



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

Distr.: General
18 December 2009

English only

Chemical Review Committee

Sixth meeting

Geneva, 15–19 March 2010

Item 4 (c) of the provisional agenda*

**Operational issues: working procedures and policy
guidance developed to facilitate the Committee's work**

**Guidance to intersessional task groups on reviewing notifications of
final regulatory action and supporting documentation for chemicals
scheduled for consideration by the Chemical Review Committee**

Note by the Secretariat

1. The process for drafting decision guidance documents set out in decision RC-2/2 provides for the creation of task groups to work intersessionally. The Committee developed a paper to provide guidance to such groups in reviewing candidate chemicals with the understanding that it was a work in progress that could be amended in the light of experience gained.
2. The annex to the present note contains guidance to intersessional task groups amended to reflect the discussions at the Committee's fifth meeting and to include additional suggestions made by the Secretariat in consultation with the Bureau. The annex has not been formally edited by the Secretariat.
3. The amended guidance aims:
 - (a) To define more precisely the intersessional task groups' roles and tasks;
 - (b) To ensure that the task groups' reports are sufficiently detailed and clearly document why criteria are considered to have been met or not met;
 - (c) To stress communication between task group members and the need to make available draft task group reports prior to Committee meetings.
4. The Committee may wish to consider the amended guidance, which is intended to facilitate the intersessional task groups' future work, with the understanding that it will be further updated as necessary.

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

Annex

Chemical Review Committee Working Procedures:

Guidance to inter-sessional Task Groups on reviewing notifications of final regulatory actions and supporting documentation for chemicals scheduled for consideration by the Chemical Review Committee

Introduction

The Conference of the Parties at its second meeting (COP.2) adopted, in decision RC.2/2, a process for the preparation of decision guidance documents by the Chemical Review Committee. This process called for the creation of Task Groups by the CRC that would work inter-sessionally to undertake a preliminary review of the chemicals scheduled for consideration by the CRC.

This document has been developed to guide the operation of inter-sessional Task Groups in the review of chemicals for which notifications of final regulatory actions to ban or severely restrict their use have been submitted by Parties in at least two PIC regions in line with Article 5 of the Convention. It briefly explains the role of the Task Groups, how they operate and the structure, content and level of detail needed in preparing a report of the outcome of their preliminary review to the full Committee.

This working paper will continue to evolve based on the experience gained by the CRC. A similar approach would be taken when reviewing proposal for severely hazardous pesticide formulations submitted in accordance with Article 6 of the Convention.

This document is part of a series of policy guidance and working procedures developed to facilitate the work of the CRC and to help ensure consistency and transparency. A full set of these documents are available on the Convention website or upon request to the Convention Secretariat.

Membership and composition of Inter-sessional Task Groups

For each chemical scheduled for review by the CRC, an inter-sessional Task Group is established by the Secretariat in consultation with the Bureau. Task Groups consist of one to two coordinators and a representative group of members of the CRC. All members of the CRC are expected to participate in the work of at least one Task Group. Members may participate in as many Task Groups as they wish by simply informing the Task Group Coordinator(s) and the Secretariat of their interest.

Role of Inter-sessional Task Groups

It is not feasible for the CRC to initiate a detailed review of each chemical in the time available at its annual meeting. The role of an inter-sessional Task Group is to undertake a preliminary review of the documentation available in support of the individual candidate chemicals in the light of the information requirements and criteria set out in Annexes I and II of the Convention respectively. The preliminary review by the Task Group is intended to facilitate the work of the Committee by ensuring that for each of the chemicals scheduled for consideration by the Committee a detailed review of the notifications and supporting documentation has been undertaken. The work of the inter-sessional Task Group does not replace the requirement for each of the candidate chemicals to be considered by the full Committee.

For each chemical a Task Group will prepare a report which includes their assessment of whether the individual notifications and supporting documentation meet the requirements of the Convention. It is essential that the report provides sufficient detail in order that the full Committee can understand the reasoning behind the conclusions of the Task Group with respect to the individual requirements. The analysis of the individual notifications as amended by the CRC will form part of the report of the meeting. In undertaking the preliminary review, the Task Group should consider the policy guidance and working procedures developed to guide the work of the CRC.

It should be noted that the work of Task Groups is not to initiate a debate on whether or not there is agreement with the national regulatory action, but rather whether the regulatory action meets the requirements set out in Annexes I and II of the Convention. It is also not the aim of the Task Group to discuss whether or not there is agreement with the outcome of the risk evaluation performed by the notifying Party in support of the national decision.

Operation of Inter-sessional Task Groups

Prior to a CRC meeting

Approximately two months prior to the CRC meeting the notifications and supporting documentation for all of the chemicals scheduled for review by the CRC are sent to all Committee members. At the same time Task Groups are created.

Individual Task Group members are expected to review the notifications and supporting documentation in detail, complete the analysis table (Excel templates provided by the Secretariat) with the required information and send the file to the Task Group Coordinator within two weeks upon receipt of the notifications and supporting documentation. The partly completed template will serve as a means for each Task Group member to become familiar with the information in the notifications and supporting documentation. Task Group Coordinators are to prepare the first draft of the report of the preliminary review of a chemical and take the lead in initiating and mediating discussions among the Task Group members. All Task Group members are expected to contribute to the further development of the draft report of the preliminary review and to play a role in the discussions at the CRC meeting.

The Task Group Coordinator will circulate the draft report of the preliminary review to all Task Group members by e-mail for comment four weeks prior to the CRC meeting. Each Task Group member should review and provide comments on the draft report to the coordinator within 2 weeks. Communication among members of the Task Group during the inter-sessional period is critical. Most Task Group discussion take place by e-mail and conference calls are recommended, where possible. Task Group members should ensure that all other members in the group are copied on e-mail correspondence. Task Group Coordinators will finalize the draft report taking into account the inputs from Task Group members. The draft Task Group report will be posted on the Convention website (www.pic.int) two weeks before the CRC meeting. Comments from CRC members and observers will be collected by the Secretariat and made available at the Task Group meeting.

The members of the inter-sessional Task Groups will have the opportunity for a face to face meeting to review and finalise the draft report immediately prior to the CRC meeting. The Task Group meeting is open to all member and observers. The final report of Task Group will be made available to the full Committee as a Conference Room Paper (CRP).

During the CRC meeting

Task Group members should be prepared to respond to any questions that may be raised by Committee members regarding the preliminary review of the chemical. Following consideration of the results of the Task Group reports, the Committee will discuss and decide whether the individual notifications meet the requirements of the Convention. Where the notification is found to meet the requirements of the Convention the analysis will be the basis for the rationale prepared by the CRC which will be annexed to the report of the meeting. Where there are two notifications from two PIC regions that meet the requirements of the Convention the Committee will prepare a recommendation to the COP to list the chemical in Annex III of the Convention along with the rationale supporting this recommendation.

Undertaking the preliminary review by an inter-sessional Task Group

It is recommended that the inter-sessional Task Group follow a two-step process in undertaking the preliminary review to facilitate the review and preparation of the draft report. The first step is to

systematically review and organise the information available to the Committee for each chemical according to the criteria of Annex II of the Convention. The second is to prepare a detailed analysis of this information that addresses each of the criteria in Annex II of the Convention.

The analysis forms the main body of the Task Group report and should explain the basis for the Task Group conclusions as to whether the individual criteria of Annex II have been satisfied or not. The analysis should also highlight those areas that the Task Group considers need particular attention by the CRC.

Step 1 - Organize information

In order to facilitate a structured review of the information provided to Task Groups, an analysis table (Excel file containing templates) and brief guidance on its completion has been developed to assist in summarizing the information in the notifications and supporting documentation. The templates set out the individual elements for the information requirements and criteria contained in Annexes I and II of the Convention, respectively.

A template is to be completed for each notification. The completed templates will serve as a means to locate in the supporting documentation specific information relevant to the individual elements of Annex I and II. The completed templates will facilitate the preparation of the analysis by the Task Group Coordinators and its subsequent review by Task Group members and the full Committee. The completed templates are thus an important component of the report of the Task Groups preliminary review and should be included as an annex.

The template is available in an electronic “interactive” format. Prior to completing the templates it is recommended that the Task Groups familiarise themselves with the associated guidance. The following are contained in the Excel file:

Guidance for completing individual country templates: Guidance on how to complete the individual sections of the templates for each notification.

Summary report: A summary of the information provided in the individual notifications. This report is automatically generated from the information inserted in the templates prepared for each country’s notification.

Country templates: Set out the individual elements of Annexes I and II of the Convention, completed templates facilitate the identification of where in the supporting documentation information relevant to the individual elements might be found.

Step 2 – Analysis of information available for individual notifications

Based on the information available to the Committee in the notifications and supporting documentation, the Task Group should for each notification establish whether or not the individual criteria of Annex II have been met. For each notification a detailed analysis, addressing the individual criteria in Annex II of the Convention should be prepared, that clearly states whether the information available is sufficient to satisfy these criteria and if so how. The analysis should explain the conclusions for the individual criteria in sufficient detail that members of the Task Group and of the full Committee can understand how the conclusion was reached.

Based on the information in the notification and supporting documentation, the analysis should thus include information such as:

- a review of the scope of the regulatory action, precise identity of the chemical(s) concerned, ban versus severe restriction, etc.;
- the reason for which the action was taken, including highlights of the supporting risk evaluation;
- a conclusion as to whether the notification meets the individual criteria in Annex II and the associated analysis that was the basis for this conclusion.

The systematic review and analysis of the information available to support individual notifications and preparation of a detailed analysis is the primary function of the inter-sessional Task Groups and is key to the successful operation of the CRC. Where a notification is determined by the Committee to meet the requirements of the Convention, the analysis will form the basis for the preparation of the rationale which will be included in the report of the meeting. Where there are two notifications from two PIC regions for the same chemical that are found to meet the requirements of the Convention and which the Committee decides to recommend to the Conference of the Parties that it be listed in Annex III the individual rationale will accompany the recommendation.

Task Group Reports

The Task Group report should include a cover page that sets out the names of the Task Group members, a list of the information available to the Task Group for each notification, a brief summary of the principal conclusions clearly stating which, if any, of the notifications meet the criteria of Annex II. It should also as appropriate highlight those elements in the notifications for which particular consideration/scrutiny by the Committee is recommended.

The main body of the report should consist of the detailed analysis outlining, for each notification, whether or not the criteria contained in Annex II of the Convention have been met. An overall conclusion as to whether or not to recommend inclusion of the chemical in Annex III of the Convention should be made.

An example of a completed Task Group report, which can also be used as an outline for a Task Group report, is provided in an annex to this document. The completed excel templates should be annexed to the Task Group report.

Example of a completed Task Group report

Rotterdam Convention

CRCx Meeting : Geneva/Rome, March 20xx

Report of the Task Group on Chemical X

Task Group members *(to be updated at Sunday pre-meeting)*

Chair:

Members:

Observers:

Secretariat:

Information available to the Task Group

(List documents)

1. Introduction

Example:

Two notifications on Chemical X from Country 1 and Country 2 have been verified by the Secretariat as containing the information requirements of Annex I of the Rotterdam Convention. These two notifications underwent a preliminary review by the Secretariat and Bureau, who evaluated whether or not the notifications appeared to meet the requirements of the Convention. The notifications, supporting documentation and results of the preliminary review were made available to the Chemical Review Committee for their consideration (document UNEP/FAO/RC/CRCx/x).

The purpose of this report is to present the Task Group's analysis of the notifications and supporting documentation and to put forward recommendations for the consideration of the Committee.

The report contains an overall analysis, together with a recommendation to the Committee. The report draws its conclusions based on the information provided in an annex, which consists of a spreadsheet summarising the information provided in the notifications of the two Parties, and an analysis of the compatibility of each notification with the requirements of Annex I and Annex II.

2. Analysis of the notification from Country 1 (to be prepared for each individual notification)

2.1 Scope of the notified regulatory action

Example:

The notified regulatory action relates to Chemical X and the pesticidal use of the chemical as XXX. The decision made was to severely restrict the uses of Chemical X.

The notification was found to comply with the information requirements of Annex I.

The following table and analysis sets out how the notification from Country 1 meets the criteria of Annex II (see annex for cross reference to detailed information in the notification and supporting documentation).

Criteria	Country 1
(a)	Met/Not Met
(b)(i)	Met/Not Met
(b)(ii)	Met/Not Met
(b)(iii)	Met/Not Met
(c)(i)	Met/Not Met
(c)(ii)	Met/Not Met
(c)(iii)	Met/Not Met
(c)(iv)	Met/Not Met
(d)	Met/Not Met

2.2 Compatibility with the criteria of Annex II (a)

Example:

The regulatory action was taken to protect human health and the environment. Chemical X has been used as XXX. The notification describes the specific risks and outlines that a severe restriction of Chemical X use significantly reduces the exposure of aquatic organisms. **(include reference to where the information is contained in the notification and/or supporting documentation)**

2.3 Compatibility with the criteria of Annex II (b)

In this section, the report needs to outline the information used to establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation must be based on a review of scientific data in the context of the conditions prevailing in the party in question. The documentation provided must demonstrate that this is the case and information should be included in the report.

For each of the headings below, please state whether the information available is sufficient to satisfy the criteria and provide the reasoning for how this conclusion was reached, including references to the relevant information in the notification and/or supporting documentation.

i) Data had been generated according to scientifically recognized methods

ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures.

i, ii) Example:

Country 1 undertook research studies prior to the regulatory action and published the results on a internationally peer reviewed scientific journal: Review of the Persistence, Bioaccumulation, and Toxicity of Country X in Aquatic environments in relation to Country 1's toxic substances management policy, (Reference: R. James Maguire, Water Qual. Res. J. Canada, 2000, volume 35 (4), 633-679. See table 5, page 662, for a list of studies that were undertaken.) A detailed review conducted by the Government of Country 1 concluded that Chemical X is extremely toxic to aquatic organisms, and is sufficiently persistent and bioaccumulative to warrant virtual elimination from the environment in the country.

iii) Final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action

Example:

The exposure was based on measured concentrations of Chemical X in seawater in Country 1. Chemical X compounds were reported to partition the aquatic environment, being more persistent in sediment than in water. Seawater and sediment samples taken in 1994 exceeded acute and chronic toxicity, and chronic toxicity thresholds, respectively. In marine sediments, Chemical X was found more frequent in 1994 than a decade earlier, despite initial regulatory control actions taken. Due to the chemical characteristics of long persistence in sediment, Chemical X concentrations in marine sediments are expected to exceed chronic toxicity thresholds for years to come.

The risk evaluation took into account these exposure data and the ecotoxicological endpoints for Chemical X and the result was an unacceptable risk to aquatic organisms as fish, molluscs and other invertebrates. High concentrations of Chemical X in sediments caused high frequency of imposex (imposition of male characteristics on female organisms) on molluscs.

Accordingly the risk evaluation clearly took into account the conditions prevailing in Country 1 and it is concluded that criterion Annex II (b) has been met.

2.4 Compatibility with the criteria of Annex II (c)

Consider whether the final regulatory action provides a sufficiently broad basis to merit the listing of the chemical in Annex III, by taking into account

i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses

Example:

The final regulatory action prohibited uses of Chemical X as antifouling paints for ships which was the main use of Chemical X, therefore led to a significant decrease in the quantity of the chemical use, while the use

of Chemical X in material and wood preservatives remain allowed and do not reflect a major use pattern in Country 1 compared to use in antifouling paints (Reference: Focused summary; Introduction, paragraph b, last sentence).

- ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification

Example:

It is expected that since the regulatory action will remove this source of Chemical X to the aquatic environment, this led to a significant reduction of risk to the environment. Although persistence in the marine environment at some locations will maintain elevated levels for some time, removing this source of input will allow recovery to occur (Reference: Page 7 of notification, last paragraph of 2.4.2).

- iii) Whether the considerations that led to the final regulatory action been taken are applicable only in a limited geographical area or in other limited circumstances

Example:

Chemical X in antifouling paints used on ship hulls could cause risk in the aquatic environment wherever such ship may travel, and therefore the relevance of the final regulatory action is not limited to Country 1. (reference)

- iv) Whether there is evidence of ongoing international trade in the chemical (this information may be found in the notification or obtained, when available, through the Secretariat)

Example:

There is evidence of ongoing international trade, Country 1 had provided estimated quantity of the chemical imported and exported.

Accordingly there is sufficient information to conclude that criterion Annex II c has been met.

2.5 Compatibility with the criteria of Annex II (d)

Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III. (If yes, reference should be provided)

Example:

There is no indication in the notification that concerns for intentional misuse prompted the regulatory action.

3. Analysis of the notification from Country 2 (to be prepared with the same information as provided above for Country 1)

4. Conclusion

Example:

The task group concluded that the notification of final regulatory action of Country 1 met the information requirements of Annex I and the criteria set out in Annex II to the Convention.

The task group also concluded that the notification of final regulatory action of Country 2 met the information requirements of Annex I and the criteria set out in Annex II to the Convention.

5. Recommendation

Example:

Consequently, the Task Group recommends that the Chemical Review Committee conclude that the above discussed notifications from Country 1 and 2 have met the criteria set out in Annex I and Annex II of the Convention.

6. Points to be considered by the CRC *(This section should highlight those elements in the notifications for which particular consideration or scrutiny by the Committee is recommended, as appropriate)*

Example:

The task group noted that three compounds of Chemical X were referenced in the notification from Country 1, while that from Country 2 referenced seven compounds.