrict or prohibit future import of such chemicals, and notify other countries on a formal basis of their decision concerning such imports. Exporting countries are then expected to inform their export industry of these decisions and take steps within their authority to ensure that their export industry does not make shipments contrary to the decisions of participating importing countries. A Joint FAO/UNEP group of experts on PIC has been established to develop and provide guidance on the implementation of the PIC procedure.

**Key words:** international agencies, chemical industry, information systems.

**Riassunto** (*Organizzazione e obiettivi dello schema di notifica del "prior informed consent". Parte I. Sviluppo e realizzazione*). - L'interesse nello scambio delle sostanze chimiche ha portato alla creazione e all'adozione dell'*International code of conduct on the distribution and use of pesticides* (Codice internazionale di condotta sulla distribuzione e sull'uso dei pesticidi) da parte della Food and Agriculture Organization delle Nazioni Unite (FAO) e alle *London guidelines for the exchange of information on chemicals in international trade* (Linee guida per lo scambio di informazioni nel commercio internazionale delle sostanze chimiche) da parte dell'United Nations Environment Programme (UNEP). Entrambi i codici sono volontari, rivolti soprattutto a governi o industrie e contengono sia linee di condotta pratiche sia considerazioni etiche. Oltre ai più vasti provvedimenti di scambio di informazione e di notifica delle esportazioni, è stata sviluppata una procedura chiamata "prior informed consent" (PIC) per garantire l'attuazione di questi principi. Scopo del PIC è la creazione di un sistema internazionale in cui i paesi importatori partecipanti siano in grado di ottenere informazioni sulle sostanze chimiche il cui uso è vietato o severamente limitato in altri paesi, di decidere se l'importazione delle stesse sostanze chimiche debba essere permessa, limitata o proibita, e infine di rendere edotti gli altri paesi sulle decisioni che sono state prese al riguardo. I paesi esportatori, a loro volta, dovranno informare le industrie esportatrici di queste decisioni e mettere in atto le azioni di loro competenza per far sì che le ditte esportatrici non facciano spedizioni in contrasto con le decisioni dei paesi importatori. Un gruppo congiunto di esperti FAO/UNEP ha stabilito di sviluppare e guidare l'avvio delle procedure PIC.

**Parole chiave:** agenzie internazionali, industria chimica, sistemi di informazione.

#### Background

Concern about the trade in chemicals including pesticides has led to the development and adoption of two internationally accepted codes of practice. In 1985 the Food and Agriculture Organization of the United Nations (FAO) adopted the *International code of conduct on the distribution and use of pesticides* [1]. In 1987, the United Nations Environment Programme (UNEP) adopted the *London guidelines for the exchange of information on chemicals in international trade* (the London guidelines) [2]. Both codes are voluntary, are

addressed largely to governments and industry, and incorporate both practical guidelines and ethical considerations.

There are provisions in these documents concerning information exchange. The main element of these provisions has been for governments to inform one another of control actions to ban or severely restrict a chemical for health or environmental reasons. Notification of the first export of such chemicals is to be sent by the exporting country to importing countries. This procedure provides participating countries with information on how certain chemicals are regulated in other countries.

In 1989 these information exchange provisions were expanded in both the London guidelines and the FAO code of conduct to include the concept of prior informed consent (PIC). This refers to the principle that international shipment of a chemical that is banned or severely restricted in order to protect human health and the environment should not proceed without the agreement, where such agreement exists, or contrary to the decision of the relevant authority in the importing country.

To ensure the implementation of this principle a PIC procedure has been established, which operates in addition to the broader information exchange and export notification provisions.

### Objectives of prior informed consent

The goal of PIC is to create an international system whereby participating importing countries will obtain information concerning chemicals whose use has been banned or severely restricted in other countries, decide whether to allow, restrict or prohibit future import of such chemicals, and notify other countries on a formal basis of their decision concerning such imports. Exporting countries are then expected to inform their export industry of these decisions and take steps within their authority to ensure that their export industry does not make shipments contrary to the decisions of participating importing countries. PIC is aimed at preventing the trade of unwanted chemicals.

The aim of the PIC procedure is not to "black-list" pesticides or other chemicals. It is not a recommendation to ban or severely restrict the use of a chemical, but rather a procedure for formally obtaining and disseminating the decisions of importing countries as to whether they wish to receive future shipments of chemicals included in the procedure.

### Cooperation and coordination between FAO and UNEP

The London guidelines apply to both pesticides and chemicals, while the FAO code of conduct is limited to pesticides. The information exchange procedures of the London guidelines and the code of conduct operate in essentially the same way, with some minor differences due to the fact that many countries have regulatory schemes for pesticides, but not for other chemicals. FAO and UNEP have agreed to coordinate and implement PIC jointly, with FAO acting as the lead agency on pesticides and UNEP through its International Register of Potentially Toxic Chemicals (IRPTC) as the lead agency for other chemicals.

A Joint FAO/UNEP group of experts on prior informed consent has been established to develop and provide guidance on the implementation of the PIC

procedure. At present this group meets approximately every nine months. The experts, who participate in their individual capacity, are generally drawn from government/national regulatory agencies. The present joint group includes representatives from thirteen countries, namely Canada, Colombia, Ecuador, Gambia, Ireland, Malaysia, the Netherlands, the Philippines, Sri Lanka, Tanzania, Turkey, the United Kingdom and the United States. Observers at expert meetings are limited to four from industry and four from public interest groups representing environmental, health and consumer groups.

### Guidance for governments on the operation of the PIC procedure

An operational guide for participating countries entitled *Guidance for governments on the operation of the PIC procedure* [3] is the principal document on the operation of the information exchange and PIC procedures. The document is divided into two parts: the first gives a general overview of the procedures and describes the responsibilities of participating countries; the second provides detailed guidance on the implementation of the procedures and the tasks that the designated national authority is expected to perform.

### Identification of chemicals to be included in the PIC procedure

For the purpose of the PIC procedure, chemicals are divided into the following three use categories:

- 1) agricultural chemicals, including pesticides for agricultural, household, public health or other use;
- 2) industrial chemicals;
- 3) consumer product chemicals.

In the context of the PIC procedure, the terms "banned" and "severely restricted" have been defined as follows:

*Banned chemical.* - A chemical for which all registered uses have been prohibited by final government action, or for which all requests for registration or equivalent action for all uses have, for health or environmental reasons, not been granted.

Included in this definition are chemicals which have been withdrawn by industry either from the market or from further consideration in the registration approval process and where there is clear evidence that such action has been taken for health or environmental reasons.

*Severely restricted chemical.* - A chemical for which virtually all registered uses have been prohibited by final government regulatory action, but for which certain specific registered uses remain authorized.

Not all government control actions qualify as a ban or severe restriction under the procedure. For a reported control action to be considered for inclusion in the PIC procedure:

- it must be a final governmental regulatory action;
- it must be based on an assessment of scientific knowledge;
- it will not trigger PIC if it is based on toxicity alone;
- it will not trigger PIC if it is a severe restriction relating to the handling of the chemical;
- it must be a severe restriction on a major use of the chemical in the country;
- the chemical must already be in use in the country.

Once the procedure is fully operational, any notification of a ban or severe restriction on a chemical entering into force after 1 January 1992 will result in the chemical's inclusion in the PIC procedure. Chemicals which have been banned or severely restricted in five or more countries prior to this date will also be included.

In addition to chemicals identified through the notification system under the procedure, the London guidelines and the code of conduct provide the possibility of including acutely hazardous pesticides that may not be banned or severely restricted in any country, but which are known to represent a hazard under prevailing conditions of use, particularly in developing countries.

At present those pesticide formulations which meet the following basic criteria are considered as potential candidates:

a) pesticides whose active ingredients are in the WHO class 1a (highly hazardous) list of pesticides and whose typical formulations also fall into WHO class 1a; and

b) pesticide formulations causing significant problems under conditions of use in developing countries and which appear in official reports of international organizations or government agencies or for which detailed documentation from other sources is available.

## Operation of the PIC procedure

### *Designation and participation of national authorities*

As of 1 May 1994 a total of 156 designated national authorities from 115 countries have been registered with FAO and UNEP. In many instances countries have nominated separate designated national authorities to handle pesticides and other chemicals. At the end of 1993 the United Nations was composed of 184 member states. FAO and UNEP will therefore continue to encourage governments to nominate and to fully participate in the PIC procedure.

The designated national authority has the responsibility of receiving, sending and managing information and carrying out the functions associated with the PIC procedure as well as with information exchange. The designated national authority is normally a person within a national organization involved in the management of chemicals. In the case of pesticides, the registration authority or the equivalent is generally nominated to serve as the designated national authority.

### *Notification of control actions*

Countries taking a final control action to ban or severely restrict the use of a chemical for health or environmental reasons are to notify FAO/UNEP, providing the reasons for the action and other relevant information.

FAO/UNEP review such notifications for completeness and to ensure compliance with the definitions of the code of conduct and the London guidelines. This information is entered into the IRPTC data base of control actions taken by all member governments of FAO and UNEP. This inventory of control actions is the basis for the identification of those chemicals considered as candidates for the PIC procedure.

### *Decision guidance documents*

Once a chemical is considered as qualifying for PIC a decision guidance document (DGD) is prepared. The DGD is intended to help governments to analyze the potential hazards connected with the handling and use of the chemical and to assist them in taking a decision regarding future imports.

The information contained in the DGD is by no means exhaustive as it is not intended as a full review of scientific data, but to give sufficient information to help a government make a decision regarding import. It contains scientific data on dangerous properties of the chemical, references to epidemiological studies, methods to reduce risk and other relevant information about risks as well as the reasons for the reported control action.

### *Decision regarding future imports*

After receiving the DGD, participating importing countries are asked to provide an initial response to FAO/UNEP on their decision concerning future import and use of the chemical in their country within 90 days. The information requested on the importing country response form includes:

- whether the import of the chemical will be generally allowed in the future;
- whether import will be allowed under certain specific conditions;
- whether import will be prohibited.

Governments may provide an interim response and request further information or technical assistance in formulating a final response. They are also expected to ensure that their own national authorities responsible for controlling import of chemicals are informed of these decisions.

Any decision to ban or severely restrict the import of a chemical must apply equally to production for domestic use.

### *Dissemination of future import decisions*

The import decisions contained in the importing country response forms are compiled in a summary document on the import status of chemicals in the PIC procedure. Designated national authorities in participating countries are provided with regular updates (every six months) on the import decisions for chemicals in the PIC procedure.

### *Exporting country responsibilities*

Exporting countries are expected to inform their export industry of importation decisions and take steps, within their authority, to ensure that their export industry does not make shipments contrary to the decisions of the importing countries.

### **Current status of chemicals in the PIC procedure**

A chemical is not included in the PIC procedure until a DGD has been finalized and circulated to designated national authorities.

In September 1991 the first set of six decision guidance documents were issued on pesticides (aldrin, dieldrin, dinoseb and dinoseb salts, DDT, fluoroacetamide, and HCH (mixed isomers)) [4]. By June 1994 some 70 countries had provided import responses to these documents.

In late 1991 and early 1992 a further batch of DGDs for six pesticides (chlordane, chlordimeform, cyhexatin, EDB, heptachlor and mercury compounds) were distributed [5]. By June 1994 58 responses had been received.

In addition, DGDs for the first five industrial chemicals (polychlorinated biphenyls, polychlorinated terphenyls, polybrominated biphenyls, tris (2,3, dibromopropyl) phosphate and crocidolite) were distributed in March 1993 to those countries which had nominated a designated national authority for consumer and industrial chemicals [6].

### **Future development of the PIC procedure**

The PIC procedure as contained in the London guidelines and the code of conduct is at present a voluntary procedure. The member states of the European Union have adopted a regulation on the import and export of certain dangerous chemicals. Its purpose is to help enforce the import decisions notified under the PIC procedure

and to transfer the responsibility for enforcement from the importing country to the member states of the European Community. The regulation requires industry to provide export notification for chemicals that are banned or severely restricted in the European Community. Member states are legally bound to comply with the import restrictions identified by the importing countries participating in the PIC procedure.

There is also increasing interest on the part of many countries in investigating the feasibility of incorporating the PIC procedure into a legally binding instrument.

It must be remembered that the prior informed consent procedure has not been solely the result of efforts on the part of FAO and UNEP, but has been developed and is being implemented with cooperation from the chemical industry, various non-governmental organizations and the designated national authorities of importing and exporting countries. It is considered to represent a dynamic process which will be modified based on experience gained in its implementation.

Submitted on invitation.

Accepted on 12 September 1994.

### REFERENCES

1. FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS. 1990. *International code of conduct on the distribution and use of pesticides (amended version)*. FAO, Rome.
2. UNITED NATIONS ENVIRONMENT PROGRAMME. 1989. *The amended London guidelines for the exchange of information on chemicals in international trade*. UNEP, Geneva.
3. FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS / UNITED NATIONS ENVIRONMENT PROGRAMME. 1991. *Guidance for governments on the operation of the PIC procedure*. FAO/UNEP, Rome-Geneva.
4. FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS / UNITED NATIONS ENVIRONMENT PROGRAMME. 1991. *Decision guidance documents (aldrin, DDT, dieldrin, dinoseb and dinoseb salts, fluoroacetamide, HCH (mixed isomers))*. FAO/UNEP, Rome-Geneva.
5. FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS / UNITED NATIONS ENVIRONMENT PROGRAMME. 1991. *Decision guidance documents (chlordane, chlordimeform, cyhexatin, EDB, heptachlor, mercury compounds)*. FAO/UNEP, Rome-Geneva.
6. FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS / UNITED NATIONS ENVIRONMENT PROGRAMME. 1993. *Decision guidance documents (polychlorinated biphenyls, polychlorinated terphenyls, polybrominated biphenyls, tris (2,3, dibromopropyl), phosphate, crocidolite)*. FAO/UNEP, Rome-Geneva.