UNITED NATIONS

PIC

United Nations Environment Programme

Food and Agriculture Organization of the United Nations

Distr.
GENERAL

UNEP/FAO/PIC/ICRC.2/9
15 December 2000

ENGLISH ONLY

INTERIM CHEMICAL REVIEW COMMITTEE
Second session
Rome, 19 – 23 March 2001

PRELIMINARY ANALYSIS OF THE PROBLEMS FREQUENTLY ENCOUNTERED BY PARTIES IN THEIR PREPARATION OF NOTIFICATIONS OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Note by the secretariat

1. The purpose of this note is to provide the Interim Chemical Review Committee with a preliminary analysis of the problems frequently encountered by Parties[1]/ in their preparation of notifications of final regulatory action to ban or severely restrict a chemical, as requested by the Intergovernmental Negotiating Committee, at its seventh session. The Interim Chemical Review Committee might wish to take the results of this preliminary analysis into account when considering the report of task group 1 (UNEP/FAO/PIC/ICRC.2/5) under agenda item 6 (a) of the provisional agenda.

1. Background

2. The Intergovernmental Negotiating Committee, at its seventh session in Geneva from 30 October to 3 November 2000, noting that there were some aspects of the implementation of the interim prior informed consent (PIC) procedure that gave cause for concern, requested the secretariat to prepare an analysis of the problems frequently encountered by Parties in their preparation of notifications of final regulatory action to ban or severely restrict a chemical. It agreed that a preliminary version of the analysis was to be made available to the Interim Chemical Review Committee for consideration at its second session, and that the final analysis and any recommendations from the Interim Chemical Review Committee should be submitted to the Intergovernmental Negotiating Committee at its eighth session.

[1]/ During the interim period before the Convention enters into force, a "Party" is 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.

2. Requirements of the Rotterdam Convention regarding notification of final regulatory action

3. Article 5 requires each Party to notify the secretariat in writing of each final regulatory action taken to ban or severely restrict a chemical. The notification must contain the information listed in Annex I of the Convention, where available. In order to facilitate the submission of notifications by Parties, a form for "Notification of final regulatory action to ban or severely restrict a chemical" (notification form) was sent to all designated national authorities (DNAs) in June 1999, together with instructions on how it should be completed.

4. Once a notification is received, the secretariat is required to verify, within six months of receipt, whether it contains the information required by annex I of the Convention. A synopsis of the notifications received, including summaries of those notifications that are verified to contain all the information required and information regarding those notifications that do not contain the information, is communicated, through the PIC Circular, to all Parties every six months.

3. Status of submissions of notifications of final regulatory action from Parties as of 30 November 2000

5. Table 1 gives an overview of the number of notifications that had been submitted by Parties as of 31 October 2000, including a breakdown of how many were verified to contain/not contain all the information required in annex I of the Convention. Further detailed information on the status of implementation of the interim PIC procedure may be found in UNEP/FAO/PIC/ICRC.2/3. At the moment, the limited number of notifications available does not lend itself to a further analysis of whether or not some PIC regions are having more problems than others.

Table 1: Notifications submitted under the interim PIC procedure

	Submitted between 11 September 1998 and 31 May 2000	Submitted between 1 June 2000 and 31 October 2000	Total submitted
Notifications verified to meet the requirements of Annex I of the Convention	6	42	48
Notifications verified not to meet the requirements of Annex I of the Convention	62	24	86
Total submitted	68	66	134

4. A preliminary analysis of the problems encountered by Parties in completing the form for notification of final regulatory action and possible options to address them

A. Defining the problems

a) Current version of the notification form and instructions

6. In order to facilitate the implementation of the interim PIC procedure, the secretariat developed a revised form for “Notification of final regulatory action to ban or severely restrict a chemical” (notification form) in June 1999. This notification form is contained in Appendix II of this note. In developing the form, the secretariat based itself on the information requirements of annex I of the Convention. The individual fields of the notification form mirror the specific information elements of Annex I. To assist DNAs in

completing the form a detailed set of instructions were also developed. In the instructions an attempt was made to link the information to be provided with the relevant criteria in annex II of the Convention.

7. The form and the instructions, which were distributed to all DNAs in June 1999, exist in English, French and Spanish. They are available on the Rotterdam Convention website at http://www.pic.int.

b) Experience in use of the current version of the notification form and instructions

8. The secretariat has developed a checklist to assist it in its verification of submitted notifications. For each notification, a completed checklist is sent to the DNA indicating the result of the secretariat's verification, as well as a draft summary of the notification, to be included in the next PIC Circular. Where a notification is found to be incomplete, the checklist identifies the missing information. The DNA has the opportunity to supplement the information provided in the original notification and to comment on the secretariat's draft summary of the notification, before the result of the verification is published in the next PIC Circular.

9. In verifying submitted notification forms, some types of information are missing more frequently than others. Annex I of the Convention clearly indicates that the notification shall include the information elements listed in the Annex. The secretariat is of the understanding that all the information elements of annex I, with the exception of 2 (b) (iii), 2 (c) and 2 (d) are required; the secretariat draws its conclusion on whether a notification contains all the information required, i.e. is "complete", on this basis.

10. As noted above, the verification process is such that where a notification is found to be incomplete the DNA has the opportunity to supplement the information provided. To date, additional information has been provided in only a few cases, however, with this supplemental information those notifications were later verified to be "complete".

11. The secretariat has prepared, in Appendix I of this note, a summary of the most common problems it has encountered in verifying the submitted notification forms for completeness.

B. Issues to consider

12. The present approach to defining and addressing the problems associated with completing the notification form necessarily reflects the perspective of the secretariat, as it has been developed based on its experience. At present there is only limited direct knowledge of the difficulties encountered from the perspective of the DNA. The results of the present analysis and any proposals for revision to the form and guidance will need to be discussed with DNAs, to ensure that their needs are taken into consideration.

13. The observations of the secretariat compiled in Appendix 1 to this note are accompanied by an initial list of questions that have arisen when trying to understand the difficulties in completing the notification form. These questions may assist in identifying ways in which the notification form and instructions might be revised in order to improve the number of "complete" notifications.

14. The revision of the notification form is only one aspect of the issue. The Interim Chemical Review Committee might also wish to consider providing guidance to the secretariat regarding its approach to assessing the "completeness" of submitted notifications.

15. The results of these deliberations will form the basis for a more detailed analysis of these issues and possible solutions for presentation to the Intergovernmental Negotiating Committee, at its eighth session.

C. Next steps

16. The Interim Chemical Review Committee might wish to review the problems and questions raised in appendix I of this note and group them according to their level of complexity, as a first step towards proposing options to address the problems identified. It may be that some problems can be resolved relatively simply through incorporation of explicit instructions on the form itself, others may require further consideration, including revision/regrouping of the current version of the form. Finally, there may be aspects that take longer to resolve, e.g. where further information would need to be gathered from DNAs.

17. Some preliminary considerations regarding possible measures to address the problems identified are given below:

(a) clarifying which essential information elements must be provided in a notification, in order for the Interim Chemical Review Committee to be able to effectively apply the criteria listed in Annex II and to develop a decision guidance document;

(b) reordering of the notification form, linking similar information elements, in order to facilitate the provision of associated information and avoid duplication in different sections of the form;

(c) re-focussing the instructions on how to fill out the form;

(d) increasing DNAs understanding of the relationship between the information provided by the submitting State and the information necessary for the Interim Chemical Review Committee to apply criteria of annex II of the Convention;

(e) providing DNAs with guidance on generic information sources where requested information might be found;

(f) preparing a compilation of representative examples of notifications; and

(g) providing hands-on training to DNAs on how to fill out a notification form.

APPENDIX I

Summary of the most common problems the secretariat has encountered in verifying submitted notifications, together with some questions and possible options that might be considered

18. Below is a summary of the most common problems the secretariat has encountered when verifying whether submitted notifications contain all the information required by annex I of the Convention. These observations by the secretariat are accompanied by questions and possible options to consider in resolving the identified concerns.

19. The summary below refers to specific sections in the notification form, as contained in Appendix II of this note. In developing the form, the secretariat based itself on the information requirements of annex I of the Convention. The individual sections of the notification form mirror the specific information elements of annex I.

a) Reading the instructions: The instructions for completing the notification form are contained in a separate document. Experience in the verification process suggests that they are frequently not considered.

There may be a number of reasons why this occurs including: the instructions are too long, are too complicated or are separated from the notification form and unavailable to the individual completing the form.

One option to encourage greater use of the instructions is to incorporate "basic" instructions in the form itself. This annotated form would provide simple guidance to DNAs, identify the mandatory information versus that which is non-mandatory etc. Further detailed instructions and worked examples could be provided in a separate "reference" document. This might also be used as a training tool in workshops.

b) Obligatory information: The secretariat considers that all sections of the notification form, with the exception of **2.5.3** (Estimated quantity of the chemical produced, imported, exported and used, where available), **2.6** (Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions), **2.7.1** (Assessment of socio-economic effects of the final regulatory action), **2.7.2** (Information on alternatives and their relative risks) and **2.7.3** (Relevant additional information) are mandatory and must be filled in. Often, sections are left blank. If a mandatory section is left blank, the secretariat will verify the notification as incomplete.

Annotation of the notification form, clearly identifying those sections that are mandatory, might be one approach to addressing this problem. A similar approach might be to ensure that, where no information is available at national level for one or more of the mandatory sections, the DNA explicitly states this in the form.

c) Section 1 on identity of chemical: The secretariat considers that sections 1.1 (Common name), 1.2 (Chemical name), 1.3 (Trade names) and 1.4 (Code numbers such as CAS number and Customs code) are mandatory. There are two situations encountered:

i) one or more of these sections are often not filled in, so the chemical cannot be specifically identified; in such cases additional information must be requested from the DNA;

ii) partial information is provided, sufficient to precisely identify the chemical, although some elements such as 1.3 (Trade names) are not given.

At the present time, both these situations result in the notification form being verified as incomplete. In the second instance, it might be possible to consider the notification complete and allow it to move to the next stage of the process. For example, a list of relevant trade names is recognised as an important component of a decision guidance document, one option could be that such information is collected by the task group of the Interim Chemical Review Committee charged with drafting the decision guidance document.

d) Section 1.6 on Information on hazard classification where the chemical is subject to classification requirements: The secretariat considers that section 1.6 is mandatory, however, it is often lacking in submitted notification forms, which are then verified as incomplete.

The international hazard classification is readily available for most chemicals. It might be an option to consider the notification as complete and allow it to move on to the next stage of the process with the understanding that this information would be added by the task group of the Interim Chemical Review Committee charged with drafting the decision guidance document.

e) Section 1.7 on Use or uses of the chemical: Often there is a discrepancy between the information given in this section and the information given in sections 2.5.1 and 2.5.2 on uses that are prohibited by the final regulatory action and uses that remain allowed. Some Parties might never have registered the substance or mixture containing the substance. Therefore, the DNA is reluctant to mention uses that have never taken place in their country. Also, when reporting on "old" regulatory actions, the DNA often indicates that there are "no" uses, as they were prohibited several years ago.

It seems clear that the information requested in this section is not well understood by DNAs. Further guidance is needed regarding the information on use or uses that is being sought, for example:

i) Uses of the chemical at the time the notification is filled in?
ii) Uses that were allowed before the regulatory action came into force?
iii) Possible uses that would be permitted if registration had been granted ?

There is also a need to clarify the link between the information requested in sections 2.5.1 and 2.5.2 on use(s) and section 1.7 on uses prior to the final regulatory action..

f) Section 2.2 on Information specific to the final regulatory action: The information provided in section 2.2 describing the regulatory action is often not provided in sufficient detail, nor is it linked to the information given in sections 2.5.1 and 2.5.2 on the categories for which the regulatory action applies or the affected uses.

How might the summary of the regulatory action be better described and linked to the uses prohibited/uses that remain allowed in section 2.5?

g) Section 2.3 - Was the final regulatory action based on a risk or hazard evaluation? It is considered mandatory to respond to this section as the risk evaluation is a key component in the development of the decision guidance document by the Interim Chemical Review Committee. Very often this section is left blank.

How might this section be better linked to the criteria in point (b) of Annex II of the Convention that the Interim Chemical Review Committee must consider?

h) Section 2.4 on Reasons for the final regulatory action: Expected effects of the final regulatory action – Most often the information provided here is limited. Yet this section is important for the Interim Chemical Review Committee in order that it might apply the criteria in point c) of annex II of the Convention. It would appear that there is a also some redundancy with the information requested in Section 2.3

i) **Section 2.5 on Category or categories where the final regulatory action has been taken:** Often one of the sections is left blank, which presumably means that the regulatory action does not affect that category e.g. applies to pesticide use only or industrial chemical use only. However, the section does not allow for the collection of information on whether there are ongoing uses in other categories that are not affected by the regulatory action.

It might be that clarifying the relationship of the information requested in this section with that in sections 1.7, 2.2.1 and 2.4.1/2.4.2 would help to ensure that coherent information is provided regarding the overall use(s) of the chemical subject to the regulatory action.

j) **Section 2.5.3 on Estimated quantity of the chemical produced, imported, exported and used, where available:** The secretariat does not consider this section to be mandatory and notification forms lacking this information are verified as complete. Very few of the submitted notifications have contained this information, even though one of the criteria in Annex II (point (c) (iv)) is that there is evidence of ongoing international trade in the chemical.

Presuming that there is in fact ongoing international trade in the chemical, further information on quantities might be of interest to the Intergovernmental Negotiating Committee in its deliberations on including the chemical in the Convention. This might be information that could be compiled by the task group of the Interim Chemical Review Committee in drafting the decision guidance document and preparing a recommendation to the Intergovernmental Negotiating Committee.

k) **Section 2.6 on Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions:** The secretariat does not consider this section to be mandatory and notification forms lacking this information are verified as complete. However, very few of the submitted notifications have contained this information.

This is information that would be of interest to a Party when making an import decision. This might be a section of the decision guidance document that could be completed by the task group of the Interim Chemical Review Committee charged with drafting the decision guidance document.

l) **Section 2.7.1 on Assessment of socio-economic effects of the final regulatory action:** The secretariat does not consider this section to be mandatory and notification forms lacking this information are verified as complete. Very few of the submitted notifications have contained this information.

This is information that might be of interest to the Intergovernmental Negotiating Committee in its deliberations on including the chemical in the Convention and would also be of relevance to Parties when making import decisions. It is in many ways closely linked to a discussion on alternatives. This might be a section of the decision guidance document that could be completed by the task group of the Interim Chemical Review Committee charged with drafting the decision guidance document.

m) **Section 2.7.2 on Information on alternatives and their relative risks:** The secretariat does not consider this section to be mandatory and notification forms lacking this information are verified as complete. Very few of the submitted notifications have contained this information.

This is information that would be of interest to a Party when making an import decision. This might be a section of the decision guidance document that could be completed by the task group of the Interim Chemical Review Committee charged with drafting the decision guidance document.

APPENDIX II

FORM FOR

"NOTIFICATION OF FINAL REGULATORY ACTION

TO BAN OR SEVERELY RESTRICT A CHEMICAL" -

DEVELOPED BY THE SECRETARIAT IN JUNE 1999

Interim Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

UNEP

FORM
FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY:

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	
1.3	**Trade names and names of preparations**	
1.4	**Code numbers**	
1.4.1	**CAS number**	
1.4.2	**Harmonized System customs code**	
1.4.3	**Other numbers (specify the numbering system)**	

1.5	**Indication regarding previous notification on this chemical, if any**
1.5.1	❑ This is a first time notification of final regulatory action on this chemical.
1.5.2	❑ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ❑ This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: _____

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.6	**Information on hazard classification where the chemical is subject to classification requirements**
International classification systems	**Hazard class**
Other classification systems	**Hazard class**

1.7	**Use or uses of the chemical**
1.7.1	❑ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
1.7.2	❑ **Industrial**
	Describe the industrial uses of the chemical in your country:

1.8	**Properties**
1.8.1	**Description of physico-chemical properties of the chemical**

1.8.2	**Description of toxicological properties of the chemical**	
1.8.3	**Description of ecotoxicological properties of the chemical**	

PART II: FINAL REGULATORY ACTION

2.	**FINAL REGULATORY ACTION**	
2.1	**The chemical is:** ❑ **banned** **OR** ❑ **severely restricted**	
2.2	**Information specific to the final regulatory action**	
2.2.1	**Summary of the final regulatory action**	
2.2.2	**Reference to the regulatory document**	
2.2.3	**Date of entry into force of the final regulatory action**	

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	❑ **Yes** ❑ **No**
	If yes, give information on such evaluation	
	Reference to the relevant documentation	

2.4	**Reasons for the final regulatory action**	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	❑ **Yes** ❑ **No**
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	❑ **Yes** ❑ **No**
	If yes, give summary of the known hazards and risks to the environment	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.5	**Category or categories where the final regulatory action has been taken**	
2.5.1	**Final regulatory action has been taken for the chemical category**	❑ **Industrial**
	Use or uses prohibited by the final regulatory action	
	Use or uses that remain allowed	

2.5.2	**Final regulatory action has been taken for the chemical category**	❑ **Pesticide**
	Formulation(s) and use or uses prohibited by the final regulatory action	
	Formulation(s) and use or uses that remain allowed	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	**Year**
Produced		
Imported		
Exported		
Used		

2.6	**Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions**

2.7	**Other relevant information that may cover:**
2.7.1	**Assessment of socio-economic effects of the final regulatory action**

2.7.2	**Information on alternatives and their relative risks**	
2.7.3	**Relevant additional information**	

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	
Address	
Telephone	
Telefax	
E-mail address	
Designated National Authority	
Institution	
Address	
Name of person in charge	
Position of person in charge	
Telephone	
Telefax	
E-mail address	

Date, signature of DNA and official seal: _____
