



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

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### Compliance Committee for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade Second meeting

Rome, 19–21 March 2024 and Online, 30 September 2024  
Item 5 (b) of the agenda\*

#### Review of systemic issues of general compliance: notifications of final regulatory actions

### Notifications of final regulatory actions<sup>1</sup>

#### Note by the Secretariat

#### I. Introduction

1. During its first meeting, the Compliance Committee (the “Committee”) of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (the “Rotterdam Convention”) adopted decision CC-1/3 by which it agreed to a questionnaire for Parties to the Rotterdam Convention for the identification of issues being faced by Parties in relation to the notification of final regulatory actions<sup>2</sup> and requested the Secretariat, subject to the availability of resources, to make it available to Parties in English, French and Spanish, with an invitation to complete it by 30 June 2023.

2. By its decision RC-11/5, the Conference of the Parties at its eleventh meeting adopted the programme of work of the Compliance Committee for the biennium 2024–2025. Among other things, the programme of work mandated the Committee, based on information from Parties including the questionnaire circulated to Parties, to identify and review issues being faced by Parties in relation to the notification of final regulatory actions, including a quantitative and qualitative analysis, and in particular with regard to the information requirements set out in Annex I to the Convention.

3. At the face-to-face sessions of its second meeting (Rome, 19–21 March 2024), the Committee adopted decision CC-2/4 on notifications of final regulatory actions, by which it requested the Secretariat to:

- (a) Continue to collect information from Parties for the identification of issues faced by Parties in relation to the submission of notification of final regulatory actions, including on:
  - (i) Definitions of final regulatory action, linkages with national actions and when there is an obligation to transmit a notification to the Secretariat;
  - (ii) Laws or other measures adopted to implement the Convention that require the use of risk or hazard evaluation, to request further information on these requirements and how they may relate to the Convention.

\* UNEP/FAO/RC/CC.2/1/Rev.1.

<sup>1</sup> This document has not been formally edited.

<sup>2</sup> UNEP/FAO/RC/CC.1/4/Rev.1.

4. Committee members Jimena Nieto and Matthias Wolf took the lead on these activities as agreed at the abovementioned face-to-face sessions.
5. In its decision CC-2/4 on notifications of final regulatory actions, the Committee also decided to recommend that the Conference of the Parties at its twelfth meeting consider deciding:

(a) That the Secretariat's technical assistance plan for 2026–2029 continue to include awareness-raising activities and exchange of experiences and information on bridging information to conduct risk evaluations;

(b) To encourage the United Nations Environment Programme, the Food and Agriculture Organization of the United Nations and other relevant entities, in the context of their activities in support of the technical assistance plan, to continue their efforts in assisting Parties in their actions to prepare and adopt final regulatory actions and to submit notifications of those final regulatory actions to the Secretariat.

## **II. Implementation**

### **A. Background**

6. As requested by the Committee in decision CC-1/3, the Secretariat prepared an electronic version of the questionnaire (hereinafter "2023 questionnaire") and made it available to Parties in English, French and Spanish, with an invitation to complete it by 30 June 2023. The login and password were provided to each Party's official contact points (OCPs) and designated national authorities (DNAs) received the questionnaire without the login details. DNAs and OCPs were therefore to cooperate to provide one consolidated response on behalf of the Party completing the questionnaire. A summary of responses received is available in section B of the present note, while section C sets out some conclusions.

7. Following the development of the questions to collect information as requested in decision CC-2/4 (hereinafter "2024 questions"), the Secretariat circulated on 19 July 2024 a communication to all Parties with an invitation to respond to the questions to collect information, including on notifications of final regulatory action. A reminder was also transmitted to all Parties on 21 August 2024 by email. As at 15 September 2024, responses were received from 58 Parties (31 States and 1 regional economic integration organization on behalf of its member states that are Parties to the Convention) and have been made available on the Convention website.<sup>3</sup> A summary of the responses received is set out in section D of the present note.

### **B. Summary of responses to the 2023 questionnaire**

#### **1. Overview**

8. 39 responses were received to the questionnaire circulated following the first meeting of the Committee, including 1 from a regional economic integration organisation on behalf of its member states that are Parties to the Convention, representing in total 60 Parties. The report on the responses to the questionnaire for the identification of issues being faced by Parties to the Rotterdam Convention in relation to the notification of final regulatory actions, including the text of the questionnaire, is available in document UNEP/FAO/RC/CC.2/INF/3.

9. Although the responses covered all United Nations geographical regions and Rotterdam Convention Prior Informed Consent (PIC) regions,<sup>4</sup> this represents 36% of the 165 Parties to the Convention, therefore does not represent a full picture of the challenges being faced by Parties in relation to the notification of final regulatory actions. Responses were received from:

- (a) 7 Parties in the Africa PIC region;
- (b) 2 Parties from the Asia PIC region;
- (c) 36 Parties<sup>5</sup> in the Europe PIC region;

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<sup>3</sup>

<https://www.pic.int/Implementation/Legalmatters/GeneralIssuesActivities/Activities20242025/Questionstocollectinformation/tabid/10008/language/en-US/Default.aspx>.

<sup>4</sup> <https://www.pic.int/Countries/PICRegions/tabid/1070/language/en-US/Default.aspx>.

<sup>5</sup> Including a response received by 1 regional economic integration organization on behalf of its 27 member states that are Parties.

- (d) 9 Parties in the Latin America and the Caribbean PIC region;
- (e) 1 Party in the North America PIC region;
- (f) 4 Parties in the Near East PIC region;
- (g) 1 Party in the Southwest Pacific PIC region.

10. Response rates were particularly low from the Asia PIC region and from the Near East PIC region. Neither are the results from the Southwest Pacific and North America PIC regions necessarily indicative of the challenges being faced by Parties, as only one Party from the Southwest Pacific PIC region responded, and the North America PIC region is made up of only one Party.

11. The responses do nonetheless provide useful qualitative and quantitative information about specific challenges in relation to notifications of final regulatory actions. Over 70% of respondents confirmed in the questionnaire that they have taken a final regulatory action.

12. 94% of responding Parties from the Europe PIC region and 77% of responding Parties from the Latin America and the Caribbean PIC region reported having taken a final regulatory action, meaning these 2 regions had the Parties with the most final regulatory actions.

13. The information provided by respondents on issues being faced by Parties is presented in this report separated into different phases, namely:

- (a) Preparation and adoption of final regulatory actions;
- (b) Use of Rotterdam Convention tools, guidance and materials for the preparation of final regulatory actions;
- (c) Submission of a notification of final regulatory action;
- (d) Other issues faced related to notifications of final regulatory actions.

## 2. Preparation and adoption of final regulatory actions

14. 10 of 60, corresponding to 17% of respondent Parties, have faced issues in preparing and adopting final regulatory actions, with the respondents facing issues being from the Africa PIC region (2 respondents), Asia PIC region (1 respondent), Latin America and the Caribbean PIC region (4 respondents) Near East PIC region (2 respondents) and from the Southwest PIC region (1 respondent).

15. The types of challenges being faced related mostly to issues with actions at national level prior to the submission of the notification form to the Secretariat. Issues were presented in the questionnaire divided into institutional and governance issues (exchange of information and coordination between national stakeholders, and priority setting); issues with information required by the final regulatory action notification form (actions prior to submission of information to the Secretariat).

16. For those who did face issues, these related to issues such as:

- (a) Not having the capacity to undertake a risk evaluation;
- (b) Issues with the regulatory authority to submit a notification;
- (c) Lack of supporting information and documentation when decisions were taken a long time prior to their submitted notification of final regulatory action;
- (d) Lack of national scientific data or research to support the adoption of final regulatory actions, leading to limited information being available to provide in the final regulatory action notification form;
- (e) Notifications not containing Annex I information requirements.

### (a) Institutional and governance challenges: Laws or other measures adopted to implement the Convention requiring the use of risk or hazard evaluations

17. To the question of whether the laws or other measures adopted by their country or organization to implement the Convention required the use of risk or hazard evaluations, 17 respondent Parties responded "Yes" and 43 Parties responded "No"<sup>6</sup>. Further information on these requirements or how they relate to the specific criteria of Annex II to the Convention was not sought within this questionnaire.

<sup>6</sup> Including a response received by 1 regional economic integration organization on behalf of its 27 member states that are Parties.

18. Six of the respondent Parties highlighted that in spite of this requirement in laws or other measures, they do not conduct risk evaluations or do so by bridging information from other Parties or international organizations due to lack of national capacity, scientific and technical expertise or lack of a legal basis for action, including due to lack of full domestication of the Convention. Half of those Parties also reported facing subsequent challenges in relation to the criteria under Annex II to the Convention, as the final regulatory action may not be based on a risk evaluation involving prevailing conditions within the Party taking the action, as required pursuant to criterion (b) (iii) of Annex II. One Party also responded facing challenges due to the lack of available experimental data on the characteristics of a chemical.

19. From the information available from the responses to the questionnaire, it is clear that there are marked differences between the PIC regions as to whether Parties in preparing and/or adopting final regulatory actions have laws or measures in place requiring the use of risk of hazard evaluations:

(a) For the Africa PIC region, all six respondents from that region indicated having laws and measures in place requiring the use of risk or hazard evaluations. On closer review, the responses indicate that these domestic requirements can be satisfied through use of bridging information. The lack of national laboratory capacity or capacity to undertake risk evaluations was also identified as a challenge for Parties in this region;

(b) None of the respondents in the Asia PIC region had laws or measures in place requiring the use of risk or hazard evaluations;

(c) For the Europe PIC region, 4 of 36 Parties, corresponding to 11% of the respondent Parties for this region, had laws or measures in place requiring the use of risk or hazard evaluations;

(d) For the Latin America and the Caribbean PIC region, 2 of 9, corresponding to 22% of respondent Parties for this region, indicated that they had laws or measures in place requiring the use of risk or hazard evaluations;

(e) For the Near East PIC region, 2 of 4, corresponding to 50% of respondents for this region had laws or measures in place requiring the use of risk of hazard evaluations;

(f) For the Southwest Pacific and North America PIC regions, both respondents had laws or measures in place requiring the use of risk of hazard evaluations.

20. It is also noted that although only 23 Parties have transmitted texts of national legislation to the Secretariat<sup>7</sup>, 31 Parties (including one regional economic integration organization) responded to this question indicating that they have laws or measures in place.

**(b) Institutional and governance challenges: Mechanism for coordination and communication**

21. Lack of a mechanism for coordination and communication was identified as one of the main challenges for most Parties in preparing and/or adopting a final regulatory action, although here too with regional differences. Overall, 6 of 60, corresponding to 10% of respondent Parties, identified institutional and governance challenges, half of them indicating that the main issue related to a lack of mechanism for coordination and communication between national stakeholders. This was the case for equal numbers of respondents from the Africa, Near East, and Latin America and the Caribbean PIC regions. 2 respondents from each PIC region identified this as a priority, corresponding to 33% of respondents for each of the 3 PIC regions.

**(c) Institutional and governance challenges: Awareness raising**

22. Another issue faced by respondents was a lack of awareness, identified by 4 of 60, corresponding to 6% of respondent Parties, as a challenge at both the time of preparation and adoption of a final regulatory action. These respondents were from the Africa, Latin America and the Caribbean, and the Near East PIC regions.

**3. Use of Rotterdam Convention tools, guidance and materials for the preparation of final regulatory actions**

23. The respondents indicated a high level of awareness and use of the tools, guidance and other materials that have been developed to support Parties in relation to final regulatory actions. 21 of 60, corresponding to 35% of respondent Parties from all PIC regions except the North America PIC region, indicated that they had indeed used these in preparing their final regulatory actions. The highest levels of use were reported by respondents in the Europe PIC region (6 respondents), followed

<sup>7</sup> See document UNEP/FAO/RC/CC.2/4 on Laws, regulations, policies, procedures and other measures to implement the Rotterdam Convention.

by respondents from the Latin America and the Caribbean PIC region (6 respondents), the Africa PIC region (5 respondents) and the Asia PIC region (1 respondent).

24. Of the tools, guidance and materials, the most commonly used were the FRA Evaluation Toolkit; FAO Pesticide Registration Toolkit; Database of notifications of final regulatory actions; and the PIC Circular. There may be a link between the lack of awareness identified in section B.2 (c) above and the respondents who indicated that they have not used any of these materials.

#### **4. Submission of a notification of final regulatory action**

25. The majority of respondents indicated that they had not faced issues either related to or following the submission of a notification of final regulatory action to the Secretariat – 88% and 86% respectively. Of those not facing issues related to submission, the majority were from the Europe PIC region (35 respondent Parties), followed by the Africa (7 respondent Parties), Latin America and the Caribbean (5 respondent Parties), Near East (4 respondent Parties), Asia (1 respondent Party), North America PIC region (1 respondent Party) and the Southwest Pacific region (1 respondent Party). Of those not facing issues following submission, the majority were from the Europe PIC region (35 respondent Parties), followed by the Africa (7 respondent Parties), Latin America and the Caribbean (7 respondent Parties), Near East (3 respondent Parties), Asia (1 respondent Party), and the Southwest Pacific region (1 respondent Party).

26. Of those facing issues following submission of a notification of final regulatory action to the Secretariat, four of six meaning six percent of the total number of respondent Parties reported that they were facing issues related to queries from the Secretariat related to verification of information required by Annex I and to the provision of supporting documentation. Only three Parties mentioned the provision of information required by Annex I as a challenge following transmission of a notification of final regulatory action. One Party did indicate challenges when final regulatory actions exist and the transmitting authority does not have access to all the necessary information to notify the Secretariat, resulting in challenges with regard to the information requirements set out in Annex I to the Convention.

#### **5. Other issues faced related to final regulatory actions**

27. Parties also had an open-field question to provide information on other issues they may be facing in relation to final regulatory actions. Additional challenges identified included:

(a) The time required for national internal validation processes could result in delays in the adoption of a final regulatory action (one respondent);

(b) The need for coordination and synergies with matters related to the Stockholm Convention on Persistent Organic Pollutants, particularly when a chemical is already listed in Annexes A (elimination) or B (restriction) to that convention and the obligations under both conventions are to be implemented in parallel (two respondents);

(c) The need for Parties to receive specific support from the Secretariat once they have undertaken a risk evaluation and prior to the submission of the notification of final regulatory action (one respondent);

(d) Lack of participation by non-governmental organizations in questions related to chemicals management (one respondent);

(e) Certain actions are based on what is defined under national laws as mitigation/risk reduction measures, although they are severe restrictions. Due to the definition under national law, it falls outside the scope of the Convention and therefore no obligation exists to notify such measures. This may indicate some lack of clarity around certain definitions under the Convention (two respondents);

(f) The need for periodic training for all Parties to the Convention, in particular those with limited capacity, on the development of final regulatory actions (two respondents);

(g) Lack of resources to conduct national stakeholder consultations prior to and following the preparation of a notification of final regulatory action (three respondents);

(h) Lack of scientific data related to risk evaluation and lack of financial resources to prepare and notify final regulatory actions, including to undertake risk evaluations (four respondents).

28. Lastly, 7 of 39 respondents (corresponding to 18% of respondents) in the Africa, Europe and Latin America and the Caribbean PIC regions indicated uncertainties about where to transmit notifications, such as email addresses, and issues related to which national authority could transmit information to the Secretariat.

## C. Conclusions from the 2023 questionnaire

29. Recalling that 60 out of 165 Parties responded to the questionnaire, it is notable that most of the respondents had taken a final regulatory action.
30. The main issues identified by responding Parties to the questionnaire related to:
- (a) Institutional and governance challenges, in particular laws and measures in place requiring the use of risk or hazard evaluations, the need to improve coordination and communication between national stakeholders, and awareness raising, in particular at the time of developing a final regulatory action;
  - (b) A lack of resources, in particular scientific data and resources to conduct national consultations, for the effective implementation of the Convention;
  - (c) Challenges related to national processes, including validation processes prior to adoption of a final regulatory action or matching national definitions with those under the Convention such as mitigation in relation to risk evaluation.
31. There are very different levels of laws and measures in place to implement the Rotterdam Convention, including whether these require the use of risk or hazard evaluations. This may directly correlate with challenges Parties face in relation to the notification of final regulatory actions and the difficulties relating to laws, regulations, policies, procedures and other measures to implement the Convention<sup>8</sup>, however further information would be needed from Parties for more in-depth analysis.
32. Responses seem to indicate a need for a better understanding of certain terms and definitions under the Convention, to improve understanding of how national actions link to what is considered or defined as a final regulatory action and consequently need to be notified to the Secretariat.
33. There were no specific challenges apparent from the responses provided with regard to the information requirements set out in Annex I to the Convention. Most of the respondents indicated that they had not faced any issues in relation to this aspect of implementation of the Convention, although it is reiterated that given the small proportion of Parties that responded, this is unlikely to represent a full picture. Consequently, additional information may be needed to fully understand the challenges faced by Parties at different levels of implementation in different PIC regions.
34. There remains weak capacity at the national level to undertake risk and/or hazard evaluations, even when laws and measures in place require the use of risk or hazard evaluations. Furthermore, although a number of Parties bridge information particularly in the Africa region according to the responses to the questionnaire, the criterion (b)(iii) of Annex II whereby the final regulatory action needs to be based on a risk evaluation involving prevailing conditions within the Party taking the action remains a significant challenge to many Parties. One of the possible challenges that may be the cause of this challenge is the lack of national laboratory capacity or capacity to undertake risk evaluations.
35. In some instances, the challenges faced result from differences in terminology in national legislative and administrative measures with respect to the terms set out in the Convention, particularly “Severely restricted chemical” or “Final regulatory action”.
36. Challenges faced by some Parties related to procedural matters of how to transmit a notification of final regulatory action could be addressed through awareness raising and capacity-building activities.
37. With respect to the Secretariat, the responses demonstrated a high level of use of the materials, tools and guidance available, including the FRA Evaluation Toolkit, in relation to their decision-making and notification of final regulatory actions. From the responses provided, there seems to be sufficient guidance and materials to support Parties in this respect.

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<sup>8</sup> See document UNEP/FAO/RC/CC.2/4 on Laws, regulations, policies, procedures and other measures to implement the Rotterdam Convention.

## D. Summary of responses to the 2024 questions to collect information from Parties

38. In response to the questions to collect information circulated following the face-to-face sessions of the second meeting of the Committee, 19 of the 58 responding Parties<sup>9</sup> indicated they had not adopted a definition of final regulatory action whilst 38 Parties responded that they had. For those who provided additional information regarding their definition, all except one Party responded that the definition matches the definition contained in Article 2 of the Convention.

39. The majority, namely 45 of 58 responding Parties, had measures in place to adopt a final regulatory action, whilst 11 responding Parties did not.

40. 43 responding Parties had measures and/or procedures in place to submit a final regulatory action to the Secretariat within 90 days of it taking effect. 11 Parties responded that they did not have in place such measures and/or procedures.

41. Parties also had an open-field question to provide information on what may be needed to assist in overcoming the challenges faced in adopting or notifying the Secretariat of a final regulatory action. As further information on what could assist in addressing the challenges faced, most responding Parties indicated the need for technical assistance and capacity building, including for the exchange of experiences between Parties. Responding Parties also identified that primary legislation was in place but that there was a need for secondary legislation setting out specific procedures for implementation of the Convention. A number of responding Parties expressed having faced challenges with the deadline set out in paragraph 1 of Article 5 that notifications need to be submitted no later than ninety days after the date on which the final regulatory action has taken effect.

42. The responses to the questions to collect information confirmed the information collected in the 2023 questionnaire, namely that Parties face challenges related to a lack of capacity to implement the Convention's provisions.

## III. Proposed action

43. The Committee is invited to consider the information contained in the present note and may wish to:

- (a) Request the Secretariat to collect more information from Parties on the challenges faced with submission of a notification of final regulatory action within 90 days of it taking effect;
- (b) Recall its decision CC-2/4 and include in its draft programme of work for the biennium 2026–2027 that it be entrusted to:
  - (i) Continue, based on the information from Parties, to identify and review issues being faced by Parties in relation to the notification of final regulatory actions, including challenges faced with submission of a notification of final regulatory action within 90 days of it taking effect;
  - (ii) Develop recommendations for consideration by the Conference of the Parties on steps that could be taken by Parties, the Conference of the Parties, the Compliance Committee and others to support Parties with the notification of final regulatory actions.

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<sup>9</sup> The responses are available at: <https://www.pic.int/Implementation/Legalmatters/GeneralIssuesActivities/Activities20242025/Questionstocollectinformation/tabid/10008/language/en-US/Default.aspx>.