



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

Distr.: General

4 July 2018

English only

Chemical Review Committee

Fourteenth meeting

Rome, 11–14 September 2018

Item 5 of the provisional agenda*

Updates to the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee

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Note by the Secretariat

I. Introduction

1. The Chemical Review Committee has adopted several papers on working procedures and policy guidance covering a broad range of issues related to its work, some of which have been revised subsequently. The papers are intended to facilitate the work of the Committee and to help to ensure consistency and transparency. The compilation of the working procedures and policy guidance has been made available as the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee (2018).¹

2. At its thirteenth meeting, the Committee decided to request the Secretariat to update section 1.4 of the Handbook, on a process for determining evidence of ongoing international trade, in the light of the relevant discussions held at the meeting. In addition, the Secretariat would update section 2.6 of the Handbook, on guidance to assist parties and the Committee when a chemical under consideration was a persistent organic pollutant listed under the Stockholm Convention, to add two examples discussed at the meeting, relating to the notification of final regulatory action on perfluorooctane sulfonic acid (PFOS) from China and hexabromocyclododecane from Japan. These revisions to the Handbook would be considered by the Committee at its fourteenth meeting.

3. Pursuant to its mandate, the Secretariat has updated the two sections of the Handbook. The draft revisions of the two sections of the Handbook are set out in the annex to the present note, without formal editing.

II. Proposed action

4. The Committee may wish to finalize the revision of the two sections of the Handbook submitted by the Secretariat.

* UNEP/FAO/RC/CRC.14/1.

¹ <http://www.pic.int/tabid/1060/language/en-US/Default.aspx>.

Annex

Draft revision of sections 1.4 and 2.6 of the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee

1.4 Process for determining evidence of ongoing international trade

Reference: UNEP/FAO/RC/CRC.1/28, annex III

This paper describes the process followed by the Secretariat in determining ongoing international trade in a chemical scheduled for review by the Chemical Review Committee (CRC).

The criteria for listing banned or severely restricted chemicals in Annex III of the Convention are set out in Annex II. Criterion (c) (iv) requires that the CRC consider “whether there is evidence of ongoing international trade in the chemical”. In order to ensure that such information is available to the CRC the Secretariat, once it receives a second notification of final regulatory action for a chemical, initiates the collection of information on the international trade in that chemical.

This process, originally developed by the interim CRC, was adopted by the CRC at its first [session/meeting](#). The Conference of the Parties at its second [session/meeting](#) noted the paper and encouraged industry bodies, non-governmental organizations and Parties to provide the information requested for the determination of ongoing trade in chemicals. [The current version of the document has been revised by the CRC at its 14th meeting to reflect experience gained.](#)

Process for determining evidence of ongoing international trade

1. The process for determining whether or not there is ongoing international trade in a chemical must be as simple and pragmatic as possible, in order that it does not needlessly complicate the process for the development of decision-guidance documents.
2. The simplest solution would be to have trade (import/export) information provided by countries as part of their submitted notifications of regulatory action. Where no information on imports or exports is provided by the notifying countries specific follow-up with industry associations and designated national authorities in other countries will be needed.
3. When the secretariat has received at least one notification from each of two PIC regions, the collection of information on evidence of trade could be undertaken from all possible sources simultaneously, as follows:
 - (a) For notifying countries, as a first step, the guidance on completing the notification form should make countries aware of the importance of including information on their imports and exports. Second, as part of the letter sent to countries to verify the completeness of their submitted notification of final regulatory action, they will be informed that, once a second notification from another PIC region is provided, they will be requested to provide, where available, information on:
 - (i) Whether or not they manufactured the chemical and, if so, whether they continue to export it;
 - (ii) The last time that they imported the chemical;
 - (b) The relevant industry association (pesticide or industrial chemical) will be requested to provide a response as to whether the particular chemical is manufactured and traded. A positive response would be taken as evidence of trade. A negative response would require specific follow-up;
 - (c) A general call for information on continued use, import and export of the chemical could be posted on the Rotterdam website or included in the PIC circular each time that there were two verified notifications from two regions. This would also allow non-governmental organizations and others to provide information on evidence of continued production, use or trade.
4. Evidence of ongoing international trade for the chemical will be provided to the Committee for its consideration, along with the verified notifications of final regulatory action and supporting documentation submitted by the notifying countries.
5. [If there is no information on ongoing trade of the chemical available to the Committee, it cannot be excluded that international trade takes place.](#)

2.6 Guidance to assist parties to the Rotterdam Convention and the Chemical Review Committee when a chemical under consideration is a persistent organic pollutant listed under the Stockholm Convention

Reference: UNEP/FAO/RC/CRC.10/INF/14/Rev.1

The purpose of the document is to assist parties to the Rotterdam Convention and the CRC in their work when a chemical under consideration by the CRC is a persistent organic pollutant (POP) listed under the Stockholm Convention. This working paper was adopted by the CRC at its 10th meeting and welcomed by the COP at its seventh meeting. The current version of the document has been revised by the CRC at its 14th meeting to reflect experience gained.

1. Introduction

1. The preparation of this document was requested by the conferences of the parties to the Basel, Rotterdam and Stockholm conventions at their second simultaneous extraordinary meetings in May 2013¹ and initiated by the first joint meeting of the Chemical Review Committee (CRC) of the Rotterdam Convention and the Persistent Organic Pollutants Review Committee (POPRC) of the Stockholm Convention held on 20 October 2014 in Rome. At their joint meeting, the CRC and POPRC members decided to set up a joint intersessional working group to review the information already available, summarize existing guidance and develop further guidance to assist parties to the Rotterdam Convention and the CRC in their work when a chemical under consideration by the CRC is a persistent organic pollutant (POP) listed under the Stockholm Convention.²

2. In response, the intersessional working group prepared the present draft guidance in accordance with the workplan agreed by the joint meeting as set out in annex II to the report of the meeting.

3. The present draft guidance is structured along the standard sequence of events in the process foreseen by the Rotterdam Convention: notification of a final regulatory action (FRA); review of notifications by the CRC; development of a draft decision guidance document (DGD); and submission of import responses for a chemical listed in Annex III to the Rotterdam Convention. If a chemical is a POP, this fact may be taken into account by the parties to the Rotterdam Convention and by the CRC when their action is required at the relevant stages of the above-mentioned process.

4. The present draft guidance is part of a collection of policy guidance and working procedures related to the work of the CRC, of which some parts are referenced in it. As referred to in document UNEP/FAO/RC/CRC.10/INF/18, these policy guidance and working procedures are compiled in a handbook available on the Rotterdam Convention's website.³ In general, CRC's policy guidance and working procedures are works in progress and will be further amended in the light of experience gained. Further guidance to parties to the Rotterdam Convention can be found in the Resource Kit⁴ and the e-Learning Tool.⁵

2. Submission of a notification of final regulatory action by a party (Article 5)

5. The Rotterdam Convention sets out provisions that apply when a party has banned or severely restricted a chemical. Article 5 of the Convention outlines obligations of parties and the process for submission and review of notifications of FRA. Each party that has adopted a FRA shall notify the Secretariat in writing of such action. Annex I to the Rotterdam Convention details the information requirements to be provided by the notifying party.

6. Parties to the Stockholm Convention are required to prohibit, eliminate and/or restrict the production, use, import and export of POPs listed in Annexes A or B to Convention to the extent in force for the specific party. If they are also parties to the Rotterdam Convention, these actions must be notified to the Secretariat if they qualify as a FRA under the Rotterdam Convention.

¹ UNEP/FAO/CHW/RC/POPS/EXCOPS.2/4, para 22 of annex I, decisions BC.Ex-2/1, RC.Ex.2/1, SC.Ex-2/1.

² UNEP/FAO/RC/POPS/CRC-POPRC.1/7.

³ <http://www.pic.int>

⁴ <http://www.pic.int/Implementation/ResourceKit/tabid/1064/language/en-US/Default.aspx>

⁵ <http://www.pic.int/Implementation/ElectronicInteractiveToolkit/tabid/3849/language/en-US/Default.aspx>

7. If a party to the Rotterdam Convention is not a party to the Stockholm Convention, it may wish to set up a national policy to ban or severely restrict chemicals due to their globally relevant hazardous properties. Such FRA, if they qualify as FRA under the Rotterdam Convention, must also be notified to the Secretariat.
8. When the Secretariat receives FRAs on the same chemical that meet the requirements of Annex I from two or more Prior Informed Consent (PIC) regions, these notifications will be forwarded to the CRC for review against the criteria of Annex II.
9. In order to review the notifications against the criteria of Annex II to the Rotterdam Convention, it is essential for the CRC to have sufficiently detailed information to determine whether the FRA was based on a risk evaluation taking into account the conditions in the notifying party. As laid down in the “Working paper on the application of criteria (b) of Annex II”,⁶ the CRC should consider risk evaluations under the Montreal Protocol and the Stockholm Convention as adequate support for meeting the criteria of Annex II (b), (i) and (b) (ii), as long as the Committee can establish that a risk evaluation involving prevailing conditions in the notifying party has been undertaken.
10. In order for the CRC to determine whether the notification meets criterion Annex II (b) (iii), parties should indicate in as much detail as possible, when notifying a chemical already listed under the Stockholm Convention, the considerations on which their national FRA is based. Such information may include:
- (a) A national risk evaluation, in addition to the risk profile/risk management evaluation of the POPRC, and a clear indication if that national risk evaluation takes into account prevailing conditions within the notifying party;
 - (b) Other considerations of the notifying party as to why a risk identified in the POPRC risk profile/risk management evaluation is relevant under the prevailing conditions of the party, and if the FRA is based on these considerations. Such considerations are called “bridging information”⁷ and may include:
 - (i) A comparison of the conditions of use of the chemical in the notifying party with those that were considered in the POPRC’s evaluation (e.g. formulation type(s), concentration of the notified chemical, use patterns including products containing the chemical, climatic and/or geographic and social conditions);
 - (ii) A comparison of the relevance of risk mitigation measures within the party and the recommended risk mitigation measures in the POPRC’s evaluation (e.g. availability and actual use of personal protective equipment, occupational, bystander and consumer exposure limits, use restrictions to protect human health and the environment, etc.);
 - (c) A statement whether a POP has been banned or severely restricted based on its listing under the Stockholm Convention, but not on a national or regional risk evaluation taking into account prevailing conditions within the notifying party. If this is the case, criterion Annex II (b) (iii) would not be met;
 - (d) An explanation on how a POPRC’s evaluation of a chemical has supported a FRA on a somewhat different, but related chemical (see also section 3.2 of this guidance) to support, but not supplant, the other requirements of Annex II (b) (iii).
11. Documents supporting these considerations might be available for example as published or internal national risk evaluation reports, introductory remarks of legal texts, or as reports of meetings of national regulatory authorities, parliaments, etc. If these documents cannot be made available to the Rotterdam Convention secretariat for confidentiality reasons, their content (and the reason why they cannot be disclosed) should be described in as much detail as possible in section 2 of the notification form, or as supporting documentation.
12. The legal text of the national FRA and other relevant documents referenced in the notification should be provided as supporting documentation to the notification, preferably in English. If this is not possible, a focused summary of the supporting documentation should be prepared in English by the notifying party. If the translation of the focused summary into English cannot be made by the party itself, the Secretariat may be contacted for support, where necessary.

⁶ See “Working paper on the application of criteria (b) of Annex II” in the handbook (www.pic.int/crcguidance/).

⁷ See “Bridging information” in the handbook (www.pic.int/crcguidance/).

13. When notifying the FRA, data from the Stockholm Convention risk profile or risk management evaluation may contribute to certain sections of the notification form, such as identity of the chemical, risk or hazard evaluation, alternatives or properties of the chemical.

3. Review of notifications by the CRC (Article 5, para 6)

3.1 Priority setting of candidate chemicals

14. In the light of the controls on trade imposed under the Stockholm Convention and the Montreal Protocol, the third meeting of the Conference of the Parties (COP) to the Rotterdam Convention endorsed the approach that, in the interest of facilitating the work of the CRC, lower priority should be given to chemicals already subject to such multilateral environmental agreements. On the other hand, chemicals under consideration for inclusion in such agreements or newly included but subject to lengthy phase out periods would be treated in the usual way.⁸

15. This priority setting only becomes relevant when the CRC has to evaluate a considerably large number of notifications in one meeting. If this is the case, the CRC's bureau, after a preliminary review of notifications prior to a CRC meeting, sets priorities of candidate chemicals to be reviewed by the Committee.

3.2 Determining the identity of a substance or group of substances

16. Chemicals (individual substances or groups of related substances, such as congeners or salts and esters) currently evaluated in the context of, or already listed under, the Stockholm Convention, may differ from those individual substances or groups notified under the Rotterdam Convention, even if they have the same name. In cases where the CRC considers information that was provided as part of the notification of FRA that itself was based on an evaluation of the chemical under the Stockholm Convention, differences as regards the exact chemical identity of the chemical or group of substances and their possible implications should be documented in the CRC's rationale and the draft DGD. A rationale for taking into consideration the information from the Stockholm Convention included in the notification of FRA, despite the different chemical identities, should be included with the CRC's recommendation.

3.3 Application of criterion (b) of Annex II to the Rotterdam Convention

17. As already mentioned in section II of this document, the CRC should consider risk evaluations under the Montreal Protocol and the Stockholm Convention as adequate support for meeting the criteria of Annex II (b), (i) and (b) (ii), as long as the Committee can establish that a risk evaluation involving prevailing conditions in the notifying party has been undertaken. However, with regard to criterion (b) (iii), additional information must be provided. Bridging information describing the prevailing conditions in the notifying country could suffice. Further guidance is laid down in the "Working paper on the application of criterion (b) of Annex II" and in the "Bridging information".⁹

18. So far, there has been no instance where the CRC concluded that bridging information together with a risk evaluation under the Stockholm Convention met criterion (b). However, "Working paper on the application of criterion (b) of Annex II"¹⁰ contains an example of bridging information in the notification from Jamaica regarding aldicarb (which is not a POP). This example showed that the results of a risk evaluation undertaken in the United States of America were used for the national risk evaluation and decision-making in Jamaica. In this case, information on exposure from the United States of America was "bridged" by comparing it with the exposure conditions prevailing in Jamaica. The risk evaluation, which thus involved the prevailing conditions of exposure within Jamaica, concluded that the risks resulting from aldicarb use in Jamaica were not acceptable.

19. An example where information from the Stockholm Convention has been considered by the CRC is the notification from Japan for perfluorooctane sulfonate, its salts and its precursors. CRC-7 considered criterion (b) (i)-(iii) of Annex II to the Rotterdam Convention to be met because the notification included data on exposure in Japan (monitoring data from Japan as well as estimated exposure concentrations in Japan). This data, in addition to hazard data from the Stockholm Convention's risk profile, had been used in a risk evaluation involving prevailing conditions in Japan.

20. Another example relates to a notification on hexabromocyclododecane from Japan considered by the CRC at its thirteenth meeting. CRC-13 considered the criterion (b) (i)-(iii) of Annex II to be

⁸ UNEP/FAO/RC.COP.3/26, paragraph 62.

⁹ www.pic.int/crcguidance/

¹⁰ www.pic.int/crcguidance/

met because Japan had based its final regulatory action on the risk profile for the chemical conducted by the Persistent Organic Pollutants Review Committee, which included some data from Japan, as well as a risk evaluation conducted by the Government of Japan in line with its domestic processes.

21. If a notification contains a statement that the FRA to ban or severely restrict a POP was exclusively based on its listing under the Stockholm Convention, but not on a national or regional risk evaluation taking into account prevailing conditions within the notifying party, criterion (b) (iii) and thus criterion (b) of Annex II to the Rotterdam Convention as a whole is not met.

19-22. An example relates to a notification of final regulatory action from China on perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride in the pesticides category considered at the thirteenth meeting of the Committee. The notification was found to not meet criterion (b) (iii) as China had based its risk evaluation on the risk profile and risk management evaluation documents developed by the Persistent Organic Pollutants Review Committee of the Stockholm Convention, but there was no information to confirm whether that risk evaluation had taken into account the prevailing conditions in China.

3.4 Consideration of ongoing international trade

20-23. According to criterion (c) (iv) of Annex II, the CRC has to “consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account [...] whether there is evidence of ongoing international trade in the chemical.”

21-24. Possible sources of information on ongoing trade in a chemical are described in “Process for determining evidence of ongoing international trade”.¹¹

22-25. In addition to the information described in this working paper, the CRC may use information on trade from the section on production, use and releases contained in the POPRC’s risk profile.

23-26. Furthermore, the CRC may take into account if parties to the Stockholm Convention have requested exemptions from the restrictions of production and use. For example, CRC-2 considered such information as an indication that there was possibly ongoing international trade with mirex.

4. Development of a draft decision guidance document (Article 7, para 1)

24-27. The CRC prepares a draft DGD¹² for each chemical it recommends for listing in Annex III to the Rotterdam Convention. The DGD contains basic information on the chemical, among other things its hazard classification, additional sources of information on the chemical and information on possible alternatives. It includes details of the notifications of FRA on which the CRC’s recommendation for inclusion in Annex III is based. It is intended to assist parties to make informed decisions on the future import of a chemical listed in Annex III. It is not intended to be the only source of information on a chemical, nor as a comprehensive scientific treatise on the chemical. The DGD is not revised following its approval by the COP, except if the COP decides to remove the chemical from Annex III.

25-28. The DGD is developed according to the process adopted by decision RC-2/2. Any CRC expert volunteering to do so can participate in the drafting group. The development of the draft DGD follows a work plan agreed by the CRC. This work plan generally allows for several commenting rounds for drafting group members, CRC members and observers. The draft DGD, together with a table of comments and how they have been addressed, is discussed and endorsed by the subsequent CRC meeting and afterwards presented to the COP for approval.

26-29. All drafting group members and observers are invited to comment on draft DGDs when they are circulated for this purpose by the Secretariat. However, the general principles about the scope and content of DGDs should be respected when commenting. These are laid down in “Working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals” and the “Working paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations”.¹³ The working papers explain that, in general, the information in the DGD reflects the information available to the CRC prior to its decision to develop a decision guidance document. Such information is either provided by the notifying parties in their notifications and supporting documentation for banned or severely restricted chemicals, or in

¹¹ www.pic.int/crcguidance/

¹² See “Process for drafting decision-guidance documents and accompanying explanatory notes” in the handbook (www.pic.int/crcguidance/).

¹³ www.pic.int/crcguidance/

proposals to list a severely hazardous pesticide formulation, and the respective additional information collected by the Secretariat according to Article 6 paragraph 3. However, some information might be taken from additional internationally recognized sources, such as WHO/FAO/UNEP publications, POPRC's risk profiles or risk management evaluations that may be particularly useful to complement the following sections of the DGD:

- (a) Section 1: Identification and uses;
- (b) Section 3.3: Alternatives;
- (c) Section 4.5: Waste management;
- (d) Annex I: Further information on the chemical.

[27-30.](#) When information from an international evaluation such as POPRC's risk profiles or risk management evaluations is included in a DGD, the reference in the text should be to this document, rather than to the individual references quoted therein.

[28-31.](#) Examples of how information from POPRC documents may be incorporated in a DGD can be found in the DGDs for:

- (a) Commercial pentabromodiphenyl ether (including tetrabromodiphenyl ether and pentabromodiphenyl ether);¹⁴
- (b) Commercial octabromodiphenyl ether (including hexabromodiphenyl ether and heptabromodiphenyl ether);¹⁵
- (c) Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls.¹⁶

5. Submission of import responses for chemicals listed in Annex III to the Rotterdam Convention (Article 10)

[29-32.](#) According to Article 10 of the Rotterdam Convention, each party is obliged to submit to the Secretariat their import response concerning the future import of chemicals listed in Annex III to the Rotterdam Convention. Parties must still provide an import response under the Rotterdam Convention, even if they have already taken national decisions for POPs under the Stockholm Convention, including, for example, decisions on national bans of import and use.

[30-33.](#) Parties can use these national decisions on POPs under the Stockholm Convention to establish their import response for chemicals listed in Annex III to the Rotterdam Convention. This is especially useful for industrial chemicals, where a legal infrastructure does not yet exist in many countries.

¹⁴ UNEP/FAO/RC/COP.6/8/Add.1; sections 1, 2, 3.3 and 4.5; Annex I sections 3.7, 4.1, 4.1.1, 4.1.5 and 5.6.

¹⁵ UNEP/FAO/RC/COP.6/9/Add.1; sections 2, 3.2-3.4 and 4.5; Annex I sections 2.2.9, 3.7, 4.1.5 and 5.6.

¹⁶ UNEP/FAO/RC/COP.6/10/Add.1; sections 1, 2.2, 3.3 and 4.5; Annex I introduction, sections 4.1 and 5.4.