



Food and Agriculture Organization of the United Nations

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

# UNEP/FAO/RC/CRC.19/14

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**Chemical Review Committee Nineteenth meeting** Rome, 3–6 October 2023

# **Report of the Chemical Review Committee on the work of its nineteenth meeting**

# I. Opening of the meeting

1. The nineteenth meeting of the Chemical Review Committee under the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was held at the headquarters of the Food and Agriculture Organization of the United Nations (FAO), Viale delle Terme di Caracalla, Rome, from 3 to 6 October 2023.

2. The meeting was opened at 9.45 a.m. on Tuesday, 3 October 2023, by the Chair of the Committee, Noluzuko Gwayi (South Africa).

3. Opening remarks were delivered by Christine Fuell, Executive Secretary ad interim of the Rotterdam Convention, and Rolph Payet, Executive Secretary of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, the Rotterdam Convention and the Stockholm Convention on Persistent Organic Pollutants.

4. In her statement, Ms. Fuell welcomed participants, thanking members for the work carried out during the intersessional period. She noted that the current meeting was being held at a critical time for the sound management of chemicals and waste, and drew attention to a number of important events, meetings and activities that had taken place since the previous meeting of the Committee. The Conference of the Parties to the Convention on Biological Diversity at its fifteenth meeting, held in December 2022, had adopted the Kunming-Montreal Global Biodiversity Framework, target 7 of which called for a reduction of pollution risks and the negative impact of pollution from all sources by 2030; the meetings of the conferences of the Parties to the Basel, Rotterdam and Stockholm conventions had been held in Geneva in May 2023 under the theme "Accelerating action: targets for the sound management of chemicals and waste"; and the International Conference on Chemicals Management at its fifth session, held in Bonn, Germany, in September 2023, had set a target on highly hazardous pesticides. In addition, the Global Symposium on Soils and Water, taking place concurrently at FAO headquarters in Rome, exemplified the activities led by FAO to ensure sustainable plant production and protection that reduced the risks posed by hazardous chemicals and pesticides, contributing to the protection of human health and the environment. In conclusion, she highlighted the large number of notifications of final regulatory action pending review by the Committee, due to an increasing number of notifications being submitted by Parties.

5. Mr. Payet, in his opening statement, said that the increase in the production and use of chemicals in all regions of the world presented a challenge to the attainment of the Sustainable Development Goals. The recent Sustainable Development Goals Summit, held in New York on 18 and 19 September 2023, had aimed to provide renewed impetus at all levels of government to accelerate the implementation of the 2030 Agenda for Sustainable Development. There was wide recognition of the contribution that could be made to the achievement of the Sustainable Development Goals through coordinated and integrated action on the sound management of chemicals and waste. For example, the adoption by the International Conference on Chemicals Management at its fifth session of the global

framework on chemicals for a planet free of harm from chemicals and waste offered an opportunity for the engagement of major groups and stakeholders in strengthening activities to address the life cycle of chemicals and waste, thereby contributing to the implementation of the Rotterdam Convention. Of relevance to that objective was the continued implementation by the Secretariat of training and capacity-building activities within the framework of the technical assistance plan.

# II. Organizational matters

#### A. Attendance

6. The following members of the Committee attended the meeting: Jonah Ormond (Antigua and Barbuda), Anahit Aleksandryan (Armenia), Adam Barlow (Australia), Juergen Helbig (Austria), Mirijam Seng (Belgium), Christian Bart (Canada), Cangmin Li (China), Carles Escriva (Germany), Joseph Cantamanto Edmund (Ghana), Carlos Enrique Acevedo González (Guatemala), Suresh Lochan Amichand (Guyana), Dinesh Runiwal (India), Yenny Meliana (Indonesia), Judite Dipane (Latvia), Hassan Azhar (Maldives), Saida Ech-Chayeb (Morocco), Charles Bodar (Kingdom of the Netherlands), Zaigham Abbas (Pakistan), Christian Sekomo Birame (Rwanda), Aïta Sarr Seck (Senegal), Suzana Andrejevic Stefanovic (Serbia), Noluzuko Gwayi (South Africa), Sumith Jayakody Arachchige (Sri Lanka), Victorine Augustine Pinas (Suriname), Sarah Maillefer (Switzerland), Palarp Sinhaseni (Thailand), Hasmath Ali (Trinidad and Tobago), Daniel William Ndiyo (United Republic of Tanzania).

7. The members of the Committee from Nepal, Tunisia and Zimbabwe were unable to attend.

8. The following States were represented as observers: Argentina, Australia, Brazil, Canada, China, Croatia, Estonia, Guatemala, Indonesia, Italy, Japan, New Zealand, Norway, Oman, Paraguay, Qatar, Romania, Russian Federation, Saudi Arabia, Serbia, Slovenia, South Africa, United Republic of Tanzania, United States of America.

9. Non-governmental organizations were also represented as observers. The names of those organizations are included in the list of participants (UNEP/FAO/RC/CRC.19/INF/32).

#### **B.** Adoption of the agenda

10. In considering the sub-item, the Committee had before it the provisional agenda (UNEP/FAO/RC/CRC.19/1/Rev.1) and the annotated provisional agenda (UNEP/FAO/RC/CRC.19/1/Rev.1/Add.1).

- 11. The Committee adopted the following agenda on the basis of the provisional agenda:
  - 1. Opening of the meeting.
  - 2. Organizational matters:
    - (a) Adoption of the agenda;
    - (b) Organization of work.
  - 3. Review of the outcomes of the eleventh meeting of the Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade that are relevant to the work of the Committee.
  - 4. Rotation of the membership.
  - 5. Technical work:
    - (a) Consideration of draft decision guidance documents:
      - (i) Methyl bromide;
      - (ii) Paraquat;
    - (b) Report of the Bureau on the preliminary review of notifications of final regulatory action;
    - (c) Review of notifications of final regulatory action:
      - (i) Bromacil;
      - (ii) Carbaryl;

- (iii) Chlorfenvinphos;
- (iv) Chlorpyrifos;
- (v) Diarsenic pentaoxide;<sup>1</sup>
- (vi) Ethion;
- (vii) Mercury;
- (viii) Methidathion;
- (ix) Thiodicarb.
- 6. Venue and dates of the twentieth meeting of the Committee.
- 7. Other matters.
- 8. Adoption of the report of the meeting.
- 9. Closure of the meeting.

12. The Committee decided that, under agenda item 7 (Other matters), it would consider the revised indicative list of perfluorooctanoic acid (PFOA) substances under Annex III to the Convention; a report on activities to facilitate effective participation in the work of the Committee; and the intersessional work on new notifications of final regulatory action.

13. The Chair informed the Committee that the intention had been to include on the agenda of the current meeting a review of two notifications of final regulatory action for brodifacoum. However, following the withdrawal by one Party of its notification, consideration of the chemical had been removed from the provisional agenda of the meeting.

#### C. Organization of work

14. The Committee decided to conduct the meeting in accordance with the scenario note prepared by the Chair (UNEP/FAO/RC/CRC.19/INF/1) and the tentative schedule for the meeting (UNEP/FAO/RC/CRC.19/INF/2), subject to adjustment as necessary. It also decided that contact groups and drafting groups would be established as needed throughout the meeting.

# III. Review of the outcomes of the eleventh meeting of the Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade that are relevant to the work of the Committee

15. Introducing the item, the representative of the Secretariat summarized the information provided in document UNEP/FAO/RC/CRC.19/INF/28, on the outcomes of the eleventh meeting of the Conference of the Parties to the Rotterdam Convention relevant to the Committee's work.

16. In the ensuing discussion, one member expressed regret that the Conference of the Parties had not reached consensus on listing six chemicals in Annex III to the Convention, even though the Chemical Review Committee had found that the criteria set out in Annex II had been met, and a large majority of Parties had supported the listing. As a consequence, those countries that would benefit most from the listing of those chemicals in Annex III were not able to fully benefit from full protection under the prior informed consent procedure of the Convention, thus weakening human health and environmental protection in those countries.

17. The Committee took note of the information provided.

# IV. Rotation of the membership

18. Introducing the item, the representative of the Secretariat drew attention to the information provided in document UNEP/FAO/RC/CRC.19/INF/3, on the rotation of the membership of the Chemical Review Committee. The term of office of one member of the Bureau, Vice-Chair,

<sup>&</sup>lt;sup>1</sup> Also referred to as arsenic pentoxide (CAS No. 1303-28-2).

Jonah Ormond (Antigua and Barbuda), would end on 30 April 2024, so a new Bureau member from the Latin American and Caribbean States would need to be appointed by the Committee.

19. The Committee took note of the information provided.

20. Subsequently, Victorine Pinas (Suriname) was elected as the new Bureau member from the Latin American and Caribbean States, with a term of office commencing at the closure of the current meeting of the Committee.

# V. Technical work

#### A. Consideration of draft decision guidance documents

#### 1. Methyl bromide

21. Introducing the sub-item, the representative of the Secretariat recalled that, at its eighteenth meeting, the Chemical Review Committee had reviewed a notification of final regulatory action for methyl bromide submitted by Colombia and had concluded that the notification met the criteria set out in Annex II to the Convention. Previously, at its first meeting, the Committee had reviewed a notification of final regulatory action for methyl bromide submitted by the Kingdom of the Netherlands and had concluded that the notification met the criteria set out in Annex II to the Convention. Accordingly, by its decision CRC-18/3, the Committee had decided to recommend to the Conference of the Parties that it list methyl bromide in Annex III to the Convention as a pesticide. The Committee had established an intersessional drafting group to prepare a draft decision guidance document for methyl bromide.

22. At the current meeting, the Committee had before it the draft decision guidance document prepared by the intersessional drafting group (UNEP/FAO/RC/CRC.19/3) and a compilation of comments and responses relating thereto (UNEP/FAO/RC/CRC.19/INF/4).

23. Jonah Ormond, chair of the intersessional drafting group, reported on the outcome of the group's work, and Sarah Maillefer, the drafter of the group, presented the draft decision guidance document.

24. In the ensuing discussion, several members of the Committee expressed support for the draft decision guidance document. It was noted that methyl bromide was already listed under the Montreal Protocol on Substances that Deplete the Ozone Layer, with exemptions for certain uses. The listing of methyl bromide in Annex III to the Rotterdam Convention would complement the reporting requirements under the Montreal Protocol for the import and export of methyl bromide for controlled uses, although care would need to be taken to coordinate national-level regulatory mechanisms pertaining to the import and export of methyl bromide under the two instruments.

25. The Committee requested the Secretariat to prepare a draft decision by which the Committee would adopt the draft decision guidance document and forward it, along with the related compilation of comments, to the Conference of the Parties for consideration at its twelfth meeting.

26. Subsequently, the representative of the Secretariat presented the draft decision on the adoption of the draft decision guidance document, prepared at the Committee's request.

27. The Committee adopted decision CRC-19/1, by which it adopted the draft decision guidance document for methyl bromide (UNEP/FAO/RC/CRC.19/3) and decided to forward it, together with the related compilation of comments (UNEP/FAO/RC/CRC.19/INF/4), to the Conference of the Parties for its consideration. The decision is set out in annex I to the present report.

#### 2. Paraquat

28. Introducing the sub-item, the representative of the Secretariat recalled that, at its eighteenth meeting, the Chemical Review Committee had reviewed notifications of final regulatory action for paraquat submitted by Malaysia and Mozambique and had concluded that both notifications met the criteria set out in Annex II to the Convention. Accordingly, by its decision CRC-18/4, the Committee had decided to recommend to the Conference of the Parties that it list paraquat in Annex III to the Convention as a pesticide. The Committee had established an intersessional drafting group to prepare a draft decision guidance document for paraquat.

29. At the current meeting, the Committee had before it the draft decision guidance document prepared by the intersessional drafting group (UNEP/FAO/RC/CRC.19/4) and a compilation of comments and responses relating thereto (UNEP/FAO/RC/CRC.19/INF/5).

30. Juergen Helbig, chair of the intersessional drafting group, reported on the outcome of the group's work and Suzana Andrejevic Stefanovic, the drafter of the group, presented the draft decision guidance document.

31. Following the presentation, all the members who spoke expressed support for the draft decision guidance document, as presented to the Committee.

32. The Committee requested the Secretariat to prepare a draft decision by which the Committee would adopt the draft decision guidance document and forward it, along with the related compilation of comments, to the Conference of the Parties for consideration at its twelfth meeting.

33. Subsequently, the representative of the Secretariat presented the draft decision on the adoption of the draft decision guidance document, prepared at the Committee's request.

34. The Committee adopted decision CRC-19/2, by which it adopted the draft decision guidance document for paraquat (UNEP/FAO/RC/CRC.19/4) and decided to forward it, together with the related compilation of comments (UNEP/FAO/RC/CRC.19/INF/5), to the Conference of the Parties for its consideration. The decision is set out in annex I to the present report.

# **B.** Report of the Bureau on the preliminary review of notifications of final regulatory action

35. In considering the sub-item, the Committee had before it the report of the Bureau on the preliminary review of notifications of final regulatory action (UNEP/FAO/RC/CRC.19/2), information on trade in chemicals under consideration by the Committee (UNEP/FAO/RC/CRC.19/INF/6) and a summary record of notifications of final regulatory action for chemicals reviewed by the Interim Committee or the Committee and of notifications scheduled for review by the Committee (UNEP/FAO/RC/CRC.19/INF/7).

36. Presenting the outcome of the preliminary review, Mr. Helbig, a member of the Bureau, said that, based on the information available at the time, the Bureau had undertaken a preliminary review of the new notifications of final regulatory action and relevant supporting documentation. The main purpose of the preliminary review had been to assign each candidate chemical to an intersessional task group. The preliminary review had also provided an opportunity for the Bureau and the Secretariat to seek further clarification or information about those chemicals where needed.

37. The Bureau had established four intersessional task groups, each of which was responsible for undertaking a preliminary assessment of the assigned chemicals, including the review of the new notifications and the supporting documentation. Committee members were designated as chairs, drafters or members of the groups, based on their expertise. All Committee members had been encouraged to join any of the task groups.

38. Between March and July 2023, the intersessional task groups had reviewed the new notifications and prepared draft reports for five chemicals: bromacil, chlorpyrifos, diarsenic pentaoxide, ethion and mercury. The draft reports had been posted on the Convention website for comments by members and observers, and the intersessional task groups had met face to face, with the participation of observers, immediately before the meeting to finalize their reports. The chair or drafter of each task group would present their task group's findings.

39. The Committee took note of the information presented.

#### C. Review of notifications of final regulatory action

#### 1. Bromacil

40. The Committee had before it notifications of final regulatory action on bromacil in the pesticide category from two prior informed consent regions, namely Europe (Türkiye) and Latin America and the Caribbean (Costa Rica) (UNEP/FAO/RC/CRC.19/5), along with the related supporting information (UNEP/FAO/RC/CRC.19/INF/8 and UNEP/FAO/RC/CRC.19/INF/9). The Committee also had before it a conference room paper containing the report of the intersessional task group that had been established to undertake a preliminary assessment of the notification, which is reproduced in document UNEP/FAO/RC/CRC.19/INF/31.

41. Hassan Azhar, chair of the intersessional task group, and Carles Escriva, the drafter of the group, reported on the outcome of the group's work.

#### (a) Outcomes of the intersessional task groups

#### (i) Notification from Costa Rica

42. The intersessional task group had found that the notification of final regulatory action submitted by Costa Rica on bromacil in the pesticide category met all the criteria of Annex II to the Convention.

#### (ii) Notification from Türkiye

43. The intersessional task group had found that the notification of final regulatory action submitted by Türkiye on bromacil in the pesticide category did not meet the criterion in paragraph (b) (iii) of Annex II to the Convention. The task group had therefore concluded that the notification of final regulatory action from Türkiye did not meet all the criteria of Annex II to the Convention.

#### (b) Discussion of the notifications

44. In the ensuing discussion, all the members who spoke concurred with the task group's conclusions with respect to the notifications from Costa Rica and Türkiye. Several members expressed appreciation for the multidimensional and integrated approach taken by Costa Rica with regard to the criterion in paragraph (b) (iii), as the information provided was not simply a comparison between the value measured in water with water quality standards for human health but included analysis showing the persistence of the chemical in water in areas of the country where the chemical had been banned in 2008.

#### (c) Next steps

45. On the basis of the discussion, the Committee agreed that the notification from Costa Rica met all the criteria of Annex II to the Convention and that the notification from Türkiye met all the criteria of Annex II except the criterion in paragraph b (iii). It established a contact group, with Mr. Azhar serving as chair and Mr. Escriva as drafter, to develop a draft rationale for its conclusions on the notification from Costa Rica, based on the notification received and the comments made during the discussion. If necessary, the chair of the contact group could convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the draft rationale.

46. Subsequently, the Committee, having considered the draft rationale prepared by the contact group, adopted decision CRC-19/5, to which the rationale is attached. The decision is set out in annex I to the present report.

47. The Committee decided that, as only one notification of final regulatory action from one prior informed consent region in respect of bromacil met the criteria set out in Annex II to the Convention, namely the notification from Costa Rica, no further action would be taken on the chemical at present.

#### 2. Carbaryl

48. The Committee had before it a notification of final regulatory action on carbaryl in the pesticide category from the Africa prior informed consent region (Mozambique) (UNEP/FAO/RC/CRC.19/6), along with the related supporting information (UNEP/FAO/RC/CRC.19/INF/10). At its fourth meeting, the Committee had concluded that a notification related to carbaryl in the pesticide category from the Europe prior informed consent region (European Union) met all the criteria of Annex II to the Convention (UNEP/FAO/RC/CRC.17/INF/8). The Committee had also considered the notification from Mozambique at its eighteenth meeting, at which time there were diverging views with regard to whether the notification met the criterion in paragraph (b) (iii) of Annex II to the Convention, and the Committee had deferred further discussion of the matter to its nineteenth meeting.<sup>2</sup> No additional information had since been received from Mozambique with respect to its risk evaluation.

49. Several members at the present meeting said that they were unable to determine whether the criterion in paragraph (b) (iii) of Annex II had been met but that it would be helpful to have chemical-specific bridging information. One member said that the notification did not meet the criterion in paragraph (b) (iii) because it did not include information on actual anticipated exposure in the country.

50. Several members were, however, of the view that the notification did meet the criterion in paragraph (b) (iii). One pointed out that, as notified by Mozambique, many formulations containing carbaryl had been registered during the survey period, imports had been documented for the survey

<sup>&</sup>lt;sup>2</sup> UNEP/FAO/RC/CRC.18/15, paras. 54-80.

period and the active substance was classified as a carcinogen and was therefore considered a highly hazardous pesticide by the Government of Mozambique. She also noted that it would be very difficult to conduct chemical-specific surveys in countries where many farmers were illiterate. Several other members said that the criterion had been met, as the Government of Mozambique had evaluated the prevailing conditions in the country and the hazardous properties of the chemical and had adopted the final regulatory action to protect farmers' health.

51. One member noted that the product was not registered in the European Union owing to health and environmental concerns, and that in the United States of America personal protection equipment was required for its use. As the notification from Mozambique indicated that 93 per cent of farmers in the country did not use personal protection equipment, exposure and adverse effects could be anticipated if the product continued to be used in the country, and, on that basis, he considered the criterion in paragraph (b) (iii) to have been met. Another member voiced support for that view and said that the bridging information mentioned made it easy to conclude that the criterion in paragraph (b) (iii) had been met.

52. Several members requested the opportunity to discuss the matter further in a contact group.

53. On the basis of the discussion, the Committee assigned an additional mandate to the contact group established under the sub-item on chlorfenvinphos, namely to discuss whether the criterion in paragraph (b) (iii) of Annex II had been met for carbaryl and, in the event that it considered that the notification met that criterion, to develop a draft rationale for that conclusion. If necessary, the chair of the contact group could convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the draft rationale.

54. Subsequently, the chair of the contact group reported that the group had been unable to reach agreement on whether the notification for carbaryl, as well as those for chlorfenvinphos, methidathion and thiodicarb, met the criterion in paragraph (b) (iii) of Annex II. Further discussion ensued, during which a number of members reiterated their views on the question.

55. In addition, one member, supported by another, asked that the Mozambique notifications be set aside until the Committee received the additional information it needed to further consider the matter. Others were opposed to that, however, saying that they preferred to have the opportunity for a short discussion at the next meeting. Another said that any additional information received should be chemical-specific, including bridging information from sources of information cited in the notifications and information on how a risk evaluation had been undertaken to determine whether the exposure for the specific pesticide was unacceptable or of concern. Such information, he said, would enable the Committee, as a scientific body, to validate the assumptions and links made during its discussions. Another member echoed the need to formulate a very specific request for information that would address members' concerns.

56. One member, noting that the discussion had revealed a need for more guidance on the application of paragraph (b) (iii) of Annex II, requested that the next Chemical Review Committee orientation workshop for new members provide training on the review of notifications. Saying that a better understanding of the notifications of Mozambique might lead to a change in views on the notification, he encouraged all members to attend the workshop.

57. As members still had different views on whether the notification from Mozambique for carbaryl met the criterion in paragraph (b) (iii) of Annex II to the Convention, although they agreed that it met all the other criteria of Annex II, and members also had different views on how to proceed on the item, the Committee noted that it was not possible to complete its consideration of the item and that the notification would therefore automatically be included in the agenda for its twentieth meeting.

58. The Chair urged members to use the time during the intersessional period to familiarize themselves with the supporting documentation submitted by Mozambique and the guidance in the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee on the application of the criterion, and to attend the orientation workshop for new members.

#### 3. Chlorfenvinphos

59. The Committee had before it a notification of final regulatory action on chlorfenvinphos in the pesticide category from the Africa prior informed consent region (Mozambique) (UNEP/FAO/RC/CRC.19/7), along with the related supporting information (UNEP/FAO/RC/CRC.19/INF/11). At its eighteenth meeting, the Committee had concluded that a notification related to chlorfenvinphos in the pesticide category from the Europe prior informed consent region (Norway) met all the criteria of Annex II to the Convention (UNEP/FAO/RC/CRC.19/INF/12). The Committee had also considered the notification from

Mozambique at its eighteenth meeting, at which time there were diverging views with regard to whether the notification met the criterion in paragraph (b) (iii) of Annex II to the Convention, and the Committee had deferred further discussion of the matter to its nineteenth meeting.<sup>3</sup> No additional information had since been received from Mozambique with respect to its risk evaluation.

60. During the discussion, a number of members said that they were unable to conclude that the notification from Mozambique met the criterion in paragraph (b) (iii), with most citing an insufficiency of information on how chlorfenvinphos was used in the country. One member said that a survey-based risk evaluation was inadequate, as the risk evaluation should be specific to chlorfenvinphos.

61. Several other members, however, argued that the notification clearly satisfied the criterion. One highlighted the hazardous nature of chlorfenvinphos as a class Ib pesticide with an  $LD_{50}$  below 50 mg/kg, and noted that the chemical had been shortlisted for the survey on which the notification was based, meaning that it had been imported during the survey period and farmers had thus been using it. If the farmers did not use personal protection equipment, the risk was unacceptable. For several others, it was clear that the Government of Mozambique had taken into account the prevailing conditions in the country and the hazardous properties of the chemical when adopting the final regulatory action, thus meeting the criterion. One cautioned against dismissing all notifications from Mozambique on the same basis, reiterating that each chemical should be reviewed on its own merits.

62. One member, while agreeing with the view expressed by the previous speaker, acknowledged the concerns of certain other members and suggested that additional information be requested as the need arose.

63. On the basis of the discussion, the Committee agreed that the notification from Mozambique met all the criteria of Annex II except the criterion in paragraph (b) (iii). The Committee agreed to establish a contact group, with Hasmath Ali serving as chair and Mirijam Seng as drafter, to further discuss whether the notification on chlorfenvinphos met the criterion in paragraph b (iii) of Annex II to the Convention and, in the event that it considered that the notification met that criterion, to develop a draft rationale for that conclusion. If necessary, the chair of the contact group could convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the draft rationale.

64. Subsequently, the chair of the contact group reported that the group had been unable to reach agreement and further discussion ensued, as described in paragraphs 54 and 55 of the present report.

65. As members still had different views on whether the notification from Mozambique for chlorfenvinphos met the criterion in paragraph (b) (iii) of Annex II to the Convention, although they agreed that it met all the other criteria of Annex II, and members also had different views on how to proceed, the Committee noted that it was not possible to complete its consideration of the item regarding chlorfenvinphos and that the notification would therefore automatically be included in the agenda for its twentieth meeting.

66. The Chair urged members to use the time during the intersessional period to familiarize themselves with the supporting documentation submitted by Mozambique and the guidance in the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee on the application of the criterion, and to attend the orientation workshop for new members.

#### 4. Chlorpyrifos

67. The Committee had before it notifications of final regulatory action on chlorpyrifos in the pesticide category from two prior informed consent regions, namely Asia (Malaysia and Sri Lanka) and Europe (European Union and Türkiye) (UNEP/FAO/RC/CRC.19/8), along with the related supporting information (UNEP/FAO/RC/CRC.19/INF/13, UNEP/FAO/RC/CRC.19/INF/14, UNEP/FAO/RC/CRC.19/INF/15/Rev.1 and UNEP/FAO/RC/CRC.19/INF/16). The Committee also had before it a conference room paper containing the report of the intersessional task group that had been established to undertake a preliminary assessment of the notifications, which is reproduced in document UNEP/FAO/RC/CRC.19/INF/31.

68. Jonah Ormond, chair of the intersessional task group, and Judite Dipane, the drafter of the group, reported on the outcome of the group's work.

<sup>&</sup>lt;sup>3</sup> UNEP/FAO/RC/CRC.18/15, paras. 91–119.

#### (a) Outcomes of the intersessional task groups

#### (i) Notification from Malaysia

69. The intersessional task group had found that the notification of final regulatory action submitted by Malaysia on chlorpyrifos in the pesticide category met all the criteria of Annex II to the Convention.

#### (ii) Notification from Sri Lanka

70. The intersessional task group had found that the notification of final regulatory action submitted by Sri Lanka on chlorpyrifos in the pesticide category met all the criteria of Annex II to the Convention.

#### (iii) Notification from the European Union

71. The intersessional task group had found that the notification of final regulatory action submitted by the European Union on chlorpyrifos in the pesticide category met all the criteria of Annex II to the Convention.

#### (iv) Notification from Türkiye

72. The intersessional task group had found that the notification of final regulatory action submitted by Türkiye on chlorpyrifos in the pesticide category did not meet the criterion in paragraph (b) (iii) of Annex II to the Convention.

73. The task group had therefore concluded that the notification of final regulatory action from Türkiye did not meet all the criteria of Annex II to the Convention.

#### (b) Discussion of the notifications

74. In the ensuing discussion, all the members who spoke concurred with the task group's conclusions with respect to the notifications from Malaysia, Sri Lanka and Türkiye.

75. With regard to the notification from the European Union, one member offered additional information regarding the risk evaluation aspect of the final notification of regulatory action, explaining that in the European Union the onus for demonstrating the safety of an active substance was on applicants seeking approval, who had to submit data for use in a risk evaluation. In the case of chlorpyrifos, there had been insufficient data to identify safe use, leading to the conclusion that the criteria set out in the legislation had not been met. As a result, the active substance had not been approved for use in the European Union, and it was not considered necessary to complete an environmental risk evaluation.

76. Several members welcomed the clarification provided, with some asking to see the information referred to and one suggesting that it be used to clarify and strengthen the argument for considering that the risk evaluation criterion might have been met.

#### (c) Next steps

77. On the basis of the discussion, the Committee agreed that the notifications from Malaysia and Sri Lanka met all the criteria of Annex II to the Convention, that the notification from Türkiye met all the criteria of Annex II except the criterion in paragraph (b) (iii), and that the notification from the European Union required further discussion. It established a contact group, with Mr. Ormond serving as chair and Ms. Dipane as drafter, to further discuss the notification from the European Union and, in the event that it considered that the notification met that criterion of Annex II, to develop a draft rationale for that conclusion. The group was also to develop a draft rationale for its conclusions on the notifications from Malaysia and Sri Lanka, based on the notifications received and the comments made during the discussion. If necessary, the chair of the contact group could convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the draft rationale.

78. Subsequently, a member of the Committee presented document

UNEP/FAO/RC/CRC.19/INF/15/Rev.2, the annex to which contained additional documentation provided by the European Union to support its notification of final regulatory action for chlorpyrifos in the pesticide category, namely the list of endpoints of the European Union initial risk assessment for chlorpyrifos.

79. Subsequently, the chair of the contact group reported that the group had reached agreement that the notification from the European Union met the criterion in paragraph (b) (iii), and had therefore concluded that the notification of final regulatory action on chlorpyrifos from the European Union, in

addition to the notifications from Malaysia and Sri Lanka, met all the criteria of Annex II to the Convention.

80. Subsequently, the Committee, having considered the draft rationale prepared by the contact group, along with a draft decision and a draft workplan prepared by the Secretariat, adopted decision CRC-19/3. The decision, to which the rationale is annexed, is set out in annex I to the present report.

81. The Committee agreed that the intersessional drafting group established to prepare the draft decision guidance document for chlorpyrifos would be chaired by Mr. Ali, with Ms. Dipane as the drafter. The composition of the intersessional drafting group is set out in annex II to the present report, and the workplan is set out in annex III.

#### 5. Diarsenic pentaoxide

82. The Committee had before it notifications of final regulatory action on diarsenic pentaoxide in the industrial category from two prior informed consent regions, namely Asia (Republic of Korea) and Europe (European Union) (UNEP/FAO/RC/CRC.19/9), along with the related supporting information (UNEP/FAO/RC/CRC.19/INF/17 and UNEP/FAO/RC/CRC.19/INF/18). Two additional supporting documents from the European Union pertaining to its notification were subsequently received by the Secretariat, including one that was set out in a conference room paper. Those documents were available in document UNEP/FAO/RC/CRC.19/INF/18/Rev.1. The Committee also had before it a conference room paper containing the report of the intersessional task group that had been established to undertake a preliminary assessment of the notifications, which is reproduced in document UNEP/FAO/RC/CRC.19/INF/31.

83. Victorine Augustine Pinas, chair of the intersessional task group, and Christian Bart, the drafter of the group, reported on the outcome of the group's work.

#### (a) Outcomes of the intersessional task groups

#### (i) Notification from the Republic of Korea

84. The intersessional task group had found that the notification of final regulatory action submitted by the Republic of Korea on diarsenic pentaoxide did not meet the criterion in paragraph (b) (iii) of Annex II to the Convention. The task group had therefore concluded that the notification of final regulatory action from the Republic of Korea did not meet all the criteria of Annex II to the Convention.

#### (ii) Notifications from the European Union

85. The intersessional task group had found that the notification of final regulatory action submitted by the European Union on diarsenic pentaoxide met the criteria of Annex II to the Convention, pending the review of additional information on occupational exposure received from the European Union relevant to the criterion in paragraph (b) (iii).

#### (b) Discussion of the notifications

86. In the ensuing discussion, all the members who spoke concurred with the task group's conclusions with respect to the notification from the Republic of Korea. With regard to the notification from the European Union, some members, who had already had the opportunity to review the additional information on occupational exposure provided by the European Union, expressed the view that all the criteria of Annex II to the Convention had been met. Many members, however, requested that consideration of the notification be suspended to allow all members sufficient time to review the additional information provided by the European Union.

#### (c) Next steps

87. On the basis of the discussion, the Committee agreed that the notification from the Republic of Korea met all the criteria of Annex II except the criterion in paragraph b (iii). The Committee assigned an additional mandate to the contact group established under the sub-item on mercury, namely to further discuss whether the notification from the European Union met the criterion in paragraph (b) (iii) and, in the event that it considered that the notification met that criterion, to develop a draft rationale for that conclusion, based on the notifications received and the comments made during the discussion. If necessary, the chair of the contact group could convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the draft rationale.

88. Subsequently, the Chair reported that the contact group had concluded that the notification from the European Union had met the criterion in paragraph (b) (iii) of Annex II and had prepared a draft rationale on the conclusions of the Committee on that notification.

89. The Committee therefore requested the Secretariat to prepare a draft decision by which the Committee would adopt the rationale for the conclusions of the Committee on the notification from the European Union.

90. Subsequently, the Committee, having considered the draft rationale prepared by the contact group, adopted decision CRC-19/6, to which the rationale is attached. The decision is set out in annex I to the present report.

91. The Committee decided that, as only one notification of final regulatory action from one prior informed consent region in respect of diarsenic pentaoxide met the criteria set out in Annex II to the Convention, namely the notification from the European Union, no further action would be taken on the chemical at present.

#### 6. Ethion

92. The Committee had before it notifications of final regulatory action on ethion in the pesticide category from two prior informed consent regions, namely Africa (Mozambique) and Europe (Türkiye) (UNEP/FAO/RC/CRC.19/10), along with the related supporting information (UNEP/FAO/RC/CRC.19/INF/19 and UNEP/FAO/RC/CRC.19/INF/20). The Committee also had before it a conference room paper containing the report of the intersessional task group that had been established to undertake a preliminary assessment of the notification, which is reproduced in document UNEP/FAO/RC/CRC.19/INF/31.

93. Daniel William Ndiyo, chair of the intersessional task group, and Mirijam Seng, the drafter of the group, reported on the outcome of the group's work.

#### (a) Outcomes of the intersessional task groups

#### (i) Notifications from Mozambique

94. The intersessional task group had found that the notification of final regulatory action submitted by Mozambique on ethion in the pesticide category met the criteria of Annex II to the Convention, except the criterion in paragraph (b) (iii), for which the group had not reached a decision.

#### (ii) Notification from Türkiye

95. The intersessional task group had found that the criterion in paragraph (b) (iii) had not been met. The task group had therefore concluded that the notification of final regulatory action from Türkiye did not meet all the criteria of Annex II to the Convention.

#### (b) Discussion of the notification

96. In the ensuing discussion, all the members who spoke concurred with the task group's conclusions with respect to the notification from Türkiye. With regard to the notification from Mozambique, some members expressed the view that the criterion in paragraph (b) (iii) had not been met, as ethion was registered for use in the country for veterinary purposes, but the survey results referred to in the notification had not evaluated ethion specifically and only related to crop uses rather than veterinary uses of pesticides. Other members, however, were of the view that the criterion in paragraph (b) (iii) had been met, as the results of the survey could be assumed to apply to the way that subsistence farmers in Mozambique used ethion. It had been established that those farmers both grew crops and kept animals, and therefore it was highly likely that they used pesticides in the same way in both instances, namely without using personal protection equipment and without reading the labels on the pesticides.

#### (c) Next steps

97. On the basis of the discussion, the Committee agreed that the notification from Türkiye met all the criteria of Annex II except the criterion in paragraph b (iii). The Committee established a contact group, with Mr. Ndiyo serving as chair and Ms. Seng as drafter, with a mandate to discuss whether the criterion in paragraph (b) (iii) of Annex II had been met in the notification from Mozambique and, in the event that it considered that the notification met that criterion, to develop a draft rationale for that conclusion. If necessary, the chair of the contact group could convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the draft rationale.

98. Subsequently, the chair of the contact group reported to the Committee on the outcomes of the group. The contact group had concluded that further information or clarification was needed from

Mozambique before a decision could be made on whether the criterion in paragraph (b) (iii) of Annex II had been met. In particular, information was sought on how a formulation "101% EC" of ethion (1010 grams per litre) was technically feasible, and how Mozambique calculated the  $LD_{50}$  value for the formulation "Eticide 101% EC", as a result of which the formulation was classified as highly hazardous (class Ib). In addition, more chemical-specific bridging information was required on how the survey applied to the former use of ethion as a veterinary pesticide in Mozambique; how people in Mozambique were exposed to it; and how that related to the information already submitted by Mozambique.

99. In the ensuing discussion, views were expressed as to whether the chemical should be placed on the agenda for the next meeting, or whether further discussion of the chemical should be set aside until additional information was forthcoming from Mozambique. Some members were of the opinion that sufficient information had been presented by Mozambique for the Committee to reach a decision on whether the criterion in paragraph (b) (iii) of Annex II had been met, and that further consideration of that information, and of the guidance in the Handbook on how to apply the criterion in paragraph (b) (iii) in such circumstances, particularly with regard to the distinction between risk assessment and risk evaluation, would enable the Committee to reach a conclusion on the matter. Others expressed the view that the chemical should only be considered if additional information was made available as the currently available information did not enable the Committee to reach a conclusion on the criterion in paragraph (b) (iii) of Annex II.

100. The Chair informed the Committee that, in the absence of consensus on whether all the criteria in Annex II had been met for ethion and whether to set the matter aside until additional information was received, consideration of the chemical would automatically be included in the agenda for the next meeting. The Committee furthermore agreed to request the Secretariat to approach Mozambique to seek the additional information specified in paragraph 98 of the present report.

#### 7. Mercury

101. The Committee had before it four notifications of final regulatory action on mercury from three prior informed consent regions, namely one in the pesticide and industrial categories from the Asia prior informed consent region (Indonesia), two in the industrial category from the Europe prior informed consent region (European Union and Türkiye), and one in the industrial category from the Latin America and the Caribbean prior informed consent region (Colombia) (UNEP/FAO/RC/CRC.19/11), along with the related supporting information (UNEP/FAO/RC/CRC.19/INF/21, UNEP/FAO/RC/CRC.19/INF/22, UNEP/FAO/RC/CRC.19/INF/23 and UNEP/FAO/RC/CRC.19/INF/24). The Committee also had before it a conference room paper containing the report of the intersessional task group that had been established to undertake a preliminary assessment of the notifications, which is reproduced in document UNEP/FAO/RC/CRC.19/INF/31.

102. Victorine Pinas, chair of the intersessional task group, and Christian Bart, the drafter of the group, reported on the outcome of the group's work.

#### (a) Outcomes of the intersessional task groups

#### (i) Notification from Indonesia

103. The intersessional task group had found that the notification of final regulatory action submitted by Indonesia on mercury in the pesticide and industrial categories did not meet the criteria of paragraph (b) of Annex II to the Convention.

104. The task group had therefore concluded that the notification of final regulatory action from Indonesia did not meet all the criteria of Annex II to the Convention.

#### (ii) Notification from the European Union

105. The intersessional task group had found that the notification of final regulatory action submitted by the European Union on mercury in the industrial category met all the criteria of Annex II to the Convention.

#### (iii) Notification from Türkiye

106. The intersessional task group had found that the notification of final regulatory action submitted by Türkiye on mercury in the industrial category did not meet the criteria of paragraph (b) of Annex II to the Convention.

107. The task group had therefore concluded that the notification of final regulatory action from Türkiye did not meet all the criteria of Annex II to the Convention.

#### (iv) Notification from Colombia

108. The intersessional task group had found that the notification of final regulatory action submitted by Colombia on mercury in the industrial category met all the criteria of Annex II to the Convention.

#### (b) Discussion of the notifications

109. In the ensuing discussion, all the members who spoke concurred with the task group's conclusions with respect to the notifications from Indonesia, the European Union, Türkiye and Colombia. One member enquired as to the interlinkages in the implementation of the Rotterdam Convention and the Minamata Convention on Mercury. The Chair responded that those were autonomous conventions and mutually supportive of one another. She added that the obligations of Parties to the Minamata Convention, including those related to import and export, were specified in that Convention, much as the obligations with respect to methyl bromide were specified in the Montreal Protocol on Substances that Deplete the Ozone Layer.

#### (c) Next steps

110. On the basis of the discussion, the Committee agreed that the notifications from the European Union and Colombia met all the criteria of Annex II to the Convention, whereas the notifications from Indonesia and Türkiye met all the criteria of Annex II except the criteria in paragraph (b). It established a contact group, with Ms. Pinas serving as chair and Mr. Bart as drafter, to develop a draft rationale for the Committee's conclusion on the notifications from the European Union and Colombia, based on the notifications received and the comments during the discussion. If necessary, the chair of the contact group could convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the draft rationale.

111. The Committee requested the Secretariat to prepare a draft decision, including a recommendation to list mercury in Annex III to the Convention in the industrial category, and a decision to prepare a draft decision guidance document, as well as a draft workplan for the preparation of the draft decision guidance document.

112. Subsequently, the Committee, having considered the draft rationale prepared by the contact group, adopted decision CRC-19/4, to which the rationale is attached. The decision is set out in annex I to the present report.

113. The Committee agreed that the intersessional drafting group established to prepare the draft decision guidance document for mercury would be chaired by Ms. Pinas, with Mr. Bart as the drafter. The composition of the intersessional drafting group is set out in annex II, and the workplan is set out in annex III.

#### 8. Methidathion

114. The Committee had before it a notification of final regulatory action on methidathion in the pesticide category from the Africa prior informed consent region (Mozambique) (UNEP/FAO/RC/CRC.19/12), along with the related supporting information (UNEP/FAO/RC/CRC.19/INF/25). The Committee had considered the notification from Mozambique at its eighteenth meeting, at which time there were diverging views with regard to whether the notification met the criterion in paragraph (b) (iii) of Annex II to the Convention, and the Committee had deferred further discussion of the matter to its nineteenth meeting.<sup>4</sup> No additional information had since been received from Mozambique with respect to its risk evaluation.

115. During the discussion, some members expressed the view that the notification did not meet the criterion in paragraph (b) (iii) of Annex II, in particular as methidathion had not been among the chemicals shortlisted to be part of the later stages of the survey conducted by Mozambique. Furthermore, one member noted that the risk evaluation survey had been carried out during the period 2010–2013, when the formulation had not been imported into the country. Several other members expressed the view that the criterion in paragraph (b) (iii) had been met based on the available information because the chemical was registered for use in all cropping systems covered by the survey, was classified as close to a highly hazardous pesticide, and could not be used in a safe manner owing to prevailing national conditions, meaning that the level of risk was unacceptable. In addition, one member noted that, despite the lack of recorded imports during the period of the study, the chemical could have been stockpiled or traded informally, while another member, recalling that the Committee had previously concluded that the criterion in paragraph (b) (iii) had been met for terbufos,

<sup>&</sup>lt;sup>4</sup> UNEP/FAO/RC/CRC.18/15, paras. 120-148.

highlighted the many similarities between the information that Mozambique had provided on methidathion and on terbufos.

116. In response to a query from one member, the Secretariat clarified that it had requested additional information from Mozambique but had not received a response to that request. One member, supported by a number of others, underlined the importance of taking into account the difficulties faced by developing countries in providing the information required by the Committee in a suitable format and stated that, in his opinion, Mozambique had provided sufficient information for the criterion in paragraph (b) (iii) to be considered to have been met. Another member also highlighted the importance of considering on a case-by-case basis the chemicals for which notifications had been received from Mozambique.

117. On the basis of the discussion, the Committee assigned an additional mandate to the contact group established under the sub-item on chlorfenvinphos, namely to discuss whether the criterion in paragraph (b) (iii) of Annex II had been met for methidathion and, in the event that it considered that the notification met that criterion, to develop a draft rationale for that conclusion. If necessary, the chair of the contact group could convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the draft rationale.

118. Subsequently, the chair of the contact group reported that the group had been unable to reach agreement and further discussion ensued, as described in paragraphs 54 and 55 of the present report.

119. As members still had different views on whether the notification from Mozambique for methidathion met the criterion in paragraph (b) (iii) of Annex II to the Convention, although they agreed that it met all the other criteria of Annex II, and members also had different views on how to proceed, the Committee noted that it was not possible to complete its consideration of the item regarding methidathion and the notification would therefore automatically be included in the agenda for its twentieth meeting.

120. The Chair urged members to use the time during the intersessional period to familiarize themselves with the supporting documentation submitted by Mozambique and the guidance in the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee on the application of the criterion, and to attend the orientation workshop for new members.

#### 9. Thiodicarb

121. The Committee had before it a notification of final regulatory action on thiodicarb in the pesticide category from the Africa prior informed consent region (Mozambique) (UNEP/FAO/RC/CRC.19/13), along with the related supporting information (UNEP/FAO/RC/CRC.19/INF/26). At its seventeenth meeting, the Committee had concluded that a notification related to thiodicarb in the pesticide category from the Europe prior informed consent region (European Union) met all the criteria set out in Annex II to the Convention (UNEP/FAO/RC/CRC.19/INF/27). The Committee had considered the notification from Mozambique at its eighteenth meeting, at which time there were diverging views with regard to whether the notification met the criterion in paragraph (b) (iii) of Annex II to the Convention, and the Committee had deferred further discussion of the matter to its nineteenth meeting.<sup>5</sup> No additional information had since been received from Mozambique with respect to its risk evaluation.

During the discussion, some members expressed the view that the notification did not meet the 122. criterion in paragraph (b) (iii) of Annex II. One member, thanking the Secretariat for taking the initiative to request additional information from Mozambique, expressed regret that no such information had been received, as bridging information or further details regarding the survey process were necessary for the Committee to be able to reach a conclusion regarding the criterion in paragraph (b) (iii), especially as thiodicarb had not been one of the chemicals shortlisted by Mozambique for the second step of the national project to reduce risks of highly hazardous pesticides. Another member underlined the need for additional information on the exposure component of the risk evaluation, and a third member noted firstly that the survey conducted by Mozambique could not be considered to be a risk evaluation and secondly that thiodicarb had not been imported into Mozambique during the period of the survey, namely 2010–2013. Other members, however, expressed the view that the criterion in paragraph (b) (iii) had been met, as thiodicarb had been used in Mozambique in the cotton cropping system, which was one of the systems considered in the survey, and there was therefore evidence that farmers could not protect themselves sufficiently from the chemical. Several members expressed a desire to continue consideration of the notification in a contact group, with one member noting the

<sup>&</sup>lt;sup>5</sup> UNEP/FAO/RC/CRC.18/15, paras. 222–238.

importance of taking into account the views of developing countries and the ways that those countries could benefit from the prior informed consent procedure.

123. On the basis of the discussion, the Committee assigned an additional mandate to the contact group established under the sub-item on chlorfenvinphos, namely to discuss whether the criterion in paragraph (b) (iii) of Annex II had been met for thiodicarb and, in the event that it considered that the notification met that criterion, to develop a draft rationale for that conclusion. If necessary, the chair of the contact group could convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the draft rationale.

124. Subsequently, the chair of the contact group reported that the group had been unable to reach agreement and further discussion ensued, as described in paragraphs 54 and 55 of the present report.

125. As members still had different views on whether the notification from Mozambique for thiodicarb met the criterion in paragraph (b) (iii) of Annex II to the Convention although they agreed that it met all the other criteria of Annex II, and members also had different views on how to proceed, the Committee noted that it was not possible to complete its consideration of the item regarding thiodicarb and therefore the notification would automatically be included in the agenda for its twentieth meeting. The Chair urged members to use the time during the intersessional period to familiarize themselves with the supporting documentation submitted by Mozambique and the guidance in the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee on the application of the criterion, and to attend the orientation workshop for new members.

# VI. Venue and dates of the twentieth meeting of the Committee

126. The Committee agreed to hold its twentieth meeting at the headquarters of FAO in Rome from 17 to 20 September 2024, back to back with the twentieth meeting of the Persistent Organic Pollutants Review Committee of the Stockholm Convention. The Committee also agreed that the duration of the meeting might be adjusted, in consultation with the Bureau, depending on the number of notifications or proposals to be considered by the Committee at the meeting and the availability of financial resources.

### VII. Other matters

#### A. Revised indicative list of perfluorooctanoic acid substances under Annex III to the Convention

127. Introducing the sub-item, the representative of the Secretariat recalled that the Conference of the Parties, by decision RC-10/7, had amended Annex III to the Rotterdam Convention to include perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds and, by decision RC-10/8, had requested the Secretariat to prepare, in consultation with the Chemical Review Committee, an indicative list of PFOA, its salts and PFOA-related compounds, make it available on the website of the Convention, and update it periodically. A draft indicative list had been prepared by the Secretariat and presented to the Committee at its eighteenth meeting, as set out in document UNEP/FAO/RC/CRC.18/INF/32. She drew attention to the fact that PFOA, its salts and PFOA-related compounds, under a slightly different definition, were also listed in Annex A to the Stockholm Convention had also requested its Secretariat to prepare an indicative list of those substances and, by decision SC-11/8, had invited Parties and observers to submit to the Secretariat information relevant to updating that list. The preparation of the updated indicative list before the Committee, as set out in document UNEP/FAO/RC/CRC.19/INF/29, had therefore been conducted in coordination with the

preparation of the updated indicative list that would be before the Persistent Organic Pollutants Review Committee, as set out in document UNEP/POPS/POPRC.19/INF/16, at its nineteenth meeting.

128. One member, recalling that PFOA, its salts and PFOA-related compounds included more than 300 different chemicals, expressed the view that a set of import and export procedures should be established for the implementation of the requirements of the Convention, and, to that end, she encouraged the Secretariat to continue its work with the World Customs Organization on customs code harmonization in relation to PFOA, its salts and PFOA-related compounds.

129. The Committee took note of the information provided.

# **B.** Report on activities to facilitate effective participation in the work of the Committee

130. Introducing the sub-item, the representative of the Secretariat recalled that, in decision RC-11/2 on the operation of the Chemical Review Committee, the Conference of the Parties had welcomed the activities conducted by the Secretariat for new Committee members, and requested the Secretariat to continue implementing training activities for new and existing members within the framework of the technical assistance plan, subject to the availability of resources, and to consider using various delivery techniques and information channels, such as workshops and online training, reporting on the results to the Conference of the Parties at its twelfth meeting.

131. The Secretariat had conducted a face-to-face orientation workshop from 6 to 8 March 2023, and another such workshop was included in the programme of work of the Rotterdam Convention for the biennium 2024–2025, subject to the availability of funding, and would be open both to the new Committee members starting their terms of office in May 2024 and to existing Committee members.

132. In addition, webinars for all Committee members and observers had been scheduled in order to support effective meeting participation.

133. Furthermore, a range of materials was available to members to familiarize them with the work of the Committee, including the Pocket Guide for Effective Participation in the Chemical Review Committee under the Rotterdam Convention, which was available in the six official languages of the United Nations; the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee, which was available in English; a video on the work of the Committee, which was available in English; a video on the work of the Committee, which was available on the Convention website; recordings of previous training sessions and webinars; and a quiz for self-assessment on knowledge related to the work of the Committee.

134. Finally, the Secretariat was due to hold more workshops that would provide support for Parties with regard to making enhanced science-based decisions, under the activity of the programme of work entitled "From science to action". Such workshops had already been held in Nigeria in 2022 and 2023 for English-speaking countries in the African region, in Spain for the Mediterranean subregion and in Argentina for the Latin American and Caribbean region.

135. In the ensuing discussion, many members expressed their gratitude to the Secretariat for its ongoing efforts in providing technical support and training to members, with several members underlining the importance of the orientation workshops. A number of members suggested that more time should be spent on the simulation exercise relating to notifications of final regulatory action during the orientation workshops, in particular consideration of the interpretation of the criterion in paragraph (b) (iii) of Annex II, with one member suggesting that the recent notifications from Mozambique be used for that purpose.

136. In addition, one member expressed his appreciation of the work carried out by the Secretariat to ensure transparency in and full understanding of the implementation of the Rotterdam Convention among all stakeholders, including members of the Committee, observers and those participating in the meeting of the Conference of the Parties, and underlined the importance of making Parties aware of the benefits for them of implementing the Convention fully.

137. The Committee took note of the information provided.

#### C. Intersessional work on new notifications of final regulatory action

138. The representative of the Secretariat said that, with the publication of PIC Circular LVII in June 2023, a large number of new notifications of final regulatory action had been identified for the Committee's possible consideration at future meetings, meaning that the Committee had considerable work ahead of it, in addition to the substantial number of notifications already received. As a rotation of membership was due to take place on 1 May 2024, it would only be possible to begin intersessional work after 1 May 2024, so as to involve new members in that work. The Secretariat would consult with the Bureau on the plan for and scheduling of the intersessional work and would inform Committee members of the detailed plan in a timely manner.

139. The Committee took note of the information provided.

# VIII. Adoption of the report of the meeting

140. The Committee adopted the report on the basis of the draft that had been circulated during the meeting, as orally amended, and on the understanding that the finalization of the report would be entrusted to the Rapporteur, working in consultation with the Secretariat.

# IX. Closure of the meeting

141. Following the customary exchange of courtesies, the Chair declared the meeting closed at 12.40 p.m. on Friday, 6 October 2023.

# Annex I

# Decisions adopted by the Chemical Review Committee at its eighteenth meeting

CRC-19/1:	Methyl bromide
CRC-19/2:	Paraquat
CRC-19/3:	Chlorpyrifos
CRC-19/4:	Mercury
CRC-19/5:	Bromacil

CRC-19/6: Diarsenic pentaoxide

# CRC-19/1: Methyl bromide

The Chemical Review Committee,

*Recalling* paragraphs 1 and 2 of Article 7 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

*Recalling also* its decision CRC-18/3, adopted at its eighteenth meeting, in which it recommended, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties list methyl bromide in Annex III to the Convention as a pesticide,

*Adopts* the draft decision guidance document for methyl bromide<sup>1</sup> (CAS No. 74-83-9) and decides to forward it, together with the related tabular summary of comments,<sup>2</sup> to the Conference of the Parties for its consideration.

<sup>&</sup>lt;sup>1</sup> UNEP/FAO/RC/CRC.19/3. <sup>2</sup> UNEP/FAO/RC/CRC.19/INF/4.

# CRC-19/2: Paraquat

The Chemical Review Committee,

*Recalling* paragraphs 1 and 2 of Article 7 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

*Recalling also* its decision CRC-18/4, adopted at its eighteenth meeting, in which it recommended, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties list paraquat in Annex III to the Convention as a pesticide,

*Adopts* the draft decision guidance document for paraquat<sup>1</sup> (CAS Nos. 4685-14-7, 1910-42-5, 27041-84-5, 2074-50-2) and decides to forward it, together with the related tabular summary of comments,<sup>2</sup> to the Conference of the Parties for its consideration.

<sup>&</sup>lt;sup>1</sup> UNEP/FAO/RC/CRC.19/4.

<sup>&</sup>lt;sup>2</sup> UNEP/FAO/RC/CRC.19/INF/5.

# **CRC-19/3:** Chlorpyrifos

The Chemical Review Committee,

*Recalling* Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

1. *Concludes* that the notifications of final regulatory action for chlorpyrifos submitted by the European Union, Malaysia and Sri Lanka<sup>1</sup> meet the criteria set out in Annex II to the Convention;

2. *Adopts* the rationale for the Committee's conclusion set out in the annex to the present decision;

3. *Recommends*, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties list chlorpyrifos in Annex III to the Convention as a pesticide;

4. *Decides*, in accordance with paragraph 1 of Article 7 of the Convention, to prepare a draft decision guidance document for chlorpyrifos;

5. *Also decides*, in accordance with the process for drafting decision guidance documents set out in decision RC-2/2 and amended by decision RC-6/3, that the composition of the intersessional drafting group to prepare the draft decision guidance document for chlorpyrifos and the workplan of the group shall be as set out in annexes II and III, respectively, to the report of the Committee on the work of its nineteenth meeting.

<sup>&</sup>lt;sup>1</sup> See UNEP/FAO/RC/CRC.19/8.

Annex to decision CRC-19/3

# Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by the European Union, Malaysia and Sri Lanka in respect of chlorpyrifos in the pesticide category meet the criteria of Annex II to the Rotterdam Convention

1. The notifications on chlorpyrifos from the European Union, Malaysia and Sri Lanka have been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. These notifications underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notifications appeared to meet the requirements of the Convention.

2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in UNEP/FAO/RC/CRC.19/8, UNEP/FAO/RC/CRC.19/INF/15/Rev.2, UNEP/FAO/RC/CRC.19/INF/13 and UNEP/FAO/RC/CRC.19/INF/14. Information on trade was made available in document UNEP/FAO/RC/CRC.19/INF/6.

# I. European Union

### A. Scope of the regulatory action notified by the European Union

3. The regulatory action notified by the European Union relates to chlorpyrifos (CAS No. 2921-88-2) in the pesticide category.

4. The regulatory action is notified as a ban. It is prohibited to place on the market or use plant production products containing chlorpyrifos under Commission implementing regulation (EU) 2020/18 dated 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos, in accordance with regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of the plant products on the market, amending the annex to Commission implementing regulation (EU) No. 540/2011 (*Official Journal of the European Union*, L 7, 13 January 2020, p.14). Disposal, storage, placing on the market and use of existing stocks of plant protection products containing chlorpyrifos are prohibited as of 16 April 2020.

5. The ban on chlorpyrifos was based on the evaluation of the hazards and risk to human health (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4 of the European Union notification).

#### **B.** Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

6. Before the final regulatory action, chlorpyrifos was used as an acaricide and insecticide. The pesticide formulations in the European Union were Pyrinex 250 CS, Pyrinex, EF-1551 EC, RIMI 101 RB, Chlorpyrifos-ethyl 5G GR, SAP250 CS, Dursban, OMS 0971, Lorsban, Brodan, Killmaster, Suscon, Coroban, Terial, Danusban, Durmet, Eradex (UNEP/FAO/RC/CRC.19/8, annex, sect. 1.3 of the European Union notification).

7. In the recitals to the final regulatory action, the following concerns were identified as a result of the chlorpyrifos assessment:

(a) It cannot be excluded that chlorpyrifos has a genotoxic potential;

(b) Consequently, it is not possible to establish health-based reference values for chlorpyrifos or to conduct the relevant consumer and non-dietary risk assessments;

(c) Furthermore, developmental neurotoxicity (DNT) effects were observed in rats and epidemiological evidence exists showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children;

(d) It is appropriate to classify chlorpyrifos as toxic for reproduction, category 1B.

8. Therefore, the Committee concludes that the final regulatory action was taken in order to protect human health; accordingly, the criterion in paragraph (a) of Annex II is met.

### C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

- *(i)* Data have been generated according to scientifically recognized methods;
- *(ii)* Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
- *(iii)* The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action.

9. The overall conclusion of the European Union risk assessment of chlorpyrifos in relation to impacts on human health, based on the information available and the proposed conditions of use, is that the EU approval criteria for active ingredients and plant protection products are not satisfied.

10. The supporting documentation (UNEP/FAO/RC/CRC.19/INF/15/Rev.2) contains the main results of the risk assessment. As a first step, the risk evaluation of the active substance chlorpyrifos was done by a rapporteur member State, taking into account proposed uses and exposure conditions that prevail in the EU. The rapporteur member State then submitted its renewal assessment report (RAR) to the European Food Safety Authority (EFSA). After the commenting period for member States, the applicants and the public, in April 2019, the EFSA convened an expert discussion related to chlorpyrifos impacts to mammalian toxicology and human health. On 31 July 2019, EFSA issued a statement on the outcome of the risk assessment for human health for chlorpyrifos. Concerns were raised with regard to chromosome aberration and DNA damage (oxidative stress and topoisomerase II inhibition), resulting in an unclear genotoxic potential. Consequently, the experts determined that it was not possible to establish health-based reference values for chlorpyrifos or to conduct relevant consumer and non-dietary risk assessments. Therefore, the experts also determined that it cannot be excluded that there is a probability of adverse effects to human health at any level of exposure.

11. The renewal report, which summarizes the results of the evaluation process, concludes that from the assessments made on the basis of the available information (RAR, comments thereon, EFSA statement, applicant comments on the EFSA statement and draft renewal report), no plant protection product containing the active substance chlorpyrifos is expected to satisfy the requirements laid down in article 29(1) of regulation (EC) No. 1107/2009 and the uniform principles laid down in regulation (EU) No. 546/2011.

12. Because the European Union approval criteria related to the effects of chlorpyrifos on human health were not satisfied, the results of other risk assessment components, such as the initial environmental risk assessment, could not alter this conclusion. This is the reason why only concerns for human health are listed as reasons for the final regulatory action.

13. Summarizing the above, the final regulatory action was based on a risk evaluation which identified concerns for human health under the foreseen conditions of use of chlorpyrifos as an active ingredient in pesticides in the European Union.

14. Based on the above, the Committee concludes that the criteria in paragraph (b) (i), (ii) and (iii) of Annex II are met.

15. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole are met.

#### D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit 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;

16. The European Union reported on notified export of chlorpyrifos to 22 countries in 2022 (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.5.1 of the European Union notification).

17. The final regulatory action is a total ban of all uses of chlorpyrifos in plant protection products in the European Union.

18. Consequently, it is expected that the regulatory action will lead to a reduction of risk for human health from use of plant protection products containing chlorpyrifos in the European Union.

- 19. Hence, the Committee concludes that the criterion in paragraph (c) (i) is met.
  - (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;

20. Since the final regulatory action cancelled the registration and banned all applications of chlorpyrifos as a plant protection product, a significant reduction of the health risk can be expected.

- 21. Hence, the Committee concludes that the criterion in paragraph (c) (ii) is met.
  - (*iii*) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

22. The notification stated that the similar human health problems are likely to be encountered in other regions where the chlorpyrifos is used, particularly in developing countries.

- 23. Therefore, the Committee concludes that the criterion in paragraph (c) (iii) is met.
  - (iv) Whether there is evidence of ongoing international trade in the chemical;

24. In response to the Secretariat request to provide information on ongoing international trade in candidate chemicals for nineteenth meeting of the Chemical Review Committee, UNEP/FAO/RC/CRC.19/INF/6 confirmed ongoing international trade in chlorpyrifos. The notification gives information on notified export to 22 countries in 2022.

25. Therefore, the Committee concludes that the criterion in paragraph (c) (iv) is met.

#### E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

26. The notification does not refer to the data of intentional misuses of chlorpyrifos in the European Union.

27. Based on the above point, the Committee concludes that the criterion in paragraph (d) is met.

#### F. Conclusion

28. The Committee concludes that the notification of final regulatory action by the European Union meets the criteria set out in Annex II to the Convention.

# II. Malaysia

#### A. Scope of the regulatory action notified by Malaysia

29. The regulatory action notified by Malaysia relates to chlorpyrifos (CAS No. 2921-88-2) in the pesticide category.

30. The regulatory action is notified as a severe restriction. Based on the circular from the Pesticides Board dated 28 April 2021 informing of the Pesticides Board's decision dated 9 April 2021, the registration of chlorpyrifos pesticides for use in agriculture is cancelled. The regulatory action entered into force on 1 May 2023 (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.2 of the Malaysia notification and UNEP/FAO/RC/CRC.19/INF/13, annex, pp. 4–7).

31. The ban on the use of all types of chlorpyrifos formulations in agriculture in Malaysia as of 1 May 2023 was decided due to the risks of adverse effects to human health, ecology and the environment through agricultural use of chlorpyrifos, as well as food safety risks due to the maximum residue limit (MRL) violations of chlorpyrifos residues in agricultural commodities (UNEP/FAO/RC/CRC.19/8, annex, sect. 3 of the Malaysia notification and UNEP/FAO/RC/CRC.19/INF/13, annex, p.8).

32. Chlorpyrifos may still be used in public health to control urban pests, such as cockroaches, termites, mosquitoes, ants, flies and bugs (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.2 of the Malaysia notification and UNEP/FAO/RC/CRC.19/INF/13, annex, pp. 4–7).

#### **B.** Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

33. Before the final regulatory action, chlorpyrifos was registered as a plant protection product for use to control pests in various types of crops and for use in public health to control urban pests, such as cockroaches, termites, mosquitoes, ants, flies and bugs (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.3 of the Malaysia notification). The pesticide formulations registered in Malaysia were CHEMITOX 75, G-505, STARFOS 505, LORSBAN 40EC, NURELLE-D505 EC, DURSBAN 75+, ECLIPSE 505, PEST-BAN 100, FIGHTER 505, TRICEL 21.2EC, TRICEL 38.7 EC, ZA 505 (UNEP/FAO/RC/CRC.19/8, annex, sect. 1.3 of the Malaysia notification). According to the internal report from the Department of Agriculture's Pesticides Monitoring Program, chlorpyrifos residues consistently exceeded national MRLs in recommended crops, including crops intended for export. In addition, according to data generated by the National Poison Centre Malaysia over a 10-year period (2006–2015), 40 per cent of reported cases of insecticide poisoning involved pesticides from the organophosphate group, with chlorpyrifos being the most commonly reported pesticide. The data from 2016–2019 recorded that 24 per cent of insecticide poisoning cases (1,374 cases) involved chlorpyrifos (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4.1 of the Malaysia notification and UNEP/FAO/RC/CRC.19/INF/13, annex, p. 8).

34. Therefore, the Committee concludes that the final regulatory action was taken in order to protect human health; accordingly, the criterion in paragraph (a) of Annex II is met.

#### C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

- *(i)* Data have been generated according to scientifically recognized methods;
- *(ii)* Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
- (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

35. The notification states that the final regulatory action was based on a risk evaluation to protect human health (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4.1 of the Malaysia notification). The scope of the review considered the assessment of risks for humans and socioeconomic impacts (UNEP/FAO/RC/CRC.19/8, annex, sects. 2.4.2.1 and 2.5.3.1 of the Malaysia notification and UNEP/FAO/RC/CRC.19/INF/13, annex, pp. 4–7). The Pesticides Board reviewed and scrutinized many research information documents and publications related to chlorpyrifos from within and outside the country (UNEP/FAO/RC/CRC.19/INF/13, annex).

36. The following topics were covered by the chlorpyrifos pesticide review:

- (a) Physico-chemical, toxicological and ecotoxicological information;
- (b) Assessment of chlorpyrifos poisoning cases in Malaysia;

(c) Evaluation of the studies conducted by other regulatory bodies such as the European Food Safety Authority (EFSA), the Department of Pesticide Regulation in California, and the United States Environmental Protection Agency;

(d) Evaluation of the study of the exposure of chlorpyrifos among paddy farmers in Malaysia;

- (e) Evaluation of alternative pesticides to chlorpyrifos;
- (f) Impact assessment on the agriculture sector.

37. In the supporting documentation (UNEP/FAO/RC/CRC.19/INF/13), the national and international risk evaluations are presented, including the study conducted by Rozita Hod and others (2011) on the relationship between the chlorpyrifos blood level among paddy farmers in Selangor and exposure symptoms, the assessment of carbofuran and chlorpyrifos by the National Poison Centre Malaysia (unpublished report, 2021), the conclusion on the peer review of the pesticide risk assessment of the active substance chlorpyrifos by EFSA (2011), the Human health risk assessment

(2020) and Ecological risk assessment (2021) of chlorpyrifos by United States Environmental Protection Agency, and the justification of cancellation of chlorpyrifos registrations in California by the California Department of Pesticide Regulation (2020).

38. In a study conducted by Rozita Hod and others (2011), the presence of chlorpyrifos and the pesticides exposure symptoms of paddy farmers in Sabak Bernam, Malaysia were investigated. The study involved 100 respondents and showed that 7 per cent of the respondents had chlorpyrifos in their blood, with a mean value of 7.29 nanograms per millilitre blood (SD 5.84 nanograms per millilitre). The percentage of farmers who experienced at least one pesticide exposure symptom was 75 per cent. The farmers had low scores on safe practice of pesticide use, despite their high scores for knowledge and attitude.

39. Assessment of carbofuran and chlorpyrifos by the National Poison Centre of Malaysia concludes that based on 10 years of data (2006–2015), 40 per cent of reported cases of insecticide poisoning involved pesticides from the organophosphate group, with chlorpyrifos having the highest number of cases. Data on poisoning cases received by the National Poison Centre from 2016 to 2019 showed that chlorpyrifos accounted for 24 per cent of all reported cases of insecticide poisoning (n = 1,374), and contributed more to intentional poisoning cases than unintentional cases. Acute poisoning caused by chlorpyrifos can have severe effects and can lead to long-term neurological disorders. Scientific evidence shows that exposure to chlorpyrifos in pregnant women and children can cause neurotoxic effects that can affect children's growth and development.

40. The EFSA initial statement, dated 31 July 2019, and its updated statement, dated 11 November 2019, confirmed the EFSA conclusions on the peer review of the pesticide risk assessment of the active substance chlorpyrifos (UNEP/FAO/RC/CRC.19/INF/13, annex, p. 592). In Commission implementing regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, in accordance with regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the annex to Commission implementing regulation (EU) No. 540/2011, concerns were identified concerning developmental neurotoxicity (DNT) for which epidemiological evidence exists, showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children. It was concluded that the concerns raised for chlorpyrifos with regard to chromosome aberration and DNA damage (oxidative stress and topoisomerase II inhibition) may apply to chlorpyrifos-methyl, resulting in an unclear genotoxicity potential, developmental neurotoxicity (DNT) effects observed at the lowest dose tested in the DNT study with chlorpyrifos, decreased cerebellum height corrected by brain weight, indicating a health concern, as well as concluding that the epidemiological evidence supports the developmental neurological outcomes in children for both chlorpyrifos and chlorpyrifos-methyl.

41. The California Department of Pesticide Regulation (DPR) evaluated the strengths and uncertainties associated with the use of the available database for deriving critical endpoints for chlorpyrifos. Following the recommendation of the Scientific Review Panel (SRP), DPR thoroughly evaluated developmental neurotoxicity as the critical endpoint for the chlorpyrifos risk assessment. Based on the evaluation of the toxicity database and exposure analyses, this assessment supports the finding that chlorpyrifos meets the criteria to be listed as a toxic air contaminant, pursuant to the law of California.

42. According to the supporting documentation, Malaysia used findings from the international risk assessments and compared these with local conditions of use of chlorpyrifos in plant protection products. Malaysia anticipated that the risks to human health under Malaysian conditions are much higher than in the European Union and California. Malaysia said that the hot and humid conditions in the tropics can make wearing proper protective clothing sometimes impossible, and if the proper protective equipment is available, the cost might be an issue for poor farmers (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4.1 of the Malaysia notification).

43. Summarizing the above, the final regulatory action was based on a risk evaluation, which included health hazard evaluation of chlorpyrifos and the prevailing conditions of the use of pesticides in Malaysia (application doses, methods, protective measures, agricultural practices).

44. Based on the above, the Committee concludes that the criteria in paragraph (b) (i), (ii) and (iii) of Annex II are met.

45. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole are met.

#### D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit 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;

46. Malaysia reported that significant quantities of chlorpyrifos were imported in 2020, while the imported quantities in 2021 were lower (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.5.1 of the Malaysia notification). Consequently, it is expected that the regulatory action will lead to a significant reduction of the quantity of the chemical used.

- 47. Hence, the Committee concludes that the criterion in paragraph (c) (i) is met.
  - (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;

48. Since the final regulatory action cancelled the registration and banned the use of all pesticides containing chlorpyrifos in the agricultural sector, it can be expected that this will reduce poisoning cases and MRL violations, which will represent a significant reduction of the health risk for farmers and consumers.

- 49. Hence, the Committee concludes that the criterion in paragraph (c) (ii) is met.
  - (iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

50. The notification stated that the hot and humid conditions in the tropics can make wearing proper protective clothing impossible, and if the proper protective equipment is available, the cost might be an issue for poor farmers. The same concerns are considered to be relevant for countries with similar conditions, as well as where the farmers use pesticides without protective equipment.

- 51. Therefore, the Committee concludes that the criterion in paragraph (c) (iii) is met.
  - (iv) Whether there is evidence of ongoing international trade in the chemical;

52. In response to the Secretariat request to provide information on ongoing international trade in candidate chemicals for nineteenth meeting of the Chemicals Review Committee, UNEP/FAO/RC/CRC.19/INF/6 confirmed ongoing international trade in chlorpyrifos. The notification gives information on quantities of chlorpyrifos imported in 2020 and 2021.

53. Therefore, the Committee concludes that the criterion in paragraph (c) (iv) is met.

#### E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

54. The Pesticides Board's decision to ban the use of chlorpyrifos pesticides in the agricultural sector was based on concerns over its potential risk to human health, ecology and the environment through agricultural activities, as well as food safety risks due to the high content of pesticide residues in the products. Malaysia noted that chlorpyrifos residues consistently exceeded national residue limits in recommended crops, and dietary risk assessments showed the risk to consumers from long-term exposure to chlorpyrifos residue exceeding legal limits. The National Poison Centre over a 10-year period (2006–2015) recorded that 40 per cent of reported cases of insecticide poisoning involved pesticides from the organophosphate group, with chlorpyrifos being the most commonly reported pesticide. Chlorpyrifos contributed more to intentional poisoning cases than unintentional cases. The notification or supporting documentation mention variable reasons for severely restricting chlorpyrifos such as MRL exceedance and poisoning cases including unintentional poisoning cases. Consequently, intentional misuse was not the sole reason for severely restricting chlorpyrifos.

55. Based on the above point, the Committee concludes that the criterion in paragraph (d) is met.

### F. Conclusion

56. The Committee concludes that the notification of final regulatory action by Malaysia meets the criteria set out in Annex II to the Convention.

# III. Sri Lanka

#### A. Scope of the regulatory action notified by Sri Lanka

57. The regulatory action notified by Sri Lanka relates to chlorpyrifos (CAS No. 2921-88-2) in the pesticide category.

58. The regulatory action is notified as a ban. Sri Lanka, by this action, prohibited all applications of chlorpyrifos pesticides as well as its production, trade and import. The ban was introduced by the decision of the Pesticide Technical & Advisory Committee of Sri Lanka dated 5 April 2013. As a result of the decision, the registration of all products and formulations containing the active ingredient chlorpyrifos was cancelled on 28 December 2016 (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.2. of the Sri Lanka notification). The ban entered into force on 28 December 2016 but dealers and farmers were given a grace period to finish off the old stock of chlorpyrifos products by 28 December 2018.

59. The ban on chlorpyrifos was based on the evaluation of the hazards and risk to human health and to the environment (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4. of the Sri Lanka notification).

#### **B.** Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

60. Before the final regulatory action, the residential indoor use of chlorpyrifos for termite controls was prohibited. However, all uses of chlorpyrifos for agricultural pest control remained allowed. More than 21 trade products containing chlorpyrifos, e.g., Pyrinex, Vltashield, Pyrimac, Pyriban, Lidorban, Unifos 400, Cyren 40, Mackfos (UNEP/FAO/RC/CRC.19/8, annex, sect. 1.3 of the Sri Lanka notification) were used in Sri Lanka.

61. The ban on all use of chlorpyrifos formulations was based on a risk and hazards evaluation related to human health (excessive occupational exposure of farmers and poisoning cases among the farming communities) and to the environment (risks to indigenous fish communities).

62. Therefore, the Committee concludes that the final regulatory action was taken in order to protect human health and the environment; accordingly, the criterion in paragraph (a) of Annex II is met.

#### C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

- *(i)* Data have been generated according to scientifically recognized methods;
- *(ii)* Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
- (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

63. The notification states that the final regulatory action was based on a risk evaluation to protect human health (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4.2.1 of the Sri Lanka notification) and the environment (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4.2.2 of the Sri Lanka notification). The scope of the review considered the assessment of risks relevant to human health and to the environment as well as socioeconomic impacts (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.5.3.1 of the Sri Lanka notification). The final regulatory action was based on review of many research information documents and publications related to chlorpyrifos from within and outside the country (UNEP/FAO/RC/CRC.19/INF/14, annex).

- 64. The following topics were covered by the chlorpyrifos pesticide review:
  - (a) Physico-chemical, toxicological and ecotoxicological information;

(b) Human health assessment conducted by the United States Environmental Protection Agency (EPA);

(c) Evaluation of studies collected by Annals of the Sri Lanka Department of Agriculture;

- (d) Study on use of chlorpyrifos pesticides related to the environment;
- (e) Evaluation of alternative pesticides to chlorpyrifos;
- (f) Impact assessment on the agriculture sector.

65. In the supporting documentation (UNEP/FAO/RC/CRC.19/INF/14), the national and international risk evaluations are presented, including the human health assessment on chlorpyrifos conducted by EPA in 2000 on exposure to chlorpyrifos by children in the USA due to increasing susceptibility of children occurring at high doses in the developmental neurotoxicity study. This study had been used as a basis for Sri Lanka's 2004 decision to ban the use of chlorpyrifos for indoor termite control (UNEP/FAO/RC/CRC.19/8, sect. 2.4.1 of the notification).

66. The study by Aponso and others (2002) on exposure and risk assessment for farmers occupationally exposed to chlorpyrifos in Sri Lanka showed that farmers using chlorpyrifos on cucurbits (grows on trellises = canopies) can be exposed to unnecessarily high levels of chlorpyrifos via dermal exposure. It was revealed that wearing long pants during spraying did not necessarily reduce the exposure. More than 30 per cent of the farmers in the study used more than the officially recommended dose of chlorpyrifos to achieve better pest control. Many of the knapsack spray tanks were old and about 30 per cent were leaking. Many of the workers did not use a head cover despite the fact that the curcurbit crops grow and are sprayed on over-head canopies. Most farmers did not use gloves when mixing concentrated pesticides (UNEP/FAO/RC/CRC.19/INF/14, pp. 197-205). All except three farmers showed a hazard quotient higher than 1, which indicates a risk to the applicator. The margin of safety values were greater than 1 in all cases. It is clear that the amount of compound applied is the deciding factor. However, the use of sound equipment and long-sleeved shirts can reduce exposure by 6-10 per cent. The farmers received an occupational dose higher than the reference dose (RfD) for chlorpyrifos, but it was below the no-observed-effect level (NOEL) (UNEP/FAO/RC/CRC.19/INF/14, pp. 225 and 227). Although the study concludes that under conditions of this worst-case scenario, farmers experience a minimal risk despite taking limited precautions, this might be due to the fact that in this study only small areas were sprayed (UNEP/FAO/RC/CRC.19/INF/14, p. 293). The study was interpreted by the notifying country to indicate the high occupational risk of chlorpyrifos to the farmers under use conditions in Sri Lanka.

67. The study by Aponso and others (2003) on "Analysis of water for pesticides in two major agricultural areas of the dry zone" showed that in the Polonnaruwa and Dambulla areas of Sri Lanka 83 per cent of the farming community was reported to have clinical symptoms related to acute toxicity, but 21 per cent of the group surveyed had confirmed effects related to pesticide exposure. It was stated that pesticides usage statistics in Sri Lanka indicate that about 60 per cent of total insecticides were organophosporus pesticides – major organophosporus pesticides used in agriculture are chlorpyrifos 40 per cent emulsifiable concentrate. The study concludes that farmers take minimal precautions when handling pesticides and 70 per cent do not apply the recommended dosage. It also reports that unwarranted practices such as washing spray equipment in streams and disposal of empty containers close to water bodies would have a high potential to contaminate internal water bodies such as water wells and small water reservoirs. Furthermore, it concludes that there are strong indications of acute pesticide poisoning potential among the farmers. (UNEP/FAO/RC/CRC.19/INF/14, p. 320).

68. The results of the study by Sumith and others (2012) on potential impact of agricultural pesticides on widely distributed fishes (Teleostei, family: Cyprinidae) in agricultural areas in Sri Lanka showed that chlorpyrifos, diazinon and carbosulfan had the greatest number of agricultural applications and identified as dominant pollutants. The study revealed dynamic impact of agricultural pollutants (including chlorpyrifos) on indigenous fish communities and their existence. Stringent pesticide management options and good agricultural practices are recommended to protect fish in agricultural catchments in Sri Lanka (UNEP/FAO/RC/CRC.19/INF/14, p. 336).

69. According to the supporting documentation, the list of chemical alternatives was considered sufficient for all uses of chlorpyrifos (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.5.3.2 of the Sri Lanka notification). Integrated pest management has been practised as government policy over the years in Sri Lanka.

70. Summarizing the above, the final regulatory action was based on an evaluation of risks to human health and to the environment, taking into account the prevailing conditions of the use of pesticides, especially chlorpyrifos, in Sri Lanka (application doses, methods, protective measures, agricultural practices).

71. The notification (sect. 2.5.3.3) refers to the study of Eddleston and others (2005) on self-poisonings with organophosphorous pesticides, including chlorpyrifos, in Sri Lanka, as an additional basis for the final regulatory action, other than a hazard or risk evaluation.

72. Based on the above, the Committee concludes that the criteria in paragraph (b) (i), (ii) and (iii) of Annex II are met.

73. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole are met.

#### D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit 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;

74. Sri Lanka reported on reducing the import of chlorpyrifos during the period 2011–2013 (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.5.1 of the Sri Lanka notification). Consequently, it is expected that the regulatory action will lead to zero exposure, as no quantity of chlorpyrifos could be used in the country.

- 75. Hence, the Committee concludes that the criterion in paragraph (c) (i) is met.
  - (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;

76. Since the final regulatory action cancelled the registration and banned the use of chlorpyrifos, a significant reduction of the health risk and chemical burden to the environment can be expected.

- 77. Hence, the Committee concludes that the criterion in paragraph (c) (ii) is met.
  - (iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

78. The notification stated that similar human health and environmental risks associated with the use of chlorpyrifos are anticipated in other states and regions, in particular under similar cultural and agro-climatic conditions in developing countries.

- 79. Therefore, the Committee concludes that the criterion in paragraph (c) (iii) is met.
  - *(iv)* Whether there is evidence of ongoing international trade in the chemical;

80. In response to the Secretariat request to provide information on ongoing international trade in candidate chemicals for nineteenth meeting of the Chemicals Review Committee, UNEP/FAO/RC/CRC.19/INF/6 confirmed ongoing international trade in chlorpyrifos. The notification gives information on quantities of chlorpyrifos imported in 2011, 2012 and 2013.

81. Therefore, the Committee concludes that the criterion in paragraph (c) (iv) is met.

#### E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

82. The notification refers to the studies on the misuse of chlorpyrifos formulations for suicide. However, since the risk evaluation was based on many other considerations, intentional misuse was only one of several aspects considered before taking the final regulatory action. The studies were not reported in the notification form in the sections concerning the risk or hazard evaluation. They are mentioned in the section which cites them as an additional basis for the final regulatory action, other than a hazard or risk evaluation.

83. In addition, in the CRC Working Paper on the Application of Criterion (d) of Annex II, the United Nations legal opinion states that criterion (d) only takes effect if not all Annex II criteria (a) to (c) are met. Only if intentional misuse is the sole reason for the final regulatory action might it be considered that there is no adequate reason for listing the chemical in Annex III.

84. Based on the above point, the Committee concludes that the criterion in paragraph (d) is met.

#### F. Conclusion

85. The Committee concludes that the notification of final regulatory action by Sri Lanka meets the criteria set out in Annex II to the Convention.

# III. Conclusion

86. The Committee concludes that the notifications of final regulatory action from the European Union, Malaysia and Sri Lanka meet all the criteria set out in Annex II to the Convention.

# CRC-19/4: Mercury

The Chemical Review Committee,

*Recalling* Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

1. *Concludes* that the notifications of final regulatory action for mercury submitted by Colombia and the European Union<sup>1</sup> meet the criteria set out in Annex II to the Convention;

2. *Adopts* the rationale for the Committee's conclusion set out in the annex to the present decision;

3. *Recommends*, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties list mercury in Annex III to the Convention as an industrial chemical;

4. *Decides*, in accordance with paragraph 1 of Article 7 of the Convention, to prepare a draft decision guidance document for mercury;

5. *Also decides*, in accordance with the process for drafting decision guidance documents set out in decision RC-2/2 and amended by decision RC-6/3, that the composition of the intersessional drafting group to prepare the draft decision guidance document for mercury and the workplan of the group shall be as set out in annexes II and III, respectively, to the report of the Committee on the work of its nineteenth meeting.

<sup>&</sup>lt;sup>1</sup> See UNEP/FAO/RC/CRC.19/11.

#### Annex to decision CRC-19/4

# Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by Colombia and the European Union in respect of mercury in the industrial category meet the criteria of Annex II to the Rotterdam Convention

1. The notifications on mercury from Colombia and the European Union have been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. These notifications underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notifications appeared to meet the requirements of the Convention.

2. The notifications and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.19/11 and UNEP/FAO/RC/CRC.19/INF/22 and UNEP/FAO/RC/CRC.19/INF/24. Information on trade was made available in document UNEP/FAO/RC/CRC.19/INF/6.

# I. Colombia

#### A. Scope of the regulatory action notified by Colombia

3. The regulatory action notified by Colombia relates to mercury (CAS No. 7439-97-6) in the industrial category.

4. The regulatory action is notified as a ban.

5. Based on Law 1658 of 15 July 2013, the government of Colombia prohibited the marketing and use of mercury. The regulation eradicates the use of mercury in the national territory in: (1) all industrial and production processes within a period not exceeding 10 years (till 15 July 2023), and (2) for mining within a maximum period of five years (till 15 July 2018). Currently the deadline for industrial uses other than mining has not been met; this is the reason why the use of mercury in the production of dental amalgam will continue until 15 July 2023.

#### **B.** Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

6. The government of Colombia prohibited the marketing and use of mercury under Law 1658 of 15 July 2013. It was determined that in order to protect and safeguard the human health and preserve renewable natural resources and the environment, the use, import, production, marketing, handling, transportation, storage, final disposal and release into the environment of mercury in industrial activities, whatever they may be, must be regulated throughout the national territory.

7. Specifically, Article 3 of the law establishes the measures to reduce and eliminate the use of mercury in the country as follows: "Article 3. Reduction and elimination of the use of mercury. The Ministries of Environment and Sustainable Development; Mines and Energy; Health and Social Protection and Work, will establish the necessary regulatory measures that will allow to reduce and eliminate, in a safe and sustainable way, the use of mercury in the different industrial activities of the country. Eradicate the use of mercury throughout the national territory, in all industrial and productive processes within a period not exceeding ten (10) years and for mining within a maximum period of five (5) years ...".

8. Therefore, the Committee concludes that the final regulatory action was taken in order to protect human health and the environment; accordingly, the criterion in paragraph (a) of Annex II is met.

#### C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the

conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

- *(i)* Data have been generated according to scientifically recognized methods;
- *(ii)* Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
- (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

9. The risk evaluation on human health and the environment conducted by Colombia is presented in section 2.4.1 of the notification and provides evidence for unacceptable level of risk for the human health and the environment from the use of mercury. The notification and its supporting documents in UNEP/FAO/RC/CRC.19/INF/24 include several human health and environmental studies/investigations/measurements, as well as relevant evaluations that have been carried out in different regions of Colombia over a period of 20 years (1991–2011), notably:

(a) Mercury report. Eng. Manuel Salgado Alba, Reference intoxication by Heavy Metals, Environmental Risk Factors, National Institute of Health. UNEP/FAO/RC/CRC.19/INF/24, annex, document 2, p. 12;

(b) Protocol for Surveillance and Control of Acute Mercury Poisoning, September 25 2010. National Institute of Health. UNEP/FAO/RC/CRC.19/INF/24, annex, document 3, p. 21;

(c) Scientific, Regulatory and Technical Evidence on the Mercury Problem at the Level National and International Health Sector and Other Related Sectors. Revision Systematics of Literature. October 2012. Association agreement no. 447 of 2012 signed between the Ministry of Health and Social Protection and the Foundation for Education and Social development. UNEP/FAO/RC/CRC.19/INF/24, annex, document 4, p. 50;

(d) Quantification of Anthropogenic Releases of Mercury in Colombia: calculations and quantifications for the year 2009. Version 1.0. Ministry of Environment, Housing and Development Territory, Columbia. University of Antioquia, Diagnosis and Control Group of Pollution. December 2010. UNEP/FAO/RC/CRC.19/INF/24, annex, document 5, p. 197;

(e) National Diagnosis of Environmental Health. Ministry of Environment and Sustainable Development, Colombia. December 2012. UNEP/FAO/RC/CRC.19/INF/24, annex, document 6, p. 280.

10. The information obtained in these studies and evaluations was taken into account in the discussions held in the Congress of the Republic of Colombia for the development of Law 1658 of 2013. The reference to part of this information is evidenced in the congressional gazettes mentioned below:

(a) Congress Gazette no. 156 of 2011. UNEP/FAO/RC/CRC.19/INF/24, annex, document 7;

(b) Congress Gazette no. 473 of 2012. UNEP/FAO/RC/CRC.19/INF/24, annex, document 8;

(c) Congress Gazette no. 937 of 2012. UNEP/FAO/RC/CRC.19/INF/24, annex, document 9;

(d) Congress Gazette no. 613 of 2013. UNEP/FAO/RC/CRC.19/INF/24, annex, document 10;

(e) Congress Gazette no. 430 of 2013. UNEP/FAO/RC/CRC.19/INF/24, annex, document 11.

11. The data includes extensive neuro-epidemiological studies in exposed populations (occupational and general) and studies in different environmental compartments (freshwater, soil, sediment, biota, etc.), as well as food (fish), with a view to establishing the levels of mercury and the perception of risk, and generating scientific, regulatory and technical evidence on the mercury problem both at the national and international levels of the health sector and other related sectors. Mercury measurements have been made in humans, mainly in workers and communities surrounding mining activities or adjacent to riverine areas.

12. The evaluation conducted established that mercury is a toxic substance, that when entering the human body produces disorders, mainly at the central nervous system level. The presence of mercury in the air, water, soil and food (mainly fish) in concentrations above the allowed limit has caused a

serious public health problem in Colombia. Regions such as the northeast of Antioquia, the south of Bolívar, Chocó, Santander, Nariño, Caldas and Vaupés, among others, carry out artisanal gold mining and mercury is used for the final extraction of this precious metal. Its use occurs in an indiscriminate and poorly controlled way, a situation that has caused environmental contamination and has affected people's health. Exposure to mercury is also increased in industrial areas that use this substance (Protocol for Surveillance and Control of Acute Mercury Poisoning, UNEP/FAO/RC/CRC.19/INF/24, annex, document 3).

13. Studies conducted by the government of Antioquia in the municipalities of Segovia and Remedios, in the northeast of the department, found a concentration of mercury of approximately  $340 \ \mu g/m^3$  in the air (300 times higher than the World Health Organization guidelines for public maximum exposure to mercury vapour). Approximately 26 to 6,118 ppm of Hg is discharged into rivers by miners in the region. Additionally, the main food of these communities is fish, which has been shown to be affected by the emission of mercury. Studies completed by Corantioquia, the University of Antioquia, and the University of Cartagena have revealed a concentration above 1.06  $\mu$ g Hg/g in most of the species found in the rivers of the surrounding area (Congress Gazette no. 156 of 2011, UNEP/FAO/RC/CRC.19/INF/24, annex, document 7).

14. Mercury contamination in Colombia originated from the gold exploitation processes in which the mineral containing the precious metal is extracted by joining it with mercury to form an amalgam. During the process, mercury spills into water bodies and the environment. Subsequently, the amalgam obtained is burned in the open air, leaving the gold and releasing the toxic mercury vapours into the atmosphere. All these activities are performed very close to miners' households, in such a way that families breathe a large part of the volatilized mercury vapour. Even remote populations can be affected by the mobilization of this substance (Protocol for Surveillance and Control of Acute Mercury Poisoning, UNEP/FAO/RC/CRC.19/INF/24, annex, document 3).

15. Studies carried out in populations (occupational and general) exposed to mercury have made it possible to establish its relationship to the development of the observed manifestations (Fawer and others, 1983; Piikivi, 1989; Marh and others, 1987). The neuroepidemiological and toxicological study of the Suratá river pollutants carried out in the mining population of that region (Santander, 1992) raised the possible relationship between chronic exposure to mercury and the presence of neurological diseases. Tirado and others (2000) suggest that this form of exposure can cause neuropsychological and behavioural deficits in the population. In 1995, Olivero and others reported that the inhabitants of southern Bolívar presented signs of mercury intoxication such as hand tremors, neurological disorders and visual problems, among others. In this region, frequent cases of congenital malformations have also been reported, although without evidence of association with mercury exposure (Protocol for Surveillance and Control of Acute Mercury Poisoning, UNEP/FAO/RC/CRC.19/INF/24, annex III).

16. According to the National Public Health Surveillance System (SIVIGILA), during 2010 and in the first half of 2011, 201 cases of mercury poisoning were reported in Colombia, and 96 per cent of the cases were of occupational or accidental origin, as follows: 85 per cent (n = 171) occupational, 11 per cent (n = 22) accidental (Mercury Report, UNEP/FAO/RC/CRC.19/INF/24, annex, document 2).

17. Occupational exposure is most frequent in the reported cases, with mining and quarrying occupations associated with the highest number of cases, given the use of mercury as an input for gold mining. The most significant conclusions indicate that the most frequent notifiers during the period were Antioquia, followed by Bogotá, Bolívar, Risaralda, Santander and Valle del Cauca. The highest percentage of intoxications reported were occupational, with respiratory the most frequent route of exposure and, according to the analysis by occupation, the highest number of intoxicated were miners or stonemasons (Scientific, Regulatory and Technical Evidence on the Mercury Problem at the Level National and International Health Sector and Other Related Sectors. Revision Systematics of Literature, UNEP/FAO/RC/CRC.19/INF/24, annex, document 4).

18. It was identified that some population groups deserve special attention in relation to exposure to mercury, since they have a greater probability of exposure to dangerous levels, or because as carriers of disease, the intoxication effects can be exacerbated:

- (a) Workers exposed to mercury;
- (b) General population next to sources of mercury contamination (mines, industries);

(c) Populations in areas contaminated by mercury, especially indigenous and riverine, whose main source of proteins is fish;

(d) People using mercury-containing medications for a long time;

(e) People with central nervous system diseases, patients with chronic kidney and broncopulmonary failure;

(f) Pregnant women and toddlers

(Scientific, Regulatory and Technical Evidence on the Mercury Problem at the Level National and International Health Sector and Other Related Sectors. Revision Systematics of Literature, UNEP/FAO/RC/CRC.19/INF/24, annex, document 4).

19. The Committee confirms that the criteria in paragraphs (b) (i), (ii) and (iii) of Annex II are met.

20. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole are met.

#### D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit 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;

21. Prior to the final regulatory action, mercury was used in mining, chlor-alkali industry, production of energy-saving lamps and manufacture of dental amalgams (UNEP/FAO/RC/CRC.19/11, annex, sect. 2.3.1 of the Colombia notification). The final regulatory action prohibited the use of mercury in mining activities on 15 July 2018, and will prohibit all other industrial activities except the manufacture of dental amalgams on 15 July 2023. Therefore, the final regulatory action is expected to lead to a significant decrease in the quantity of the chemical used and the number of its uses in Colombia.

- 22. Hence, the Committee concludes that the criterion in paragraph (c) (i) is met.
  - (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;

23. According to sections 2.4.2.1 and 2.4.2.2 of the Colombia notification, it is expected that the regulatory action taken by Colombia would reduce occupation and environmental exposure to mercury in humans and reduce the anthropogenic releases and emissions of mercury to the environment.

24. Since Colombia's final regulatory action prohibits the use of mercury in all industrial and production processes (till 15 July 2023), and for mining (till 15 July 2018), it is expected that it will result in a significant reduction of risk for human health and the environment since these uses were reported to occur in Colombia prior to the final regulatory action, and evidence provided suggested that they presented an unacceptable level of risk for the human health and the environment.

- 25. Hence, the Committee concludes that the criterion in paragraph (c) (ii) is met.
  - (iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

26. Section 2.5.2 of the notification states that mercury can be used in other countries for the manufacture of products with added mercury and in gold extraction, mainly in countries in development; therefore, the considerations leading to the final regulatory action being taken are expected to be applicable to other geographical areas where mercury is used in similar conditions.

- 27. Therefore, the Committee concludes that the criterion in paragraph (c) (iii) is met.
  - *(iv)* Whether there is evidence of ongoing international trade in the chemical;

28. According to section 2.5.1 of the notification, Colombia reported imported quantities of mercury between 2006 and 2013, as well imports of 3.5 metric tons for 2020, which is the quota allowed under Decree 1041 of 2018 for exclusive use in the manufacture of dental amalgam. This suggests ongoing international trade of mercury, since Colombia's exemption for the manufacture of dental amalgam is in place until 15 July 2023.

29. Therefore, the Committee concludes that the criterion in paragraph (c) (iv) is met.

#### E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

30. There is no indication in the notification that consideration related to intentional misuse prompted the final regulatory action.

31. Therefore, the Committee concludes that the criterion in paragraph (d) is met.

#### F. Conclusion

32. The Committee concludes that the notification of final regulatory action by Colombia meets the criteria set out in Annex II to the Convention.

#### II. European Union

#### A. Scope of the regulatory action notified by the European Union

33. The regulatory action notified by the European Union relates to mercury (CAS No. 7439-97-6) in the industrial category.

34. The use of mercury as an industrial chemical is severely restricted in the European Union pursuant to regulation (EU) 2017/852 on mercury, regulation (EC) 1907/2006 (REACH), directive 2011/65/EU (RoHS) and directive 2006/66/EC (batteries and accumulators). More specifically:

(a) In 2006, directive 2006/66/EC introduced a prohibition on the placing on the market of batteries and accumulators containing mercury;

(b) In 2007, directive 2007/51/EC introduced a restriction under directive 76/769/EEC on the placing on the market of mercury in fever thermometers and in other measuring devices intended for sale to the general public;

(c) Regulation (EC) No. 1907/2006 (REACH) repealed directive 76/769/EEC. Commission regulation (EC) No. 552/2009 amended annex XVII to REACH by incorporating in entry 18.a the restrictions on certain measuring devices containing mercury that was adopted under directive 2007/51/EC;

(d) In 2011, directive 2011/65/EU (RoHS) established a restriction on the placing on the market of electric and electronic equipment to a maximum concentration value of 0.1 per cent of mercury, allowing exemptions for certain applications for a limited time period;

(e) Commission regulation (EU) No. 847/2012 amended annex XVII to REACH by incorporating in entry 18.a a restriction on the placing on the market of mercury-containing and mercury-using measuring devices intended for industrial and professional uses. The restriction started to apply from 10 April 2014;

(f) Regulation (EU) 2017/852 on mercury was adopted in May 2017. This regulation complements the European Union acquis and lays down the provisions that are needed to ensure the complete alignment of the European Union acquis with the Minamata Convention on Mercury establishing measures and conditions concerning the use and storage of and trade in mercury, mercury compounds and mixtures of mercury, and the manufacture and use of and trade in mercury-added products, and the management of mercury waste.

#### B. Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

35. Sections 2.4.2.1 and 2.4.2.2 of the notification state that the final regulatory action has been taken in order to protect human health and the environment and further explain that mercury is a chemical of global concern owing to its long-range atmospheric transport, its persistence in the environment once anthropogenically introduced, its ability to bioaccumulate in ecosystems and its significant negative effects on the environment and on human health, which include significant adverse neurological and other health effects, with particular concerns expressed about its harmful effects on infants and unborn children. Mercury can be transformed to methylmercury, the most toxic form, which biomagnifies especially in the aquatic food chain, making populations and wildlife with a high intake of fish and seafood particularly vulnerable.

36. Therefore, the Committee concludes that the final regulatory action was taken in order to protect human health and the environment; accordingly, the criterion in paragraph (a) of Annex II is met.

#### C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

- *(i)* Data have been generated according to scientifically recognized methods;
- *(ii)* Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
- (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

37. According to section 2.4.1 of the notification, a risk assessment was conducted in the European Union in the context of the restriction under REACH on mercury-containing measuring devices intended for industrial and professional uses. The following documents supporting this risk assessment are provided in UNEP/FAO/RC/CRC.19/INF/22:

(a) Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC). "Opinion on an Annex XV dossier proposing restrictions on mercury in measuring devices. ECHA/RAC/RES-O-0000001363-81-02/F". ECHA/SEAC/ RES-O-0000001363-81-03/F. Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted on 8 June 2011) and SEAC's opinion (adopted on 15 September 2011) European Chemicals Agency;

(b) Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC). "Background document to the opinions on the Annex XV dossier proposing restrictions on mercury in measuring devices". ECHA/RAC/RES-O-0000001363-81-02/F. ECHA/SEAC/RES-O-0000001363-81-03/S1. 15 September 2011. European Chemicals Agency.

38. While this risk assessment was conducted in the context of the restriction on mercury-containing measuring devices intended for industrial and professional uses, it includes information on the risks associated with mercury that is not limited to those measuring devices and that could support the other directives and regulations that comprise the final regulatory action notified by the European Union.

39. According to the RAC opinion and its background document, mercury and its compounds are highly toxic to humans, ecosystems and wildlife, with amongst others serious chronic irreversible adverse neurotoxic and neurodevelopmental effects. The RAC opinion includes a persistent, bioaccumulative and toxic (PBT) assessment for mercury-methylmercury concluding that there is an equivalent level of concern in terms of persistency, due to mercury cycling and methylation versus demethylation rates under anaerobic conditions, as well as the clear potential for bioaccumulation and toxicity identified for methylmercury (UNEP/FAO/RC/CRC.19/INF/22, p. 31).

40. The hazard and fate of mercury and its compounds are described in numerous peer-reviewed reports, which were referenced in the Background Document (UNEP/FAO/RC/CRC.19/INF/22, p. 42):

(a) United Nations Environment Programme, *Global Mercury Assessment* (2002; see also UNEP, 2008a and b);

(b) United Nations Environment Programme, World Health Organization, & International Labour Organization, *Methylmercury - Environmental Health Criteria 101* (1990);

(c) Risk and Policy Analysts Limited, "Risks to Health and the Environment Related to the Use of Mercury Products", prepared for the European Commission (Norfolk: 2002).

41. It is estimated that 3.5–7.6 tons of mercury are placed on the market in mercury-containing measuring devices in 2010. These amounts are used to estimate the maximum potential for mercury emissions to the environment that might ultimately occur. This assumption is considered appropriate because of an estimated low separate collection rate of mercury waste and resulting inadequate waste treatment of a substantial part of the devices. This inappropriate waste collection leads in the long term to a relatively high share of mercury used in these devices being released to the environment. For measuring equipment using mercury (porosimeters, mercury probes used for capacitance-voltage

determinations and mercury electrodes used in voltammeters) the total use is 5–15 metric tons per year (mostly porosimeters: 5–14 metric tons per year). It should be noted that these figures are the amount of mercury the laboratories purchase and cannot be used to estimate maximum potential for emission, as is the case for the measuring equipment containing mercury. To estimate emissions several additional factors need to be considered. These include number of measurements carried out, practices to purify and regenerate used mercury and the risk management measures and operational conditions applied to control the emissions and exposures (UNEP/FAO/RC/CRC.19/INF/22, p. 10).

42. The total mercury consumption in Europe was in 2007 estimated to be 320–530 metric tons: 160–190 metric tons of the total amount were used in chlor-alkali production and 90–110 were used in dental amalgams. The amount used in mercury measuring devices thus equals about 4 per cent of the total, while the restricted devices will be lower due to the large use in porosimeters (UNEP/FAO/RC/CRC.19/INF/22, p. 10).

43. Once released to the environment, mercury persists in the environment, where it circulates between air, water, sediments, soil and biota in various forms. Mercury can be transformed to methylmercury, the most toxic form, which biomagnifies, especially in the aquatic food chain, making populations and wildlife with a high intake of fish and seafood particularly vulnerable (UNEP/FAO/RC/CRC.19/INF/22, p. 32).

44. Several existing pieces of legislation in the European Union abate the risks arising from mercury in different stages of the life cycle of measuring devices. However, none of the measures currently in place is sufficient to remove the concern fully, although there is a difference between their observed effectiveness with regard to measuring devices containing mercury and measuring devices using mercury (UNEP/FAO/RC/CRC.19/INF/22, p. 32).

45. The emissions from mercury measuring devices, although relatively small, contribute to the overall emissions of mercury to the environment and thereby also to the exposure of species and of humans via the environment. Therefore, measuring devices containing or using mercury are of concern (UNEP/FAO/RC/CRC.19/INF/22, p.32).

46. The Committee confirms that the criteria in paragraphs (b) (i), (ii) and (iii) of Annex II are met.

47. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole are met.

#### D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit 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;

48. The European Union notification includes several directives and regulations that apply to mercury. It is expected that these measures would lead to a significant decrease in the quantity of the chemical used and the number of its uses.

- 49. Hence, the Committee concludes that the criterion in paragraph (c) (i) is met.
  - (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;

50. The final regulatory action notified by the European Union severely restricts the industrial use of mercury in several sectors through different directives and regulations. It is expected that these measures would result in a significant reduction of risk for human health and the environment in the European Union.

- 51. Hence, the Committee concludes that the criterion in paragraph (c) (ii) is met.
  - (iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

52. Section 2.5.2 of the notification states that similar human health and environmental problems are likely to be encountered in other regions where the substance is used, particularly in developing countries and especially for women and children, and, through them, future generations.

53. Therefore, the Committee concludes that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

54. According to section 2.3.2 of the notification, certain uses of mercury remain allowed in the European Union, which suggests that international trade of this chemical may be ongoing.

55. Therefore, the Committee concludes that the criterion in paragraph (c) (iv) is met.

#### E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

56. There is no indication in the notification that consideration related to intentional misuse prompted the final regulatory action.

57. Therefore, the Committee concludes that the criterion in paragraph (d) is met.

#### F. Conclusion

58. The Committee concludes that the notification of final regulatory action by the European Union meets the criteria set out in Annex II to the Convention.

#### III. Conclusion

59. The Committee concludes that notifications of final regulatory action submitted by Colombia and the European Union fulfil the criteria set out in Annex II to the Convention.

### CRC-19/5: Bromacil

The Chemical Review Committee,

*Recalling* Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

1. *Concludes* that the notification of final regulatory action for bromacil submitted by Costa Rica<sup>1</sup> meets the criteria set out in Annex II to the Convention;

2. *Adopts* the rationale for the Committee's conclusion set out in the annex to the present decision;

3. *Notes* that, as only a notification of final regulatory action from one prior informed consent region in respect of bromacil meets the criteria set out in Annex II to the Convention, it will take no further action on the chemical at present.

<sup>&</sup>lt;sup>1</sup> See UNEP/FAO/RC/CRC.19/5.

#### Annex to decision CRC-19/5

## Rationale for the conclusion by the Chemical Review Committee that the notification of final regulatory action submitted by Costa Rica in respect of bromacil in the pesticide category meets the criteria of Annex II to the Rotterdam Convention

1. The notification on bromacil from Costa Rica has been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. This notification underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notification appeared to meet the requirements of the Convention.

2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.19/5 and UNEP/FAO/RC/CRC.19/INF/9. Information on trade was made available in document UNEP/FAO/RC/CRC.19/INF/6.

#### A. Scope of the regulatory action notified by Costa Rica

3. The regulatory action notified by Costa Rica relates to bromacil (CAS No. 314-40-9) in the pesticide category. Based on Executive Decree No. 40423-MAG-MINAE-S, Costa Rica prohibited the registration, import, export, manufacture, formulation, storage, distribution, transport, repackaging, handling, sale, mixing and use of technical grade active ingredients and formulated synthetic pesticides containing the active ingredient 5-bromo-3-sec-butyl-6-methyluracil (common name: bromacil), and its lithium salt. Imports of the active ingredient bromacil and formulated pesticides were prohibited from 5 May 2017. Six months after this date, the export, manufacture, formulation, storage, distribution, transportation, repackaging, handling, sale, mixing and use of the technical grade and formulated synthetic pesticides that contain bromacil and its lithium salt were also prohibited. The final regulatory action was taken for the pesticide category. All formulations containing bromacil active ingredient, as well as all uses in Costa Rica, are banned. There are no uses that remain allowed. Date of entry into force of the final regulatory action: 5 June 2017.

#### **B.** Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

4. Section 2.2.1 of the notification states that the executive decree prohibits the use of bromacil in the national territory based on the high risk of contaminating groundwater, aquifers and humans. This section draws a timeline of the final regulatory action. There is a first prohibition in 2008 for the use of bromacil in certain farms. In 2014, bromacil could be found in the same area in aquifers, which showed persistency. In 2015, an institutional commission composed by the Ministry of Health, the Ministry of Agriculture and the Ministry of Environment created the Single Plan to gradually eliminate bromacil in order to prevent aquifers in vulnerability regions to be contaminated. The final regulatory action entered into force in 2017 and was a coordinated effort of the three authorities and, thus, the notification contains elements relating to human health and environment.

5. Furthermore, the referenced document in section 2.2.2 and submitted with the supporting documentation, Executive Decree No. 40423-MAG-MINAE-S, states in paragraph XV that for the benefit and protection of the health of citizens, the State must regulate chemicals or related substances for agricultural use so that they are handled correctly and reasonably and do not create risks to human health and the environment. Consequently, it is necessary to prohibit the use of bromacil and its lithium salt.

6. Section 2.4.2.2 of the notification states that the final regulatory action is relevant to the environment and gives a summary of the risk evaluation. Section 2.4.2.1, on the other hand, states that although the levels of bromacil in freshwater raised a health concern, no health risk assessment was conducted. The notification states that the reason for the regulatory action was not relevant to human health.

7. Therefore, the Committee concludes that the final regulatory action was taken in order to protect the environment; accordingly, the criterion in paragraph (a) of Annex II is met.

#### C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

- *(i)* Data have been generated according to scientifically recognized methods;
- *(ii)* Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
- *(iii)* The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action.

8. Although a health risk assessment was not carried out for the final regulatory action, the levels of bromacil in drinking water generated a health concern. Since 2014, the presence of bromacil was detected in water whose concentrations exceeded the level established in Executive Decree 38924-S "Regulation for the Quality of Potable Water and its reforms", which is why it was considered as a potential risk to human health. The different State institutions generated several actions. For example, there was a suspension of the consumption of water from the contaminated aqueducts, as this water could not be used for the preparation of meals or direct intake. To solve this situation, drinking water was supplied with cisterns.

9. The groundwater ubiquity score (GUS) is an experimentally calculated value that relates pesticide half-life and Koc (mobility) (from laboratory data). The GUS may be used to rank pesticides for their potential to move toward groundwater. Although it is not a risk assessment, GUS is a useful ranking method. The identification of environmental hazards was the main reason to take the final regulatory action on bromacil, such as the value of toxicity for fish, daphnia and algae. This includes the persistence in soils and water sediment; the mobility, bioaccumulation and solubility. This information allowed the characterization of the hazard with the GUS index, which was higher than 2.8. Therefore, it was concluded that it had a high contaminating potential in the aquifers.

10. Additionally, two vulnerability studies were conducted in the Peje and Destierro River basins, in which the water intakes of the aqueducts of Cairo, Francia, Louisiana and Milano in Siquirres and Guácimo are located. In the first study, carried out in 2009, it was determined that the Peje and Destierro River basins are of high and extreme hydrogeological vulnerability and in the second, carried out in 2011, it was determined that the study area is highly vulnerable, from the hydrogeological point of view. In the Destierro river basin, there are areas with medium vulnerability. The experts who carried out this study determined that, in the lower middle basin of the Destierro and Peje Rivers, the vast majority of pineapple cultivation areas were located in zones of high vulnerability, as well as that in the immediate recharge areas of the source of the Milano River and the area closest to the headwaters of the Cairo River are pineapple farms. Concentrations of bromacil in aqueducts of the Cairo, Francia, Louisiana and Milano Rivers ranged from 0.25 to  $2.73 \mu g/L$ .

11. As a summary of the key hazard identifications from section 2.4.2.2, Costa Rica mentions persistence of bromacil, the toxicity to algae and fish, the risk associated with vulnerable regions and the capacity of the chemical to easily leach and reach aquifers. These are the main components of what triggered the final regulatory action in the country.

12. The Committee confirms that the criteria in paragraph (b) (i), (ii) and (iii) of Annex II are met.

13. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole are met.

#### D. Annex II paragraph (c) criteria

*(c)* Consider whether the final regulatory action provides a sufficiently broad basis to merit 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;

14. In Costa Rica, all formulations containing bromacil as an active ingredient and all its uses were prohibited. As of the publication of the bromacil prohibition decree, imports of the active ingredient and formulated synthetic pesticides were prohibited. Six months after the publication of this decree, the export, manufacture, formulation, storage, distribution, transportation, repackaging, handling, sale, mixing and use of the technical grade active ingredient and formulated synthetic pesticides containing,

as active ingredient, the bromacil and its lithium salt were prohibited. It is therefore expected that the regulatory action will lead to a significant reduction of the quantity of the chemical used.

- 15. Hence, the Committee concludes that the criterion in paragraph (c) (i) is met.
  - (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;

16. Parallel to the reasoning in paragraph 33, since virtually all uses of bromacil have been prohibited, it is expected that the regulatory action will lead to a significant reduction of the quantity of the chemical used. It is therefore expected that the regulatory action will remove exposure to bromacil and thus risks will accordingly be reduced.

- 17. Hence, the Committee concludes that the criterion in paragraph (c) (ii) is met.
  - (iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

18. The notification does not indicate relevance of the considerations to other states and regions. The level of bromacil in freshwater raised concerns in Costa Rica. The same concerns are considered to be relevant to other regions.

19. Therefore, the task group concludes that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

20. The Secretariat collected information on trade (UNEP/FAO/RC/CRC.19/INF/6). The received information shows that there is evidence of ongoing international trade.

21. Several countries confirmed ongoing trade: Australia, Canada, Japan, New Zealand and Trinidad and Tobago. Also, CropLife, the NGO La Grande Puissance de Dieu, and Pesticide Action Network confirmed ongoing trade of bromacil.

22. Therefore, the Committee concludes that the criterion in paragraph (c) (iv) is met.

#### E. Annex II paragraph (d) criterion

*(d)* Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

23. There is no indication in the notification or supporting documentation that concerns for intentional misuse of bromacil prompted the regulatory action.

24. Therefore, the Committee concludes that the criterion in paragraph (d) is met.

#### F. Conclusion

25. The Committee concludes that the notification of final regulatory action by Costa Rica meets the criteria set out in Annex II to the Convention.

## CRC-19/6: Diarsenic pentaoxide

The Chemical Review Committee,

*Recalling* Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

1. *Concludes* that the notification of final regulatory action for diarsenic pentaoxide submitted by the European Union<sup>1</sup> meets the criteria set out in Annex II to the Convention;

2. *Adopts* the rationale for the Committee's conclusion set out in the annex to the present decision;

3. *Notes* that, as only a notification of final regulatory action from one prior informed consent region in respect of diarsenic pentaoxide meets the criteria set out in Annex II to the Convention, it will take no further action on the chemical at present.

<sup>&</sup>lt;sup>1</sup> See UNEP/FAO/RC/CRC.19/9.

#### Annex to decision CRC-19/6

## Rationale for the conclusion by the Chemical Review Committee that the notification of final regulatory action submitted by the European Union in respect of diarsenic pentaoxide in the industrial category meets the criteria of Annex II to the Rotterdam Convention

1. The notification on diarsenic pentaoxide from the European Union has been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. The notification underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notification appeared to meet the requirements of the Convention.

2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.19/9 and UNEP/FAO/RC/CRC.19/INF/18/Rev.1. Information on trade was made available in document UNEP/FAO/RC/CRC.19/INF/6.

#### A. Scope of the regulatory action notified by the European Union

3. The regulatory action notified by the European Union relates to diarsenic pentaoxide (CAS No. 1303-28-2) in the industrial category. The European Union severely restricted the uses of diarsenic pentaoxide to protect human health by commission regulation (EU) No. 125/2012 of 14 February 2012 amending annex XIV to regulation (EC) No. 1907/2006 (REACH), under which diarsenic pentaoxide was included in annex XIV (authorization list) of the REACH regulation, which contains substances of very high concern that are subject to authorization. The listing of diarsenic pentaoxide in annex XIV has the effect that any use of this substance after 21 May 2015 (the sunset date) is prohibited (except for exempted uses as described in section 2.3.2 of the notification), unless a company submits an application for authorization and the authorization is granted. Since no applications for authorization have been submitted to date, only the exempted uses remain allowed. Hence, the final regulatory action severely restricts the use of diarsenic pentaoxide.

#### **B.** Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

4. The final regulatory action by the European Union was taken pursuant to regulation (EC) No. 1907/2006 (REACH regulation). Pursuant to the REACH regulation, substances that have certain properties (CMR, PBT, vPvB, and those for which there is scientific evidence of probable serious effects to human health or the environment which gives rise to an equivalent level of concern to CMR, PBT, and vPvB substances) may be identified as substances of very high concern (SVHCs) and are candidates for eventual inclusion in annex XIV (authorization list). The authorization process aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available.

5. The final regulatory action notified by the European Union severely restricts the industrial use of diarsenic pentaoxide, which has been classified as a carcinogen, category 1A H350 ("May cause cancer") under regulation (EC) No. 1272/2008 (CLP regulation).

6. Therefore, the Committee concludes that the final regulatory action was taken in order to protect human health; accordingly, the criterion in paragraph (a) of Annex II is met.

#### C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

*(i) Data have been generated according to scientifically recognized methods;* 

- *(ii)* Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
- *(iii)* The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

7. The notification states that the final regulatory action was based on a risk or hazard evaluation in the context of the restriction under REACH. The REACH authorization process aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available. Pursuant to the REACH regulation, substances that have certain properties (CMR, PBT, vPvB, and those for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to CMR, PBT, and vPvB substances) may be identified as substances of very high concern (SVHCs) and are candidates for eventual inclusion in annex XIV (authorization list).

8. The route to authorization starts when an EU member State or the European Chemicals Agency (ECHA), at the request of the European Commission, proposes a substance to be identified as a substance of very high concern (SVHC). The proposal is prepared according to annex XV to REACH. Comments can be made on the properties of the substance, its uses and alternatives during a 45-day consultation of interested parties. When comments are received that provide new information or challenge the basis for the identification as an SVHC, both the proposal and the comments are referred to the Member State Committee (MSC), a scientific committee that reviews the information to agree on the identification of the substance as an SVHC. If the committee reaches a unanimous agreement, the substance is added to the candidate list, otherwise the matter is referred to the European Commission for decision making. ECHA regularly prioritises substances from the candidate list for inclusion in the authorization list (REACH annex XIV), based on information on the intrinsic properties, wide dispersive use and high volumes that fall within the scope of the authorization requirement. Comments can be submitted in a three-month consultation, which are taken into account by the MSC when preparing its opinion. The European Commission takes the final decision on the inclusion of substances in the authorization list. The annex XIV entry specifies the sunset date, after which the substance is not allowed to be placed on the market or used in the European Union, unless the companies that cannot replace the substance and therefore applied for an authorization are granted such authorization, which is company- and use-specific and limited in time.

9. Pursuant to the REACH regulation, only certain uses are exempted from the authorization requirement (e.g., uses as intermediates or for scientific research and development activities, as described in the document "Generic exemptions from the authorization requirement of the European Chemicals Agency"). The exemption concerning mixtures mentioned in section 1 of the linked document applies when the substance is present in mixtures below 0.1 per cent (weight/weight) (generic concentration limit specified in regulation (EC) No. 1272/2008). From the exemptions specific to certain intrinsic properties mentioned in section 2, those referring to article 57 (a) and to hazards to human health apply for diarsenic pentaoxide as a category 1A carcinogen. Although the notification of final regulatory action states that data on the underlying hazard evaluation are not publicly available, the hazard evaluation should have been done in the process of harmonising the classification and labelling of the substance under the Dangerous Substance Directive (directive 67/548/EEC) (sect. 2.4.2.1 of notification).

10. In addition, by commission regulation (EC) No. 552/2009 of 22 June 2009 diarsenic pentaoxide, as a member of the substance group arsenic compounds, was added to annex XVII of REACH (entry 19), restricting its use to prevent the fouling by micro-organisms, plants or animals of the hulls of boats, fishing equipment and any submerged equipment as well as its use in the treatment of industrial waters and in the preservation of wood. Some exempted uses may still be covered by entry 19 of REACH annex XVII restricting (without defining concentration limits) the use of arsenic compounds in the treatment of industrial waters and for wood preservation as well as certain uses as anti-fouling (sect. 2.5.3.4 of notification).

11. The decision to list an SVHC in the REACH authorization list with a view to phasing out the uses of the substance is a risk management measure without the intervening step of a specific risk assessment. However, information on occupational exposure to diarsenic pentaoxide in the European Union has been available (glass industry; UNEP/FAO/RC/CRC.19/INF/18/Rev.1, document 4), and this information has been used in the European Union decision-making process in addition to the intrinsic properties of the chemical that are the basis for the SVHC classification, i.e., its carcinogenic, mutagenic and reprotoxic (CMR) classification, and other exposure data such as production and use volumes and use pattern. Thus, the final regulatory action for diarsenic pentaoxide is primarily based

on a hazard evaluation, whilst also taking into account information on exposure under the prevailing conditions of use in the European Union. Document 4 in the annex to document UNEP/FAO/RC/CRC.19/INF/18/Rev.1 mentions that diarsenic pentaoxide was likely to be used in small volumes in the production of artisanal glass, together with or as a substitute for diarsenic trioxide. An occupational health risk from this use cannot be excluded, especially in small production facilities in the Murano area (Venice, Italy). This information has been communicated to ECHA by the Italian competent authorities and has been taken into account by ECHA when prioritising the candidate substance diarsenic pentaoxide for inclusion in annex XIV of the REACH regulation. Therefore, the basis for the final regulatory action can be considered as a risk evaluation within the context of the Rotterdam Convention.

12. The Committee confirms that the criteria in paragraph (b) (i), (ii) and (iii) of Annex II are met.

13. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole are met.

#### D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit 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;

14. Prior to regulatory action taken by the European Union, several uses of diarsenic pentaoxide were allowed and only the few exempted uses remain allowed as a result of the regulatory action; therefore, it is expected that these measures would lead to a significant decrease in the quantity of the chemical used and the number of its uses.

- 15. Hence, the Committee concludes that the criterion in paragraph (c) (i) is met.
  - (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;

16. The final regulatory action notified by the European Union severely restricts the industrial use of diarsenic pentaoxide which has been classified as a carcinogen, category 1A H350 ("May cause cancer") under regulation (EC) No. 1272/2008 (CLP regulation). It is expected that these measures would result in a significant reduction of risk for human health in the European Union.

- 17. Hence, the Committee concludes that the criterion in paragraph (c) (ii) is met.
  - (iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

18. Section 2.5.2 of the notification states that similar human health problems are likely to be encountered in other regions where the substance is used, particularly in developing countries.

- 19. Therefore, the Committee concludes that the criterion in paragraph (c) (iii) is met.
  - (iv) Whether there is evidence of ongoing international trade in the chemical;

20. According to section 2.3.2 of the notification, certain exempted uses of diarsenic pentaoxide remain allowed in the European Union, which suggests that international trade of this chemical may be ongoing.

21. Therefore, the Committee concludes that the criterion in paragraph (c) (iv) is met.

#### E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

22. There is no indication in the notification that consideration related to intentional misuse prompted the final regulatory action rationale.

23. Therefore, the Committee concludes that the criterion in paragraph (d) is met.

## F. Conclusion

24. The Committee concludes that the notification of final regulatory action by the European Union meets the criteria set out in Annex II to the Convention.

## Annex II

## Composition of the intersessional drafting groups

## Drafting group on chlorpyrifos

Chair:	Hasmath Ali (Trinidad and Tobago)		
Drafter:	Judite Dipane (Latvia)		
Members:	Jonah Ormond (Antigua and Barbuda)		
	Adam Barlow (Australia)		
	Juergen Helbig (Austria)		
	Mirijam Seng (Belgium)		
	Christian Bart (Canada)		
	Carles Escrivá (Germany)		
	Joseph Cantamanto Edmund (Ghana)		
	Carlos Enrique Acevedo González (Guatemala)		
	Suresh Lochan Amichand (Guyana)		
	Dinesh Runiwal (India)		
	Yenny Meliana (Indonesia)		
	Hassan Azhar (Maldives)		
	Shankar Prasad Paudel (Nepal)		
	Charles Bodar (Kingdom of the Netherlands)		
	Christian Sekomo Birame (Rwanda)		
	Suzana Stefanovic (Serbia)		
	Noluzuko Gwayi (South Africa)		
	Sumith Jayakody Arachchige (Sri Lanka)		
	Sarah Maillefer (Switzerland)		
	Daniel William Ndiyo (United Republic of Tanzania)		

### Drafting group on mercury

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Chair:	Victorine Pinas (Suriname)
Drafter:	Christian Bart (Canada)
Members:	Jonah Ormond (Antigua and Barbuda)
	Anahit Aleksandryan (Armenia)
	Adam Barlow (Australia)
	Juergen Helbig (Austria)
	Li Cangmin (China)
	Joseph Cantamanto Edmund (Ghana)
	Suresh Lochan Amichand (Guyana)
	Dinesh Runiwal (India)
	Yenny Meliana (Indonesia)
	Judite Dipane (Latvia)
	Saida Ech-chayeb (Morocco)

Shankar Prasad Paudel (Nepal)

Charles Bodar (Kingdom of the Netherlands)

Zaigham Abbas (Pakistan)

Christian Sekomo Birame (Rwanda)

Aïta Sarr Seck (Senegal)

Suzana Stefanovic (Serbia)

Noluzuko Gwayi (South Africa)

Palarp Sinhaseni (Thailand)

Hasmath Ali (Trinidad and Tobago)

Daniel William Ndiyo (United Republic of Tanzania)

## Annex III

Tasks to be carried out	Responsible persons	Deadlines
Draft an internal proposal based on the information available to the Committee	Chair Drafter	15 December 2023
Send the draft internal proposal to the drafting group members for comments via email	Secretariat	15 December 2023
Replies	Drafting group members	19 January 2024
Update the internal proposal on the basis of comments from drafting group members	Chair Drafter	19 February 2024
Send the updated internal proposal to the Committee members and observers for comments via email	Secretariat	19 February 2024
Replies	Committee members and observers	19 March 2024
Draft a decision guidance document on the basis of the comments of the Committee members and observers	Chair Drafter	15 April 2024
Send the draft decision guidance document to the drafting group members for comments via email	Secretariat	15 April 2024
Replies	Drafting group members	3 May 2024
Finalize the draft decision guidance document on the basis of the comments of the drafting group members	Chair Drafter	24 May 2024
Send the draft decision guidance document to the Secretariat	Chair Drafter	24 May 2024
Submit the draft decision guidance document for consideration by the Committee at its twentieth meeting	Secretariat	5 August 2024

# Workplan for the preparation of draft decision guidance documents