



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

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Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Sixth meeting

Geneva, 28 April–10 May 2013

Item 5 (a) of the provisional agenda*

Matters related to the implementation of the Convention: status of implementation

Proposals to increase the number of notifications of final regulatory action and guidance to assist parties in their preparation

Note by the Secretariat

I. Introduction

1. At its fifth meeting, the Conference of the Parties to the Rotterdam Convention adopted decision RC-5/2 on increasing the number of notifications of final regulatory action and communication between parties. The decision called on parties and the Secretariat to take actions to address issues related to notifications of final regulatory action and export notifications. Matters relating to export notifications are addressed separately in document UNEP/FAO/RC/COP.6/5.
2. In paragraph 2 of decision RC-5/2 the parties requested the Secretariat to propose ways and means of improving levels of notifications of final regulatory action submitted by parties under Article 5 of the Convention and to submit its proposals for the consideration of the Conference of the Parties at its sixth meeting. Annex I to the present note sets out the Secretariat's proposals.
3. In paragraph 5 of the decision the parties requested the Secretariat to prepare guidelines to assist parties in preparing notifications of final regulatory actions to ban or severely restrict pesticides and industrial chemicals, giving particular regard to the explanation of terms and definitions used in the Convention, notably the term "severely restricted chemicals."
4. The Secretariat drafted guidelines and submitted them to the Chemical Review Committee at its eighth meeting in March 2012.¹ Following the meeting, five Committee members and four observers submitted comments on the guidelines. Some Committee members suggested renaming them, saying that they should be referred to as "guidance" rather than "guidelines" because they did not provide certain details commonly associated with guidelines. The Secretariat incorporated the comments received into a revised version of the document, which, adopting the suggested terminology, is now entitled "Guidance to assist parties in preparing notifications of final regulatory action to ban or

* UNEP/FAO/RC/COP.6/1.

¹ UNEP/FAO/RC/CRC.8/INF/11.

severely restrict pesticides and industrial chemicals”. The guidance is presented in annex II to the present note.

II. Proposed action

5. The Conference of the Parties may wish:
 1. To take note of the activities that the Secretariat is undertaking with regard to notifications of final regulatory action to ban or severely restrict pesticides and industrial chemicals.
 2. To request the Secretariat to implement the proposals to increase the number of notifications of final regulatory action set out in annex I to the present note.
 3. To take note of the guidance to assist parties in preparing notifications of final regulatory actions set out in annex II to the present note.

Annex I

Proposals for increasing the number of notifications of final regulatory actions submitted pursuant to Article 5 of the Rotterdam Convention

1. Under Article 5 of the Rotterdam Convention, parties are required to notify the Secretariat of final regulatory actions. Some parties have not done so, however, owing to certain challenges and circumstances. The reasons that parties do not submit notifications of final regulatory action may differ from one party to another. They could include, for instance, inadequate technical and institutional capacity, as well as limited human and financial resources. Issues relating to notifications are further described in documents UNEP/FAO/RC/COP.4/11 and UNEP/FAO/RC/COP.5/4.
2. Some of the issues regarding notifications cannot be adequately addressed by the Secretariat alone. Within its mandate, however, the Secretariat can draw on its experience to work with parties, providing as much information and assistance as possible to support their efforts to submit notifications of final regulatory action.
3. To increase the number of notifications of final regulatory action submitted, the Secretariat proposes to build on existing activities and materials currently available to enhance their effectiveness, to take more proactive actions to work with parties on the submission of notifications of final regulatory action and to continue, in the context of technical assistance activities, to emphasize the importance of notifications for the effectiveness of the prior informed consent procedure and the implementation of the Convention.
4. Three proposed areas for priority actions have been identified:
 - (a) Encourage the increased use of existing training and guidance materials and develop additional materials;
 - (b) Support parties in their submission of notifications through various initiatives;
 - (c) Focus on technical assistance activities to increase capacity and highlight the importance of notifications.

Proposal 1: Encourage the increased use of existing training and guidance materials and develop additional materials

5. The Secretariat has developed various materials to assist parties in the preparation of notifications. They include:
 - *Interactive Training on the Operation of the Rotterdam Convention (ITORC)*, an e-learning tool, which allows for self-directed learning about the practical aspects of the Convention
 - *Guidance to DNAs on the operation of the Convention*, a publication developed to provide comprehensive guidance to designated national authorities (DNAs) on the rights and obligations of parties under the Convention
 - *Guidance to complete the form for notification of final regulatory action*, a publication containing explanations and examples of information that can be provided in the form for submitting notifications of final regulatory action
 - *Cross-cutting issues*, a publication that makes available information that might assist parties in the development and strengthening of their national chemicals management infrastructure and in the evaluation of chemicals
 - *Guidance to assist Parties in preparing notifications of final regulatory action to ban or severely restrict pesticides and industrial chemicals*, as requested by the Conference of the Parties at its fifth meeting and developed by the Secretariat;
 - *Video on the process for listing chemicals in Annex III*
6. The information in these materials ranges from detailed descriptions of obligations and policy considerations to hands-on guidance in the application of procedures and implementation of the Convention. The Secretariat will work to make it easier for designated national authorities to understand what materials to use under a given set of circumstances in order to make the development

of notifications easier. This could include repackaging or reformulating the materials to make them more cohesive and intuitive.

7. Further training and guidance materials will also be developed where needed. Such materials could include guidance on, for example, bridging information and risk evaluation. Materials developed will support and link to other activities undertaken to support parties in their submission of notifications, such as dedicated sessions at workshops providing technical assistance.

8. Any new materials developed will be made available on the Rotterdam Convention website and to designated national authorities through various channels and in various media, such as electronic or printed copy. The Secretariat will also make better use of distribution channels, such as regional centres, regional offices and other contacts, to maximize the distribution of new materials and to raise awareness of existing materials.

Proposal 2: Support parties in their submission of notifications through various initiatives

9. The Secretariat receives notifications of final regulatory action on an ad hoc basis as each party submits them upon taking final regulatory action to ban or severely restrict chemicals. It seems apparent, however, that some parties have taken final regulatory action but have not, for various reasons, notified the Secretariat. Designated national authorities may need support in following through on the submission of notifications of final regulatory action once the action has been taken.

10. The Secretariat regularly searches for information on final regulatory actions that have been taken by parties but not notified to the Secretariat. It does so through internet research; monitoring of the media; frequent contact with Basel and Stockholm Convention regional centres and in particular FAO field offices for information on actions taken by parties related to chemicals. Other activities include periodic calls and reminders to designated national authorities and work to highlight the benefits and importance of notifications and encourage their submission.

11. The Secretariat will continue these activities and will combine them with offers of support and assistance to designated national authorities in the preparation of notifications of final regulatory action.

Proposal 3: Focus on technical assistance activities to increase capacity and highlight the importance of notifications

12. The Secretariat will, upon request, arrange for the provision of specific technical assistance to parties in preparing notifications. The Secretariat could provide, for instance, limited human resources, such as through the use of experts from within the region of the requesting party to assist in collecting and reviewing relevant information and preparing notifications. Parties are invited to express interest in specific assistance in writing to the Secretariat.

13. It is possible that more notifications would be received if more time was spent in workshops and other meetings to ensure a deeper understanding of the notification process, benefits of notifications, the Convention and the information requirement contained in Annex I in particular. These topics are already addressed in technical assistance activities undertaken by the Secretariat, and the Secretariat will continue to ensure that notifications are a top priority topic addressed in national, subregional and regional workshops and that more emphasis and time are allocated to notifications when working with parties. The Secretariat might also offer webinars (online seminars) to provide training in the preparation of notifications, discuss specific issues relating to notifications and assist in their completion.

14. Notifications are based on final regulatory actions, so they occur at the end of a chain of events. Strengthening parties' ability to take final regulatory actions supports the submission of notifications. Therefore working closely with partners, such as the FAO pesticide management group, UNEP Chemicals, UNITAR, SAICM, OECD, donor countries and other relevant institutions is a valuable component of efforts to improve the capacity of parties to regulate hazardous chemicals.

Budget implications

15. Funding for the activities proposed in the present document is included under activity 15 (RC) of the budget of the programme of work for the 2014–2015 biennium.¹

¹ UNEP/FAO/CHW/RC/POPS/EXCOPS.2/3 and UNEP/FAO/RC/COP.6/INF/15.

Annex II

Guidance to assist parties in preparing notifications of final regulatory action to ban or severely restrict pesticides and industrial chemicals

Introduction

1. Notifications of final regulatory action constitute an important component of information exchange under the Rotterdam Convention, allowing information on potentially hazardous chemicals to be shared between parties.
2. Parties are encouraged to contact the Secretariat at any time for support and assistance in the completion of notifications of final regulatory action. Parties may contact the Secretariat at any time before, during and after the preparation of notifications. Upon submission of a notification, a party may continue to submit the information requested in Annex I to the Convention with the assistance of the Secretariat.
3. Each party to the Convention must decide for itself whether and to what extent to regulate a given chemical. Based on an evaluation of the chemical, a party may come to the conclusion that the risk to human health or the environment posed by the chemical is unacceptable, not manageable, or acceptable only under certain circumstances. The party may then choose to regulate the chemical. If it does so, and if its regulation of the chemical constitutes a “final regulatory action” as defined in the Convention, then, according to Article 5 of the Convention, the party, within 90 days of taking the final regulatory action, “shall notify the Secretariat in writing of such action”.
4. The present guidance is intended to provide parties with information that will assist them in preparing and submitting notifications of final regulatory action.

1. What is a final regulatory action under the Rotterdam Convention?

5. Article 2 (e) of the Rotterdam Convention defines a final regulatory action as follows:

“Final regulatory action” means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical[.]”

2. What are a “banned chemical” and a “severely restricted chemical” under the Rotterdam Convention?

6. Article 2 of the Convention sets forth the following definitions:

(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;

7. Inasmuch as a “banned chemical” is a chemical “all uses of which within one or more categories have been prohibited” pursuant to Article 2, paragraph (b), it should be relatively easy to

recognize whether a chemical that is the subject of a regulatory action is a “banned chemical”. It may be more difficult, however, to determine whether the subject of a regulatory action is a “severely restricted chemical” according to Article 2, paragraph (c), since one must exercise judgment in evaluating whether the regulatory action has prohibited “virtually all use” of the chemical while continuing to allow “certain specific uses”. Beyond the definitions in Article 2, the Convention itself offers no guidance in the determination of whether a chemical is a “severely restricted chemical”. In making this determination parties may wish to consider a number of factors:

- The percentage of end uses of the chemical that have been prohibited
- The percentage by which the quantity of the chemical used is reduced
- The extent to which human or environmental exposure has been or is expected to be reduced
- The decrease in overall market share of the chemical over some period of time
- Other factors depending on national circumstances

8. For example, a party might take a final regulatory action to ban one of three uses of a chemical, with the effect of reducing the quantity used by 99 per cent and virtually eliminating human and environmental exposure, while at the same time allowing for limited and restricted uses. The party might conclude that the chemical is a severely restricted chemical even though uses of it are still allowed.

9. Parties may differ from one another in their approach to determining whether a chemical is a severely restricted chemical. It would be helpful, therefore, if parties submitting notifications of final regulatory action would provide clear and comprehensive explanations of the reasons why the chemicals that are subject to those actions meet the definition of severely restricted chemicals in Article 2 of the Convention. This explanation may be provided in either section 2.3.2¹ or section 2.5.1² of the notification form. At all times, relevant information may be submitted as supporting documentation accompanying the notification.

10. Parties may also restrict substances to varying degrees for different uses. They may also authorize the use of a chemical for a short period of time, for a limited number of crops, in small quantities or in certain pack sizes. These situations can make it relatively complex to assess whether a chemical has been severely restricted.

3. **Obligation to notify the Secretariat of a final regulatory action**

11. Article 5, paragraph 1, of the Convention states as follows:

“Each Party that has adopted a final regulatory action shall notify the Secretariat in writing of such action. Such notification shall be made as soon as possible and in any event no later than ninety days after the date on which the final regulatory action has taken effect, and shall contain the information required by Annex I, where available.”

12. The Convention contains no provision to invalidate a notification of final regulatory action submitted by a party on the grounds of its submission after the 90-day period specified in Article 5 of the Convention. At the fifth meeting of the Chemical Review Committee, the Senior Legal Officer of UNEP provided a legal opinion to the effect that a notification submitted after the 90-day deadline, once verified by the Secretariat and submitted to the Chemical Review Committee, was valid. In the light of that opinion, the Committee concluded that the notification submitted after the 90-day deadline met the requirements of Annex I to the Convention. After accepting that the chemical met the criteria in Annex II, the Committee recommended that the chemical be listed in Annex III and agreed to prepare a decision guidance document for the chemical that was the subject of the notification.³ Subsequently the Conference of the Parties adopted a decision listing the chemical in Annex III to the Convention, stating, as it has stated in respect of all chemicals added to Annex III, that “all the requirements for listing the chemical in Annex III to the Convention have been met”.⁴ Parties that have not yet submitted notifications for final regulatory actions taken more than 90 days ago may wish to take this information into account.

¹ Use or uses prohibited by the final regulatory action and Use or uses that remain allowed.

² Estimated quantity of the chemical produced, imported, exported and used.

³ See the report of the fifth meeting of the Chemical Review Committee, regarding the Committee’s consideration of endosulfan (UNEP/FAO/RC/CRC.5/16, paras. 22–73 and 174–176).

⁴ UNEP/FAO/RC/COP.5/26, annex I, decision RC-5/5.

4. Purpose and benefits of making notifications of final regulatory action

13. Notifications of final regulatory action provide a means by which parties can get information on what action is taken by other parties on which chemicals and for what reason. Communication between designated national authorities provides a means by which parties can seek even further information on final regulatory actions taken by other parties. Such information enables them to make better-informed decisions on whether to take risk management measures, to take regulatory action or to import chemicals into their territories.

14. If the Secretariat receives one notification from each of at least two PIC regions that fulfil the information requirements of Annex I, then the notifications are submitted to the Chemical Review Committee for review.

15. If the Committee recommends a chemical for listing in Annex III to the Convention, that recommendation triggers the preparation of a draft decision guidance document by the Committee that provides all parties with detailed information on the properties of the chemical and the notifying party's reason for banning or severely restricting the chemical. Such information increases awareness of the possible risks of the chemical and assists parties in making informed decisions about whether to allow the import of the chemical in conformity with the provisions of the Convention. The provision of information on hazardous chemicals is one of the primary objectives of the Convention and, being at the core of the prior informed consent procedure under the Convention, constitutes a major benefit to all parties.

16. Parties may wish to prioritize the submission of notifications of final regulatory action for chemicals for which one notification has already been verified to meet the information requirements of Annex I. This could lead to more chemicals being reviewed by the Committee, and consequently more chemicals could be subject to the prior informed consent procedure under the Convention.

17. Even if a notification of a final regulatory action does not meet all the information requirements presented in Annex I, it provides useful information to parties. Parties having similar geographical patterns, agricultural practices and industries may often use the same chemicals in similar ways. A notification submitted by one such party for a given chemical enables another such party to make a better-informed decision on whether to continue using the chemical.

5. Practices in completing forms for notification of final regulatory action and for information exchange

18. Article 5 provides that each party "shall notify the Secretariat in writing" that it has adopted a final regulatory action in respect of a given chemical and that the notification to the Secretariat should contain "the information required by Annex I, where available". A model form of notification of final regulatory action has been prepared by the Secretariat to facilitate the submission of notifications by designated national authorities and to promote completeness and consistency in submitted notifications. The form also makes it easier for the Secretariat to verify whether a notification contains the information required by Annex I to the Convention and facilitates the review of notifications by the Chemical Review Committee against the criteria of Annex II. Use of the form is encouraged but is not mandatory. Parties may therefore submit notifications in any written format.

19. Parties may submit notifications to the Secretariat by e-mail, ordinary post or facsimile.

(a) Information requirements of Annex I

20. Paragraph 1 of Article 5 provides that a notification of final regulatory action "shall contain the information required by Annex I, where available." Annex I focuses on the properties, identification and uses of the chemical that is the subject of the final regulatory action, as well as specific and general information related to the final regulatory action.

21. Owing to significant limitations in capacity, legislation and institutional organization, some developing countries and countries with economies in transition may be unable to satisfy the information requirements of Annex I. As a consequence, they may be hesitant to notify the Secretariat of a final regulatory action, given that the notification form requests data that may not be documented at the national level or be otherwise available. This could include scientific or chemical-specific information and studies on risk evaluation.

22. As noted above, paragraph 1 of Article 5 states that parties "shall notify the Secretariat" of the adoption of a final regulatory action. The Convention does not, however, state that parties that cannot provide all of the information required by Annex I should not comply with this requirement. All parties, therefore, are encouraged to submit notifications of final regulatory action even if they are unable to provide some or all of the information required by Annex I. Parties are encouraged to

provide as much information as possible that is specific to the final regulatory action, such as that outlined in paragraph 2 (a) of Annex I and other relevant information as provided for in paragraph 2 (d) of Annex I.

23. An area of uncertainty for some parties could be whether a notification should be made when a party's final regulatory action was not based on a risk or hazard evaluation undertaken by the party for the purposes of the Convention. Section 2 (a) (iv) of Annex I provide that notifications should include an indication of whether a final regulatory action was taken on the basis of a risk or hazard evaluation and, if so, information on the evaluation, including reference to relevant documentation. Nothing in the Convention, however, says that parties must undertake such an evaluation. Where, however, such parties have based final regulatory actions on evaluations undertaken by other parties or for the purposes of other multilateral environmental agreements, they may wish to consider providing so-called "bridging information" in relation to those evaluations. Information on the nature and use of such bridging information is set out in the report of the third meeting of the Conference of the Parties (UNEP/FAO/RC/COP.3/26, paras. 63–66) and in policy guidance adopted by the Chemical Review Committee (UNEP/FAO/RC/CRC.8/INF/5, p. 46).

24. Parties are encouraged to contact the Secretariat at any time for support and assistance in completing and submitting the forms for notification of final regulatory action. Parties may contact the Secretariat at any time before, during and after preparation and submission of notifications. Upon submission of notifications, parties may continue to submit the information requested in Annex I with the assistance of the Secretariat.

(b) Support in completing the notification form

25. Designated national authorities requiring support in completing forms for notification of final regulatory action are invited to contact the Secretariat for assistance. In general, the Secretariat can be contacted by e-mail at pic@fao.org or pic@pic.int. The website of the Convention also provides contact information for Secretariat staff members.

26. Under Article 16 of the Convention, parties with relatively advanced programmes for regulating chemicals "should provide technical assistance, including training, to other Parties". In accordance with Article 16, designated national authorities may seek support from other designated national authorities on issues regarding the completion of the form for notification of final regulatory action, either in general or with regard to the specific circumstances, documentation and rationale pertaining to a regulatory action in the notifying party, as well as all other substantive issues pertaining to the implementation of the Convention.

27. Other designated national authorities may have experience in solving particular problems in completing notifications or finding sources for needed information. The contact details of all designated national authorities may be accessed on the website of the Convention by clicking on the *Countries* menu, *Designated National Authorities* submenu and *Database* link.⁵

28. The Resource Kit is a compendium of publications containing information on all aspects of the Convention. It is available in English, French, Spanish, Arabic, Chinese and Russian. The publication *Cross-cutting Issues* contains information on and links to online documents, publications and websites where scientific information on chemicals can be found. The Resource Kit can be found on the website of the Convention by clicking on the *Implementation* menu and then the *Resource Kit* submenu.⁶

29. Another publication, *Guidelines to complete the form for notification of final regulatory action*, provides an explanation for each section of the notification form. It also provides an example of the type of information that is often provided by parties. This publication is considered a work in progress and designated national authorities are encouraged to inform the Secretariat if information or explanations provided are not clear or are otherwise insufficient.

30. The publication *Guidance to Designated National Authorities* also contains useful information on the Convention, reasons for submitting notifications, how to submit notifications and the benefits of submitting notifications. This publication is a valuable resource for designated national authorities.

(c) Publication and dissemination of notifications of final regulatory action

31. Paragraph 4 of Article 5 of the Convention requests the Secretariat to communicate to the parties every six months a synopsis of the information received on notifications of final regulatory action. The Convention also requests the Secretariat to provide information regarding those

⁵ <http://www.pic.int/Countries/DesignatedNationalAuthorities/Database/tabid/1375/language/en-US/Default.aspx>.

⁶ <http://www.pic.int/Implementation/ResourceKit/tabid/1064/language/en-US/Default.aspx>.

notifications that do not contain all the information required by Annex I. This is done through the PIC Circular. Information published in the PIC Circular is also available on the Convention website.

32. The PIC Circular, prepared by the Secretariat every six months, is a comprehensive document that compiles information on all notifications of final regulatory action submitted by parties. It is the main source of information on notifications and it may be accessed on the website of the Convention by clicking on the *Implementation* menu and then the PIC Circular submenu.⁷ The PIC Circular contains a list of all notifications of final regulatory action received since the entry into force of the Convention.

33. There are two PIC Circulars published over a 12-month period. Notifications of final regulatory action received between 1 November of a given year and 30 April of the next year are published in the PIC Circular distributed in the following June; those received between 1 May and 31 October of a given year are published in the PIC Circular distributed in December of that year.

(d) Other means of information exchange

34. In addition to the exchange of information through the PIC Circular, Article 14 of the Convention requests parties to exchange scientific, technical, economic and legal information concerning the chemicals within the scope of the Convention, including toxicological, ecotoxicological and safety information. In section (c) of paragraph 1, it also requests parties to facilitate the provision of information to other parties, directly or through the Secretariat, on domestic regulatory actions that substantially restrict one or more uses of the chemicals, as appropriate.

6. Summary

- Each party decides how and why to take a final regulatory action to ban or severely restrict a chemical.
- Any final regulatory action on a chemical that is taken to protect human health or the environment should be notified to the Secretariat in writing.
- Each party has the obligation to notify the Secretariat of a final regulatory action taken even if the information requirements in Annex I are not fully satisfied and even if the notification is made beyond the ninety day period set forth in Article 5.
- A notification, even if submitted later than ninety days after it has taken effect, once verified by the Secretariat as satisfying the information requirements of Annex I will, together with a second notification for the same chemical from a party from a different PIC region, be submitted to the Chemical Review Committee for its consideration and possible recommendation to the Conference of the Parties for listing in Annex III to the Convention.
- Even if a notification of a final regulatory action does not meet all the information requirements of Annex I, parties still benefit from the information and rationale provided by the notifying party.
- The information requested in the notification form is based on the information requirements outlined in Annex I to the Convention and is designed to support parties in their submission of notifications.
- Each party should provide as much of the information requested in Annex I as possible. Each party, however, should complete and submit the form for notification even if it cannot provide all of the information requested.
- Each party, where needed, should seek the support of the Secretariat, other parties or any other relevant stakeholder in their efforts to collect all relevant information specific to a final regulatory action.
- The PIC Circular and PIC website are the primary means of information exchange on notifications of final regulatory action.
- The PIC Circular is prepared every six months and contains information on all notifications of final regulatory action received by the Secretariat.

⁷ <http://www.pic.int/Implementation/PICCircular/tabid/1168/language/en-US/Default.aspx>.