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

Chemical Review Committee
Seventeenth meeting
Rome (online), 20–24 September 2021

Report of the Chemical Review Committee on the work of its seventeenth meeting

Introduction

1. In the light of the ongoing coronavirus disease (COVID-19) pandemic, it was not possible to hold the seventeenth 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 face to face at the headquarters of the Food and Agriculture Organization of the United Nations (FAO) in Rome, as had originally been planned. Instead, the Bureau decided that, as an exceptional measure, owing to the pandemic, the meeting would be held online from 20 to 24 September 2021.

I. Opening of the meeting

2. The meeting was opened at 1 p.m. (UTC + 2) on Monday, 20 September 2021, by the Chair of the Committee, Ms. Noluzuko Gwayi (South Africa).

3. Opening remarks were delivered by Mr. Rémi Nono Womdim, Executive Secretary of the Rotterdam Convention, and Mr. 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 his opening statement, Mr. Nono Womdim welcomed the participants to the online meeting, while expressing the hope that in-person meetings could resume in the near future. In the meantime, the Bureau had agreed to prioritize notifications of final regulatory action for seven pesticides for review, rather than the 12 industrial chemicals and pesticides that could have been possible in a face-to-face setting. It was expected that many more notifications would need to be reviewed in the future, which attested to the effectiveness of the Convention. Many Parties, supported with technical assistance by the Secretariat, had increased their capacity to take final regulatory action on hazardous chemicals and pesticides and submit the respective notifications, in accordance with the primary objective of the Convention to protect human health and the environment. In line with that objective, the new FAO strategic framework for the period 2022–2031 aimed to increase the preparedness and effectiveness of its Members to realize the transformation to more efficient, inclusive, resilient and sustainable agrifood systems.

5. In recognition that the sound management of chemicals was a prerequisite for achieving the Sustainable Development Goals at all levels of governance, the FAO part of the Secretariat focused in particular on the reduction of risks from hazardous pesticides, promoting less hazardous alternatives and innovative approaches. The Secretariat continued to provide targeted information to members of the Chemical Review Committee on the operations of the Committee, as well as online training and webinars in four languages on the Resource Kit, bridging guidance, the PIC Circular, final regulatory actions, import responses and other topics of relevance to the implementation of the Convention. In conclusion, he wished the members of the Chemical Review Committee fruitful and successful deliberations during the present meeting and throughout the intersessional period.

6. In his opening statement, Mr. Payet praised the Chemical Review Committee for continuing, despite the challenges presented by the COVID-19 pandemic, to contribute to the operation of the Convention by identifying chemicals and pesticide formulations that were hazardous to human health and the environment. The work of the Committee not only formed the basis for international action on harmful chemicals that transcended the boundaries of the Basel, Rotterdam and Stockholm conventions, it also engaged with the global dynamics for sustainable development under the 2030 Agenda for Sustainable Development. He thanked the members of the Committee, past and present, for their responses to the survey seeking information on their capacity-building needs to participate effectively in the work of the Committee. The Secretariat had also taken note of the suggestions of Committee members for enhancing the content of online webinars and their comments on the usefulness of the resources provided, including the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee and the Pocket Guide for Effective Participation in the Chemical Review Committee under the Rotterdam Convention. The Secretariat would continue to provide full support to the Committee in its work.

7. He noted that the present meeting would be the last one for several members of the Committee and he thanked them for their contribution to the work of the Committee and for assisting Parties to make full use of the benefits of the Rotterdam Convention. He expressed confidence that the deliberations of the Committee during the present meeting and during the intersessional period would form a comprehensive review of all related aspects marked by transparency and inclusiveness in meeting the objectives of the Convention.

II. Organizational matters

A. Attendance

8. The following members of the Committee attended the meeting: Mr. Jonah Ormond (Antigua and Barbuda), Ms. Eliana Rosa Munarriz (Argentina), Ms. Anahit Aleksandryan (Armenia), Mr. Juergen Helbig (Austria), Ms. Mara Curaba (Belgium), Mr. Martin Lacroix (Canada), Ms. Jinye Sun (China), Ms. Lady Jhoana Domínguez Majin (Colombia), Ms. Gloria Judith Venegas Calderón (Ecuador), Mr. Timo Seppälä (Finland), Mr. Joseph Cantamanto Edmund (Ghana), Mr. Suresh Lochan Amichand (Guyana), Mr. Dinesh Runiwal (India), Ms. Yenny Meliana (Indonesia), Ms. Kristīne Kazerovska (Latvia), Mr. Hassan Azhar (Maldives), Mr. Peter Korytár (Malta), Mr. Shankar Prasad Paudel (Nepal), Mr. Peter Dawson (New Zealand), Mr. Zaigham Abbas (Pakistan), Ms. Agnieszka Jankowska (Poland), Mr. Christian Sekomo Birame (Rwanda), Ms. Aïta Sarr Seck (Senegal), Ms. Noluzuko Gwayi (South Africa), Mr. Sumith Jayakody Arachchige (Sri Lanka), Ms. Sarah Maillefer (Switzerland), Ms. Nuansri Tayaputch (Thailand), Mr. Youssef Zidi (Tunisia), Mr. Daniel William Ndiyo (United Republic of Tanzania), Mr. Clorence Matewe (Zimbabwe).

9. One member of the Committee was unable to attend.

10. The following States were represented as observers: Argentina, Australia, Brazil, Canada, Chile, China, Costa Rica, Dominican Republic, Estonia, Ethiopia, France, Germany, Guatemala, India, Indonesia, Japan, Kazakhstan, Kenya, Kuwait, Malaysia, Marshall Islands, Mauritius, Mexico, Netherlands, Nigeria, Norway, Paraguay, Qatar, Russian Federation, Saudi Arabia, Serbia, Slovenia, South Africa, State of Palestine, Suriname, Thailand, Togo, United Kingdom of Great Britain and Northern Ireland, United States of America, Yemen.

11. Non-governmental organizations were also represented as observers. The names of those organizations are included in the list of participants (UNEP/FAO/RC/CRC.17/INF/34).

B. Adoption of the agenda

12. In considering the sub-item, the Committee had before it the provisional agenda (UNEP/FAO/RC/CRC.17/1) and the annotations to the provisional agenda (UNEP/FAO/RC/CRC.17/1/Add.1).

13. 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. Rotation of the membership.

4. Technical work:

(a) Report of the Bureau on the preliminary review of notifications of final regulatory action;

(b) Review of notifications of final regulatory action:

(i) Carbaryl;

(ii) Chlorfenvinphos;

(iii) Iprodione;

(iv) Methidathion;

(v) Methyl parathion;

(vi) Terbufos;

(vii) Thiodicarb.

5. Venue and dates of the eighteenth meeting of the Committee.

6. Other matters.

7. Adoption of the report of the meeting.

8. Closure of the meeting.

14. The Committee decided that, under agenda item 6 (other matters), the Secretariat would report on activities to facilitate effective participation in the work of the Committee, and on the intersessional period between the seventeenth and eighteenth meetings of the Committee.

C. Organization of work

15. The Committee decided to conduct the meeting in accordance with the scenario note prepared by the Chair (UNEP/FAO/RC/CRC.17/INF/1) and the tentative schedule for the meeting (UNEP/FAO/RC/CRC.17/INF/2), subject to adjustment as necessary. It also decided that contact groups and drafting groups would be established as needed throughout the meeting. The documents pertaining to each agenda item were identified in the annotations to the provisional agenda (UNEP/FAO/RC/CRC.17/1/Add.1) and in the list of pre-session documents by agenda item (UNEP/FAO/RC/CRC.17/INF/3).

III. Rotation of the membership

16. Introducing the item, the representative of the Secretariat drew attention to the information provided in document UNEP/FAO/RC/CRC.17/INF/4, on the rotation of the membership of the Chemical Review Committee.

17. She informed the Committee that since its sixteenth meeting, no replacement of members had taken place. However, by decision RC-10/1, the Conference of the Parties to the Rotterdam Convention, at the online segment of its tenth meeting, in July 2021, had extended the terms of office of 17 current members of the Committee until the closure of the tenth meeting, currently scheduled for June 2022. In addition, the terms of office of all the Bureau members, including the Chair of the Chemical Review Committee, would end at the closure of the tenth meeting of the Conference of the Parties, unless they were appointed for a consecutive term where this was possible in accordance with the terms of reference of the Committee.

18. She further noted that, in accordance with the rules of procedure of the Conference of the Parties, while the Chair of the Chemical Review Committee was elected by the Conference of the Parties, the other four Bureau members were elected by the Committee itself. It was important to ensure that the Bureau was operational during the intersessional period. She outlined two possible options to ensure the continuity of the functions of the Bureau. First, four new Bureau members from the Asia-Pacific States, the Eastern European States, the Latin American and Caribbean States, and the Western European and other States could be elected at the present meeting, with the member from the African States to follow later pending the outcome of the face-to-face segment of the tenth meeting of the Conference of the Parties related to the election of the Chair of the Committee; or second, following the election of new members at the face-to-face segment of the tenth meeting of the

Conference of the Parties, the Committee could agree on its Bureau members by means of online correspondence.

19. In response to queries from Committee members, the representative of the Secretariat clarified that, in accordance with decision RC-10/1, the terms of office of the aforementioned 17 members had been extended until the closure of the tenth meeting without specifying a date. This addressed possible challenges that could arise in the event of any further delay in holding the face-to-face segment of the meeting. She further clarified that it was the prerogative of members within the different regions to adopt the approach they favoured in proposing their preferred nominees; however the approach for the African region would be determined by the outcome of the face-to-face segment of the tenth meeting of the Conference of the Parties as the Chair of the Committee was the Bureau member from that region.

20. The Committee took note of the information provided in document UNEP/FAO/RC/CRC.17/INF/4.

21. Subsequently, members reported on the approaches that the regional groups had chosen to adopt with regard to the election of Bureau members to replace members whose terms of office would expire at the closure of the face-to-face segment of the tenth meeting of the Conference of the Parties, in June 2022.

22. For the Asia-Pacific States and the Eastern European States, respectively, Ms. Jinye Sun (China) and Ms. Kristīne Kazerovska (Latvia) would remain in office until the closure of the face-to-face segment of the tenth meeting of the Conference of the Parties. Once the new members from those regions were elected by the Conference of the Parties, those regions would proceed to elect their new Bureau members by electronic means.

23. For the Latin American and Caribbean States, Mr. Jonah Ormond (Antigua and Barbuda) would serve as the Bureau member, with a term of office commencing at the closure of the present meeting of the Committee.

24. For the Western European and other States, Mr. Juergen Helbig (Austria) would serve as the Bureau member, with a term of office commencing at the closure of the present meeting of the Committee.

25. For the African States, the election would be delayed, pending the outcome of the discussion related to the election of the Chair of the Committee at the face-to-face segment of the tenth meeting of the Conference of the Parties. If necessary, a Bureau member would be appointed by the region by electronic means following the closure of the tenth meeting of the Conference of the Parties.

26. The Committee agreed to the proposed course of action for the rotation of the membership.

IV. Technical work

A. Report of the Bureau on the preliminary review of notifications of final regulatory action

27. 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.17/2), information on trade in chemicals under consideration by the Committee (UNEP/FAO/RC/CRC.17/INF/5) 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.17/INF/6).

28. Presenting the outcome of the preliminary review, Mr. Martin Lacroix, a member of the Bureau, said that, on the basis of 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 establish an intersessional task group for each candidate chemical. 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.

29. Owing to the heavy workload expected at the present meeting, the Bureau had advised the Committee to bring forward intersessional work on a first set of candidate chemicals, and to follow that with further intersessional work on a second set of chemicals. Four intersessional task groups for candidate chemicals had been established for each set of chemicals. Committee members had been

designated as chairs, drafters or members of the groups. All the Committee members had been encouraged to join any of the task groups.

30. In view of the challenges posed by the holding of a meeting online and on the basis of the experience gained at the sixteenth meeting of the Committee, the Bureau had agreed to prioritize certain chemicals for inclusion in the provisional agenda of the seventeenth meeting of the Committee. It had limited to seven the number of chemicals in the first set. Consideration of the notifications for the remaining five chemicals would be postponed to future Committee meetings.

31. The intersessional task groups had been charged with undertaking an initial review of the notifications and supporting documentation submitted by the notifying Parties, including any additional documentation, information or clarification received further to the preliminary review by the Bureau. The task groups had prepared an analysis to determine whether the candidate chemicals met the criteria in Annexes I and II to the Convention. The draft task group reports for the first set of chemicals, consideration of which was on the agenda of the present meeting, had been posted on the Convention website in April 2021. The intersessional task groups had met online, with the participation of observers, a week prior to the present meeting to finalize their reports. A representative of each task group would present to the Committee the findings of that task group.

32. The Committee took note of the information presented.

B. Review of notifications of final regulatory action

1. Carbaryl

33. Owing to time constraints, the Committee was unable to take up the sub-item on carbaryl. Consequently, in accordance with rule 16 of the rules of procedure for the Conference of the Parties, applicable mutatis mutandis to the proceedings of the Committee, it was understood that consideration of the sub-item was incomplete and would be included automatically in the provisional agenda for the Committee's eighteenth meeting.

2. Chlorfenvinphos

34. Owing to time constraints, the Committee was unable to take up the sub-item on chlorfenvinphos. Consequently, in accordance with rule 16 of the rules of procedure for the Conference of the Parties, applicable mutatis mutandis to the proceedings of the Committee, it was understood that consideration of the sub-item was incomplete and would be included automatically in the provisional agenda for the Committee's eighteenth meeting.

3. Iprodione

35. The Committee had before it notifications of final regulatory action on iprodione in the pesticide category from two prior informed consent regions, namely, Africa (Mozambique) and Europe (European Union) (UNEP/FAO/RC/CRC.17/5), along with the related supporting information (UNEP/FAO/RC/CRC.17/INF/11 and UNEP/FAO/RC/CRC.17/INF/12). The Secretariat had determined that the two notifications met the criteria set out in Annex I to the Convention, and an intersessional task group had been established to undertake a preliminary assessment of the notifications and supporting documentation to determine whether they met the criteria of Annex II to the Convention. The Committee had before it a conference room paper containing the task group's report.

36. Mr. Christian Sekomo Birame, the chair of the intersessional task group, and Mr. Timo Seppälä, the drafter of the group, reported on the outcome of the group's work.

(a) Notifications

(i) Notification from the European Union

37. The final regulatory action taken by the European Union prohibited the placing on the market or use of plant protection products containing iprodione in the European Union as of 6 March 2018. The task group had determined that the action had been taken to protect human health and the environment, in accordance with the criterion in paragraph (a) of Annex II.

38. With respect to the criteria in paragraph (b) of Annex II, the task group had reviewed the supporting documentation and concluded that it had been generated according to scientifically recognized methods, and that data reviews had been performed and documented according to generally recognized scientific principles and procedures. Consequently, the criteria in

paragraph (b) (i) and (ii) had been met. With respect to the criterion in paragraph (b) (iii), the chemical had been subject to the European Union procedure for the renewal of approval of active substances, and had failed to meet the approval criteria owing to a number of concerns. On that basis, the task group had concluded that the criterion in paragraph (b) (iii) had been met, meaning that all the criteria in paragraph (b) of Annex II had been met.

39. The task group had also concluded that the notification met the criteria in paragraph (c) of Annex II. The final regulatory action prohibited all applications of iprodione as a plant protection product within the European Union, thus fulfilling the criterion in paragraph (c) (i). As the identified concerns had prevented the approval of iprodione as a pesticide, the ban of all iprodione formulations in the European Union could be expected to result in a significant reduction of risk to human health and the environment, meaning that the criterion in paragraph (c) (ii) had also been met. In terms of paragraph (c) (iii), the task group considered that the human health and environmental risks identified were applicable to regions outside the European Union. In addition, while the exposure assessment was based on simulation modelling with models and scenarios developed for and representative of European conditions, similar conditions could also be found outside the European Union. Hence, the task group had concluded that the criterion in paragraph (c) (iii) had been met. Finally, recent communications submitted to the Secretariat by the European Union and CropLife International had confirmed the ongoing trade in iprodione, meaning that the criterion in paragraph (c) (iv) had also been met.

40. As there was no indication in the notification or the supporting documentation that the regulatory action had been prompted by concerns over the intentional misuse of iprodione, the task group had considered the criterion in paragraph (d) of Annex II as having been met.

41. Based on its preliminary assessment, the task group had concluded that, overall, the notification from the European Union satisfied the criteria set out in Annex II to the Convention.

(ii) Notification from Mozambique

42. In Mozambique, the further import and use of iprodione had been banned by the National Directorate of Agrarian Services in 2014. Assessments by the United States Environmental Protection Agency and the European Food Safety Authority had classified iprodione as likely to be carcinogenic or classified as category 2 in terms of carcinogenicity, leading to the conclusion by Mozambique that under local conditions of use in the country it was harmful to human health and required risk mitigation measures. Thus, the final regulatory action had been taken to protect human health, meaning that the notification met the criterion in paragraph (a) of Annex II.

43. With respect to the criteria in paragraph (b) of Annex II, the notification referred to a consultancy study that was itself based on international assessments and property data which were considered scientifically sound, generated according to scientifically recognized methods and reported according to generally recognized scientific principles and procedures. The task group had therefore concluded that the notification met the criteria of paragraph (b) (i) and (ii) of Annex II. The group had noted that even though carcinogenicity evaluations by the various authorities had not led to the consistent classification of iprodione as category 1A or 1B for carcinogenicity of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), the chemical was considered of particular concern for use in Mozambique. The risk evaluation referred to a study initiated by the Government of Mozambique with a view to minimizing the greatest risks associated with pesticide use in the country. The final regulatory action had been based on a hazard evaluation of iprodione and an assessment of the general conditions of pesticide use in Mozambique, taking into account risk evaluations carried out in other countries. The task group had therefore concluded that the notification met the criterion of paragraph (b) (iii), thus satisfying the requirements of paragraph (b) overall.

44. In terms of the criteria in paragraph (c), the final regulatory action had banned the import and use of iprodione in Mozambique and cancelled the registration of all products containing iprodione and was thus expected to eliminate exposure to the chemical in Mozambique. The task group had therefore concluded that the criterion in paragraph (c) (i) had been met. The criterion in paragraph (c) (ii) was also considered as having been met as iprodione was identified as equivalent or similar to a GHS category 1A and 1B carcinogen and the ban of all iprodione formulations in Mozambique would minimize the risk from exposure to the extent possible. The final regulatory action had been based on information on the use of and exposure to pesticides during application and on international information on hazards, and as no specific exposure values for iprodione in Mozambique had been derived, the considerations were not geographically limited. A survey on pesticide use in Mozambique had revealed poor use of personal protective equipment, mainly owing to illiteracy, which constituted conditions that could also be found elsewhere. On that basis, the task group had concluded that the criterion in paragraph (c) (iii) had also been met. Finally, recent communications submitted to the

Secretariat by the European Union and CropLife International confirmed ongoing trade in iprodione, meaning that the criterion in paragraph (c) (iv), and thus all the criteria in paragraph (c) had been met.

45. The task group had also determined that the criteria in paragraph (d) had been met as there was no indication that the regulatory action had been prompted by concerns over the intentional misuse of iprodione.

46. Therefore, the task group had concluded that the notification of final regulatory action from Mozambique met all the criteria set out in Annex II to the Convention.

(b) Discussion of the notifications

47. In the ensuing discussion, many members thanked the task group for its work and concurred with the conclusion that the notification from the European Union met all the criteria of Annex II. One member, supported by another, nevertheless cautioned that, consistent with the conclusions of a previous discussion of a European Union notification for another chemical, compliance with the European Union parametric drinking water limit should not form part of the rationale for finding that the notification met the criteria of paragraph (b).

48. Several members also supported the task group's conclusions with respect to the notification from Mozambique, but one, supported by several others, said that the notification presented issues that were common to the four notifications submitted by Mozambique for the Committee's consideration at the present meeting, and that those common issues merited further discussion in a dedicated contact group.

(c) Next steps

49. Based on the discussion, the Committee agreed that the notification from the European Union met all the criteria of Annex II to the Convention, but that the notification from Mozambique required further discussion. It established a contact group, with Mr. Sekomo Birame serving as chair and Mr. Seppälä as drafter, to further discuss the notification from Mozambique and, in the event that the contact group considered that it met the criteria of Annex II, to develop a draft rationale for that conclusion. The group was also to develop a draft rationale for its conclusion on the notification from the European Union, 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 rationale or rationales, as appropriate.

50. The Committee also agreed to establish a contact group to discuss common concerns related to the notifications from Mozambique on iprodione, methidathion, terbufos and thiodicarb. Further information about the group is provided in section IV.B.8 of the present report.

51. Subsequently, Mr. Sekomo Birame, chair of contact group, and Mr. Seppälä, the drafter of the group, reported that the group had agreed on a draft rationale for the notification from the European Union.

52. In view of the limited time available, the Committee requested the Secretariat to prepare a draft decision for the chemical, which would take into account the possible outcomes of the ongoing discussion of the Mozambique notification for iprodione. The Secretariat was also requested to prepare a draft workplan for the preparation of a draft decision guidance document in the event that iprodione was to move forward to the next stage of the process.

53. Mr. Sekomo Birame, the chair of the contact group, later reported that the group had been converted to a drafting group and Mr. Seppälä, the drafter, reported that the group had finalized a draft rationale for the notification from Mozambique.

54. With respect to the notification from the European Union, one member expressed satisfaction that the draft rationale did not use the European Union parametric drinking water limit as a basis for determining whether the criterion in paragraph (b) (iii) of Annex II to the Convention had been met, reiterating that the Committee had faced that issue in the past in its consideration of other chemicals.

55. With respect to the notification from Mozambique, one member, supported by another, noting that it relied heavily on a general survey on pesticide use in the country, underscored the fact that there had been no consensus among members that a general survey alone was a sufficient basis for concluding that the notification satisfied the criterion in paragraph (b) (iii) of Annex II to the Convention. The members had been unable to find a precedent for a conclusion that the general survey was sufficient; although such surveys had been considered in the past, they had always been supported by specific information on the chemical or substantial bridging information. Likewise, there were no

examples in the Handbook to support the setting of a precedent with the Mozambique notification; however, in the case of the notification for iprodione, the members had succeeded in identifying bridging information in the documentation provided and had thus been able to conclude that the notification met the criteria of the Convention.

56. A number of other members also supported the conclusion that the Mozambique notification met those criteria. One member, noting that it was very difficult for developing countries to carry out a risk assessment, suggested that the Committee should clarify the meaning of "risk evaluation" under the Convention to arrive at a better understanding of the requirements, particularly when reviewing notifications from developing countries. Two other members echoed that suggestion.

57. Having considered the draft rationales, along with a draft decision and a draft workplan prepared by the Secretariat, the Committee adopted decision CRC-17/1. The decision, to which the rationales are annexed, is set out in annex I to the present report; the composition of the intersessional drafting group established to prepare the draft decision guidance document is set out in annex II; and the workplan is set out in annex III.

58. Following the adoption of the decision, one member, noting that the notifications showed that a good effort had been made to establish that the criteria of Annex II had been met and demonstrated good ways of conducting risk evaluations, encouraged other developing countries to follow their example when submitting their notifications. Another noted, however, that although the general survey by Mozambique had been appropriate for domestic decision-making at the time, it had not been conducted with the submission of a notification under the Rotterdam Convention in mind and might not be considered to be in line with the criteria of Annex II. The Committee had not found any information in the Handbook or any previous decisions of the Committee on notifications that had based the risk evaluation on a general survey only. Other members considered the general survey to be sufficient to meet the criterion in paragraph (b) (iii) of Annex II, including because it had clearly demonstrated the risks associated with the use of the chemicals. Another member, highlighting the difficulties experienced by some developing countries in obtaining the information required for a risk evaluation, proposed looking at the possibility of providing capacity-building or support during the risk evaluation process.

4. Methidathion

59. The Committee had before it two notifications of final regulatory action on methidathion in the pesticide category from two prior informed consent regions, namely, Africa (Mozambique) and Latin America and the Caribbean (Uruguay) (UNEP/FAO/RC/CRC.17/6), along with the related supporting information (UNEP/FAO/RC/CRC.17/INF/13 and UNEP/FAO/RC/CRC.17/INF/14). The Secretariat had determined that the two notifications met the criteria set out in Annex I to the Convention. 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 and supporting documentation to determine whether they met the criteria in Annex II to the Convention.

60. Mr. Peter Korytár, chair of the intersessional task group, and Ms. Lady Jhoana Domínguez Majin, the drafter of the intersessional task group, reported on the outcome of the group's work.

(a) Notifications

(i) Notification from Mozambique

61. The final regulatory action taken by Mozambique banned the import and use of methidathion in its territory on account of its toxic nature and hazardous properties, as established in decision 001/DNSA/2014 of the National Directorate of Agrarian Services. The action had been taken to protect human health, and thus the criterion in paragraph (a) of Annex II had been met.

62. With regard to the criteria in paragraph (b) of Annex II, the task group had concluded that the final regulatory action had been based on a hazard evaluation of methidathion in which a methidathion formulation registered in Mozambique was classified as "coming close to" the criteria for highly hazardous pesticides of the Joint Meeting on Pesticide Management of FAO and the World Health Organization (FAO/WHO JMPM). In addition, the task group further concluded that the final regulatory action was also based on the prevailing conditions of use of pesticides in Mozambique and the resulting risks, which had indicated that the prevailing conditions of use of methidathion in the country would result in an unacceptable risk to workers. The task group had also considered that a description of the anticipated risk as a consequence of the use of the chemical in the notifying country

was sufficient for fulfilling the criterion in paragraph (b) (iii). The task group had therefore concluded that the criteria in paragraph (b) of Annex II had been met.

63. In terms of the criteria in paragraph (c) of Annex II, the task group had concluded that the criteria had been met. Since the notified final regulatory action was a ban on the use of methidathion in the country it would be expected to lead to zero exposure, fulfilling the criterion in paragraph (c) (i); the ban would also lead to a significant reduction of risk to human health from potential release of methidathion, fulfilling the criterion in paragraph (c) (ii); the human health problems associated with exposure to the chemical were likely to be encountered in other countries with similar conditions, meaning that the regulatory action could be relevant to other regions, satisfying the criterion in paragraph (c) (iii); and data provided by CropLife International confirmed that international trade in methidathion was ongoing, fulfilling the criterion in paragraph (c) (iv).

64. Regarding the criterion in paragraph (d) of Annex II, there was no indication in the notification or supporting documentation that the regulatory action had been prompted by concerns over the intentional misuse of the chemical. The task group had therefore concluded that the criterion had been met.

65. Accordingly, the task group recommended that the Committee consider the notification from Mozambique to have satisfied all the criteria set out in Annex II to the Convention.

(ii) Notification from Uruguay

66. The final regulatory action taken by Uruguay banned the import, registration and renewal of plant protection products based on methidathion formulations. Uruguay had highlighted that methidathion was classified as a highly hazardous organophosphate insecticide, class Ib of the WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification (2009). In taking the action, Uruguay had established that the environmental impact quotient of the chemical for workers and the environment was higher than for any of the alternative active ingredients used in Uruguay for the control of insects in pome and stone fruit trees. The action had therefore been taken to protect human health and the environment, and the criterion in paragraph (a) of Annex II had thus been met.

67. With regard to the criteria in paragraph (b) of Annex II, the task group had reviewed the methodology used to calculate the environmental impact quotient of methidathion, based on the active ingredient concentration of formulations containing the chemical, the dose, the application frequency and good agricultural practices used in the country. The task group had concluded that the final regulatory action had been generated according to scientifically recognized methods, that data reviews had been performed and documented according to generally recognized scientific principles and procedures, and that the final regulatory action had been based on a risk evaluation involving the prevailing conditions within the Party taking the action. The task group therefore concluded that the criteria in paragraph (b) (i) and (ii) had meet met. The task group also found that the notification had been supported by a risk evaluation and had used information on prevailing conditions in the country to evaluate the expected exposure to methidathion in Uruguay compared to alternative chemicals, satisfying the criterion in paragraph (b) (iii). The task group had therefore concluded that the criteria in paragraph (b) of Annex II had been met.

68. In terms of the criteria in paragraph (c) of Annex II, the task group had concluded that the criteria had been met. Since the notified final regulatory action was a ban, it would be expected to lead to a significant reduction in the quantity of methidathion used in the country, fulfilling the criterion in paragraph (c) (i); the regulatory action to ban the use of methidathion was also expected to significantly reduce the quantity of the chemical used, the health risks for workers and consumers, and contamination of the environment, fulfilling the criterion in paragraph (c) (ii); the notification stated that similar human health and environmental problems were likely to be encountered in other regions where the chemical was used, particularly in developing countries, satisfying the criterion in paragraph (c) (iii); and data provided by CropLife International confirmed that international trade in methidathion was ongoing, fulfilling the criterion in paragraph (c) (iv).

69. Regarding the criterion in paragraph (d) of Annex II, there was no indication in the notification or supporting documentation that the regulatory action had been prompted by concerns over the intentional misuse of the chemical. The task group had therefore concluded that the criterion had been met.

70. Accordingly, the task group recommended that the Committee consider the notification from Uruguay to have satisfied all the criteria set out in Annex II to the Convention.

(b) Discussion on the notifications

71. In the ensuing discussion, members voiced general support for the conclusions of the task group, although several members stressed the need for further discussion to clarify certain issues pertaining to the notifications. The cross-cutting issues related to the notifications submitted by Mozambique, for example, were deemed worthy of further consideration by a dedicated contact group.

72. Regarding the notification from Uruguay, some members said that there was a need for caution in applying the environmental impact quotient methodology in the country risk evaluation for methidathion. One member said that the methodology was more suited to an evaluation of comparative risk of a number of chemicals, rather than the actual risk presented by a single chemical; in addition, the methodology had been developed in the United States, and the weightings given to certain risk factors were more applicable to the United States context than to circumstances in a developing country. In addition, as noted in FAO guidance on the use of the environmental impact quotient, the simplicity of the tool might lead to a sacrifice in accuracy and specificity, leading to false negatives or positives. As such, the notification from Uruguay might not meet the criterion in paragraph (b) (iii) of Annex II. Another member concurred that the tool was useful for a comparison of risk factors across pesticides, but such an approach did not meet the criteria presented in Annex II to the Rotterdam Convention. Some other members expressed the view that those criteria had been met, but welcomed further discussion on the matter.

(c) Next steps

73. On the basis of the discussion and the range of views expressed by members, the Committee agreed to establish a contact group, to be chaired by Mr. Korytár with Ms. Domínguez Majin acting as the drafter, to discuss further the notifications from Mozambique and Uruguay. In the event that the contact group considered that the criteria of Annex II had been met for either notification, it would develop a draft rationale for the relevant notification. The chair of the contact group could, if necessary, convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the rationale.

74. The Committee also agreed to include consideration of the notification from Mozambique on this chemical in the work of the contact group established to discuss common concerns related to the notifications from Mozambique on iprodione, methidathion, terbufos and thiodicarb. Further information about the group is provided in section IV.B.8 of the present report.

75. Subsequently, the chair of the contact group reported back on the group's work. The group had not arrived at consensus and had concluded that further discussion was needed on whether the notifications from Mozambique and Uruguay met the criteria of Annex II, specifically the criterion of paragraph (b) (iii). Ms. Domínguez Majin gave a presentation summarizing the current status of the work of the contact group on the draft rationales for Mozambique and Uruguay for methidathion, with additional text updates suggested by the chair and the drafter of the contact group.

76. In the ensuing discussion, several members of the Committee concurred that further discussion was needed on the notifications of Mozambique and Uruguay for methidathion. Some members stated that the general pesticide use survey carried out in Mozambique had not generated sufficient chemical-specific data to meet the criterion of paragraph (b) (iii) of Annex II. There was also a request that the Committee be provided with further information on the environmental impact quotient methodology used in the Uruguay risk evaluation for methidathion to assess whether it could be used to support the risk evaluation stipulated in paragraph (b) of Annex II.

77. One member stated that, as exemplified by the case of Mozambique, international organizations supporting the development of notifications of final regulatory action for chemicals should ensure that all the criteria set out in Annex II to the Rotterdam Convention were fully met. He also suggested, in response to a proposal that the item be considered further at the eighteenth meeting of the Committee, that the item only be added to the agenda of that meeting if the notifying Parties provided further supporting information.

78. The Committee agreed to continue its consideration of the draft notifications on methidathion from Mozambique and Uruguay at its eighteenth meeting, following clarification by the Legal Officer that such inclusion in the agenda of the next meeting was in line with the rules of procedure pertaining to items for which consideration had not been completed at a meeting. To that end, and given that half of the Committee's membership would change before its eighteenth meeting, the text of the draft rationales, as they currently stood, including the updates mentioned by the chair and the drafter of the

contact group, along with a clear statement of their status, would be issued as an information document[1] for further consideration by the Committee at its eighteenth meeting.

5. Methyl parathion

79. Owing to time constraints, the Committee was unable to take up the sub-item on methyl parathion. Consequently, in accordance with rule 16 of the rules of procedure for the Conference of the Parties, applicable mutatis mutandis to the proceedings of the Committee, it was understood that consideration of the sub-item was incomplete and would be included automatically in the provisional agenda for the Committee's eighteenth meeting.

6. Terbufos

80. The Committee had before it notifications of final regulatory action for terbufos in the pesticide category from two prior informed consent regions, namely, Africa (Mozambique) and North America (Canada) (UNEP/FAO/RC/CRC.17/8/Rev.1), along with the related supporting information (UNEP/FAO/RC/CRC.17/INF/18 and UNEP/FAO/RC/CRC.17/INF/19/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 and supporting documentation to determine whether they met the criteria of Annex II to the Convention.

81. Ms. Agnieszka Jankowska, the chair of the intersessional task group, and Mr. Lacroix, the drafter of the group, reported on the outcome of the group's work.

(a) Notifications

(i) Notification from Canada

82. The notification of final regulatory action taken by Canada related to terbufos in the pesticide category. It indicated that the regulatory action had been taken to protect the environment, thus meeting the criterion in paragraph (a) of Annex II.

83. The notification indicated that the final regulatory action was based on a re-evaluation of the active ingredient terbufos and its end-use products for use on canola, corn, mustard, rutabagas and sugar beets. A document on the proposed acceptability for continuing registration provided the rationale for the final regulatory action and included a human health assessment, an environmental assessment and information on the value of terbufos for pest management in Canada. The document specified that the information in the toxicology database that had been considered was primarily based on studies made available by the registrant. Data included toxicity end points, the no-observed-adverse-effect level, the acute reference dose, acceptable daily intake determinations and comparisons of the expected effect of exposure to terbufos in humans. With regard to human health, occupational, dietary and aggregate risk assessments had been conducted, along with a deterministic assessment of the environmental risks of pest control products. Environmental risk had been characterized by the quotient method. The data included in the notification and supporting documentation were considered to be scientifically sound and generated according to scientifically recognized methods, and data reviews were considered to have been performed and documented according to generally recognized scientific principles and procedures. Consequently, the task group had concluded that the notification met the criteria of paragraph (b) (i) and (ii) of Annex II.

84. The final regulatory action was based on a risk evaluation and was relevant to the environment. The conditions of use within Canada had been taken into account in the risk assessment. The decision by the Canadian Pest Management Regulatory Agency to conduct a re-evaluation had been based on the evaluation of the registered uses in Canada. The risk assessment had identified extremely high levels of hazard for terrestrial and aquatic organisms resulting from all currently registered uses of terbufos, supported by reports of incidents. Risk quotients determined for applications of the end-use terbufos formulations registered in Canada indicated risk for all groups of organisms. It was concluded that the use of terbufos and its associated end-use products posed an unacceptable risk of harm to the environment. Consequently, the task group had concluded that the notification met the criteria of paragraph (b) (iii). The notification therefore complied with paragraph (b) of Annex II as a whole.

85. With respect to the criteria in paragraph (c) of Annex II, the task group had noted that the final regulatory action phased out all the uses of terbufos as a pest control product in Canada in 2012; the estimated quantity of terbufos produced, imported and exported from Canada prior to the regulatory action had not been provided. The quantity of the terbufos used in the year prior to the entry into force

[1] UNEP/FAO/RC/CRC.17/INF/33.

of the ban was reported to be less than 50,000 kg. As the regulatory action banned the use of terbufos, it was expected that any quantity used as a pest control product would be reduced to zero. The task group had therefore considered the criteria in paragraph (c) (i) and (ii) as having been met.

86. The notification stated that risks associated with end-use formulations had been identified for all groups of organisms and that the environmental risk posed by terbufos was likely to be relevant in countries with similar terbufos use patterns. The task group had therefore concluded that the notification met the criteria of paragraph (c) (iii).

87. In response to the request by the Secretariat to provide information on ongoing international trade in candidate chemicals, CropLife International had confirmed ongoing international trade in terbufos by companies that were not members of CropLife International. The task force had therefore concluded that the criteria of paragraph (c) (iv) had been met.

88. Finally, there was no indication in the notification or the supporting documentation that the regulatory action had been prompted by concerns over the intentional misuse of terbufos. The criterion in paragraph (d) of Annex II was therefore considered to have been met.

89. Based on its preliminary assessment, the task group had concluded that, overall, the notification from Canada satisfied all the criteria set out in Annex II to the Convention.

(ii) Notification from Mozambique

90. The notification of final regulatory action taken by Mozambique related to terbufos in the pesticide category. Mozambique had banned the import and use of terbufos and cancelled the registration of all products containing terbufos in the country. The ban had entered into force on 15 July 2014. The decision to cancel the registration of terbufos had been the final step in a project in the country to reduce the risk posed by highly hazardous pesticides. The notification indicated that the regulatory action had been taken to protect human health, thus meeting the criterion in paragraph (a) of Annex II.

91. The notification indicated that the final regulatory action had been based on a risk evaluation elaborated under the project in Mozambique that aimed to develop and implement a risk reduction action plan relating to highly hazardous pesticides for the most dangerous pesticides and use situations. Reports prepared as part of the project provided a detailed methodology specifying that internationally recognized criteria had been used to identify highly hazardous pesticides in the country, including terbufos. The report on the survey of pesticide use practice indicated that the survey design had been informed by similar surveys and guidance prepared by various international bodies. The data included in the notification and supporting documentation were thus considered to be scientifically sound and to have been generated according to scientifically recognized methods, and data reviews were considered to have been performed and documented according to generally recognized scientific principles and procedures. Consequently, the task group had concluded that the notification met the criteria of paragraph (b) (i) and (ii) of Annex II.

92. The first stage of the project to reduce risks from highly hazardous pesticides had involved a review of all pesticides registered in Mozambique and the establishment of a shortlist of highly hazardous pesticides. The terbufos formulations registered in Mozambique had been identified as extremely hazardous (class Ia) according to the criteria of the WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification (2009). The second stage of the project had included a use survey carried out in selected regions and crop systems. The surveys had revealed that most of the farmers were applying pesticides and that the conditions of use were likely to result in undue exposure. Almost none of the farmers had owned or worn personal protective equipment and about half the farmers had not received any training in the use of pesticides. The third stage of the project had involved stakeholder consultations. The task group had thus concluded that the final regulatory action had been based on a risk evaluation involving the prevailing conditions within the Party taking the action and that the criterion in paragraph (b) (iii) had been met.

93. The notification indicated that, prior to the entry into force of the final regulatory action, terbufos had been registered for use as an insecticide on maize, sorghum, potato and beans. The notification provided quantities of the formulations imported for the years 2008 and 2009. The ban on the import and use and the cancellation of the registration of products containing terbufos were expected to lead to a significant reduction in the quantity of the chemical used. As a result, the risks to human health would be significantly reduced. The task group had therefore considered the criteria in paragraph (c) (i) and (ii) to have been met.

94. The notification stated that countries with similar conditions where the farmers used pesticides without protective equipment could make a similar decision in order to protect human health. The considerations that had led to the final regulatory action were generally applicable to other countries. The task group had therefore concluded that the notification met the criteria in paragraph (c) (iii).

95. In response to the request by the Secretariat to provide information on ongoing international trade in candidate chemicals, CropLife International had confirmed ongoing international trade in terbufos by companies that were not members of CropLife International. The task force had therefore concluded that the criteria in paragraph (c) (iv) had been met.

96. Finally, there was no indication in the notification or the supporting documentation that the regulatory action had been prompted by concerns over the intentional misuse of terbufos. The criterion in paragraph (d) of Annex II was therefore considered to have been met.

97. Based on its preliminary assessment, the task group had concluded that, overall, the notification from Mozambique satisfied all the criteria set out in Annex II to the Convention.

(b) Discussion on the notifications

98. In the ensuing discussion, all the members who took the floor on the notification from Canada said that they agreed with the conclusion of the task group that it satisfied all the criteria set out in Annex II to the Convention.

99. With respect to the notification from Mozambique, many members said that they agreed with the conclusion of the task group that it satisfied all the criteria set out in Annex II to the Convention. One member proposed that the case be inserted into the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee as the specific example that had yet to be identified in section 2.5, working paper on the application of criteria (b) of Annex II, under part III, application of criterion (b) (iii).

100. Other members, some of whom also said that they agreed with the conclusion or with the majority of the elements therein, expressed a desire for further discussion about the risk evaluation element of the notification and whether it had been based on a review of scientific data in the context of the conditions prevailing in the Party in question. Some members said that a thorough discussion was particularly important if the notification were to be considered for inclusion in the Handbook or if any precedent were to be set. Several members reaffirmed that the Convention, and the criteria therein, was the basis upon which the Committee needed to be taking its decisions, not the Handbook, although they noted that the Handbook could be updated or modified as the Committee's work evolved.

101. In response to a question from one member, Mr. Lacroix confirmed that environmental impact had not been discussed in the final regulatory action. Another member recalled that final regulatory action could be taken by a Party in order to protect human health or the environment. It was not necessary that both be addressed.

102. Several members suggested that it might be useful to look at the risk evaluation element of all the notifications of final regulatory action by Mozambique under review at the present meeting, as they probably followed the same approach and similar issues might therefore arise.

(c) Next steps

103. Based on the discussion, the Committee agreed that the notification from Canada met all the criteria of Annex II to the Convention. It established a contact group, with Ms. Jankowska serving as chair and Mr. Lacroix serving as drafter, to develop a rationale for that conclusion on the basis of the notification received from Canada and the comments made during the discussion.

104. Given the lack of consensus regarding the notification of final regulatory action by Mozambique, the same contact group was mandated to discuss the notification from Mozambique further and, in the event that the contact group considered that the criteria of Annex II had been met, also to develop a draft rationale for that conclusion, based on the notification received from Mozambique and the comments made during the discussion. If necessary, the chair could convert the contact group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the rationale or rationales, as appropriate.

105. The Committee also agreed to include consideration of the notification from Mozambique on this chemical in the work of the contact group established to discuss common concerns related to the notifications from Mozambique on iprodione, methidathion, terbufos and thiodicarb. Further information about the group is provided in section IV.B.8 of the present report.

106. Subsequently, Ms. Jankowska, the chair of the contact group, and Mr. Lacroix, the drafter of the group, reported that the group had agreed on a draft rationale for the notification from Canada but had not yet fully agreed on the wording of the draft rationale in relation to the notification from Mozambique.

107. In view of the limited time available, the Committee requested the Secretariat to prepare a draft decision for the chemical, including a recommendation to list terbufos in Annex III to the Convention in the pesticide category and a decision to prepare a draft guidance document, pending the possible outcomes of the ongoing discussion of the Mozambique notification for terbufos. The Secretariat was also requested to prepare a draft workplan for the preparation of the draft decision guidance document.

108. After further discussion of the notification from Mozambique, Ms. Jankowska and Mr. Lacroix reported that the group had agreed on a draft rationale for the notification.

109. One member, commenting on the process by which the group had reached agreement, recalled that there had initially been no consensus among members on whether a general survey of the overall use of pesticides in a country, alone, without any specific information on the chemical or any bridging information to other risk evaluations that had been conducted, was sufficient to satisfy the risk evaluation requirement in the criterion in paragraph (b) (iii) of Annex II. The group had been unable to find any evidence of the Committee's past decisions that would support the use of a general survey as the risk evaluation, and there did not seem to be any related examples in the Handbook. The group had therefore delved further into the notification and the supporting documentation and found additional information upon which to base its decision. Given that the final conclusion of the group on the notification from Mozambique on terbufos had been framed in a manner similar to section 1 (b) (iii) of part III of section 2.5 of the Handbook, the member proposed that the notification could be included in that section of the Handbook as the specific example that was currently missing. Before that was done, however, he proposed that the wording of the relevant paragraph in the Handbook be revised as it was unclear what constituted a "national policy" or a "defined hazard classification", for example. He recalled that a similar suggestion had been made at a previous meeting of the Chemical Review Committee in the context of revisions to the Handbook, but that it had been deemed to be beyond the scope of the revisions at that time.

110. Another member advised exercising caution when using the Handbook as it had been prepared when the work of the Committee had been in its infancy. He agreed that, as the Committee had now examined a good number of notifications, it should return to the texts for which no specific examples existed as it was likely that the wording gave rise to different interpretations.

111. Several members expressed their support for further consideration of the text and example in section 1 (b) (iii) of part III of section 2.5 of the Handbook, but proposed that the Committee complete its consideration of all the notifications from Mozambique that had originally been on the agenda of the present meeting before embarking on any revisions. In that respect, one member suggested that the discussion on issues arising from the notifications from Mozambique should continue intersessionally, given that, at its eighteenth meeting, the Committee would again be considering notifications from Mozambique with similar bases. Such an approach could prove more efficient.

112. Subsequently, the Committee, after considering the draft rationales, along with a draft decision and a draft workplan prepared by the Secretariat, adopted decision CRC-17/2. The decision, to which the rationale is annexed, is set out in annex I to the present report. In accordance with the decision, the composition of the intersessional drafting group established to prepare the draft decision guidance document is set out in annex II to the present report and its workplan is set out in annex III.

7. Thiodicarb

113. The Committee had before it notifications of final regulatory action on thiodicarb in the pesticide category from two prior informed consent regions, namely, Africa (Mozambique) and Europe (European Union) (UNEP/FAO/RC/CRC.17/9), along with the related supporting information (UNEP/FAO/RC/CRC.17/INF/20 and UNEP/FAO/RC/CRC.17/INF/21). The Secretariat had determined that the two notifications met the criteria set out in Annex I to the Convention, and an intersessional task group had been established to undertake a preliminary assessment of the notifications and supporting documentation to determine whether they met the criteria of Annex II to the Convention. The Committee also had before it a conference room paper containing the task group's report.

114. Mr. Zaigham Abbas, the chair of the intersessional task group, and Ms. Sarah Maillefer, the drafter of the group, reported on the outcome of the group's work.

(a) Notifications

(i) Notification from the European Union

115. The final regulatory action taken by the European Union banned the placing on the market or use of plant protection products containing thiodicarb. As the notification demonstrated that the action had been taken to protect human health and the environment, the task group had concluded that it met the criterion in paragraph (a) of Annex II.

116. With respect to the criteria in paragraph (b) of Annex II, the notification identified risks to human health and the environment, including an acute dietary risk for toddlers and adults relating to the consumption of treated grapes; high acute and long-term risks for birds and mammals from direct consumption of pellets; a potential risk for exposure of surface water via drainage on soils vulnerable to drainage; and a long-term risk to earthworms from exposure to the metabolite methomyl. In addition, thiodicarb was toxic to honeybees, and important data gaps had been identified concerning the use of thiodicarb as a molluscicide. On that basis, the task group had concluded that the notification satisfied the criteria in paragraph (b) as a whole.

117. As the final regulatory action banned the placing on the market and the use of thiodicarb as a plant protection product, it was expected to lead to a significant reduction in the quantity of the chemical used and consequently a reduced risk to the environment. The notification stated that similar human health and environmental problems were likely to be encountered in other regions where the substance was used, particularly in developing countries. While the notification did not include information on the estimated quantity of thiodicarb produced, imported, exported and used, the Secretariat had collected trade information that showed evidence of ongoing trade. Taking all that into account, the task group had concluded that the criteria in paragraph (c) of Annex II had been met.

118. As there was no indication in the notification or the supporting documentation that the regulatory action had been prompted by concerns over the intentional misuse of thiodicarb, the task group had also considered the criterion in paragraph (d) of Annex II to have been met.

119. Based on its preliminary assessment, the task group had concluded that, overall, the notification from the European Union satisfied the criteria set out in Annex II to the Convention.

(ii) Notification from Mozambique

120. The notification from Mozambique stated that the import and use of thiodicarb had been banned by the National Directorate of Agrarian Services owing to its high acute toxicity, which, combined with the prevalent improper use of pesticides, was likely to result in excessive exposure of farmers. As the notification indicated that the final regulatory action had been taken to protect human health, the task force had concluded that it met the criterion in paragraph (a) of Annex II.

121. The notification indicated that thiodicarb had been shortlisted pursuant to a study initiated by the Government with a view to reducing the risks to human health associated with the use of the most hazardous pesticides. A thiodicarb formulation registered in Mozambique was shortlisted due to its classification by Mozambique as “coming close to” the criteria for highly hazardous pesticides of the FAO/WHO JMPM. The study had included a survey on pesticide use practices that had indicated expected excessive exposure of farmers due to the prevalence of the severe improper use of pesticides, including the inadequate use of personal protective equipment. In its review, the task group had noted that the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee indicated that pesticides with a defined hazard classification could be subject to a national policy banning them, in which case a description of the anticipated risk could be sufficient and measured exposure was not mandatory. On that basis, the group had concluded that the criteria in paragraph (b) had been met.

122. The final regulatory action had cancelled the registration of all pesticides containing thiodicarb and banned their use, and could therefore be expected to lead to a significant reduction in both the quantity of the chemical used and the risk to human health. The notification stated that countries with similar conditions, where the farmers used pesticides without personal protective equipment, could take a similar decision to protect human health. While the notification provided information on the quantities of chemicals imported in 2003 and 2004, the Secretariat had collected additional information showing evidence of ongoing trade in the chemical. Taking all this information into account, the task group had concluded that the notification met the criteria in paragraph (c) of Annex II.

123. Given that there was no indication in the notification or supporting documentation that the regulatory action had been prompted by concerns over the intentional misuse of thiodicarb, the group had therefore also concluded that the notification met the criteria in paragraph (d) of Annex II.

124. Thus, the task group had concluded that the notification of final regulatory action received from Mozambique met all the criteria set out in Annex II to the Convention.

(b) Discussion of the notifications

125. During the ensuing discussion, a number of members raised concerns with regard to the reference to potential risk of exposure of surface water in the notification because there was no indication that it was not based on the same parametric drinking water limit as the groundwater threshold that the Committee had previously opined was not a basis for the criteria having been met. It was decided to revise the surface water bullet in the rationale to make it clear that it was related to the risks found in the European Union's supporting information relating to aquatic organisms. Many members thanked the task group for its work and expressed their support for the conclusion that the notification from the European Union fully met the criteria of Annex II.

126. One member, supported by several others, said there was a need for a general discussion on the Mozambique notifications that used the same approach for determining that the criteria of paragraph (b) (iii) had been met. He noted that the task group's report specifically referenced an example in the Handbook that referred to relying on the existence of a national policy, and proposed that information on the national framework for pesticide regulation in Mozambique, found in the supporting document for Mozambique, could be the starting point for a discussion on that question. A number of other members also acknowledged the need to further discuss the notifications from Mozambique in general, but nevertheless expressed their support for the task group's conclusion that the notification from Mozambique had met the criteria of Annex II. One member unequivocally supported the task group's conclusion and said that she would provide more detailed reasons for that at a later point in the discussion. Another member sought clarification of what a risk evaluation entailed and what sort of information was required.

(c) Next steps

127. Based on the discussion, the Committee agreed that the notification from the European Union had met all the criteria of Annex II to the Convention but that the notification from Mozambique required further discussion. It established a contact group, with Mr. Abbas serving as chair and Ms. Maillefer serving as drafter, to further discuss the notification from Mozambique and, in the event that the contact group considered that it met the criteria of Annex II, to develop a draft rationale for that conclusion. The contact group was also to develop a draft rationale for its conclusion on the notification from the European Union, based on the notification received and the comments made during the discussion. If necessary, the chair could convert the contact group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the rationale or rationales, as appropriate.

128. The Committee also agreed to include consideration of the notification from Mozambique on this chemical in the work of the contact group established to discuss common concerns related to the notifications from Mozambique on iprodione, methidathion, terbufos and thiodicarb. Further information about the group is provided in section IV.B.8 of the present report.

129. Subsequently, Mr. Abbas, the chair of the contact group, and Ms. Maillefer, the drafter of the group, reported that the group had agreed on a draft rationale for the notification from the European Union.

130. In view of the limited time available, the Committee requested the Secretariat to prepare a draft decision for the chemical, which would take into account the possible outcomes of the ongoing discussion of the Mozambique notification for thiodicarb. The Secretariat was also requested to prepare a draft workplan for the preparation of a draft decision guidance document in the event that thiodicarb was to move forward to the next stage of the process.

131. Mr. Abbas, the chair of the contact group, and Ms. Maillefer, the drafter of the group, later reported that the group had been unable to finalize its determination of whether the notification from Mozambique met the requirements of the Convention.

132. Several members said that they still had concerns regarding the Mozambique notification, most notably in relation to the reliance on the general survey for meeting the criterion in paragraph (b) (iii) of Annex II.

133. Consequently, the Committee, having considered a draft rationale prepared by the contact group for the notification from the European Union along with a draft decision prepared by the Secretariat, adopted decision CRC-17/3. The decision, to which the rationale is annexed, is set out in annex I to the present report.

134. The Committee also agreed to resume discussion of the notification from Mozambique at its eighteenth meeting, focusing on the issues that remained unresolved. To that end, and given that half of the Committee's membership would change before its eighteenth meeting, the text of the draft rationale prepared by the contact group for Mozambique notification, along with a clear statement of its status, would be set out in an information document[2] to be made available to the Committee at its eighteenth meeting.

8. Common concerns related to the notifications from Mozambique on iprodione, methidathion, terbufos and thiodicarb

135. Recognizing that there were different views as to whether the notifications from Mozambique on iprodione, methidathion, terbufos and thiodicarb met the criteria in paragraph (b) of Annex II, the Committee agreed to establish a contact group, chaired by Mr. Seppälä and Mr. Sekomo Birame, on common concerns related to the notifications from Mozambique on iprodione, methidathion, terbufos and thiodicarb. The mandate of the group, which was to meet prior to the chemical-specific contact groups mentioned above, was to further discuss whether the notifications from Mozambique met the criteria in paragraph (b) of Annex II to the Convention, in particular the criterion in paragraph (b) (iii), and, if so, to develop a proposal explaining the group's position. If necessary, the co-chairs could decide to convert the group into a drafting group, limited to members of the Committee, for the purpose of finalizing the wording of the proposal.

136. Subsequently, the co-chair of the group, Mr. Seppälä, reported back on the group's work. He said that the group had focused on the issue of risk evaluation in the notifications from Mozambique. Members of the group had expressed divergent views about whether the approach used in 2014 as part of the project to develop and implement a risk reduction action plan relating to highly hazardous pesticides constituted a risk evaluation in accordance with the criteria under Annex II to the Convention. With some members of the group considering that it did and others that it did not, it had not been possible for the group to reach agreement that the criterion in paragraph (b) (iii) had been met in relation to any of the notifications from Mozambique.

137. As there had been no agreement on that issue, the group had turned to the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee and the case for which the specific example that had yet to be identified in section 2.5, working paper on the application of criteria (b) of Annex II, under part III, application of criterion (b) (iii). Again, the group had been unable to reach agreement on issues such as what constituted a defined hazard classification, whether the related examples given were exhaustive, what should be included in a national policy and thus whether the 2012–2014 project in Mozambique could be considered a national policy.

138. In concluding, the co-chair said that, despite the lack of consensus, the discussion had nonetheless been valuable in terms of enabling members and observers to gain a better understanding of one another's views. The discussions subsequently continued on a chemical-by-chemical basis, as described above.

V. Venue and date of the eighteenth meeting of the Committee

139. The Committee agreed to hold its eighteenth meeting at the headquarters of FAO in Rome in September or October 2022, back to back with the eighteenth meeting of the Persistent Organic Pollutants Review Committee of the Stockholm Convention, if restrictions imposed as a result of the COVID-19 pandemic permitted the convening of a face-to-face meeting. The Committee entrusted the Secretariat to agree on the exact dates of the meeting depending on the availability of the FAO conference facilities in consultation with the Bureau of the Chemical Review Committee, and to communicate those dates to the Committee. The Committee also agreed that, in accordance with the interim programme of work and budget for 2022 approved by the Conference of the Parties to the Rotterdam Convention at its tenth meeting, the eighteenth meeting of the Committee be held over a period of up to five days, given the heavy workload that was expected.

[2] UNEP/FAO/RC/CRC.17/INF/35.

VI. Other matters

A. Report on activities to facilitate effective participation in the work of the Committee

140. The representative of the Secretariat reported on the work undertaken in response to decision RC-9/2, in which the Conference of the Parties had requested the Secretariat to establish and implement training activities for new and existing members and to report on their results to the Conference of the Parties at its tenth meeting.

141. While no face-to-face activities had been possible since the sixteenth meeting of the Committee owing to the COVID-19 pandemic, the Secretariat had continued to offer webinar training to support the participation of members and observers in the work of the Committee. Recordings of previous training sessions had been shared with all members and a new webinar had been held on 8 September 2021 on how to effectively facilitate the work of intersessional task groups as a chair and how to participate effectively in the work of the Committee as a member. Briefing webinars had been held prior to the present meeting, for all Committee members and observers, to support their effective participation in the meeting, and for the general public, on the agenda and organization of work. Two debriefing webinars would also be held on the outcomes of the meeting.

142. In November 2020, following the Committee's sixteenth meeting, the Secretariat had conducted a survey of current and past members on ways to enhance effective participation in the work of the Committee and members' needs in that regard. As the survey was conducted just after the first online meeting, feedback on the online meeting had also been solicited. The results of the survey were set out in document UNEP/FAO/RC/CRC.17/INF/32.

B. Intersessional work on new notifications of final regulatory action

143. The representative of the Secretariat said that with the publication of PIC Circular 53 in June 2021, a large number of new notifications of candidate chemicals had been identified for the Committee's consideration at future meetings, meaning that the Committee had considerable work ahead of it. Furthermore, the Conference of the Parties was to appoint 17 new members during the face-to-face segment of its tenth meeting, in June 2022, and there would be very little time for the new members to familiarize themselves with the mandate, policies and procedures of the Committee before its eighteenth meeting, planned for September or October 2022, let alone to participate effectively in intersessional work on the new candidate chemicals. A possible solution was to advance the intersessional work so that the current members could undertake the Bureau preliminary review and carry out the intersessional task group work. In that case, the Bureau would further discuss a detailed plan for the new notifications and communicate it to the Committee members in a timely manner.

144. One member cautioned that the Bureau would have to plan the intersessional work very carefully given that the many new members would not have the opportunity to participate in that work, while another expressed support for making maximum use of the current members' experience during the period prior to June 2022.

145. The Committee took note of the information provided.

VII. Adoption of the report of the meeting

146. 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.

VIII. Closure of the meeting

147. Following the customary exchange of courtesies, the Chair declared the meeting closed at 6.15 p.m. (UTC + 2) on Friday, 24 September 2021.

Annex I

Decisions adopted by the Chemical Review Committee at its seventeenth meeting

CRC-17/1: Iprodione

CRC-17/2: Terbufos

CRC-17/3: Thiodicarb

CRC-17/1: Iprodione

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 iprodione submitted by Mozambique and the European Union[3] 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 iprodione 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 iprodione;

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 iprodione 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 seventeenth meeting.

Annex to decision CRC-17/1

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

1. The notifications on iprodione from Mozambique 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.17/5, UNEP/FAO/RC/CRC.17/INF/11 and UNEP/FAO/RC/CRC.17/INF/12. Information on trade was made available in document UNEP/FAO/RC/CRC.17/INF/5.

I. Mozambique

(a) Scope of the regulatory action notified by Mozambique

3. The regulatory action notified by Mozambique relates to iprodione (CAS No. 36734-19-7) as a pesticide. Iprodione was banned by the National Directorate of Agrarian Services from further import and use in Mozambique by decision Nr 001/DNSA/2014. The regulatory action entered into force on 15 July 2014. The ban of all uses and the cancellation of the products containing iprodione in the country were decided due to the toxic nature and hazardous properties of this active substance which, combined with improper use in the country due to the local specific conditions of use, can damage human and animal health.

4. The decision to ban the registration of iprodione was taken as the last step in the project on reducing risks of highly hazardous pesticides, which identified highly hazardous pesticides (HHPs) that are registered in Mozambique. After consultations with different actors (public sector, private sector, civil society and others) the cancellation of registrations and consequent ban and non-approval of its use in Mozambique was approved.

5. The notification was found to meet the information requirements of Annex I.

[3] See UNEP/FAO/RC/CRC.17/5.

(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 Committee confirms that the regulatory action was taken to reduce the risk from iprodione to human health (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification).

7. The notification states that the ban of all uses and the cancellation of the products containing iprodione in Mozambique were decided based on the toxic nature and hazardous properties of this active substance which, combined with improper use in the country due to the local specific conditions of use, can damage human and animal health.

8. Iprodione and products containing iprodione were considered to be harmful to human health, taking into consideration the local conditions of use in Mozambique requiring risk mitigation measures. The notification refers to a consultancy report entitled "Shortlisting highly hazardous pesticides" (Come and van der Valk, 2014, see full reference below), which identified iprodione as carcinogenic equivalent or similar to GHS category 1A and 1B. The conclusion was based on the United States Environmental Protection Agency (EPA) and European Food Safety Authority (EFSA) assessments, according to which iprodione was classified as likely to be carcinogenic or in category 2 of the carcinogenicity classification.

9. The final conclusion of the HHP assessment in Mozambique identified iprodione as carcinogenic equivalent or similar to GHS category 1A and 1B, and it was therefore considered as "coming close" to being an HHP (Come and van der Valk, 2014).

10. The Committee therefore confirms that 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;

11. The notification refers to the following consultancy reports, based on international assessments and property data, and the following meeting report:

(a) A.M. Come and H. van der Valk, "Reducing risks of highly hazardous pesticides in Mozambique: Step 1 – Shortlisting highly hazardous pesticides", consultancy report undertaken under project EP/MOZ/101/UEP (2014);

(b) A.M. Come and others, "Reducing risks of highly hazardous pesticides in Mozambique: Step 2 – Survey of pesticide use practices in selected cropping systems", consultancy report undertaken under project EP/MOZ/101/UEP (2014);

(c) Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO), "Report of the second Joint Meeting on Pesticide Management and the fourth session of the FAO Panel of Experts on Pesticide Management" (pp.14–18), Geneva (2008). Available at: ww.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Report.pdf.

12. The available consultancy reports and hazard assessment criteria by the FAO/WHO Joint Meeting on Pesticide Management (JMPM) are considered scientifically sound and generated according to scientifically recognized methods and reported according to generally recognized scientific principles and procedures.

13. Iprodione was shortlisted as a pesticide "coming close" to being an HHP based on the following criteria:

(a) Pesticides for which carcinogenicity evaluations by different registration/assessment authorities did not lead to consistent classification as GHS category 1A or 1B, but which were, based on the evidence of one of these authorities, considered of particular concern for use in Mozambique (Come and van der Valk, 2014);

(b) Iprodione was classified by the United States EPA as likely to be carcinogenic. It was registered in the United States. However, all residential uses were cancelled due to cancer risk

concerns and the remaining backpack sprayers and mixers were required to wear double-layer personal protective equipment, masks and gloves. Iprodione was registered in the European Union. The European Union review of 2004 classified iprodione in category 2 of the carcinogenicity classification. The Mozambican authorities considered that the risk mitigation measures of the United States could not be achieved in Mozambique.

14. The final conclusion of the HHP assessment in Mozambique identified iprodione as carcinogenic equivalent or similar to GHS category 1A and 1B, and it was therefore considered as "coming close" to being an HHP (Come and van der Valk, 2014).

15. Iprodione and products containing it were considered harmful to human health, taking into consideration the local conditions of use in Mozambique requiring risk mitigation measures (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification).

16. The available reports developed under the reducing risks of highly hazardous pesticides in Mozambique project and included in the supporting documentation provide a detailed methodology that specifies that internationally recognized criteria established by the FAO/WHO JMPM for the identification of HHPs, together with the additional criterion used by Mozambique, were utilized for the identification of iprodione as "coming close" to being an HHP (UNEP/FAO/RC/CRC.17/INF/11, p.15). Also, the report on the survey of pesticide use practices in selected cropping systems indicates that its design was informed by reviews of various existing pesticide use or exposure surveys conducted under WHO and the Rotterdam Convention, as well as general FAO guidance on the development of this type of questionnaire. Interviewers were also trained in survey techniques (UNEP/FAO/RC/CRC.17/INF/11, pp.57–58).

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

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

18. The notification states that the final regulatory action was based on a risk or hazard evaluation involving the prevailing conditions within the Party in order to protect human health (UNEP/FAO/RC/CRC.17/5, sect. 2.4 of the Mozambique notification). With the goal of reducing the greatest risks associated with pesticide use in Mozambique, the reducing risks of highly hazardous pesticides in Mozambique project was initiated by the Government of Mozambique, with the technical support of the FAO Pesticide Management Unit, and funded by the Strategic Approach to International Chemicals Management (SAICM) Quick Start Programme Trust Fund. Its ultimate goal was to develop and implement an "HHP Risk Reduction Action Plan" in Mozambique for the most dangerous pesticides and use situations, resulting over time in the implementation of a variety of risk reduction measures based on a review of use conditions. These could include the cancellation of specific registrations of HHPs, implementation of risk mitigation measures, appropriate use restrictions, development of alternative pest management strategies, promotion of good agricultural practices, and possible phase-out of specific pesticides (UNEP/FAO/RC/CRC.17/INF/11).

19. The project was separated into three steps, the first of which involved the review of all the pesticides registered in Mozambique and the establishment of a shortlist of HHPs. This shortlist was based on an assessment of the hazards of the pesticides, based on criteria established by the FAO/WHO JMPM (FAO/WHO, 2008), and additional criteria for pesticides with characteristics coming close to JMPM criteria.

20. The iprodione formulation registered at the time in Mozambique was Iprodione 25.5% SC (UNEP/FAO/RC/CRC.17/5, sect. 1.3 of the Mozambique notification and UNEP/FAO/RC/CRC.17/INF/11, p. 49). This formulation was assessed against the FAO/WHO JMPM criteria for identification of HHPs and the following additional criterion used by Mozambique for identifying pesticides with characteristics which "come close" to being an HHP: pesticides for which carcinogenicity evaluations by different registration/assessment authorities did not lead to consistent classification as GHS category 1A or 1B, but which were, based on the evidence of one of these authorities, considered of particular concern for use in Mozambique. As a result, iprodione was on the shortlist as a pesticide "coming close" to being an HHP.

21. During the second step of the project, a use survey was carried out in selected regions and cropping systems in Mozambique. The main goal of the survey was to identify the conditions under which pesticides are being used in the country and their contribution to potential risks for human health and the environment.

22. The surveys (325 subsistence farmers interviewed) revealed that most of the farmers applied pesticides (95 per cent), and that the conditions of use were likely to result in undue (excessive) exposure. Half of the farmers interviewed had never received any training on pesticides use, and the other half, who had received training, often lacked understanding of the risks involved. Farmers were spraying vegetable crops at least 14 times per growing season. One out of three applications involved one of the HHP-containing formulations (almost 30 per cent of the interviewed farmers used HHPs).

23. In addition, almost none of the farmers (93 per cent) owned or wore adequate personal protective equipment (PPE), having only one or no protective items at all. Only 2 per cent of those applying HHPs wore adequate full-body-protection PPE. About half of the farmers had not received any training on the use of pesticides. The majority of pesticide applicators used manual sprayers (36 per cent), followed by battery-operated electric sprayers (33 per cent) and inappropriate equipment such as watering cans (13.5 per cent) or other (unknown) means (12.5 per cent). Approximately half of the farmers surveyed reported that they had noticed getting the pesticide on their clothes, bare skin or eyes during use. The main health symptoms associated with pesticide use by farmers noticing symptoms were headaches, skin rashes, burning eyes, vomiting, burning nostrils, blurred vision, dizziness and excessive sweating. Almost half of the farmers declared that they did not read pesticide labels, including use instructions such as proper dosage and protective measures, with the main reason being illiteracy. One out of four farmers poorly understood the hazard colour band on pesticide labels that indicates acute toxicity.

24. The survey results showed that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers in Mozambique. Therefore, the enforcement of risk mitigation measures that depended solely on wearing the appropriate PPE under the local conditions of use would be difficult and unlikely to give results.

25. The third step of the project consisted of a stakeholder consultation to further discuss the use and risks of HHPs in Mozambique and fine-tune the shortlist based on the survey results and the expertise and experience of stakeholders.

26. Iprodione and the products containing this active ingredient were considered harmful to human health taking into consideration the local conditions of use in Mozambique requiring risk mitigation measures. Therefore, the authorities decided to ban the active ingredient iprodione from future use in the country and to cancel the registration of all products containing it (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification, with a focus on iprodione-specific information as included in the supporting documentation).

27. Although specific information related to actual or measured exposure of agricultural workers to iprodione in Mozambique was not included as part of the risk evaluation, the notification and supporting documentation provide an assessment of the prevailing conditions of use of pesticides in Mozambique. Iprodione was imported into Mozambique in 2013 and registrations of the formulation remained in place; future use could not therefore be precluded (UNEP/FAO/RC/CRC.17/INF/11, p. 35). The registered uses for iprodione formulations were for vines, fruit trees and vegetables. Vegetable cropping systems were included in the survey of users conducted, and vegetables were the predominant crops in two of the regions of Mozambique surveyed (UNEP/FAO/RC/CRC.17/INF/11, pp. 52–77). The notification and supporting documentation indicate that the use of pesticides in general was likely to result in excessive exposure of farmers given the availability, knowledge and use of PPE among farmers, and was evidenced by a high level of reporting of adverse health effects. The final regulatory action was taken as a result of Mozambique's national objective of reducing the greatest risks associated with pesticide use.

28. Mozambique's goal to develop and implement an HHP risk reduction action plan could be considered a national policy that HHPs should not be registered based on the understanding that the prevailing conditions of use in Mozambique will result in unacceptable risks to agricultural workers. Iprodione was included in the shortlist of HHPs as "coming close" to being an HHP based on the following criteria: pesticides for which carcinogenicity evaluations by different registration/assessment authorities did not lead to consistent classification as GHS category 1A or 1B, but which were, based on the evidence of one of these authorities, considered of particular concern for use in Mozambique (Come and van der Valk, 2014). Iprodione was classified by the United States EPA as likely to be carcinogenic. The European Union review of 2004 classified iprodione in category 2 of carcinogenicity classification (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification).

29. Iprodione was registered in the United States. However, all residential uses were cancelled due to cancer risk concerns. In addition, backpack sprayers and mixers were required to wear double-layer PPE, including masks and gloves (UNEP/FAO/RC/CRC.17/INF/11, p. 327).

30. According to the survey, similar pesticide uses and application techniques to those in the United States (use on field, fruit and vegetable crops) were used in Mozambique. The Mozambican authorities considered that the risk mitigation measures required in the United States could not be achieved in Mozambique.

31. Therefore, taking into consideration the national objective of Mozambique of reducing risks of the most dangerous pesticides, including HHPs, the results of the survey of pesticide use practices in selected cropping systems in Mozambique (some of which are representative of registered iprodione uses), which included the identification of inadequate availability and use of PPE and iprodione's likely carcinogenicity, and noting the bridging information to the PPE requirements in the United States, it is concluded that the final regulatory action was based on a risk evaluation involving the prevailing conditions within the Party taking the action.

32. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

33. The Committee confirms that the criteria of paragraph (b) of Annex II 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;

34. Before the regulatory action, iprodione was used in Mozambique as a fungicide in vines, fruit trees and vegetables. There was one pesticide formulation on the market (UNEP/FAO/RC/CRC.17/5, sect. 1.3 of the Mozambique notification). The supporting documentation reported 12 litres of import in 2013 for the registered pesticide formulation (UNEP/FAO/RC/CRC.17/5, sect. 2.5.1 of the Mozambique notification and Come and van der Valk, 2014, table 6).

35. The final regulatory action banned the import and use of iprodione in Mozambique and cancelled the registration of all products containing iprodione. Although information on registration and imported amounts was available for only one formulation and for a short period of time, it is expected that the regulatory action will remove exposure to this chemical in Mozambique.

36. The Committee therefore confirms 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;

37. Iprodione was identified as carcinogenic equivalent or similar to GHS category 1A and 1B (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification). A follow-up survey (Come et al., 2014) found that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers in Mozambique. Iprodione and the products containing it were considered harmful to human health, taking into consideration the local conditions of use in Mozambique requiring risk mitigation measures (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification). The enforcement of risk mitigation measures that depended solely on wearing the appropriate PPE under the local conditions of use was considered to be difficult and unlikely to produce results.

38. The ban of all iprodione formulations in Mozambique can be considered to reduce the risk from exposure to iprodione as much as possible.

39. The Committee confirms 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;

40. The final regulatory action was based on information on use of and exposure to pesticides during application (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification) as well as international information on hazards. As no specific exposure values for iprodione in Mozambique were derived, the considerations are not geographically limited.

41. The survey on pesticide use in Mozambique revealed poor use of protective equipment (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification). The notification notes that 93 per cent of farmers did not own or wear adequate PPE, having only one or no protective items at all. Approximately half of the farmers surveyed reported that they had noticed getting pesticide on their clothes, bare skin or eyes during use. Almost half of the farmers declared they did not read

pesticide labels, including use instructions such as proper dosage and protective measures, with the main reason being illiteracy. This information was not related to the use of iprodione specifically, but pesticides use in general. Similar conditions could be found elsewhere.

42. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

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

43. According to the notification and the supporting documentation, iprodione was imported into the Mozambican market in 2013. Recent communications from the European Union and CropLife International submitted to the Secretariat confirm the ongoing trade in iprodione (UNEP/FAO/RC/CRC.17/INF/5).

44. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

45. The Committee confirms that the criteria of paragraph (c) of Annex II are 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.

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

47. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

(f) Conclusion

48. The Committee concludes that the notification of final regulatory action submitted by Mozambique 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

49. The regulatory action notified by the European Union relates to iprodione (CAS No. 36734-19-7) as a pesticide. Iprodione is not included in the list of approved active substances under Regulation (EC) No 1107/2009.[4] It was concluded that no plant protection product containing the active substance iprodione is expected to satisfy in general the requirements laid down in Article 29 (1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EC) 546/2011. As a consequence, it is prohibited to place on the market or use plant protection products containing iprodione in the European Union as of 6 March 2018. Disposal, storage, placing on the market and use of existing stocks of plant protection products containing iprodione is prohibited as of 6 June 2018.

50. The notification was found to meet the information requirements of Annex I.

(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;

51. The Committee confirms that the regulatory action was taken to reduce the risk from iprodione to human health and the environment (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 and 2.4.2.2 of the European Union notification, respectively).

52. According to the evaluation by the European Union related to human health the following concerns were identified:

(a) The genotoxic potential of metabolite RP 30228 (found as a residue and impurity in the technical material). It is noted that metabolite RP 30228 is predicted to occur in groundwater above 0.1 µg/L in one groundwater scenario developed by the European Commission Forum for the coordination of pesticide fate models and their use (FOCUS) according to the representative uses;

[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Available at: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32009R1107.

(b) lprodione currently has a harmonized classification (GHS) as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council;

(c) For the representative uses considered, residue levels exceed the default value for maximum residue levels of pesticides in or on food and feed of plant and animal origin;

(d) An acute consumer risk that cannot be excluded based on a preliminary risk assessment.

53. According to the evaluation by the European Union related to the environment the following concerns were identified:

(a) The predicted concentrations in groundwater that exceed 0.1 µg/L for relevant metabolites RP 35606 and RP 30181. Metabolite RP 35606 also exceeds 0.75 µg/L in acidic soils, and metabolite RP 30181 exceeds 0.75 µg/L in both acidic and slightly acidic to alkaline soils for both intended uses (carrots and lettuce);

(b) The high long-term risk of iprodione to aquatic organisms.

54. Furthermore, in respect of one metabolite, found as a residue in plants and as an impurity in the technical material, the pesticide authority concluded that the genotoxic potential cannot be excluded and therefore the setting of reference values for that metabolite cannot be confirmed based on the information available. Moreover, based on the available information, the dietary risk assessment could not be finalized as it is not possible to establish residue definitions for risk assessment; nevertheless, an acute consumer risk could not be excluded. Finally, the long-term risk assessment for wild mammals for all the relevant routes of exposure could not be finalized, based on the information submitted in the dossier.[5]

55. The Committee therefore confirms that 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;

56. The notification refers to a hazard and risk assessment based on the information submitted by the pesticide registration applicant. The assessment report was peer-reviewed together with consultation between EFSA, European Union member States experts and the applicant (UNEP/FAO/RC/CRC.17/5, sect. 2.4.1 of the European Union notification).

57. The procedure for the renewal of the approval of active substances is contained in Commission Implementing Regulation (EU) No 844/2012.[6] The assessment has been outlined in chapter 2 to the regulation: “The rapporteur member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge. It shall take into account the supplementary dossiers, and, where appropriate, the dossiers submitted for the approval and subsequent renewals of approval.”

58. The supporting documentation contains the following reports:

(a) European Commission Directorate-General For Health and Food Safety, “Final renewal report for the active substance iprodione”, SANTE/10627/2017 Rev. 21 (6 October 2017);

(b) EFSA, “Conclusion on the peer review of the pesticide risk assessment of the active substance iprodione”, EFSA Journal 2016;14(11):4609 (2016a). Available at: https://doi.org/10.2903/j.efsa.2016.4609;

[5] See https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R2091&qid=1619436102485&from=EN#ntr6-L_2017297EN.01002501-E0006.

[6] Commission Implementation Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

(c) EFSA, "Conclusion on the peer review of the pesticide risk assessment of the active substance iprodione", EFSA Journal 2016;14(11):4609 (2016b). Available at: https://doi.org/10.2903/j.efsa.2016.4609.

59. The supporting material (EFSA, 2016a) notes that EFSA organized a consultation of technical experts from the European Union member States to review the renewal assessment report prepared by a member State and the comments received thereon (peer review).

60. While the conclusions have been published (EFSA, 2016b, appendix A), the information in the renewal report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009, and cannot be verified in the context of the task group's work. Nevertheless, considering the process outlined in the regulation, consultancies and peer review, it can be considered that data have been generated according to scientifically recognized methods and data reviews have been performed and documented according to generally recognized scientific principles and procedures.

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

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

62. The data used in the risk evaluation are considered relevant. According to the evaluation related to human health the following information was identified:

(a) lprodione currently has a harmonized classification (GHS) as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council;

(b) Given the GHS classification and the representative uses considered, residue levels exceed the default value for maximum residue levels of pesticides in or on food and feed of plant and animal origin;

(c) An acute consumer risk that cannot be excluded based on a preliminary risk assessment.

63. According to the evaluation related to the environment the following information was identified: the high long-term risk of iprodione to aquatic organisms.

64. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

65. The Committee confirms that the criteria of paragraph (b) of Annex II 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;

66. Prior to the final regulatory action, iprodione was registered as a fungicide (UNEP/FAO/RC/CRC.17/5, sect. 2.3.1 of the European Union notification). According to the supporting documentation, iprodione was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2003/31/EC in 2003. This approval expired in December 2013. One pesticide formulation was registered in the European Union: Rovral WG (BAS 610 06 F) (UNEP/FAO/RC/CRC.17/5, sects. 1.3 and 2.4.2.1 of the European Union notification).

67. The final regulatory action prohibits all applications of iprodione as a plant protection product within the European Union.

68. The Committee therefore confirms 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;

69. According to the notification, the expected outcome of the final regulatory action is the reduction of risk to human health and the environment from the use of plant protection products containing iprodione (UNEP/FAO/RC/CRC.17/5, sects. 2.4.2.1 and 2.4.2.2 of the European Union notification).

70. The concerns regarding the use of iprodione, as identified in the evaluation (UNEP/FAO/RC/CRC.17/5, sects. 2.4.2.1 and 2.4.2.2 of the European Union notification), were considered not acceptable to allow its approval as a pesticide in accordance with Regulation (EC) No 1107/2009.

71. The ban of all iprodione formulations in the European Union can therefore be considered to result in a significant reduction of risk to human health and the environment.

72. The Committee confirms 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;

73. The human health and environmental hazards identified in the evaluation are also applicable to regions outside the European Union. The exposure assessment was based on simulation modelling with models and scenarios developed for and representative of European conditions. However, similar conditions can also be found outside the European Union.

74. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

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

75. Recent communications from the European Union and CropLife International submitted to the Secretariat confirm the ongoing trade in iprodione (UNEP/FAO/RC/CRC.17/INF/5).

76. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

77. The Committee confirms that the criteria of paragraph (c) of Annex II are 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.

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

79. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

(f) Conclusion

80. 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

81. The Committee concludes that the notifications of final regulatory action submitted by Mozambique and the European Union meet all the criteria set out in Annex II to the Convention.

82. The Committee also concludes that the final regulatory actions taken by Mozambique and the European Union provide a sufficient basis for including iprodione in Annex III to the Convention in the pesticide category and that a decision guidance document should be drafted on the basis of the notifications.

CRC-17/2: Terbufos

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 terbufos submitted by Canada and Mozambique[7] 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 terbufos 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 terbufos;

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 terbufos 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 seventeenth meeting.

Annex to decision CRC-17/2

Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by Canada and Mozambique in respect of terbufos in the pesticide category meet the criteria of Annex II to the Rotterdam Convention

1. The notifications on terbufos from Canada and Mozambique 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 (UNEP/FAO/RC/CRC.17/8/Rev.1, UNEP/FAO/RC/CRC.17/INF/18, UNEP/FAO/RC/CRC.17/INF/19/Rev.1). Information on trade was available in document UNEP/FAO/RC/CRC.17/INF/5.

I. Canada

(a) Scope of the regulatory action notified by Canada

3. The regulatory action notified by Canada relates to terbufos (CAS No. 13071-79-9) as a pesticide. Prior to the final regulatory action entering into force, terbufos was registered in Canada for use on canola, corn, mustard, rutabagas and sugar beets (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.3.1 of the Canada notification). Based on the final regulatory action, no uses of terbufos were to be allowed after December 2004, except on sugar beets for which the use of terbufos was no longer allowed after 1 August 2012. The sale of pesticides containing terbufos was prohibited in Canada effective 1 May 2012. The use of products containing terbufos was prohibited after 1 August 2012. The final regulatory action was taken as a result of the unacceptable risk to the environment posed by the registered uses of pesticides containing terbufos in Canada (UNEP/FAO/RC/CRC.17/8/Rev.1, sects. 2.2.1 and 2.2.3 of the Canada notification).

4. The notification was found to meet the information requirements of Annex I.

[7] See UNEP/FAO/RC/CRC.17/8/Rev.1.

(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;

5. The Committee confirms that the regulatory action was taken to reduce the risk from terbufos to the environment (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.4.2.2 of the Canada notification).

6. According to the evaluation related to the environment based on the available toxicity data the following concerns were identified:

(a) Risk from exposure to terbufos is classified as high to extremely high for aquatic organisms and in most cases high to extremely high for birds;

(b) Risk to mammals is classified as low for large mammals to high for small mammals;

(c) High risk of terbufos on non-target species has been documented by incident reports of adverse effects.

7. The Committee therefore concludes that the final regulatory action was taken in order to protect the environment and that the Annex II, paragraph (a), criterion 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;

8. The notification indicates that the final regulatory action is based on a risk evaluation. In the notification, reference is made to the following documents, provided as supporting documentation in UNEP/FAO/RC/CRC.17/INF/19/Rev.1:

(a) Pest Management Regulatory Agency, Health Canada, “Proposed acceptability for continuing registration (PACR 2003-02): Re-evaluation of terbufos” (24 January 2003);

(b) Pest Management Regulatory Agency, Health Canada, “Re-evaluation decision document (RRD 2004-04): Re-evaluation of terbufos” (23 March 2004);

(c) Pest Management Regulatory Agency, Health Canada, “Re-evaluation note REV2008-06: Update on the use of terbufos on sugar beets” (26 March 2008);

(d) Pest Management Regulatory Agency, Health Canada, “Pest control products sales report for 2011” (2011);

(e) Colin Macbean, *The pesticide manual: a world compendium*, sixteenth edition (excerpt) (British Crop Protection Council, 2012).

9. A re-evaluation of the active ingredient terbufos and its end-use products for use on canola, corn, mustard and rutabagas was conducted under the authority of Section 19 of the Canadian Pest Control Products Regulations.

10. The Proposed Acceptability for Continuing Registration (PACR 2003-02) document includes a human health assessment, an environmental assessment and information on the value of terbufos to pest management in Canada. This document specifies that the toxicology database considered for terbufos is primarily based on studies available from the registrant. Data include toxicity end points, no observed adverse effect level (NOAEL), acute reference dose (ARfD), acceptable daily intake (ADI) determinations and comparison to expected exposure of humans. With regard to human health, occupational, dietary and aggregate (exposures from food and drinking water) risk assessments were conducted. A deterministic assessment of the environmental risks of pest control products was also conducted. Environmental risk was characterized by the quotient method, which uses the ratio of the estimated environmental concentrations to the end point of concern for effects on non-target organisms. Quotient values less than one are considered indicative of a low hazard to non-target organisms, whereas values greater than one are considered to indicate that some degree of hazard exists for effects on non-target organisms. The risk assessments were also subject to a 60-day public consultation period to allow interested parties an opportunity to provide input into the re-evaluation decision.

11. The data included in the notification and supporting documentation are considered to be scientifically sound and generated according to scientifically recognized methods and data reviews are considered to have been performed and documented according to generally recognized scientific principles and procedures.

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

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

13. The final regulatory action to ban terbufos and its associated end-use products in Canada was based on a risk evaluation and is relevant to the environment. The conditions of use within Canada, including the registered uses, application rates and agricultural practices, have been taken into account in the risk assessments. The Canadian Pest Management Regulatory Agency's (PMRA) re-evaluation decision was based on the evaluation of the registered uses in Canada.

14. At the time of the regulatory action, terbufos products were registered in Canada and sold as a granular soil insecticide and nematicide for use on canola, corn, mustard, rutabagas and sugar beets. Terbufos has systemic and contact activity on insects. Like other organophosphates, terbufos inhibits acetylcholinesterase enzyme, interrupting the transmission of nerve impulses (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.3.1 of the Canada notification, and UNEP/FAO/RC/CRC.17/INF/19/Rev.1, annex, sect. 1, "Proposed acceptability for continuing registration (PACR 2003-02)").

15. Terbufos has low solubility in water and has moderate volatility potential from moist soil or water surfaces. n-octanol-water partition coefficients indicate potential for a bioaccumulation of the parent compound and limited bioaccumulation potential for terbufos sulfone or terbufos sulfoxide. Bioconcentration studies with fish indicate a potential for bioconcentration.

16. Terbufos is susceptible to transformation by both abiotic and biotic processes. Hydrolysis appears to be a major abiotic transformation route for parent terbufos. Hydrolysis of terbufos sulfoxide and terbufos sulfone is pH dependent and is slower than for the parent compound. The major route for biotic transformation is aerobic biotransformation with terbufos sulfoxide, terbufos sulfone and CO_2 as the major transformation products. Based on available data, terbufos will be slightly to moderately persistent in terrestrial soil systems depending on temperature and soil conditions.

17. PMRA has identified extremely high hazards to terrestrial organisms resulting from all currently registered uses of terbufos. This assessment is supported by reports of incidents in Canada and the United States.

18. PMRA has identified extremely high hazards to aquatic organisms resulting from all currently registered uses of terbufos. This assessment is supported by reports of incidents of adverse effects in the United States. Similar effects may have occurred in Canada, but there is no equivalent reporting system.

19. Risk quotients determined for applications of the end-use terbufos formulations Counter 5-G and Counter 15-G indicate risks for all groups of organisms (i.e., birds, mammals, fish and aquatic invertebrates) for all application scenarios. Based on the available toxicity data, risk is classified as high to extremely high for aquatic organisms and in most cases high to extremely high for birds. Similarly, risk to mammals is classified from low for large mammals to high for small mammals (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 3.2.3 of the Canada notification).

20. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

21. The Committee confirms that the criteria of paragraph (b) of Annex II 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;

22. The estimated quantity of terbufos produced, imported and exported from Canada prior to the regulatory action was not provided. The quantity of the active ingredient terbufos used in 2011, the year prior to the ban on terbufos entering into force, was reported to be less than 50,000 kg (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.5.1 of the Canada notification).

23. The final regulatory action phased out all uses of terbufos as a pest control product in Canada in 2012 (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.2.1 of the Canada notification) and it is therefore expected that any quantity used as a pest control product will be reduced to zero.

24. The Committee therefore confirms 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;

25. According to the notification, preventing the use of terbufos protects the environment and non-target organisms from the risk of exposure, and therefore the expected outcome of the final regulatory action is a reduction of risk for the environment from the use of plant protection products containing terbufos (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.4.2.2 of the Canada notification).

26. The phase-out of all uses of terbufos on 1 August 2012 is expected to have led to a significant reduction in the quantity of the chemical used in Canada and it is therefore expected that the risk to the environment has been significantly reduced.

27. The Committee confirms 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;

28. Risks associated with end-use terbufos formulations have been identified for all groups of organisms (i.e., birds, mammals, fish and aquatic invertebrates) for all application scenarios.

29. The notification states that environmental risks posed by terbufos are likely to be relevant in countries with similar terbufos use patterns (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.5.2 of the Canada notification).

30. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

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

31. In response to the Secretariat's request to provide information on ongoing international trade in candidate chemicals for the seventeenth meeting of the Chemical Review Committee, CropLife International confirmed ongoing international trade in terbufos by companies that are not members of CropLife International (UNEP/FAO/RC/CRC.17/INF/5).

32. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

33. The Committee confirms that the criteria of paragraph (c) of Annex II are 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.

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

35. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

(f) Conclusion

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

II. Mozambique

(a) Scope of the regulatory action notified by Mozambique

37. The regulatory action notified by Mozambique relates to terbufos (CAS No. 13071-79-9) as a pesticide. Prior to the final regulatory action entering into force, terbufos was registered in Mozambique as an insecticide to be used on maize, sorghum, potato and beans (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.3.1 of the Mozambique notification).

38. Terbufos was banned by the National Directorate of Agrarian Services from further import and use in Mozambique by decision Nr 001/DNSA/2014. The regulatory action entered into force on 15 July 2014. The ban of all uses and the cancellation of the products containing terbufos in the country were decided due to the toxic nature and hazardous properties of this active substance which,

combined with improper use in the country due to the local specific conditions of use, can harm human and animal health.

39. The decision to ban the registration of terbufos was taken as the last step in the project on reducing risks of HHPs which identified HHPs and other pesticides that are registered in Mozambique. After consultations with different actors (public sector, private sector, civil society and others), the cancellation of registrations and the consequent ban and non-approval of the use of terbufos in Mozambique was approved (UNEP/FAO/RC/CRC.17/8/Rev.1, sects. 2.2.1 and 2.2.3 of the Mozambique notification).

40. The notification was found to meet the information requirements of Annex I.

(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;

41. The Committee confirms that the regulatory action was taken to reduce the risk from terbufos to human health (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.4.2.1 of the Mozambique notification).

42. The notification states that the ban of all uses and the cancellation of the products containing terbufos in Mozambique were decided based on the toxic nature and hazardous properties of this active substance which, combined with improper use in the country due to the local specific conditions of use, can harm human and animal health.

43. The notification refers to a consultancy report entitled "Reducing risks of highly hazardous pesticides in Mozambique: Step 1 – Shortlisting highly hazardous pesticides" (Come and van der Valk, 2014), which identified the terbufos formulation as extremely hazardous (class Ia) according to the FAO/WHO JMPM criteria for HHPs based on the WHO Recommended Classification of Pesticides by Hazard.

44. The results of a survey conducted among 325 subsistence farmers in Mozambique showed that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers. Therefore, the enforcement of risk mitigation measures that depended solely on wearing the appropriate PPE under the local conditions of use would be difficult and unlikely to produce results.

45. Terbufos and the products containing this active ingredient were considered harmful to human health under the local conditions of use in Mozambique requiring risk mitigation measures. The decision to cancel the registration of terbufos was taken as the last step in the project on reducing the risks of HHPs. The expected effect of the final regulatory action was reducing the risk posed by the use of terbufos in Mozambique in the context of human health (UNEP/FAO/RC/CRC.17/8/Rev.1, sects. 2.2.1 and 2.4.2.1 of the Mozambique notification).

46. The Committee therefore confirms that 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;

47. The notification refers to the following consultancy reports, based on international assessments and property data, and the following meeting report:

(a) A.M. Come and H. van der Valk, "Reducing risks of highly hazardous pesticides in Mozambique: Step 1 – Shortlisting highly hazardous pesticides", consultancy report undertaken under project EP/MOZ/101/UEP (2014);

(b) A.M. Come and others, "Reducing risks of highly hazardous pesticides in Mozambique: Step 2 – Survey of pesticide use practices in selected cropping systems", consultancy report undertaken under project EP/MOZ/101/UEP (2014);

(c) FAO/WHO, "Report of the second Joint Meeting on Pesticide Management and the fourth session of the FAO Panel of Experts on Pesticide Management" (pp. 14–18), Geneva (2008).

Available at:
www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Report.pdf;

(d) J. Lahr, R. Kruijne and J. Groenwold, "Hazards of pesticides imported into Mozambique, 2002–2011", Alterra Wageningen University and Research Centre (2014).

48. The ultimate goal of the project was to develop and implement an HHP risk reduction action plan for the most dangerous pesticides and use situations, resulting over time in the implementation of a variety of risk reduction measures based on a review of use conditions (UNEP/FAO/RC/CRC.17/8/Rev.1, sects. 2.4 and 2.4.1 of the Mozambique notification).

49. The decision to cancel the registration of terbufos was taken as the last step in the project on reducing the risks of HHPs. The ban of all uses and the cancellation of the products containing terbufos in the country (decision Nr 001/DNSA/2014) were decided due to the toxic nature and hazardous properties of this active substance which, combined with improper use in the country due to the local specific conditions of use, can harm human and animal health (UNEP/FAO/RC/CRC.17/8/Rev.1, sects. 2.2.1 and 2.4.2.1 of the Mozambique notification).

The supporting documentation (UNEP/FAO/RC/CRC.17/INF/18) also includes the following documents referenced in the notification:

(a) University of Hertfordshire, "Terbufos", Pesticides Properties Database. Available at: https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/621.htm;

(b) FAO/WHO JMPM, "Terbufos evaluation" (2005). Available at: www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Evaluation05/2005_Terbufos1.pdf;

(c) International Programme on Chemical Safety, "Pesticide residues in food – 2003 – Joint FAO/WHO Meeting on Pesticide Residues – Terbufos – Toxicological studies", Internationally Peer Reviewed Chemical Safety Information. Available at: www.inchem.org/documents/jmpr/jmpmono/v2003pr13.htm#tox.

50. The available consultancy reports and hazard assessment criteria by the FAO/WHO international panel are considered scientifically sound and generated according to scientifically recognized methods and reported according to generally recognized scientific principles and procedures.

51. The available reports developed under the project on reducing risks of HHPs in Mozambique and included in the supporting documentation provide detailed methodology that specifies that internationally recognized criteria established by the FAO/WHO JMPM for the identification of HHPs were used to identify terbufos (UNEP/FAO/RC/CRC.17/INF/18, p.15). Also, the report on the survey of pesticide use practices in selected cropping systems indicates that survey design was informed by reviews of various existing pesticide use or exposure surveys conducted under WHO and the Rotterdam Convention, as well as general FAO guidance on the development of this type of questionnaire. Interviewers were also trained in survey techniques (UNEP/FAO/RC/CRC.17/INF/18, pp. 57 and 58).

52. The data included in the notification and supporting documentation are considered to be scientifically sound and generated according to scientifically recognized methods and data reviews are considered to have been performed and documented according to generally recognized scientific principles and procedures.

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

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

54. The notification states that the final regulatory action was based on a risk or hazard evaluation involving the prevailing conditions within the Party in order to protect human health (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.4 of the Mozambique notification). With the goal of reducing the greatest risks associated with pesticide use in Mozambique, the project on reducing risks of highly hazardous pesticides in Mozambique was initiated by the Government of Mozambique, with the technical support of the FAO Pesticide Management Unit, and funded by the SAICM Quick Start Programme Trust Fund. Its ultimate goal was to develop and implement an HHP risk reduction action plan in Mozambique for the most dangerous pesticides and use situations, resulting over time in the implementation of a variety of risk reduction measures based on a review of use conditions. These could include the cancellation of specific registrations of HHPs, implementation of risk mitigation

measures, appropriate use restrictions, development of alternative pest management strategies, promotion of good agricultural practices, and possible phase-out of specific pesticides (UNEP/FAO/RC/CRC.17/INF/18, p. 11).

55. The project was separated into three steps, the first of which involved the review of all the pesticides registered in Mozambique and the establishment of a shortlist of HHPs. This shortlist was based on an assessment of the hazards of the pesticides, based on criteria established by the FAO/WHO JMPM (FAO/WHO, 2008).

56. The terbufos formulations registered at the time in Mozambique included Moz Terbufos 15% GR, Rotam Terbufos 15% GR, and Bongo (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 1.3 of the Mozambique notification; UNEP/FAO/RC/CRC.17/INF/18, p. 203). These formulations were assessed against the following FAO/WHO JMPM criterion for identification of HHPs: pesticide formulations that meet the criteria of classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard. The oral and dermal LD_{50} value of the formulations, as provided in the registration dossier, were used as the basis for the classification. LD_{50} values for the formulations were available or could be estimated. The terbufos formulations were identified as extremely hazardous (class Ia) according to the JMPM criteria for HHPs based on the WHO Recommended Classification of Pesticides by Hazard, and therefore considered and shortlisted as HHP.

57. During the second step of the project, a use survey was carried out in selected regions and cropping systems in Mozambique. The main goal of the survey was to identify the conditions under which pesticides were being used in the country and their contribution to potential risks to human health and the environment.

58. The surveys (325 subsistence farmers interviewed) revealed that most of the farmers applied pesticides (95 per cent), and that the conditions of use were likely to result in undue (excessive) exposure. Half of the farmers interviewed had never received any training on pesticide use, and the other half, who had received training, often lacked understanding of the risks involved. Farmers were spraying vegetable crops at least 14 times per growing season. One out of three applications involved one of the HHP-containing formulations (almost 30 per cent of the farmers interviewed used HHPs).

59. In addition, almost none of the farmers (93 per cent) owned or wore adequate PPE, having only one or no protective items at all. Only 2 per cent of those applying HHPs wore adequate full-body PPE. About half of the farmers had not received any training on the use of pesticides. The majority of pesticide applicators used manual sprayers (36 per cent), followed by electric sprayers (with batteries) (33 per cent) and inappropriate equipment such as watering cans (13.5 per cent) or other (unknown) means (12.5 per cent). Approximately half of the farmers surveyed reported that they had noticed getting the pesticide on their clothes, bare skin or eyes during use. The main health symptoms associated with pesticide use by farmers noticing symptoms were headaches, skin rashes, burning eyes, vomiting, burning nostrils, blurred vision, dizziness and excessive sweating. Almost half of the farmers declared that they did not read pesticide labels, including use instructions such as proper dosage and protective measures, with the main reason being illiteracy. One out of four farmers poorly understood the hazard colour band on pesticide labels that indicates acute toxicity.

60. The survey results showed that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers in Mozambique. Therefore, the enforcement of risk mitigation measures that depended solely on wearing the appropriate PPE under the local conditions of use would be difficult and unlikely to give results.

61. The third step of the project consisted of a stakeholder consultation to further discuss the use and risks of HHPs in Mozambique and fine-tune the shortlist based on the survey results and the expertise and experience of stakeholders.

62. Terbufos and the products containing this active ingredient were considered to pose unacceptable risk to human health under the local conditions of use in Mozambique requiring risk mitigation measures. Therefore the authorities decided to ban the active ingredient terbufos from future use in the country and to cancel the registration of all products containing it (UNEP/FAO/RC/CRC.17/8/Rev.1, sects. 1.3 and 2.4.2.1 of the Mozambique notification, with a focus on terbufos-specific information as included in the supporting documentation).

63. Although specific information related to actual or measured terbufos exposure of agricultural workers in Mozambique was not included as part of the risk evaluation, the notification and supporting documentation provide an assessment of the prevailing conditions of use of pesticides in Mozambique. While no imports of terbufos formulations were recorded in the four years (2010–2013) prior to and including the period when the survey of users was carried out, registrations of those formulations remained in place and therefore future use could not be precluded (UNEP/FAO/RC/CRC.17/INF/18,

p. 33). The registered uses for terbufos formulations were for maize, sorghum, potato and beans. These cropping systems were included in the survey of users conducted, and were the predominant crops in three of the regions of Mozambique surveyed. In addition, vegetable crops were reported as being the crops most frequently oversprayed by HHPs, which poses a risk to human health given the local conditions of use (application as many as 14 times per growing season) (UNEP/FAO/RC/CRC.17/INF/18, pp. 52–77). The notification and supporting documentation indicate that the use of pesticides in general, and of HHPs (such as terbufos) in particular, was likely to result in excessive exposure of farmers given the availability, knowledge and use of PPE among farmers, and was evidenced by a high level of reporting of adverse health effects. The final regulatory action was taken as a result of the national objective of Mozambique of reducing the greatest risks associated with pesticide use.

64. The country's goal of developing and implementing an HHP risk reduction action plan could be considered as a national policy that HHPs not be registered based on the understanding that the prevailing conditions of use in Mozambique will result in unacceptable risks to agricultural workers. Terbufos and the terbufos formulations registered in Mozambique were identified as HHPs as they are classified as WHO class Ia – extremely hazardous pesticides. Therefore, taking into consideration the national objective of Mozambique of reducing risks of the most dangerous pesticides including HHPs, the results of the survey of pesticide use practices in selected cropping systems in Mozambique (some of which are representative of potential terbufos use), which included the identification of inadequate availability and use of PPE and terbufos' high acute toxicity (WHO hazard classification Ia – extremely hazardous), it is concluded that the final regulatory action was based on a risk evaluation involving the prevailing conditions within the Party taking the action.

65. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

66. The Committee confirms that the criteria of paragraph (b) of Annex II 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;

67. The notification indicates that, before the regulatory action entered into force on 15 July 2014, terbufos was registered for use as an insecticide on maize, sorghum, potato and beans. The notification also provides quantities of the formulations imported for the years 2008 (4,650 kg) and 2009 (6,750 kg) (UNEP/FAO/RC/CRC.17/8/Rev.1, sects. 2.3.1 and 2.5.1 of the Mozambique notification).

68. The final regulatory action banned the import and use of terbufos in Mozambique and cancelled the registration of all products containing terbufos. Therefore, it is expected that the regulatory action will lead to a significant reduction in the quantity of the chemical used in Mozambique.

69. The Committee therefore confirms 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;

70. Given that the ban of the import and use, and the cancellation of the registration of products containing terbufos is expected to lead to a significant reduction in the quantity of the chemical used in Mozambique, the risks to human health are expected to be significantly reduced.

71. The Committee therefore confirms 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;

72. The notification states that countries with similar conditions as well as those where farmers use pesticides without PPE could take a similar decision in order to protect human health (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.5.2 of the Mozambique notification). The considerations that led to the final regulatory action are generally applicable to other countries and are related to the intended use of terbufos as a pesticide.

73. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

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

74. In response to the Secretariat's request to provide information on ongoing international trade in candidate chemicals for the seventeenth meeting of the Committee, CropLife International confirmed ongoing international trade in terbufos by companies that are not members of CropLife International (UNEP/FAO/RC/CRC.17/INF/5).

75. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

76. The Committee confirms that the criteria of paragraph (c) of Annex II are 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.

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

78. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

(f) Conclusion

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

III. Conclusion

80. The Committee concludes that the notifications of final regulatory action submitted by Canada and Mozambique meet all the criteria set out in Annex II to the Convention.

81. The Committee also concludes that the final regulatory actions taken by Canada and Mozambique provide a sufficient basis for including terbufos in Annex III to the Convention in the pesticide category and that a decision guidance document should be drafted on the basis of the notifications.

CRC-17/3: Thiodicarb

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 thiodicarb submitted by the European Union[8] 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 thiodicarb meets the criteria set out in Annex II to the Convention, it will take no further action on the chemical at present.

Annex to decision CRC-17/3

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

1. The notification on thiodicarb 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.17/9 and UNEP/FAO/RC/CRC.17/INF/21. Information on trade was made available in document UNEP/FAO/RC/CRC.17/INF/5.

(a) Scope of the notified regulatory action

3. The regulatory action notified by the European Union relates to the use of thiodicarb (CAS No. 59669-26-0) as a pesticide. The marketing or the use of thiodicarb is banned by the final regulatory action which states that it is prohibited to place on the market or use plant protection products containing thiodicarb. Thiodicarb is no longer included in the list of authorized active ingredients in Annex I to Directive 91/414/EEC. From 31 May 2007 no authorization for plant protection products containing thiodicarb can be granted or renewed. The authorizations for plant protection products containing thiodicarb had to be withdrawn by 25 November 2007 (UNEP/FAO/RC/CRC.17/9, sect. 2.2.1 of the European Union notification).

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

(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;

5. The Committee confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.17/9 sects. 2.4.1 and 2.4.2).

6. Thiodicarb was used as an insecticide and molluscicide (foliar spraying in table and wine grapes and spreading baits to control slugs and snails in wheat, triticale, rye, barley and oats) (UNEP/FAO/RC/CRC.17/9, sects. 1.7.1 and 2.4.1 of the European Union notification).

7. A risk assessment was carried out on the basis of Directive 91/414/EEC. The evaluation was based on a review of scientific data generated for thiodicarb in the context of the conditions prevailing in the European Community (intended uses, recommended application rates, good agricultural practices).

[8] See UNEP/FAO/RC/CRC.17/9.

8. The final regulatory action to ban thiodicarb was based on a risk evaluation. The risk analysis considered the use of thiodicarb as an insecticide and molluscicide (foliar spraying in table and wine grapes and spreading baits to control slugs and snails in cereals).

9. The following concerns and risks to human health were identified (UNEP/FAO/RC/CRC.17/9, sects. 2.4.1 and 2.4.2 of the European Union notification):

(a) An acute dietary risk for toddlers resulting from the consumption of treated table grapes and for adults resulting from the consumption of wine produced from treated wine grapes;

(b) Potential of groundwater contamination under vulnerable situations;

(c) Data gaps were identified concerning the use of thiodicarb as a molluscicide, in particular regarding operator exposure.

10. The following risks to the environment were identified (UNEP/FAO/RC/CRC.17/9, sects. 2.4.1 and 2.4.2 of the European Union notification):

(a) For use of the pellet formulation (Skipper), high acute and long-term risks were identified for birds and mammals from direct consumption of pellets and additionally an acute risk from consumption of methomyl-contaminated earthworms;

(b) With regard to the use of Skipper on soils vulnerable to drainage, there is a potential risk for exposure of surface water via drainage;

(c) Thiodicarb is toxic to honeybees and there is a long-term risk to earthworms from exposure to methomyl.

11. It was concluded that thiodicarb was not demonstrated to fulfil the safety requirements laid down in Article 5 (I) (a) and (b) of Directive 91/414/EEC. In particular, concerns were identified with regard to consumer exposure and the use as a molluscicide (UNEP/FAO/RC/CRC.17/9, sect. 2.3 of the European Union notification).

12. The Committee concludes that the Annex II, paragraph (a), criterion 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;

13. The notification states that the final regulatory action was based on a risk or hazard evaluation. In the notification, reference is made to the following documents:

(a) European Commission Directorate-General for Health and Food Safety, “Review report by the European Commission for the active substance thiodicarb”, SANCO/10013/2006 Rev.1(2007), and supporting background documents (dossier, monograph and the EFSA peer review report under the Peer Review Programme);

(b) EFSA, “Conclusion regarding the peer review of the pesticide risk assessment of the active substance thiodicarb”, EFSA Scientific Report 50, 1–65 (2005) (see UNEP/FAO/RC/CRC.17/9, sect. 2.4.1 of the European Union notification).

14. The review report has been developed and finalized in support of European Commission Decision 2007/366/EC concerning the non-inclusion of thiodicarb in Annex I to Directive 91/414/EEC.

15. A member State was designated to undertake the risk assessment based on the information submitted by the applicant and to establish a draft assessment report. The report has been peer reviewed by the member States and EFSA. EFSA presented to the European Commission its conclusion on the risk assessment. The results were then reviewed by the member States and the Commission within the Standing Committee on the Food Chain and Animal Health (SCFCAH) and finalized on 14 July 2006.

16. The evaluation was based on a review of scientific data taking into account the conditions prevailing in the European Union (intended uses, recommended application rates, good agricultural

practices). Only data that have been generated according to scientifically recognized methods were validated and used for the evaluation. Moreover, data reviews were performed and documented according to generally recognized scientific principles and procedures.

17. It was concluded that thiodicarb was not demonstrated to fulfil the safety requirements laid down in Article 5 (I) (a) and (b) of Directive 91/414/EEC. In particular, concerns were identified with regard to consumer exposure and use as a molluscicide (UNEP/FAO/RC/CRC.17/9, sects. 2.3 and 2.4. of the European Union notification).

18. Therefore the Committee concludes that criteria b (i) and b (ii) are met.

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

19. The final regulatory action to ban thiodicarb in the European Union was based on a risk evaluation involving the conditions within the European Union. The risk analysis considered insecticide use on table and wine grapes (foliar spraying) and molluscicide use to control slugs and snails in cereals.

20. The following risks to human health and the environment were identified:

(a) An acute dietary risk for toddlers resulting from the consumption of treated table grapes and for adults resulting from the consumption of wine produced from treated wine grapes;

(b) For use of the pellet formulation (Skipper), high acute and long-term risks were identified for birds and mammals from direct consumption of pellets and additionally an acute risk from consumption of methomyl-contaminated earthworms;

(c) With regard to the use of Skipper on soils vulnerable to drainage, there is a potential risk for exposure of surface water: there is a potential risk to aquatic organisms due to exposure to the contaminated surface water;

(d) Thiodicarb is toxic to honeybees and there is a long-term risk to earthworms from exposure to methomyl.

21. Consequently, the Committee confirms that the criterion in paragraph (b) (iii) is met.

22. The Committee confirms that the paragraph (b) criteria 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;

23. The final regulatory action states that it is prohibited to place on the market or use plant protection products containing thiodicarb.

24. The final regulatory action is thus expected to lead to a significant decrease in the quantity of the chemical used and the number of its uses.

25. Therefore the Committee confirms 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;

26. It is expected that since the regulatory action to ban the use of thiodicarb significantly reduces the quantity of the chemical used, the risks to human health and the environment will also be significantly reduced.

27. Therefore the Committee confirms 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;

28. The notification states that similar health and environmental problems are likely to be encountered in other countries where the substance is used, particularly in developing countries (UNEP/FAO/RC/CRC.17/9, sect. 2.6 of the European Union notification).

29. Therefore the Committee confirms that the criterion in paragraph (c) (iii) is met.

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

30. The notification from the European Union gives no information on the estimated quantity of thiodicarb produced, imported, exported and used. The Secretariat collected information on trade. The information received shows that there is evidence of ongoing trade (UNEP/FAO/RC/CRC.17/INF/5).

31. Therefore the Committee confirms 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.

32. There is no indication in the notification that concerns over the intentional misuse of thiodicarb prompted the regulatory action.

33. Therefore the Committee confirms that the criterion in paragraph (d) is met.

(f) Conclusion

34. 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 group (2021–2022)

Drafting group on iprodione

Chair: Mr. Daniel William Ndiyo (United Republic of Tanzania)

Drafter: Mr. Timo Seppälä (Finland)

Members: Mr. Jonah Ormond (Antigua and Barbuda)

Ms. Eliana Rosa Munarriz (Argentina)

Mr. Juergen Helbig (Austria)

Ms. Mara Curaba (Belgium)

Mr. Martin Lacroix (Canada)

Ms. Lady Jhoana Domínguez Majin (Colombia)

Mr. Joseph Cantamanto Edmund (Ghana)

Mr. Suresh Lochan Amichand (Guyana)

Mr. Dinesh Runiwal (India)

Ms. Yenny Meliana (Indonesia)

Mr. Hassan Azhar (Maldives)

Mr. Shankar Prasad Paudel (Nepal)

Mr. Peter Dawson (New Zealand)

Mr. Christian Sekomo Birame (Rwanda)

Ms. Noluzuko Gwayi (South Africa)

Mr. Sumith Jayakody Arachchige (Sri Lanka)

Ms. Sarah Maillefer (Switzerland)

Ms. Nuansri Tayaputch (Thailand)

Mr. Clorence Matewe (Zimbabwe)

Drafting group on terbufos

Chair: Mr. Jonah Ormond (Antigua and Barbuda)

Drafter: Mr. Martin Lacroix (Canada)

Members: Ms. Eliana Rosa Munarriz (Argentina)
Mr. Juergen Helbig (Austria)
Ms. Mara Curaba (Belgium)
Mr. Timo Seppälä (Finland)
Mr. Joseph Cantamanto Edmund (Ghana)
Mr. Suresh Lochan Amichand (Guyana)
Mr. Dinesh Runiwal (India)
Ms. Yenny Meliana (Indonesia)
Ms. Kristīne Kazerovska (Latvia)
Mr. Hassan Azhar (Maldives)
Mr. Shankar Prasad Paudel (Nepal)
Mr. Peter Dawson (New Zealand)
Mr. Zaigham Abbas (Pakistan)
Ms. Agnieszka Jankowska (Poland)
Ms. Noluzuko Gwayi (South Africa)
Mr. Sumith Jayakody Arachchige (Sri Lanka)
Ms. Sarah Maillefer (Switzerland)
Ms. Nuansri Tayaputch (Thailand)
Mr. Clorence Matewe (Zimbabwe)

Annex III

Workplan for the preparation of draft decision guidance documents

Tasks to be carried out	*Responsible persons*	*Deadlines*
Draft an internal proposal based on the information available to the Committee	Chair Drafter	10 December 2021
Send the draft internal proposal to the drafting group members for comments via email	Secretariat	10 December 2021
Replies	Drafting group members	10 January 2022
Update the internal proposal on the basis of comments from drafting group members	Chair Drafter	10 February 2022
Send the updated internal proposal to the Committee members and observers for comments via email	Secretariat	10 February 2022
Replies	Committee members and observers	10 March 2022
Draft a decision guidance document on the basis of the comments of the Committee members and observers	Chair Drafter	8 April 2022
Send the draft decision guidance document to the drafting group members for comments via email	Secretariat	8 April 2022
Replies	Drafting group members	22 April 2022
Finalize the draft decision guidance document on the basis of the comments of the drafting group members	Chair Drafter	12 May 2022
Send the draft decision guidance document to the Secretariat	Chair Drafter	12 May 2022
Submit the draft decision guidance document to the Committee at its eighteenth meeting	Secretariat	September or October 2022