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

Compatibility of national regulatory practices with the notification requirements of the interim prior informed consent procedure

Note by the secretariat

Annexed to the present note is an information paper on the compatibility of national regulatory practices with the notification requirements of the interim prior informed consent (PIC) procedure, prepared in cooperation with Mr. Reiner Arndt, Chair of the Interim Chemical Review Committee, as requested by that Committee at its third session (17-21 February 2002).

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

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Annex

Compatibility of national regulatory practices with the notification requirements of the interim prior informed consent procedure.

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

1. The Interim Chemical Review Committee held its third session at Geneva from 17 to 21 February 2002. It identified a series of issues related to the application of the provisions of the Convention for which guidance was requested from the Intergovernmental Negotiating Committee. These issues have been divided into two issue papers for consideration by the Negotiating Committee at its ninth session. The first paper focuses on issues related to determining whether a regulatory action has been taken as a consequence of a risk evaluation relevant to the prevailing conditions in the notifying country (UNEP/FAO/PIC/INC.9/8). The second paper considers those issues related to the scope of submitted regulatory actions and how chemicals included in the interim prior informed consent (PIC) procedure might be best described (UNEP/FAO/PIC/INC.9/9). Both papers set out the relevant issues and propose possible options for the consideration of the Negotiating Committee. The present information paper briefly summarizes the discussion within the Interim Chemical Review Committee concerning possible challenges faced by Parties concerning the compatibility of national regulatory practices with the notification requirements of the interim PIC procedure.

Introduction

2. At the first session of the Interim Chemical Review Committee an intersessional task group was established to cooperate and coordinate work on notifications of final regulatory actions. The report of that task group (UNEP/FAO/PIC/ICRC.2/8) was reviewed by the Committee at its second session. The task group reported that, when countries are considering whether new, or current, regulatory actions comply with article 5 of the Convention, they may be faced with a number of factors that either facilitate or complicate the decision to submit a notification of final regulatory action. It concluded that an examination of these factors might explain the low number of notifications submitted to the secretariat and suggested several reasons why countries might be having difficulty in developing and submitting notifications for pesticides.

3. The second session of the Interim Chemical Review Committee established a task group to develop further the process to prioritize work on old notifications pertaining to chemicals. A further task of the group was to draft an issue paper on the compatibility of current regulatory practices with the notification requirements of the interim PIC procedure as a possible basis for practical guidance to countries. (UNEP/FAO/PIC/ICRC.2/11, para. 37 d)).

4. The Intergovernmental Negotiating Committee at its eighth session endorsed the preparation by the Interim Chemical Review Committee of an issue paper on the compatibility of current regulatory practices with the notification requirements of the interim PIC procedure and requested a report on progress at its ninth session (UNEP/FAO/PIC/INC.8/19, para. 61).

5. The third session of the Interim Chemical Review Committee had before it the draft issue paper on the compatibility of current regulatory practices with the notification requirements of the interim PIC procedure (UNEP/FAO/PIC/ICRC.3/9). In introducing the paper, the co-chair of the task group noted that the reason for looking at these issues was to define better possible reasons as to why countries were having difficulty in submitting notifications of final regulatory actions. The issues identified in the paper could be broadly characterized into two main areas, inadequate regulatory infrastructure in many developing countries and countries with economies in transition and differences between national regulatory systems and the language of the Convention.

6. In the first instance, the issues included such problems as a general lack of coordination among ministries responsible for chemicals management and poor record keeping regarding the basis for regulatory decisions, particularly those that may have been taken several years ago. In the course of its deliberations

the Committee identified a further range of issues largely related to the lack of infrastructure in countries, particularly in respect of industrial chemicals, and the difficulty of enforcing regulations that were in place. Countries were advised that they should raise any such concerns at the level of the Intergovernmental Negotiating Committee.

7. In the second instance, it was clear that many countries had developed legal systems that regulated subcategories within the Convention categories of pesticides and industrial chemicals. It was further noted that the experience in reviewing the notifications at the third session of the Review Committee had raised additional issues that would need to be further examined and brought to the attention of the Intergovernmental Negotiating Committee. These included first-time refusal of chemicals proposed for approvals and bans for chemicals that had never been placed on the domestic market, either where they had been proposed for approval or never proposed for review. The importance of fulfilling the criteria in annex II for inclusion in the Convention, especially in respect of undertaking appropriate risk evaluation under conditions prevailing in a country, was also raised.

8. The Review Committee agreed that the Chair, with the assistance of the Secretariat, would prepare a technical issue paper on the subject of compatibility for the ninth session of the Intergovernmental Negotiating Committee (UNEP/FAO/PIC/ICRC.3/19, para.55). The issues associated with regulatory actions on chemicals that have not been placed on the market of a country and that have not been proposed by industry for review, together with the importance of fulfilling the criteria in annex II, have been identified in document UNEP/FAO/PIC/INC.9/8 and will be considered under agenda item 4 (e).

9. The present paper provides a brief overview of the notification requirements and definitions in the Convention and identifies some of the possible challenges faced by parties in relating the Convention text to their national regulatory practices. There are no clear-cut answers to the challenges identified. The experience of national authorities in addressing these challenges is a topic that could be further explored in training workshops.

I. BACKGROUND

10. Article 5 of the Convention outlines the procedures for the notification of banned and severely restricted chemicals, while annex I lists the relevant information requirements. It is important to note that while countries are obliged to submit notifications of their final regulatory actions, the notifications are to contain the information required by annex I where available. It is not an obligation to provide all of the information listed in annex I for every notification.

11. The definitions in article 2 of the Convention set out the parameters within which notifications under article 5 are to be viewed in the context of the Convention. For ease of reference, the definitions of a chemical, a banned chemical and a severely restricted chemical may be found in appendix I to the present note.

12. The definition of a chemical states that it consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

13. A banned chemical means a chemical <u>all uses of which</u> within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment.

14. A severely restricted chemical means a chemical <u>virtually all use of which</u> 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.

15. In both cases, the definition applies to a chemical that has been proposed 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.

II. REPRESENTATIVE EXAMPLES OF SOME OF THE ISSUES ASSOCIATED WITH DIFFERENCES BETWEEN NATIONAL REGULATORY PRACTICES AND THE LANGUAGE OF THE CONVENTION

A. Definitions

16. The pesticide and industrial chemical categories are not explicitly defined in the Convention. At the national level, regulatory authorities may have established a range of subcategories for regulating pesticides and industrial chemicals. For example, pesticides may be regulated differently depending on whether they are used in agriculture and public health or as disinfectants etc. Similarly, for industrial chemicals there may be a broad range of subcategories established at the national level. These subcategories may make it difficult to characterize a final regulatory action as a clear ban or severe restriction for a given category under the Convention.

17. For example, in the European Union and Thailand, the industrial category of the Convention applies to at least two subcategories, public/consumer use or industrial use, that are regulated separately by consumer legislation and industrial legislation. For Thailand, the industrial category of the Convention corresponds to the national regulatory domains of public/consumer use regulated by one ministry and industrial chemicals by another. Similarly, the pesticide category of the Convention corresponds to the national regulatory domain of public health and agricultural use. In the European Union, the pesticide category has the subcategories biocides (with two further subcategories of consumer and industrial) and agricultural pesticides.

18. To decide whether a chemical is banned or severely restricted under the Convention and a notification under article 5 is required, the specific national regulatory action for the chemical must be analysed. An important consideration is the extent to which the chemical was used before the final regulatory action occurred, and the extent of use which remains after the final regulatory action has been taken. The following scenarios can be envisaged for the European Union and Thailand with respect to an industrial chemical:

(a) Scenario 1: ban of all public use and ban of all industrial use could be considered as a ban as an industrial chemical under the Convention;

(b) Scenario 2: no public use and ban of all industrial use could be considered as a ban as an industrial chemical under the Convention;

(c) Scenario 3: some industrial use remains (10 per cent of the quantity marketed in the country before the ban) and ban of all public use (90 per cent of the quantity marketed in the country before the ban) could be considered a severe restriction as an industrial chemical under the Convention;

(d) Scenario 4: some public uses remain (50 per cent of the quantity marketed in the country before the regulatory action) and some industrial uses remain (50 per cent of the quantity marketed in the country before the regulatory action) could not be considered to reflect a severe restriction as an industrial chemical under the Convention.

19. Other scenarios could include severe restrictions of industrial and public use or ban of public use and severe restriction of industrial use, etc. The same scenarios could be envisaged for pesticides where there were two or more national subcategories. With more than two subcategories for industrial or pesticides the analysis would be more complex. It is the extent of overall use that remains following the national regulatory action that is the key determinant in classifying the regulatory action as a ban or a severe restriction under the Convention.

20. The key challenge for Parties is to document the extent of use for a given chemical before and after the final regulatory action, particularly where the categories of pesticide and industrial chemicals are subdivided into two or more subcategories.

21. Individual notifications of final regulatory actions will need to be considered by the Interim Chemical Review Committee on a case-by-case basis. The experience gained in reviewing such notifications may facilitate the development of more explicit guidance to countries.

B. Various regulatory practices may be employed to reduce risk as part of the decision-making process, but may not be seen automatically to represent a ban or a severe restriction

22. In many countries chemicals are rarely banned or severely restricted outright. Rather, 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.

23. Under scenario 1, for pesticides that are already available on the market, Governments may have valid risk reduction reasons to eliminate uses slowly, over time. For instance, for many older pesticides, gradual use reductions avoid the creation of obsolete pesticide stocks and significant waste management demands.

24. Under scenario 2, for new pesticide registrations or approvals, a risk reduction approach may also be followed. Such is the case where a range of uses originally proposed are reduced through a process of negotiation until such time as the associated risks to human health or the environment are considered acceptable. For example, a manufacturer might seek registration for a pesticide intended for widespread use in agriculture. In the light of risk concerns, however, a country might only authorize use for a small application with limited environmental exposures. The manufacturer in the course of the registration process drops the request for the other agricultural uses.

25. The key challenge for Parties is how to relate such gradual actions to the definition of a severe restriction in the Convention.

26. Scenario 1 highlights the importance of countries providing as much information as possible concerning the extent to which a chemical is used both before and after the notified final regulatory action. The Convention is silent on the time over which such restrictions are to be measured. It would be a decision of the notifying country to determine where to define the date from which to measure the restriction in use.

27. Scenario 2 reflects a situation that is common in many regulatory systems. The definition of a ban or severe restriction does include reference to withdrawal from further consideration in the domestic approval process, thus it could be plausible for a country to notify such a chemical as severely restricted.

28. Individual notifications of such severe restrictions will need to be considered by the Interim Chemical Review Committee on a case-by-case basis. The experience gained in reviewing these notifications may facilitate the development of more explicit guidance to countries.

C. Other issues identified by the Interim Chemical Review Committee that might be best characterized as deficiencies in record keeping

29. Examples of national regulatory practices identified by the Interim Chemical Review Committee include a range of scenarios that illustrate some of the challenges faced by countries in preparing adequate documentation in support of their notifications. For example:

(a) Scenario 1: the cancellation of a registration/authorization for a pesticide can sometimes result from an industry's decision to withdraw notification of a substance from a re-evaluation programme or to not provide a complete package of supporting data in line with current regulatory requirements. In such cases, it may be difficult to establish whether or not there were any underlying toxicological or ecotoxicological concerns.

(b) Scenario 2: in many countries once a chemical is withdrawn from the review process there is very often no follow-up on the product nor is a final summary of the results documented; the file is simply closed.

30. The key challenge for Parties is to how to document adequately the basis for the withdrawal of chemicals from the regulatory/evaluation process.

31. Scenario 1 reflects the situation in many developed countries that have re-evaluation schemes in place. In some situations where a manufacturer has withdrawn its support for a chemical in a re-evaluation process the available information may be sufficient to complete a risk evaluation to the extent that it can be demonstrated that the chemical represents an unacceptable risk to human health or the environment. The recent notifications on regulatory actions by the European Commission (for DNOC) and Australia (for monocrotophos) might be considered as examples. In these cases, while a complete date set was not available there was sufficient information to conclude that an unacceptable risk existed. In other situations the available data are not sufficient to permit an evaluation of the level of risk to human health or the environment.

32. Scenario 2 reflects the reality in many regulatory agencies/countries where human and financial resources are limited and a chemical withdrawn from the review process it is not subject to follow-up action even where there may be concerns regarding its effects on human health and the environment.

33. The Interim Chemical Review Committee will, on a case-by-case basis, need to consider the adequacy of the information available to support notifications resulting from reevaluation schemes where a chemical is no longer permitted for use as a result of a lack of continued support by the manufacturer/registrant or where products are withdrawn from the review process prior to its completion. Countries may want to consider opportunities to improve record keeping or documentation of withdrawals and the underlying risk concerns associated with inadequate data to support continued registration of a compound.

Appendix I

Excerpt from article 2 of the Convention

"Definitions

"For the purposes of this Convention:

"(a) 'Chemical' means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial;

"(b) '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;

"(c) '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;

"…"
