IMPLEMENTATION OF THE PRIOR INFORMED CONSENT PROCEDURE

SUBMISSION OF NOTIFICATIONS OF CHEMICALS ALREADY SUBJECT TO THE PRIOR INFORMED CONSENT PROCEDURE – POSSIBLE OPTIONS TO RECONCILE THE NEED FOR INFORMATION EXCHANGE WITH AVAILABLE RESOURCES

Submission of notifications of final regulatory action for chemicals that are already subject to the interim prior informed consent procedure

Note by the secretariat

A. Introduction

1. At its seventh session the Intergovernmental Negotiating Committee requested the secretariat to prepare a paper for presentation to it at its eighth session, analysing the issue of submission of notifications of final regulatory action for chemicals that are already subject to the interim prior informed consent (PIC) procedure and outlining options that would reconcile the need for information exchange with the need to avoid placing excessive reporting burdens on Parties or appraisal burdens on the secretariat (UNEP/FAO/PIC.7/15, para. 57).
B. Background

2. During the first session of the Interim Chemical Review Committee, mention had been made of the burden imposed, especially on developing countries and countries with economies in transition, by the requirement to provide all the information stipulated in annex I to the Convention for chemicals that had already been included in the interim PIC procedure and for which a decision guidance document, providing extensive information on that chemical, already existed.

3. The Intergovernmental Negotiating Committee, at its seventh session, recognized that the principal purpose of the requirement for submission of notifications of final regulatory action was to gather information of use in identifying chemicals for inclusion in the interim PIC procedure. However, a large proportion of the notifications submitted so far related to chemicals that were already included in the interim PIC procedure, duplicated information already contained in decision guidance documents and posed a reporting burden for many countries. The Committee acknowledged that the information provided in the notifications did serve other purposes, such as that of keeping countries aware of developments relating to banned or severely restricted chemicals elsewhere in the world, and recognized the need to study the situation in greater detail.

4. The Committee decided that, as an interim measure, countries should set priorities when preparing notifications of final regulatory action relating to banned or severely restricted chemicals, with the highest priority being given to chemicals that were not already subject to the interim PIC procedure. Lower priority should be given to submitting notifications relating to chemicals that were already subject to the interim PIC procedure. The Committee also agreed that the secretariat should, when verifying whether submitted notifications contained all the information required under annex I to the Convention, give priority to notifications relating to chemicals not yet subject to the interim PIC procedure.

C. Analysis of the issues regarding submission of notifications of final regulatory action for chemicals already subject to the interim PIC procedure

5. Article 5 of the Convention requires that Parties provide notification for each final regulatory action taken to ban or severely restrict a chemical. When the Convention enters into force for a Party, it must also notify the secretariat in writing of each final regulatory action in effect at that time. These notifications must contain the information stipulated in annex I, where available. The Convention provides for no exemption, either as to the need to submit such notifications of final regulatory action or as to the content of the notifications, for chemicals already subject to the interim PIC procedure.

6. The requirements set out in annex I concerning the specific information to be contained in a notification of final regulatory action serve mainly to provide the Interim Chemical Review Committee with sufficient information to consider the criteria for listing banned or severely restricted chemicals set out in annex II of the Convention and make a recommendation on whether to include a chemical in the PIC procedure.

7. Notifications of regulatory action to ban or severely restrict a chemical already subject to the interim PIC procedure may also serve as a basis for future updating of information on regulatory actions in the decision guidance documents for that chemical. These notifications would be of special relevance if the reported regulatory action was based on different health or environmental concerns, was for another category of use, or, in the case of a severe restriction, provided for a substantially different severe restriction of use from the notifications on which the decision to include the chemical in the procedure was based. Such information might lead, where relevant, to revision of the original decision guidance document by the Interim Chemical Review Committee, adoption of the revised decision guidance document by the Intergovernmental Negotiating Committee and, ultimately, changes in Parties' responses regarding future import of the chemical in question.
8. The submission of notifications of final regulatory action to ban or severely restrict a chemical in line with article 5, in addition to serving as a basis for identifying and deciding on which chemicals should be included in the PIC procedure, also has information exchange functions. Article 5 stipulates that the secretariat shall, every six months, communicate to Parties a summary of each notification that meets the information requirements of annex I. This information is sent to all designated national authorities via the PIC Circular.

9. The provision of this information is a key information exchange activity under the Convention. It provides a mechanism for informing Parties of regulatory actions to ban or severely restrict a chemical, including those already included in the PIC procedure, taken by individual Parties. Successive issues of the PIC Circular provide a compilation of regulatory actions that serves as a possible reference source for national actions on chemicals. Interested parties are encouraged to contact the designated national authorities of notifying Parties and request a copy of the referenced documentation. Such information could be used to support a domestic regulatory action to ban or severely restrict a chemical. It is not clear to what extent Parties actually use the PIC Circular as a source of information on chemicals or have requested copies of national evaluations to support domestic regulatory actions.

10. The secretariat has developed an efficient process for verifying submitted notifications of final regulatory action. Those notifications that are deemed not to meet the information requirements of annex I are returned to the designated national authority along with a detailed analysis which identifies the missing information, in order to facilitate follow-up by the designated national authority. To date, the notifications submitted, both for chemicals already subject to the interim PIC procedure and for new chemicals, have all been successfully processed by the secretariat within established time lines.

11. The extent to which the completion of “Notification of regulatory action” forms for final regulatory actions for chemicals already subject to the interim PIC procedure is a burden to countries has not been fully defined. An analysis of the notifications that have been submitted under the interim PIC procedure might provide some insight on the issue. The total number of notifications submitted by Parties since 11 September 1998 is 157; of these, roughly 35 per cent were on chemicals already subject to the interim PIC procedure. The submitted notifications covered around 85 different chemicals, and of these roughly 25 per cent were chemicals already subject to the interim PIC procedure. In all 56 out of 162 Parties, or roughly 35 per cent, have submitted notifications, under either the original or the interim PIC procedure.

12. Given the above, it would appear that any problems that do exist might relate not so much to the fact that a chemical is subject to the interim PIC procedure as to the notification process itself. An analysis of the problems associated with the notification process in general and possible measures to address these problems are discussed in document UNEP/FAO/PIC/INC.8/8.

D. Options regarding submission of notifications of final regulatory action for chemicals subject to the interim PIC procedure

13. The following options might be considered in response to the possible problems faced by Parties in preparing notifications of final regulatory action for chemicals already subject to the interim PIC procedure. It should be noted that some of these options deviate from the procedures set out in the Convention.

Option 1

14. The first option could be based on the status quo, namely that Parties would continue to be required to submit full notifications (in line with the information requirements of annex I) for all regulatory actions on chemicals subject to the interim PIC procedure, with both Parties and the secretariat giving priority to the submission and verification of notifications on chemicals not yet included in the interim PIC procedure. This option would be in line with the interim decision of the Intergovernmental Negotiating Committee, taken at its seventh session (UNEP/FAO/PIC.7/15, para. 56).
Option 2

15. A second option could be to consider a “two-track” approach to submission of notifications of final regulatory action for chemicals already subject to the interim PIC procedure, depending on the scientific basis for the national regulatory action:

(a) For regulatory actions that are based on different concerns from those reported in the decision guidance document, a full notification, in line with the information requirements of annex I, would be required;

(b) For regulatory actions that parallel those concerns on which a chemical entered the interim PIC procedure and which are described in the decision guidance document, an abbreviated notification, not containing all of the information elements required by annex I, may be sufficient.

Full notification

16. A full notification of final regulatory action in line with the information requirements of annex I would be submitted where:

(a) The regulatory action covers a different category of use - the chemical is included in the interim PIC procedure as a pesticide, but the new regulatory action covers industrial use(s), or vice versa;

(b) The scientific basis for the regulatory action is different - the chemical is included in the interim PIC procedure because of notified regulatory actions based on human health concerns, but the new regulatory action is based on environmental concerns, or vice versa; and/or

(c) A severely hazardous pesticide formulation is included in the interim PIC procedure, but the new regulatory action bans or severely restricts all formulations of the pesticide on the basis of human health or environmental concerns.

Abbreviated notification

17. There could be several options for an abbreviated notification, which might:

(a) Simply indicate that the regulatory action is based on environmental and/or health concerns, and require no further detail regarding the scientific basis for the regulatory action (for example, the summary stipulated in point 2 (a) (vi) of annex I could be eliminated);

(b) Provide a summary of the known hazards and risks related to human health or the environment that were the basis for the reported regulatory action (i.e., the summary stipulated in point 2 (a) (vi) of annex I would be included).

18. The simplest approach would be to eliminate those elements of general information concerning the chemical that are contained in the decision guidance document. The abbreviated notification would focus on essential information concerning the national regulatory action.

19. The challenge would be to identify those elements in annex I that might be eliminated without impinging on those considered important with respect to information exchange. The principal point to consider would be the level of detail required in the submitted notification concerning the scientific basis for the regulatory action. For example, although a reported regulatory action may be based on environmental or health concerns, it may also be that the scientific rationale for the concern differs in different regions of the world. The environmental concerns serving as the basis for a regulatory action taken in a country with a temperate climate may be quite different from those in a tropical country. In the interest of information exchange among Parties, a description of the basis for the regulatory action may thus be considered an important element to retain in the abbreviated notification.
Option 3

20. Article 12 of the Convention requires that when a chemical that is banned or severely restricted by a Party is exported, that Party shall provide an export notification to the importing Party. This obligation ceases when the chemical is listed in annex III and the importing country has provided an import response that has been distributed to participating Parties via the PIC Circular. An extrapolation of this concept might be applied to the obligation to submit a notification of final regulatory action for chemicals already subject to the interim PIC procedure, so that a Party that has provided a complete import response regarding a chemical subject to the interim PIC procedure, which has been circulated in the PIC Circular, would not be obliged to submit a notification on its final regulatory action to ban or severely restrict this chemical, should it have taken such action.

E. Considerations in evaluating the proposed options

21. The request made by the Committee at its seventh session was to analyse the issue of submission of notifications of final regulatory action for chemicals already subject to the interim PIC procedure and outline options that would reconcile the need for information exchange with the need to avoid placing excessive reporting burdens on Parties or appraisal burdens on the secretariat.

22. The possible impact of the individual options described in section D above are outlined below in the context of the relevant issues that need to be considered.

Consistency with obligations under the Convention

23. Option 1 appears consistent with the obligations arising from article 5 of the Convention and with the instructions/guidance available to Parties, while options 2 and 3 deviate from the obligations under article 5. The scope for implementing these last two options without a corresponding change in the Convention text is not clear. In addition, these options would necessitate a change in the guidance to Parties regarding the notification process, complicating this process further.

Compatibility with the need for information exchange

24. Option 1 appears compatible with an information exchange activity associated with the notification process. Option 2 appears generally compatible with a process of information exchange. However, in some instances it would require greater follow-up by Parties to understand the basis for the notified regulatory action, possibly reducing the information exchange opportunities available at present with a full notification. Option 3 would not be compatible with a process of information exchange.

Appraisal burden on the secretariat

25. Option 1 would have no impact on the work of the secretariat. At present the work associated with the review of submitted notifications is handled efficiently by the secretariat. Option 1 provides sufficient flexibility should, at any point in the future, the submission of notifications for chemicals already subject to the interim PIC procedure overtake those for new chemicals. Option 2 would have limited impact on the work of the secretariat, necessitating a change in the established procedures for the verification of abbreviated notifications. Option 3 would remove completely the need to verify notifications for chemicals already subject to the interim PIC procedure.
26. Option 1 would not change the reporting burden on Parties. However, this option provides flexibility for Parties to set priorities in preparing notifications of final regulatory action. The extent to which current notification requirements for chemicals already subject to the interim PIC procedure place a burden on participating Parties is not clear. Option 2 might reduce the volume of information associated with individual notifications, but would not be expected to limit the number of notifications Parties would submit. It might also have the undesirable effect of complicating the notification process, thus increasing the burden on Parties. Option 3 removes completely the need for Parties to submit notifications of final regulatory action for chemicals already subject to the interim PIC procedure.

27. In reviewing the proposed options the Committee might also consider the following factors:

(a) The text of article 5 of the Convention and the information requirements of annex I are clear and provide no exemption, either as to the obligation to submit notifications of final regulatory action or as to the content of the notifications, for chemicals already subject to the interim PIC procedure. The implications of any proposed deviations from the procedure defined in the Convention require careful review;

(b) The analysis has highlighted the potential importance of the information exchange opportunities associated with notifications of final regulatory action. It has also established that the secretariat has developed processes for managing all submitted notifications of final regulatory action in an efficient and timely manner. What is less clear is the extent to which the requirement to provide notifications concerning chemicals subject to the PIC procedure places a burden on Parties. It may be that the problem is related to the overall process of notification itself rather than this particular subset of chemicals. Implementation of the recommendations resulting from the analysis of problems frequently encountered by Parties in their preparation of notifications may help to resolve the problems Parties are facing.

F. Possible action by the Intergovernmental Negotiating Committee

28. The Committee may wish to review the analysis carried out regarding the issue of submission of notifications of final regulatory action for chemicals that are already subject to the interim PIC procedure and their processing in accordance with articles 5 and 7 and consider whether it would wish to adopt a specific policy to resolve any problems relating to the issue further to the general guidance provided by the seventh session of the Committee.

29. The Committee may wish to consider whether, at this point in time, there is a problem of sufficient magnitude that it should consider deviating from the procedures set out in the Convention and possibly complicating the process for the submission and verification of notifications of final regulatory action. The outcome of the analysis of the problems frequently encountered by Parties in their preparation of notifications may provide insight regarding these problems and guidance as to possible opportunities for their resolution. The issue can be revisited once the actions agreed upon to address Parties’ problems with submitting notifications have been implemented and Parties have had more experience in submitting notifications.