UNITED NATIONS

PIC

United Nations Environment Programme

Food and Agriculture Organization of the United Nations

Distr.
GENERAL

UNEP/FAO/PIC/ICRC.3/9
29 November 2001

ENGLISH ONLY

INTERIM CHEMICAL REVIEW COMMITTEE
Third session
Geneva, 17-21 February 2002
Item 5 (b) (v) of the provisional agenda*

OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE: ISSUES ASSOCIATED WITH IMPLEMENTATION OF THE OPERATIONAL PROCEDURES

COMPATIBILITY OF CURRENT REGULATORY PRACTICES WITH THE NOTIFICATION REQUIREMENTS OF THE INTERIM PRIOR INFORMED CONSENT PROCEDURE

Note by the secretariat

1. At its second session, the Interim Chemical Review Committee established four task groups to work intersessionally. Task group 4 was to develop a process to prioritize work on old notifications pertaining to chemicals and identify an initial list of priority chemicals that could be the subject of further work by the Committee. The task group was also to draft an issue paper on the compatibility of current regulatory practices with the notification requirements of the interim prior informed consent (PIC) procedure as a possible basis for practical guidance to countries. A full report of the work of task group 4 is available to the Committee in document UNEP/FAO/PIC/ICRC.3/8.

2. Annexed to the present note is the draft issue paper on the compatibility of current regulatory practices with the notification requirements of the interim PIC procedure prepared by task group 4 and submitted to the secretariat. The paper also includes some possible follow-up actions by the Committee.

* UNEP/FAO/PIC/ICRC3/1.

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Annex

ISSUE PAPER ON THE COMPATIBILITY OF CURRENT REGULATORY PRACTICES WITH THE NOTIFICATION REQUIREMENTS OF THE INTERIM PRIOR INFORMED CONSENT PROCEDURE

A. Differences between the definitions in national legislation and the Rotterdam Convention - difficulties in understanding how to comply

1. The following situations or circumstances may illustrate:

(a) Differences between a Party's own legal system and the convention language;

(b) Difficulties which some countries may have in understanding how to comply.

2. These problems may be common to other participating countries and may adversely affect the ability of countries to prepare notifications of regulatory action.

3. The status of implementation of the interim PIC procedure, as submitted to the Intergovernmental Negotiating Committee at its eighth session (UNEP/FAO/PIC/INC.8/3), indicated that the number of countries notifying, and the number of notifications submitted, is still low.

ISSUE: Some countries have no regulatory system;
ISSUE: Some countries have no regulatory actions to report;
ISSUE: Chemical management and the Rotterdam Convention are not viewed as a priority.

4. The report from Thailand to the Interim Chemical Review Committee at its second session (UNEP/FAO/PIC/ICRC.2/11, para. 36) noted some examples of the challenges faced by a national Government. The following situations may be envisaged: both in the case of pesticides and industrial chemicals various departments are responsible. In the case of Thailand, the Department of Industry and the Department of Food and Drugs can regulate industrial chemicals, while notification is the responsibility of the Department of Environment. The same situation can occur with pesticides, which fall under the Departments of Agriculture and Public Health. The report indicated that the national Government was operating under the premise that a chemical had to be significantly regulated in both sectors before it could be notified as a ban or severe restriction under the PIC.

ISSUE: The structure of a national Government may complicate compliance with PIC obligations;
ISSUE: Governments may be unclear about the applicability of all the PIC provisions, and may need further guidance.

5. A pesticide manufacturer develops a product intended for widespread agricultural use. In the light of risk concerns, however, a country authorizes the use of a pesticide only for a small application with limited environmental exposures. As a result of a negotiating process, a pesticide manufacturer dropped the request for the other applications. The question rises as to whether this would still be considered a severe restriction under the PIC.

ISSUE: Governments may need further clarification of the scope of "voluntary withdrawal" in the PIC definitions

B. Need for guidance

6. Cancellation of a registration can sometimes result from an industry's decision to withdraw notification of a substance from the evaluation programme or not to provide supporting data. In such cases it needs to be established whether or not there were any underlying toxicological or ecotoxicological concerns.

ISSUE: The reasons behind voluntary actions may not be documented.

7. The European Commission has provided, in the appendix to the present report, an overview of its regulatory actions which might be regarded as bans or severe restrictions of chemicals to be notified under article 5 of the Rotterdam Convention.

ISSUE: Each national Government or regional economic integration organization may regulate in different ways, and this is likely to be of interest to other regulatory authorities, and a means to build regulatory capacity.

8. In many countries, current regulatory practices incorporate a risk reduction approach and often go far beyond the relatively simple decision to eliminate all or virtually all uses of a chemical. Governments may have very valid risk reduction reasons to eliminate uses slowly, over time. For instance, gradual use reductions avoid the creation of obsolete pesticide stocks and significant waste management demands.

ISSUE: Various kinds of regulatory practices may be employed to reduce risk, but may not constitute a ban or severe restriction.

9. The Rotterdam Convention does not include a definition for pesticide, in acknowledgement of the wide variation of definitions at the national level. The FAO International Code of Conduct on the Distribution and Use of Pesticides does include a definition for agricultural pesticides and this has been generally accepted by many Governments. But it does not identify non-agricultural pesticides.

ISSUE: Countries use different definitions.

10. With reference to industrial chemicals, it is to be noted that infrastructure to regulate industrial chemicals is lacking or insufficient. In addition, national systems to regulate industrial chemicals and associated notification schemes might be incompatible with the provisions under the Rotterdam Convention.

ISSUE: Infrastructure to regulate industrial chemicals needs to be strengthened

11. With regard to the information requested in a notification form, many designated national authorities are wondering why they have to submit physical and chemical, toxicological and ecotoxicological properties of a compound if this information is very well known by the secretariat.

12. Many compounds within one country can be banned in agriculture and still be used for health purposes or in other cases they may be banned in industrial processes and still used in agriculture. For that reason, a designated national authority needs sufficient time to come to an agreement with all sectors that are involved in the use of that compound in order to take a final regulatory action.

ISSUE: Designated national authorities need more time to submit notifications.

C. Conclusion

13. National regulatory systems vary in a number of ways, for a variety of reasons. It is not realistic to assume that all Governments will, or should, regulate chemicals and pesticides in exactly the same way. While conformity at the national level with the terms of an international agreement is to be expected, absolute agreement on the interpretation of an international agreement in the context of a national control system is not typical. A degree of flexibility in the interpretation at the national level of how a given Government conforms to the international standard is usually the norm.

D. Possible follow-up action by the Interim Chemical Review Committee

14. Following discussion of this paper by the Interim Chemical Review Committee, a next step could include circulation of a revised issue paper to designated national authorities for comments along with a request for additional information. The compilation of comments, together with a revised issue paper, could form the basis for further discussion with a broader range of countries at the ninth session of he Intergovernmental Negotiating Committee.

Appendix

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate C – Environment and Health
ENV.C3 – Chemicals

Brussels,
C-3- Chemicals/JF D(2001)

Regulatory actions within the Community that might be regarded as bans or severe restrictions of chemicals to be notified under Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure (PIC) for certain hazardous chemicals and pesticides in international trade

The main sources of regulatory actions that could be regarded as bans or severe restrictions that could lead to a notification under Article 5 of the Convention can be summarised as follows.

1. Inclusion of a substance in Annex I to Council Directive 76/769/EEC[1] – list of substances and preparations that are subject to restrictions on their marketing and use on the EU market. Whether or not the regulatory action qualifies for notification under Article 5 of the Convention can only be decided on a case-by-case basis. Each case has to be assessed individually in order to determine whether the regulatory action constitutes a ban or severe restriction within the meaning of the Convention, taking into account the use category (ies) affected by the action and the extent to which any other uses within that use category or categories remain allowed.

2. Inclusion of a substance in the Annex to Council Directive 79/117/EEC[2] prohibiting the placing on the market and use in the EU of plant protection products containing certain active substances. Normally such regulatory actions would qualify for notification under Article 5 of the Convention, unless it was established that other pesticide uses such as biocidal uses that remain allowed for a particular substance were such that not all uses or virtually all uses within the pesticides use category under the Convention had been prohibited.

3. Non-inclusion of a substance in Annex I to Council Directive 91/414/EEC[3] concerning the placing of plant protection products on the EU market, i.e. not to allow the substance for any use as a plant protection product within the Community and to require the withdrawal of authorisations for plant protection products containing that active substance because the safety requirements of the Directive have not been fulfilled. Non-inclusion can sometimes result from industry's decision to withdraw notification of a substance from the evaluation programme or not to provide supporting data. In such cases it needs to be established whether there were any underlying toxicological and/or ecotoxicological concerns. If so, the next step is to determine whether the regulatory action prohibits

[1] OJ L 262, 27.09.76, p.201, as last amended by Directive 2001/41/EC (OJ L 194, 18.07.01, p.36)

[2] OJ L 33, 08;02.79, p.36, as last amended by Directive 90/533/EEC (OJ L 296, 27/10/90, p.63)

[3] OJ L 230, 19.08.1991, p.1, as last amended by Directive 2001/36/EC (OJ L 164, 20.06.01, p.1)

all or virtually all uses within the pesticides use category under the Convention and thus whether it should be notified under Article 5.

4. Inclusion of a substance in Annex I to Directive 91/414/EEC, but with a very limited number of authorised uses or other limitations on its conditions of use such as to effectively impose a severe restriction on the use of that substance as a plant protection product. If so, it then needs to be determined whether that restriction means that virtually all uses within the pesticides use category under the Convention are prohibited, therefore justifying an Article 5 notification.

5. Non-inclusion of a substance in Annex I to Directive 98/8/EC[4] of the European Parliament and of the Council concerning the placing of biocidal products on the market, i.e. not to allow the substance for any use as a biocide within the Community. In this case the same considerations as those outlined above under point 3 in relation to plant protection products apply in determining whether or not the regulatory action qualifies for notification under Article 5 of the Convention.

6. Inclusion of a substance in Annex I to Directive 98/8/EC, but with a very limited number of authorised uses or other limitations on its conditions of use such as to effectively impose a severe restriction on the use of that substance as a biocide. If so, as in case 4 above, it then needs to be determined whether that restriction means that virtually all uses within the pesticides use category under the Convention are prohibited, therefore justifying an Article 5 notification.

Regulatory actions such as those outlined above would, where appropriate, trigger the inclusion of the chemical concerned in Annex I of Council Regulation (EEC) No 2455/92[5] concerning the export and import of certain dangerous chemicals. The Annex lists chemicals that have, for health or environmental reasons, been banned or severely restricted for use on the EU market and thus fall subject to the export notification and PIC notification procedures established in its Articles 4 and 5 respectively.

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[4] OJ L 123, 24;04.1998, p.1

[5] OJ L 251, 29.08.1992, p.13, as last amended by Commission Regulation 2247/98 (OJ L 282, 20.10.1998, p.12)