

**Rotterdam Convention on the Prior  
Informed Consent Procedure for  
Certain Hazardous Chemicals and  
Pesticides in International Trade**Distr.: General  
18 November 2015

Original: English

**Chemical Review Committee  
Eleventh meeting  
Rome, 26–28 October 2015****Report of the Chemical Review Committee on the work of its  
eleventh meeting****I. Opening of the meeting**

1. The eleventh meeting of the Chemical Review Committee under the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was held at the headquarters of the Food and Agriculture Organization of the United Nations (FAO), Viale delle Terme di Caracalla, Rome, from 26 to 28 October 2015. The meeting was opened at 9.30 a.m. on Monday, 26 October 2015, by the Chair of the Committee, Mr. Jürgen Helbig (Spain).
2. Welcoming remarks were made by Mr. William Murray, who had recently been named Executive Secretary of the FAO part of the Rotterdam Convention Secretariat, and Ms. Kerstin Stendahl, Deputy Executive Secretary of the Basel Convention on the Transboundary Movements of Hazardous Wastes and Their Disposal, the Rotterdam Convention and the Stockholm Convention on Persistent Organic Pollutants.
3. In his remarks, Mr. Murray welcomed the Committee members and briefly recounted to them his involvement with the Rotterdam Convention over the years.
4. Outlining the agenda for the current meeting, he said that the Committee would review and finalize two draft decision guidance documents and review notifications of final regulatory action for three pesticides and a proposal for the inclusion of a severely hazardous pesticide formulation. The Secretariat continued to offer the parties its full support in their submission of notifications of final regulatory action and proposals for the listing of severely hazardous pesticide formulations.
5. FAO, he said, had always cooperated closely with the Convention, as exemplified by two new instruments. The first was a strategy to address highly hazardous pesticides, which had been welcomed by the International Conference on Chemicals Management at its fourth session on the basis of a proposal developed by FAO, the Rotterdam Convention Secretariat, UNEP and the World Health Organization (WHO). The second was the FAO Pesticide Registration Toolkit, which would assist pesticide registrars in developing countries to evaluate the potential risks of pesticides in their countries, strengthen the scientific basis of pesticide registration decision-making and provide parties with robust information to support their submission of notifications of final regulatory action or proposals to list severely hazardous pesticide formulations.
6. He concluded his remarks by highlighting the critical importance of the Committee, both in terms of its recommendations to the Conference of the Parties and its contribution to knowledge sharing and information exchange.
7. Ms. Stendahl opened her remarks by welcoming Mr. Murray on behalf of the Secretariat of the Basel, Rotterdam, and Stockholm conventions and conveying to the members the good wishes of the Executive Secretary of the Conventions, Mr. Rolph Payet, who was regrettably unable to attend the meeting. The joint hosting of the Convention Secretariat by FAO and UNEP was itself an example of innovation and cooperation to strengthen the Convention.

8. The great importance of the Committee's work was evident in the recent adoption of the new Sustainable Development Goals, for all of which the sound management of chemicals and wastes was fundamental. Countries continued to face challenges in undertaking the scientifically sound assessment of chemicals, as well as in integrating socio-economic considerations into national-level decision-making on hazardous chemicals. The latter challenge had been particularly apparent at the last meeting of the Conference of the Parties, when a lack of agreement to list two chemicals and two severely hazardous pesticide formulations recommended by the Committee for listing in Annex III to the Convention had prompted the adoption of a decision to undertake intersessional work, led by Australia, to examine the process for the listing of chemicals under the Convention with the aim of increasing its effectiveness. The Secretariat, she said, looked forward to engaging with parties and observers during that process, and she also called upon the international community to work to enhance the capacity of developing countries in particular to consider scientifically sound information for regulatory action on hazardous chemicals at all levels.

9. Saying that the Committee played a key role in moving from science to action and that the current meeting was a valuable opportunity for information exchange and dialogue among experts to further enhance the sound management of chemicals and wastes, she closed her remarks by wishing the members of the Committee fruitful deliberations at the current meeting and during the critical period leading to the next meeting of the Conference of the Parties.

## **II. Organizational matters**

### **A. Officers**

10. The following officers served on the Bureau of the Committee during the meeting:

Chair: Mr. Jürgen Helbig (Spain)

Vice-Chairs: Mr. Boniface Mbewe (Zambia)

Ms. Amal Al-Rashdan (Kuwait)

Ms. Magdalena Frydrych (Poland)

Mr. Gilberto Fillmann (Brazil)

11. Ms. Frydrych served also as Rapporteur.

### **B. Attendance**

12. The following 26 members of the Committee attended the meeting: Mr. Malverne Spencer (Antigua and Barbuda), Mr. Jack Holland (Australia), Ms. Anja Bartels (Austria), Mr. Gilberto Fillmann (Brazil), Ms. Parvoleta Angelova Luleva (Bulgaria), Mr. Peter Ayuk Enoh (Cameroon), Mr. Jeffrey R. Goodman (Canada), Ms. Jinye Sun (China), Ms. Elsa Ferreras de Sanchez (Dominican Republic), Mr. Omar S. Bah (Gambia), Ms. Mirijam Seng (Germany), Ms. Ana Gabriela Ramírez Salgado (Honduras), Mr. Ram Niwas Jindal (India), Ms. Amal Al-Rashdan (Kuwait), Mr. Mohd Fauzan Yunus (Malaysia), Mr. Gaoussou Kanouté (Mali), Ms. Amal Lemsioui (Morocco), Ms. Leonarda Christina van Leeuwen (Netherlands), Ms. Magdalena Frydrych (Poland), Mr. Jung-Kwan Seo (Republic of Korea), Ms. Tatiana Tugui (Republic of Moldova), Mr. Jürgen Helbig (Spain), Ms. Sarah Maillefer (Switzerland), Ms. Nuansri Tayaputch (Thailand), Mr. N'Leodon Nadjo (Togo) and Mr. Boniface Mbewe (Zambia).

13. The members of the Committee from Congo, Ethiopia, Mexico, Pakistan and Saudi Arabia were unable to attend.

14. The following countries were represented as observers: Brazil, Canada, China, India, Japan, Kenya, Norway, Slovakia, South Africa, Ukraine, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania and United States of America.

15. Non-governmental organizations were also represented as observers. The names of those organizations are included in the list of participants (UNEP/FAO/RC/CRC.11/INF/19).

### **C. Adoption of the agenda**

16. In considering the sub-item, the Committee had before it the provisional agenda (UNEP/FAO/CRC.11/1) and the annotations to the provisional agenda (UNEP/FAO/CRC.11/1/Add.1).

17. During the discussion of the agenda one member said that the task group reports for the chemicals to be considered at the current meeting had been made available to the members of the Committee after the deadline imposed by rule 11 of the rules of procedure of the Conference of the

Parties, which required that the provisional agenda and all "supporting documents" be circulated to the parties in the official languages of the Convention at least six weeks before the start of the meeting at which they would be considered.

18. At the request of the Chair, a representative of the Secretariat explained that the guidance for intersessional task groups in the *Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee* stipulated that task group reports should be posted on the Convention website two weeks before the meetings at which they were to be considered. That period had been extended to three weeks for the current meeting in response to requests from observers. It was also explained that according to rule 26 of the rules of procedure the rules were applied *mutatis mutandis* to meetings of the subsidiary bodies of the Convention. That meant that the rules themselves, as adopted by the Conference of the Parties, contemplated that they would be adapted as necessary to correspond to the functioning of the subsidiary bodies, subject to acceptance by the Conference of the Parties. As such, there was no discrepancy in relation to those rules, with documents distributed in accordance with those provisions.

19. In addition, it was explained that according to the longstanding practice of both the Committee and the Conference of the Parties rule 11 had been understood to apply to working documents but not information documents. Except in the case of the Committee, whose meetings took place in English only, working documents were always circulated in the six official United Nations languages and were subject to the six-week deadline set out in rule 11; information and other documents, on the other hand, were with very few exceptions neither translated nor considered to be subject to the six-week deadline, although they were customarily made available as early as possible. In the future, the Secretariat would avoid using the term "supporting documents" to describe documents that contained useful information but were not subject to rule 11.

20. Arguing that the practices of the Committee could not contravene the rules of procedure, the member maintained his position that task group reports must be circulated within the deadline imposed by rule 11 and asked that his position be noted in the present report.

21. The Committee then adopted the following agenda on the basis of the provisional agenda (UNEP/FAO/RC/CRC.11/1):

1. Opening of the meeting.
2. Organizational matters:
  - (a) Adoption of the agenda;
  - (b) Organization of work.
3. Rotation of the membership.
4. Review of the outcomes of the seventh meeting of the Conference of the Parties to the Rotterdam Convention relevant to the work of the Committee.
5. Technical work:
  - (a) Consideration of draft decision guidance documents:
    - (i) Short-chained chlorinated paraffins;
    - (ii) Tributyltin compounds;
  - (b) Report of the Bureau on the preliminary review of notifications of final regulatory action and the proposal for a severely hazardous pesticide formulation;
  - (c) Review of notifications of final regulatory action:
    - (i) Atrazine;
    - (ii) Carbofuran;
    - (iii) Carbosulfan;
  - (d) Review of the proposal for the inclusion of dimethoate emulsifiable concentrate 400 g/L as a severely hazardous pesticide formulation in Annex III.
6. Venue and date of the twelfth meeting of the Committee.
7. Other matters.
8. Adoption of the report.
9. Closure of the meeting.

**D. Organization of work**

22. The Committee decided to conduct the current meeting in accordance with the scenario note prepared by the Chair (UNEP/FAO/RC/CRC.11/INF/1) and the proposed schedule for the meeting (UNEP/FAO/RC/CRC.11/INF/2), subject to adjustment as necessary. It also decided that contact groups and drafting groups would be formed as necessary.

23. The documents pertaining to each agenda item were identified in the annotations to the agenda (UNEP/FAO/RC/CRC.11/1/Add.1) and in the list of documents organized by agenda item (UNEP/FAO/RC/CRC.11/INF/17).

**III. Rotation of the membership**

24. Introducing the item, the representative of the Secretariat drew attention to the information provided in document UNEP/FAO/CRC.11/INF/3, on the membership of the Chemical Review Committee and the rotation of the membership in May 2016, noting that the Conference of the Parties at its seventh meeting had appointed the 17 members nominated by the parties listed in the annex to decision RC-7/3 to serve from 1 May 2014 to 30 April 2018. The terms of office of the remaining 14 members of the Committee would expire on 30 April 2016. The Conference of the Parties, also at its seventh meeting, had decided which parties would nominate 14 new members to serve from 1 May 2016 to 30 April 2020, and those parties, with the exception of Djibouti, had during and since that meeting nominated those new members. To familiarize them with the work of the Committee, the nominated members would be invited to participate in an orientation workshop to be organized by the Secretariat in 2016. In addition, the Conference of the Parties at its seventh meeting had elected Mr. Helbig as the Committee's new Chair, thus confirming the Committee's selection of him at its ninth meeting in accordance with the procedure set out in decision RC-6/3.

25. The representative of the Secretariat also reported that the current meeting was the last for three members of the Bureau (Mr. Mbewe, Ms. Al-Rashdan, and Mr. Fillmann) and that the Committee would therefore have to elect three new members to succeed them, subject to confirmation once the new members of the Committee had begun their terms in May 2016.

26. The Committee elected, subject to confirmation by the Committee at its twelfth meeting, the following members to serve as Vice-Chairs of the Committee, with terms of office to begin at the closure of the current meeting:

Mr. N'Ladon Nadjo (Togo – African States)

Ms. Jinye Sun (China – Asian-Pacific States)

Mr. Malverne Spencer (Antigua and Barbuda – Latin American and Caribbean States).

**IV. Review of the outcomes of the seventh meeting of the Conference of the Parties to the Rotterdam Convention relevant to the work of the Committee**

27. Introducing the item, the representative of the Secretariat summarized the information provided in document UNEP/FAO/RC/CRC.11/INF/4, on the outcomes of the seventh meeting of the Conference of the Parties to the Rotterdam Convention relevant to the Committee's work. Those outcomes included decision RC-7/1, on a proposal for activities to increase the submission of notifications of final regulatory action; decision RC-7/4, on the listing of methamidophos in Annex III to the Convention; decision RC-7/5, intersessional work on the process for listing chemicals in Annex III to the Rotterdam Convention; and decision RC-7/12, on "From science to action".

28. A discussion ensued in which one member said that the Committee should explore why some of the Committee's recommendations to list chemicals in Annex III to the Convention had failed to win the support of the Conference of the Parties, suggesting that it was due to flaws in the Committee's work such as the consideration of notifications of final regulatory action submitted after the 90-day period provided for in Article 5 of the Convention. He also said that developing countries and countries with economies in transition lacked the resources to participate in the Committee's intersessional working groups and to implement the Convention; that the chemicals listed in the Convention to date were limited to those that were generic, inexpensive and generally produced and used in developing countries and countries with economies in transition; and that assessments of the impact of listing chemicals in the Convention were not carried out.

29. Several other members responded. One recalled that the Conference of the Parties had already concluded that a party's failure to submit a notification of final regulatory action within the 90-day period of Article 5 did not divest the Committee of its obligation to consider the notification. Others expressed disappointment at the failure of the Conference of the Parties to list the chemicals that the Committee had recommended; that, however, had happened not because the Committee had not done its job properly but because a small minority of parties had blocked listing on the basis of national interest rather than scientific considerations and, perhaps, because of continuing confusion that the listing of chemicals required that they be banned. A member from a developing country noted that the failure to list chemicals in Annex III hampered her country's ability to obtain information about them.

30. The Chair took note of the important concerns expressed and invited members to raise them at the next meeting of the Conference of the Parties, noting that they were beyond the mandate of the Committee.

31. The representative of the Secretariat then reported on the outcomes of the eleventh meeting of the Persistent Organic Pollutants Review Committee of the Stockholm Convention, which had taken place the previous week, from 19 to 23 October 2015. The Committee, she said, had adopted a draft risk management evaluation recommending the listing of decabromodiphenyl ether (commercial mixture, c-decaBDE), with specific exemptions, in Annex A to the Convention; adopted a draft risk profile on short-chained chlorinated paraffins and established an intersessional working group to prepare a draft risk management evaluation for those chemicals; deferred a decision on the draft risk profile for dicofol to the next meeting of the Committee and established an intersessional working group to update the draft risk profile on the basis of information to be submitted by members; and decided that pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid) met the criteria of Annex D to the Convention and established an intersessional working group to prepare a draft risk profile pertaining to that chemical, including with regard to issues related to the inclusion of PFOA-related compounds that potentially degrade to PFOA and the inclusion of PFOA salts.

32. The Committee took note of the information.

## V. Technical work

### A. Consideration of draft decision guidance documents

#### 1. Short-chained chlorinated paraffins

33. Introducing the sub-item, the Chair recalled that at its tenth meeting the Committee had reviewed notifications of final regulatory action for short-chained chlorinated paraffins from Canada and Norway, along with the supporting information referenced therein, and, taking into account each of the specific criteria set out in Annex II to the Convention, had concluded that the criteria of that Annex had been met.

34. Accordingly, the Committee had at its tenth meeting, by its decision CRC-10/4, recommended to the Conference of the Parties that it should include short-chained chlorinated paraffins in Annex III to the Convention as industrial chemicals. In addition, the Committee had adopted a rationale for that recommendation, agreed to establish an intersessional drafting group to produce a draft decision guidance document and agreed on a workplan for its development in line with the process adopted by the Conference of the Parties in decision RC-2/2. The rationale was annexed to decision CRC-10/4 and the workplan was set out in annex III to the report of the Committee on the work of its tenth meeting (UNEP/FAO/RC/CRC.10/10).

35. At the current meeting the Committee had before it a draft decision guidance document on short-chained chlorinated paraffins prepared by the intersessional drafting group (UNEP/FAO/RC/CRC.11/2), together with a tabular summary of comments received and how they had been addressed (UNEP/FAO/RC/CRC.11/INF/7).

36. Ms. van Leeuwen, co-coordinator of the intersessional drafting group, reported on the work of the group.

37. Following the presentation, one member said that the alternatives described in the draft decision guidance document might be more harmful than short-chained chlorinated paraffins: boron had adverse effects on agriculture, which could be particularly damaging for agriculture-dependent developing countries and countries with transition economies. In addition the mention of alternatives in a decision guidance document could lead developing countries to adopt them in ignorance of their possible risks. He also suggested that the Committee's consideration of short-chained chlorinated paraffins be suspended until the Persistent Organic Pollutants Review Committee of the Stockholm Convention had concluded its preparation of a risk management evaluation for the chemicals.

38. Several members objected to the proposal to suspend consideration of short-chained chlorinated paraffins. In addition, one argued that the environmental and health effects of possible alternatives were explicitly acknowledged throughout the draft decision guidance document; another that the document recommended boron-containing compounds only for a very narrow commercial sector; and several others that in any case the Committee's mandate did not extend to the analysis of alternatives.

39. At the suggestion of one member it was agreed that the member from Canada and a representative of Norway would review the Chemical Abstract Service numbers listed in the draft decision guidance document to ensure that the draft decision guidance document reflected the Chemical Abstract Service numbers referred to in the regulatory actions of both Canada and Norway. It was also agreed that the draft decision guidance document should be revised as necessary to incorporate the information contained in the risk profile on short-chained chlorinated paraffins adopted by the Persistent Organic Pollutants Review Committee at its eleventh meeting and that members and observers could submit suggested text for the section discussing alternatives on the need for each party to make an independent evaluation of alternatives, including their risks. The Secretariat was asked to produce a revised version of the draft decision guidance document incorporating the above information and to prepare a draft decision on short-chained chlorinated paraffins for consideration by the Committee.

40. Subsequently, the Committee adopted decision CRC-11/1, as orally amended, by which it adopted the draft decision guidance document for short-chained chlorinated paraffins (UNEP/FAO/RC/CRC.11/2/Rev.1), revised in accordance with the preceding paragraph, and decided to forward it, together with the related tabular summary of comments (UNEP/FAO/RC/CRC.11/INF/7/Rev.1), to the Conference of the Parties for its consideration. The decision is set out in annex I to the present report.

## **2. Tributyltin compounds**

41. Introducing the sub-item, the Chair recalled that at its tenth meeting the Committee had reviewed a notification of final regulatory action for tributyltin compounds as industrial chemicals from Canada, along with the supporting information referenced therein, and, taking into account each of the specific criteria set out in Annex II to the Convention, had concluded that the criteria of that Annex had been met.

42. Accordingly, the Committee had at its tenth meeting, by its decision CRC-10/5, recommended to the Conference of the Parties that it should include tributyltin compounds in Annex III to the Convention as industrial chemicals. In addition, the Committee had adopted a rationale for that recommendation, agreed to establish an intersessional drafting group to produce a draft decision guidance document for tributyltin compounds for the industrial category by revising the decision guidance document adopted by the Conference of the Parties in decision RC-4/5 to include information relevant to the industrial category, and agreed on a workplan for its development in line with the process adopted by the Conference of the Parties in decision RC-2/2. The rationale was annexed to decision CRC-10/5 and the workplan was set out in annex III to the report of the Committee on the work of its tenth meeting (UNEP/FAO/RC/CRC.10/10).

43. At the current meeting the Committee had before it a draft revised decision guidance document on tributyltin compounds prepared by the intersessional drafting group (UNEP/FAO/RC/CRC.11/3), together with a tabular summary of comments received and how they had been addressed (UNEP/FAO/RC/CRC.11/INF/8).

44. Ms. Bartels, co-coordinator of the intersessional drafting group, reported on the work of the group.

45. Following her presentation, one member said that the draft decision guidance document should be set aside because it had been prepared on the basis of a single notification of final regulatory action pertaining to tributyltin compounds as an industrial chemical. The Convention, he said, required that there be at least one valid notification from each of at least two prior informed consent regions pertaining to the same chemical in the same category before the Committee could consider the listing of the chemical for that category. When a second such notification was submitted the Committee could resume its consideration of the draft decision guidance document.

46. A number of members pointed out that the question had been settled at the Committee's tenth meeting, when the Committee had concluded that it could proceed on the basis of two previously submitted notifications of final regulatory action relating to tributyltin compounds as pesticides and the one new notification relating to their use as industrial chemicals. The representative of the Secretariat read out paragraph 5 of Article 5, which required only that notifications pertain to "a

particular chemical" but said nothing about its category. In accordance with that paragraph the Secretariat had always forwarded notifications to the Committee on the basis of the chemical subject to final regulatory actions, without regard to the category. Another member suggested that the question was a matter of interpretation of the Convention and as such was a matter for the Conference of the Parties and beyond the mandate of the Committee.

47. The dissenting member subsequently submitted a note setting out the basis for his objection to consideration of the draft decision guidance document at the current meeting.

48. Following the discussion, the Committee requested the Secretariat to prepare a draft decision by which it would forward the draft decision guidance document and the related tabular summary of comments to the Conference of the Parties for consideration at its eighth meeting.

49. The Committee also agreed to establish a drafting group, composed of members only, to draft a note for the Conference of the Parties explaining the Committee's decision at its tenth meeting to recommend the listing of tributyltin compounds as industrial chemicals based on one notification of final regulatory action relating to the chemicals as industrial chemicals in addition to two notifications, previously considered and decided upon, relating to the chemicals as pesticides. The drafting group would be co-chaired by the co-coordinators of the intersessional drafting group, Ms. Bartels and Ms. Luleva.

50. The co-chair of the drafting group subsequently reported on the work of the group, saying that after some discussion the group had come to agreement on the draft text of the note to the Conference of the Parties.

51. Following the co-chair's report, the dissenting member, while agreeing to the draft note, asked that a contact group be established to resolve what he said were outstanding issues with the draft decision guidance document pertaining to technical information provided by Canada and a lack of information pertaining to international trade. He proposed that such a contact group could also consider the suggestion from an observer to the effect that the note could be revised to include clarification from the Committee about whether its understanding of paragraphs 5 and 6 of Article 5 applied only to tributyltin compounds or was also applicable to other chemicals.

52. A number of members, while indicating that they would not oppose the establishment of a contact group, nevertheless expressed strong disappointment and surprise at the proposal to reopen the discussion of the draft decision guidance document, saying that the constant revisiting of issues was hampering the Committee's work. One member, supported by another, said that there had been three rounds of comments on the document during the intersessional period leading up to the current meeting, and no comments had been received from the dissenting member; furthermore, no comments had been made on the technical aspects of the document when it had been presented to the Committee the previous day in plenary. A third member suggested that agreement on a work plan implied a commitment to the timeline for providing written comments in order to fully utilize the time for discussion at Committee meetings. Another member requested that the mandate of the contact group, if established, be very clear.

53. The Committee agreed to establish a contact group to address the new aspects of the draft decision guidance document related to information provided by Canada on industrial chemicals and to address the suggestion from the observer as taken up by the one member.

54. The co-chair of the drafting group subsequently reported that the group had agreed on revised versions of the note and the draft decision guidance document, containing one set of square brackets around text that the group had not finalized.

55. Following further discussion in plenary the Committee reached agreement and adopted decision CRC-11/2, by which it adopted the draft decision guidance document for tributyltin compounds (UNEP/FAO/RC/CRC.11/3/Rev.1) and decided to forward it, together with the related tabular summary of comments (UNEP/FAO/RC/CRC.11/INF/8/Rev.1) and the related note set out in the annex to the decision, to the Conference of the Parties for its consideration. The decision is set out in annex I to the present report.

## **B. Report of the Bureau on the preliminary review of notifications of final regulatory action and the proposal for a severely hazardous pesticide formulation**

56. Following the introduction of the item by the Chair, Ms. Frydrych, a member of the Bureau, reported that the Bureau, in consultation with the Secretariat, had undertaken a preliminary review of the notifications of final regulatory action and the proposal for a severely hazardous pesticide

formulation on the agenda for the current meeting with the aim of establishing intersessional task groups for the chemicals and setting priorities for their consideration at the current meeting. The results of that preliminary analysis, based on the information available at the time, were described in document UNEP/FAO/RC/CRC.11/4. Following the preliminary reviews, and on the recommendation of the Bureau, an intersessional task group had been established for each chemical and tasked with undertaking an initial review and preparing an analysis of whether the notification of final regulatory action pertaining to that chemical met the criteria of Annex II to the Convention and whether the proposal for a severely hazardous pesticide formulation met the criteria of part 3 of Annex IV. At the current meeting the task group coordinators would present the results of the task groups' initial review of the chemicals in order to facilitate the discussions at the meeting.

57. The Committee took note of the information.

## C. Review of notifications of final regulatory action

### 1. Atrazine

58. The Committee had before it eight notifications and supporting documentation on atrazine submitted by the European Union and seven African parties: Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo (UNEP/FAO/RC/CRC.11/5 and UNEP/FAO/RC/CRC.11/INF/9 and 10).

59. Ms. van Leeuwen, co-coordinator of the intersessional task group that had undertaken a preliminary assessment of the notifications and their supporting documentation, reported on the work of the group. She explained that, during the task group meeting that had taken place the day before the start of the current meeting, the task group had agreed to use the task group report that had previously been posted on the Convention website as the basis for its discussions. During those discussions a number of disagreements had arisen, requiring the group to insert square brackets around a number of statements and conclusions in the task group report regarding the extent to which the notifications of final regulatory action satisfied the criteria of Annex II to the Convention. She then went on to outline the task group report, indicating those statements and conclusions that had been placed in square brackets to indicate a lack of agreement.

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

60. Ms. van Leeuwen said that the notification from the European Union related to a severe restriction on the use or placing on the market of plant protection products containing atrazine.

61. Regarding the criteria of Annex II to the Convention, she said that the notification revealed that the regulatory action had been taken to protect the environment. Thus, the task group report stated that the criterion in paragraph (a) of that annex had been satisfied.

62. The task group report also stated that in accordance with the European Union's Council Directive 91/414/EEC a risk evaluation had been performed and that the evaluation had been based on an assessment of data that had undergone peer review by member State experts, the Standing Committee on Food Chain and Animal Health, the Scientific Committee on Plants and the European Commission. The task group report had accordingly concluded that the data 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, thus satisfying the criteria in paragraphs (b) (i) and (ii) of Annex II. In addition, the task group report stated that the risk evaluation had been based on a wide range of information on hazard, effect and exposure, including information on proposed conditions of use within the European Union, recommended application rates and good agricultural practices, thus satisfying the criterion in paragraph (b) (iii) of Annex II. The statements regarding the risk evaluation and the satisfaction of the criteria in paragraph (b) (iii) of Annex II were enclosed in square brackets.

63. Regarding the criteria in paragraph (c) of Annex II, the task group report stated that the final regulatory action restricted the placing on the market or the use of atrazine. The task group report accordingly stated that both the quantity of the chemical used and the risks that it posed would be significantly reduced, thus satisfying the criteria in paragraphs (c) (i) and (c) (ii) of Annex II. The statements to the effect that the criteria in paragraphs (c) (i) and (c) (ii) had been satisfied were in square brackets. As the notification stated that concerns similar to those motivating the adoption of the final regulatory action could arise in other countries where atrazine was used the task group report stated that the considerations leading to the final regulatory action were not applicable only in a limited geographical area or in otherwise limited circumstances; thus the task group report stated that the criterion in paragraph (c) (iii) was satisfied. Finally, information gathered by the Secretariat indicated that atrazine had been exported from the European Union to 16 countries in the period

between 2012 and 2015, thus providing evidence of ongoing international trade in the chemical. Accordingly, the task group report stated that the criteria in paragraph (c) (iv) of Annex II had been met. That statement was in square brackets.

64. There was no indication in the notification that intentional misuse had been the basis for the final regulatory action; thus, the task group report stated that the criterion set out in paragraph (d) of Annex II had been met.

**(b) Notifications from Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo**

65. Ms. van Leeuwen said that as Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo were all members of the Sahelian Pesticides Committee, and as their notifications all related to a single final regulatory action applicable to the Sahelian region, the intersessional task group had considered the seven notifications together.

66. The notifications, she said, related to a ban on the use as a pesticide of all products containing atrazine. With regard to Annex II to the Convention, she said that the notifications explained that the regulatory action had been taken to protect human health and the environment; thus, the task group report stated that the criterion in paragraph (a) of Annex II had been met.

67. The task group report stated that Cabo Verde, Chad, the Gambia, Mauritania, the Niger, Senegal and Togo had performed a risk evaluation based on scientific data from several internationally recognized sources (FAO, WHO, International Agency for Research on Cancer) and reports from the Sahelian Pesticides Committee, the United States of America, France's National Institute of Industrial Environment and Risk (L'Institut National de l'Environnement Industriel et des Risques) and Health Canada. The task group report therefore stated that the data in the reports 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, thus satisfying the criteria in paragraphs (b) (i) and (b) (ii) of Annex II. The statement that the criteria in those two paragraphs had been satisfied was in square brackets. In addition, the task group report stated that the risk evaluation had been prepared taking into account the prevailing conditions in the notifying countries, including the fragile ecology of those countries; the absence of an environmental management system with a buffer zone between treated fields and streams; the use of surface water as drinking water for humans and animals; the use of ground water as the only source of potable water; and the availability of alternatives to atrazine. Accordingly, the task group report stated that the criterion set out in paragraph (b) (iii) of Annex II, as well as the criteria in paragraph (b) as a whole, had been met. The statement that the criteria in paragraph (b) as a whole had been satisfied was in square brackets.

68. With regard to paragraph (c) of Annex II, the final regulatory action banned the use of all products containing atrazine; thus, the task group report stated that both the quantity of the substance used and the risks it posed to human health and the environment would be significantly reduced, and that the criteria in paragraphs (c) (i) and (c) (ii) of Annex II had been met. That statement was in square brackets. In addition, the task group report stated that as other Sahelian countries used atrazine under similar conditions and other countries had already banned it, the considerations that had led to the adoption of the final regulatory action were not applicable in only a limited geographical area or under otherwise limited circumstances. Thus, the task group report stated that the criterion in paragraph (c) (iii) of Annex II had been satisfied. Finally, information gathered by the Secretariat indicated that atrazine had been exported from the European Union to 16 countries in the period between 2012 and 2015; the task group report stated that that constituted evidence of ongoing international trade in the chemical, thus meeting the criterion in paragraph (c) (iv) of Annex II. The statement that the criterion in paragraph (c) (iv) had been satisfied was in square brackets.

69. There was no indication in the notifications that intentional misuse had been the basis for the final regulatory action; thus, the task group report stated that the criterion set out in paragraph (d) of Annex II had been met.

**(c) Discussion of the notifications**

70. In the ensuing discussion, one member said that the European Union's notification was not based on a risk assessment; that it was based only on the European Union's groundwater contamination limit of 0.1 micrograms per litre; and that the claim of a risk of groundwater contamination was based solely on modelling data without support from monitoring data. Several other members demurred, saying that the final regulatory action had been based on an evaluation of the entire dossier relating to atrazine and that while the risk to groundwater was a major concern the final regulatory action had also been based on others, including risk to aquatic organisms. A number of other members added that in any event it had long been established that it was not the place of the

Committee to question the wisdom of a party's regulatory action, including applicable limits. Another member said that the supporting data underlying the final regulatory action did in fact include monitoring data.

71. Regarding the notifications submitted by the Sahelian countries, one member said that they did not meet the criterion in paragraph (b) (iii) of Annex II because they were based on a study conducted in Burkina Faso, and thus no risk evaluation had been conducted based on conditions prevailing in the notifying countries. In response another member said that as the conditions in Burkina Faso, a Sahelian country and fellow member of the Sahelian Pesticides Committee, were similar to those in the notifying countries, the Burkina Faso study satisfied that criterion. Another member recalled a previous case – featured in the Committee's manual as a successful use of bridging information to satisfy the criterion in paragraph (b) (iii) – in which Jamaica, like the notifying parties in the case at hand, had used qualitative statements to relate a risk evaluation from the United States to conditions in Jamaica; that notification, pertaining to aldicarb, had been found to meet the Annex II criteria of the Convention. Several other members noted that while the Burkina Faso study provided information on pesticide poisoning the notifying countries had clearly considered that information in the context of their prevailing conditions, including their fragile ecologies, a lack of buffer zones between areas of application and streams and the use of groundwater as drinking water. That, they said, constituted a use of bridging information that satisfied the criterion in paragraph (b) (iii) of Annex II.

**(d) Next steps**

72. Following the discussions outlined above the Committee established a contact group, co-chaired by Ms. van Leeuwen and Ms. Salgado to further discuss the notifications of final regulatory action with the aim of determining whether they met the criteria of Annex II and, if appropriate, preparing a draft decision and draft rationale for consideration by the Committee.

73. Following the work of the contact group its co-chair reported that all but one member had agreed that the notifications from the Sahelian countries and the European Union met all criteria of Annex II. The dissenting member had expressed the view that the Sahelian notifications did not meet the criteria in paragraphs b (i), b (ii) and b (iii) of Annex II and that the European Union notification failed to meet the criteria in paragraphs (b) (iii), (c) (i) and (c) (ii). In the light of that disagreement, the group had prepared a document presenting the rationale for its conclusions regarding areas of agreement and laying out the opposing arguments with regard to those criteria on which agreement had fallen short.

74. One member expressed concern regarding the procedure followed in the contact group saying that the group had on the first day of its deliberations reached agreement on the European Union notification only to have that agreement undone late in the process by a single member. Such an outcome, he said, required serious consideration.

75. The Committee agreed that, since no consensus had been reached that the notifications from the European Union and the Sahelian countries met the criteria set out in Annex II to the Convention, further consideration of the item would be deferred to the Committee's next meeting. The document setting out the rationale and opposing arguments in respect of the Annex II criteria as applied to atrazine would be posted on the Convention website as document UNEP/FAO/RC/CRC.11/INF/18.

**2. Carbofuran**

76. The Committee had before it notifications and supporting documentation on carbofuran submitted by the European Union, Canada and seven African parties: Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo. The seven African parties were all members of the Sahelian Pesticides Committee, and their notifications all related to a single final regulatory action applicable to the Sahelian region. The notifications were set out in document UNEP/FAO/RC/CRC.11/6 and the supporting documentation supplied by the European Union was set out in document UNEP/FAO/RC/CRC.11/INF/11, that supplied by Canada in document UNEP/FAO/RC/CRC.11/INF/12 and that supplied by Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo in document UNEP/FAO/RC/CRC.11/INF/13.

77. Ms. Maillefer, the co-coordinator of the intersessional task group that had undertaken a preliminary assessment of the notifications and supporting documentation, reported on the work of the intersessional task group.

**(a) Notifications**

78. With regard to Annex II to the Convention, she said that all three notifications indicated that the regulatory action had been taken to protect human health as well as the environment; thus, the criterion in paragraph (a) of Annex II had been met.

79. The information in the notifications and supporting documentation indicated that the data had been generated according to scientifically recognized methods, the data reviews had been performed and documented according to generally recognized scientific principles and the final regulatory action had been based on a risk evaluation involving prevailing conditions within the party taking the action. Accordingly, the task group had concluded that the criteria set out in paragraph (b) of Annex II had been met.

80. Turning to the criteria set out in paragraph (c) of Annex II, she said that the task group had concluded that as the regulatory action in all three cases constituted a ban, it would necessarily lead to a significant decrease in the quantity of the chemical used as well as the number of its uses, and thus to a significant reduction in the risk to human health and the environment. The notifications did not indicate that the considerations leading to the final regulatory action were applicable only in a geographically limited area or in other limited circumstances, as carbofuran was still used as a pesticide under similar conditions in other countries. Accordingly, the task group had concluded that the criteria in paragraph (c) of Annex II had been met.

81. There was no evidence that intentional misuse had been the basis for the final regulatory action; thus, the criterion set out in paragraph (d) of Annex II had been met.

**(b) Discussion of the notifications**

82. In the subsequent discussion there were no comments on the notifications submitted by Canada and the European Union, and it was agreed that they satisfied the criteria of Annex II. The discussion focused on whether the risk evaluation underlying the notifications from the African parties was adequate.

83. One member said that the African notifications failed to meet the criteria as they were based solely on modelling data; modelling data alone was insufficient, he said, and had to be supported by monitoring data. He also reiterated the concern expressed earlier that the Committee's methods in considering the listing of chemicals in Annex III to the Convention did not include a comprehensive assessment of alternatives. Regarding his first assertion, another member said that, as reflected in the Committee handbook, there were several instances of notifications based solely on modelling that had been accepted as meeting all criteria of the Convention. As to the second point, the Chair said that it had already been considered, and it had been clarified that the Committee had no mandate to undertake an assessment of alternatives.

84. Several members said that the notifications met the requirements of Annex II, including the criteria in paragraph (b). International data on hazard together with information on exposure in the notifying countries, including use patterns, taken together constituted a risk evaluation that took into account conditions prevailing in the notifying countries. Another said that carbofuran was highly toxic to non-target organisms, especially birds and mammals, and that the notifications clearly met the criteria of Annex II.

**(c) Next steps**

85. Based on the discussion, the Committee agreed that the notifications met all the criteria of Annex II to the Convention.

86. The Committee established a drafting group, co-chaired by Ms. Maillefer and Mr. Goodmann, to draft a rationale as to how the notifications met the criteria in Annex II to the Convention. In addition, the Secretariat was to prepare a draft decision on the recommendation on the listing of carbofuran in Annex III to the Convention.

87. Ms. Maillefer subsequently presented a draft rationale prepared by the group for the conclusion that the notifications from Canada, the European Union and the Sahelian countries met the criteria of Annex II to the Convention. The Committee adopted decision CRC-11/3, by which it adopted the rationale, recommended to the Conference of the Parties that it should include carbofuran in Annex III to the Convention as a pesticide and adopted a workplan for preparing a draft decision guidance document for the chemical. The decision, to which the rationale is 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 to the present report; and the workplan is set out in annex III to the present report.

88. Prior to adoption of the draft decision as outlined above one member of the Committee, asking that his views be reflected in the present report, said that in order to avoid conflicts of interest, members of the Committee from parties that submitted notifications of final regulatory action in respect of a chemical should not serve as coordinators of intersessional task groups or chairs of contact groups or drafting groups on that chemical. The Secretariat, he said, should bear that in mind when

selecting them. The representative of the Secretariat noted that, in accordance with the Committee's established procedure for reviewing notifications of final regulatory action, task group coordinators were selected by the Bureau. She also recalled that members of the Committee served in their capacities as experts and not as representatives of their Governments. Several other members echoed the last point, stressing that coordinators and co-chairs were chosen on the basis of their expertise rather than their nationality and expressing confidence in the impartiality of their fellow Committee members that had served as coordinators and chairs. During adoption of the decision and workplan for carbofuran the objecting member said that the chair and co-chair of the intersessional drafting group should not be from any of the parties that had submitted notifications of final regulatory action. The chair said that his view would be noted.

### **3. Carbosulfan**

89. The Committee had before it notifications and supporting documentation on carbosulfan submitted by the European Union and eight African parties: Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo. The eight African parties were all members of the Sahelian Pesticides Committee, and their notifications all related to a single final regulatory action applicable to the Sahelian region. The notifications were set out in document UNEP/FAO/RC/CRC.11/7; the supporting documentation supplied by the European Union was set out in document UNEP/FAO/RC/CRC.11/INF/14 and that supplied by Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo in document UNEP/FAO/RC/CRC.11/INF/15.

90. Ms. Luleva, the co-coordinator of the intersessional task group that had undertaken a preliminary assessment of the notifications and supporting documentation, reported on the work of the intersessional task group.

#### **(a) Notification from the European Union**

91. With regard to Annex II to the Convention, she said that the notification submitted by the European Union indicated that the regulatory action had been taken to protect human health and the environment; thus, the criterion in paragraph (a) of Annex II had been met.

92. The information in the notification and supporting documentation indicated that the information used in the assessment had been generated according to scientifically recognized methods, that the reviews had been performed and documented according to generally recognized scientific principles and that the final regulatory action was based on a risk evaluation involving prevailing conditions within the European Union. Accordingly, the task group had concluded that the criteria set out in paragraph (b) of Annex II had been met.

93. In terms of the criteria set out in paragraph (c) of Annex II, Ms. Luleva said that the task group had concluded that as the final regulatory action constituted a ban it was expected to eliminate the quantity of the chemical used as well as the number of its uses and lead to a significant reduction in the risk to human health and the environment. The notification did not indicate that the considerations leading to the final regulatory action were applicable only in a geographically limited area or in other limited circumstances, and there was evidence of ongoing trade in the chemical. Accordingly, the task group had concluded that the criteria in paragraph (c) of Annex II had been met.

94. There was no evidence that intentional misuse had been the basis for the final regulatory action; thus, the criterion set out in paragraph (d) of Annex II had been met.

#### **(b) Notifications from Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo**

95. With regard to Annex II to the Convention, she said that the notifications indicated that the regulatory action had been taken to protect human health and the environment; thus, the criterion in paragraph (a) of Annex II had been met.

96. The scientific information in the notifications and supporting documentation was drawn from several internationally recognized sources and had been generated according to scientifically recognized methods and reviewed according to generally recognized scientific principles and procedures. Furthermore, the final regulatory action was based on a risk evaluation involving prevailing conditions in the Sahel. Accordingly, the task group had concluded that the criteria set out in paragraph (b) of Annex II had been met.

97. Turning to the criteria set out in paragraph (c) of Annex II, she said that the task group had concluded that as the final regulatory action constituted a ban on carbosulfan it was expected to lead to a significant decrease in the quantity of carbosulfan and a significant reduction in the risk it posed to human health and the environment. The notifications indicated that the considerations leading to the

final regulatory action were applicable to a wide geographical area and a broad range of circumstances, and there was evidence of ongoing trade in the chemical. Accordingly, the task group had concluded that the criteria in paragraph (c) of Annex II had been met.

98. There was no evidence that intentional misuse had been the basis for the final regulatory action; thus, the criterion set out in paragraph (d) of Annex II had been met.

**(c) Discussion of the notifications**

99. During the ensuing discussion many members indicated their support for the conclusions set out in the report of the task group with regard to the notification submitted by the European Union.

100. One member, however, said that the notification failed to meet the criteria of Annex II, primarily because the risk evaluation relied solely on modelling data and a possible risk to groundwater, and because there was no information on imports and exports and hence no evidence of international trade. Several members responded that, as indicated in the Committee handbook, modelling alone was in fact sufficient; in addition, however, the supporting documentation and the notification itself referred to a large amount of monitoring data. On the subject of international trade, it was pointed out that an international trade association had confirmed the existence of ongoing international trade in carbosulfan, as noted in the task group's report.

101. With regard to the notifications submitted by the Sahelian countries, one member expressed concern regarding criterion (b) (iii), questioning the strength of the bridging data. Another member pointed out that bridging data was not required, however, as an independent risk evaluation had been done using hazard data from other countries but exposure data from the notifying parties.

**(d) Next steps**

102. The Committee agreed that the notifications for Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo met all the criteria of Annex II to the Convention but was unable to reach agreement on whether the notification for the European Union did so. The Committee accordingly established a contact group, co-chaired by Ms. Luleva and Mr. Holland, to further consider the European Union notification and, if possible, reach agreement. In the event that it did reach agreement on the European Union notification the contact group was to draft a rationale for its conclusion. It was also to draft a rationale for the conclusion reached in plenary that the Sahelian country notifications of final regulatory action met the criteria of Annex II. The Committee also requested the Secretariat to prepare a draft decision to reflect the outcome of the contact group.

103. The co-chair of the contact group subsequently reported that no issues had been raised in the contact group with regard to the European Union notification and that the contact group had accordingly converted to a drafting group and prepared a draft rationale for its conclusions with regard to both the European Union and Sahelian country notifications. The Committee then adopted decision CRC-11/4, by which it adopted the rationale, recommended to the Conference of the Parties that it should include carbosulfan in Annex III to the Convention as a pesticide and adopted a workplan for preparing a draft decision guidance document for the chemical. The decision, to which the rationale is 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 to the present report; and the workplan is set out in annex III to the present report.

104. Prior to adoption of the draft decision one member of the Committee reiterated a statement made during the discussion of carbofuran, saying that in the interest of avoiding conflicts of interest the coordinators of an intersessional task group for a given chemical should not be from parties submitting notifications of final regulatory action in respect of the chemical. Other members disagreed, with one saying that there was no reason to depart from a procedure that had been in place since the Committee's inception and another reiterating that Committee members acted as independent experts and not as representatives of their Governments. At the request of the Chair, the representative of the Secretariat read out the provisions of decision RC-1/7, which laid out the rules and procedures governing conflicts of interest on the part of Committee members. The Secretariat added that the procedure prescribed by decision RC-1/7 had been followed and that no conflicts of interest preventing any member of the Committee from participating in the consideration of the chemicals on the agenda for the current meeting had been identified.

**D. Review of the proposal for the inclusion of dimethoate emulsifiable concentrate 400 g/L as a severely hazardous pesticide formulation in Annex III**

105. The Committee had before it a proposal and supporting documentation for the inclusion of dimethoate emulsifiable concentrate 400g/L as a severely hazardous pesticide formulation in Annex III submitted by Georgia (UNEP/FAO/RC/CRC.11/8), along with additional information submitted by other parties and international organizations, which had been compiled by the Secretariat in documents UNEP/FAO/RC/CRC.11/INF/16 and Add.1.

106. Mr. Fillmann, the co-coordinator of the intersessional task group that had undertaken a preliminary assessment of the proposal and its supporting documentation, reported on the work of the intersessional task group.

107. He said that the proposal from Georgia related to a pesticide retailer who had repeatedly been exposed to dimethoate between 1998 and 2010 while repacking the pesticide from large drums into half-litre containers. The retailer had reportedly been in contact with other pesticides in his profession. After suffering from headaches, in 2010 he had been diagnosed as having a cancerous growth in his throat and his voice box had been removed. The task group concluded that the proposal included adequate documentation as required in part 1 of Annex IV. The task group noted that the Secretariat had collected relevant information relating to the formulation, as outlined in part 2 of Annex IV, and had provided it to the intersessional task group and the Committee.

108. He indicated that, given the retailer's repeated and chronic exposure to various pesticides and the potential for additive or synergistic effects, the task group had found the causality of the cancer to be uncertain and was therefore unable to confirm that criterion (a) of part 3 of Annex IV to the Convention had been satisfied. Similarly, although it seemed plausible that related incidents reported in Georgia might be relevant to other States and regions, there was no documentation of that being so, nor of cases specifically caused by repacking containers; thus the requirements of criterion (b) of part 3 were also not satisfied. The task group deemed criterion (c) of part 3 to have been satisfied, as the information available suggested that the personal protective equipment required for handling products containing dimethoate had not been widely used in Georgia. It was noted that, although the worker had been provided with a facemask, he had not worn it because it was uncomfortable and inadequate. With regard to criterion (d) of part 3, the quantity of the formulation used in Georgia was not known and therefore it was not possible to judge whether that criterion was satisfied. The task group had concluded that the Chemical Review Committee should discuss whether criteria (a), (b) and (d) in Annex IV were satisfied.

109. In the ensuing discussion, all members who spoke concurred that there was insufficient evidence to conclude that criteria (a), (b) and (d) had been satisfied. There was also agreement, save on the part of one member, that criteria (c) and (e) had been met. As to criterion (e), the one member said that it had not been satisfied, suggesting that the individual in question might have diluted or mixed dimethoate with another substance and that his repacking and other handling of dimethoate was not a "use" covered by the Convention. Another member countered that the elements constituting intentional misuse were specified in the Committee's handbook and that according to those elements criterion (e) had clearly been met.

110. Following the discussion it was agreed that as criteria (a), (b) and (d) of Annex IV had not been met no further action would be taken in respect of the proposal.

**VI. Venue and date of the twelfth meeting of the Committee**

111. The Committee agreed to hold its twelfth meeting at FAO headquarters in Rome from 12 to 16 September 2016, back to back with the twelfth meeting of the Stockholm Convention's Persistent Organic Pollutants Review Committee. The Committee also decided that the Chair, in consultation with the Bureau, might adjust the length of the meeting depending on the number of chemicals to be considered by the Committee at the meeting.

112. During consideration of the item, one member suggested that the Committee consider reducing the combined length of the two back-to-back meetings and made several suggestions as to the logistical arrangements.

**VII. Other matters**

113. No other matters were discussed.

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**VIII. Adoption of the report**

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

**IX. Closure of the meeting**

115. Following the customary exchange of courtesies, the Chair declared the meeting closed at 12:05 p.m. on Wednesday, 28 October 2015.

## Annex I

### **Decisions adopted by the Chemical Review Committee at its eleventh meeting**

CRC-11/1: Short-chained chlorinated paraffins

CRC-11/2: Tributyltin compounds

CRC-11/3: Carbofuran

CRC-11/4: Carbosulfan

## CRC-11/1: Short-chained chlorinated paraffins

*The Chemical Review Committee,*

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

*Recalling* also its decision CRC-10/4, adopted at its tenth meeting in accordance with paragraph 6 of Article 5 of the Convention, in which it recommended to the Conference of the Parties that it should list short-chained chlorinated paraffins in Annex III to the Convention as industrial chemicals,

*Adopts* the draft decision guidance document for short-chained chlorinated paraffins<sup>1</sup> (CAS No. 85535-84-8) and decides to forward it, together with the related tabular summary of comments,<sup>2</sup> to the Conference of the Parties for its consideration.

## CRC-11/2: Tributyltin compounds

*The Chemical Review Committee,*

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

*Recalling* also its decision CRC-10/5, adopted at its tenth meeting in accordance with paragraph 6 of Article 5 of the Convention, in which it recommended to the Conference of the Parties that it should list tributyltin compounds in Annex III to the Convention as industrial chemicals,

*Adopts* the draft decision guidance document for tributyltin compounds<sup>3</sup> and decides to forward it, together with the related tabular summary of comments<sup>4</sup> and the note set out in the annex to the present decision, to the Conference of the Parties for its consideration.

## Annex to decision CRC-11/2

### **Note to the Conference of the Parties on the rationale for the Committee's recommendation at its tenth meeting that the Conference should list tributyltin compounds in Annex III to the Convention as industrial chemicals**

1. The Committee adopted decision CRC-10/5, by which it recommended that the Conference of the Parties should list tributyltin compounds in Annex III to the Convention as industrial chemicals. The present note is intended to assist the Conference of the Parties in its decision making and provide further information as to the Committee's discussions and rationale for its recommendation at its tenth meeting.

#### **I. The Secretariat forwarded the notification from Canada on tributyltin compounds for the industrial chemical use category.**

2. According to paragraph 5 of Article 5 of the Convention: “*When the Secretariat has received at least one notification from each of two Prior Informed Consent regions regarding a particular chemical that it has verified meet the requirements of Annex I, it shall forward them to the Chemical Review Committee...*”

3. On the basis of the above provision, the Secretariat forwarded to the Committee a new notification from Canada on tributyltin compounds for the industrial chemical use category. In transmitting the new notification, the Secretariat drew attention to two previous notifications of final regulatory action in respect of tributyltin compounds under the pesticide category submitted by Canada and the European Union, which had been reviewed by the Committee, considered and decided upon. The Secretariat had not received a notification in respect of tributyltin compounds in the industrial chemical use category from a second Prior Informed Consent region.

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<sup>1</sup> UNEP/FAO/RC/CRC.11/2/Rev.1.

<sup>2</sup> UNEP/FAO/RC/CRC.11/INF/7/Rev.1.

<sup>3</sup> UNEP/FAO/RC/CRC.11/3/Rev.1.

<sup>4</sup> UNEP/FAO/RC/CRC.11/INF/8/Rev.1.

## **II. The Committee reviewed the notification from Canada on tributyltin compounds for the industrial chemical use category.**

4. At the Committee's tenth meeting members of the Committee noted that the criteria in Annex II do not distinguish between use categories; as such they understood that their review of tributyltin compounds would take the chemicals into account regardless of the category to which the final regulatory action applied. In addition, responding to questions from members at that meeting, the Secretariat provided examples of previous experiences.<sup>5</sup> The Committee noted that it had never before faced a situation, as at its tenth meeting, in which it had found a single notification of final regulatory action pertaining to a chemical in one use category to be valid when that same chemical had already been listed in Annex III in another use category. At its tenth meeting, the Committee reviewed the notification from Canada on tributyltin compounds for the industrial chemical use category and found that the new notification met the criteria set out in Annex II.

## **III. The Committee recommended to the Conference of the Parties that tributyltin compounds should be listed in Annex III as industrial chemicals.**

5. The members of the Committee considered that as paragraphs 5 and 6 of Article 5 do not specify the need for notifications to relate to the same use category they could proceed with making a recommendation on listing based on the new notification, together with the previous notifications that had already been found to meet the criteria in Annex II. It was the understanding of the Committee at its tenth meeting that the rationale for this recommendation would apply to any chemical under any category forwarded to the Committee for its review.

6. Furthermore, in coming to its recommendation at its tenth meeting, the Committee noted that the categories of industrial chemicals and pesticides are treated differently by parties, which may have implications for the implementation of the Convention.

7. Although there was no notification on tributyltin compounds in the industrial chemical use category from a second prior informed consent region the Committee at its tenth meeting agreed that, as the notification from Canada met the criteria in Annex II to the Convention, the Committee should recommend to the Conference of the Parties that it amend the listing for tributyltin compounds in Annex III to the Convention by including tributyltin compounds as industrial chemicals.

8. Taking into account the previous conclusions by the Chemical Review Committee in respect of tributyltin<sup>6</sup> and decision RC-4/5, on the inclusion of tributyltin compounds in Annex III to the Convention,<sup>7</sup> the Committee at its tenth meeting decided to recommend in accordance with paragraph 6 of Article 5 of the Convention that the Conference of the Parties should list tributyltin compounds in Annex III to the Convention as industrial chemicals.

## **CRC-11/3: Carbofuran**

*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 carbofuran submitted by the European Union, Canada, Cabo Verde, Chad, the Gambia, Mauritania, the Niger, Senegal and Togo<sup>8</sup> meet the criteria set out in Annex II to the Convention;

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

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

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

<sup>5</sup> UNEP/FAO/RC/CRC.10/10, para 69.

<sup>6</sup> UNEP/FAO/RC/CRC.2/20, annex II, section B.

<sup>7</sup> UNEP/FAO/RC/COP.4/10, annex V.

<sup>8</sup> UNEP/FAO/RC/CRC.11/6.

6. *Decides*, in accordance with the process for drafting decision guidance documents set out in decision RC-2/2, that the composition of the intersessional drafting group to prepare the draft decision guidance document for carbofuran and the workplan of the group shall be as set out in annexes II and III to the report of the Committee's eleventh meeting, respectively.

## **Annex to decision CRC-11/3**

### **Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by the European Union, Canada, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo in respect of carbofuran meet the criteria of Annex II to the Rotterdam Convention**

1. In reviewing the notifications of final regulatory action by the European Union, Canada, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo to ban carbofuran as a pesticide, together with the supporting documentation provided by those parties, the Committee was able to confirm that the final regulatory actions had been taken to protect human health and the environment. The notifications from those parties were found to meet the information requirements of Annex I to the Rotterdam Convention.

2. The notifications and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.11/6 and UNEP/FAO/RC/CRC.11/INF/11–13. Information on ongoing international trade was provided by CropLife International in 2015 and made available in document UNEP/FAO/RC/CRC.11/INF/5.

## **I. European Union**

### **(a) Scope of the notified regulatory action**

3. The regulatory action notified by the European Union relates to the use of carbofuran as a pesticide. The marketing and the use of carbofuran are banned by the final regulatory action, which states that it is prohibited to place on the market or use plant protection products containing carbofuran and that carbofuran is not included in the list of approved active ingredients under Council Directive 91/414/EEC, which has been replaced by Regulation (EC) No 1107/2009. (UNEP/FAO/RC/CRC.11/6 section 2.2.1 of the European Union notification).

4. Complete entry into force of all provisions of Commission Decision 2007/416/EC of 13 June 2007 occurred on 13 December 2008 since all uses of plant protection products containing carbofuran were prohibited from that date at the latest (UNEP/FAO/RC/CRC.11/6 section 2.2.3 of the European Union notification).

5. The notification is 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;*

6. The Committee confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.11/6 section 2.4.2 of the EU notification).

7. Carbofuran has been used in the European Union as an acaricide, insecticide and nematicide. Various products were registered for use in some member States of the European Union. Insecticide uses involve drilling into soil at sites where maize, sugar beets and sunflowers are grown. Use as an acaricide and nematicide included use on crops such as maize, sugar beets, ornamentals, potatoes, carrots, brassica, onions, celery, chicory, beetroot, fodder beets, leeks, sweetcorn, sunflowers, soya, tobacco, rice, garlic, cauliflower, cabbage, tomatoes, peppers, aubergine, peanuts, melons, watermelons, cotton, bananas, sorghum and oilseeds. Pests controlled include numerous species of sucking insects, soil insects, chewing insects, nematodes, aphids and wireworms (UNEP/FAO/RC/CRC.11/6, section 2.3.1 of the European Union notification).

8. The risk evaluation concluded that the consumer exposure assessment indicated a potential acute risk to certain vulnerable groups of consumers. Ground water contamination was estimated at concentrations above the trigger value. Concerns remained regarding risk to birds, mammals, aquatic organisms, bees, non-target arthropods, earthworms, and soil macro-organisms (UNEP/FAO/RC/CRC.11/INF/11). The notification describes that the final regulatory action prohibits all uses of carbofuran as plant protection products, and that is expected to lead to a significant decrease

in the quantity of the chemical used, resulting in a significant reduction of risk to human health and the environment.

9. The Committee confirms that the 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;*

10. Prior to the regulatory action, a risk assessment was carried out on the basis of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009), which provided for the European Commission to issue a work programme for the examination of existing active substances used in plant protection products with a view to their possible inclusion in Annex I to the Directive, and in accordance with the provisions of Article 8 (7) of Regulation (EC) No 451/2000.

11. A member State was designated to undertake the risk assessment based on the information submitted by the notifiers and to prepare a draft assessment report, which was subject to peer review organized by the European Food Safety Authority (EFSA). The conclusions provided by EFSA were reviewed by the member States and the Commission and submitted to the Standing Committee on the Food Chain and Animal Health).

12. The evaluation was based on a review of scientific data taking into account the conditions prevailing in the European Union, including intended uses, recommended application rates and good agricultural practices. Only data 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 (UNEP/FAO/RC/CRC/11/6, section 2.4.1 of the European Union notification).

13. Analytical methods for the data provided are summarized in the supporting documentation from the European Union. Relevant data includes toxicity endpoints, no observed adverse effect level, acceptable daily intake, Acute Reference Dose (ARfD) determinations and comparison to expected exposure of humans and various organisms. (UNEP/FAO/RC/CRC/11/INF/11).

14. Thus, the Committee established that the data reviewed for the risk evaluation were generated according to scientifically recognized methods and that the data reviews were performed according to generally recognized scientific principles and procedures.

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

15. The final regulatory action to ban carbofuran was based on a risk evaluation. The risk analysis considered the insecticide uses proposed by two applicants for maize, sugar beet and sunflower crops using mechanical application to soil.

16. In the risk evaluation exposure of consumers has been estimated. A slight excess over the ARfD for toddlers has been calculated in the acute exposure assessment of carbofuran (UNEP/FAO/RC/CRC/11/INF/11).

17. The contamination of ground water has been estimated. In four of the eight relevant maize scenarios as well as in one of the two relevant sunflower scenarios the trigger value of 0.1 µg/L was exceeded (UNEP/FAO/RC/CRC/11/INF/11).

18. The risk evaluation estimated that the sublethal effects observed on birds in the field study might lead to increased mortality in the natural environment. A report on cases of secondary poisoning of birds of prey in France has been considered. A field study indicated that the application of Furadan 5 G leads to poisoning of small mammals like mice. Based on an estimated predicted environmental concentration of surface water the risk evaluation indicated a potential high acute and chronic risk for aquatic invertebrates. A high long-term risk for earthworms was estimated since the TER value was below the trigger of 5 (UNEP/FAO/RC/CRC/11/INF/11).

19. Consequently, the Committee confirms that criterion in subparagraph (iii) is met.

20. 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;*

21. The final regulatory action prohibits all uses of carbofuran as a plant protection product (UNEP/FAO/RC/CRC.11/6, section 2.3.3 of the European Union notification).

22. The estimated quantity of carbofuran produced, imported exported and used in the European Union prior to the regulatory action was not provided. Nevertheless, since the regulatory action bans the use of carbofuran (UNEP/FAO/RC/CRC.11/6, section 2.3.3 of the European Union notification), it is expected that the quantity used as a plant protection product in the European Union will be reduced to zero.

23. Therefore the Committee confirms that this sub-criterion 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;*

24. It is expected that since the regulatory action bans the use of carbofuran the risks to the environment and to human health will be significantly reduced.

25. The Committee confirms that this sub-criterion is met.

*(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;*

26. The concerns expressed regarding the acute exposure of vulnerable groups of consumers, risk of groundwater contamination and risks for birds, mammals, aquatic organisms, bees, non-target arthropods, earthworms and soil non-target organisms (UNEP/FAO/RC/CRC/11/6, sections 2.4.2.1 and 2.4.2.2 of the European Union notification), as determined by use patterns and modelled behaviour, could be encountered in other countries using carbofuran.

27. Therefore the Committee confirms that this sub-criterion is met.

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

28. The Committee confirms that, based on the information in the notifications from Europe, North America and Africa, and supporting documentation, ongoing international trade of carbofuran may be expected (UNEP/FAO/RC/CRC/11/6, UNEP/FAO/RC/CRC/11/INF/11, UNEP/FAO/RC/CRC/11/INF/12 and UNEP/FAO/RC/CRC/11/INF/13).

29. Information in document UNEP/FAO/RC/CRC.11/INF/5 confirms that international trade in carbofuran is ongoing.

30. Therefore the Committee confirms that this sub-criterion 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.*

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

32. Based on the above point the Committee confirms that the criterion in paragraph (d) is met.

**(f) Conclusion**

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

**II. Canada****(a) Scope of the notified regulatory action**

34. The regulatory action notified by Canada relates to the use of carbofuran as a pesticide. Sales of carbofuran pesticides were prohibited effective December 31, 2010. The use of products containing

carbofuran was prohibited after December 31, 2012. Carbofuran products may no longer be legally used in Canada (UNEP/FAO/RC/CRC.11/6, section 2.2.1 of the Canadian notification).

35. 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;*

36. The Committee confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.11/6, section 2.4.2 of the Canadian notification).

37. Carbofuran was used in Canada to control a broad range of insect pests on a variety of agricultural crops. It was applied to canola, mustard, sunflowers, corn (sweet, field and silage), sugar beets, green peppers, potatoes, raspberries and strawberries using conventional ground equipment and by aerial application to corn (field, silage and sweet), canola and mustard (UNEP/FAO/RC/CRC.11/6, section 2.3.1 of the Canadian notification).

38. In the notification, the following hazards to human health are reported. Use of the pesticide posed an unacceptable risk to workers engaged in certain mixing, loading, applying and post-application activities. An aggregate dietary risk assessment demonstrated that exposure to carbofuran from food and drinking water was unacceptable. Therefore, carbofuran does not meet Health Canada's current standards for human health protection.

39. In the notification, the following hazards to the environment are reported. Based on the label directions of carbofuran products that were registered at the time of the Health Canada review, use of the pesticide carbofuran posed an unacceptable risk to terrestrial and aquatic organisms. Therefore, carbofuran does not meet Health Canada's current standards for environmental protection. Furthermore, thirty-three environmental incident reports from the United States and Canada were considered during Health Canada's review of carbofuran, indicating that exposure to carbofuran under the registered use pattern resulted in avian, small wild mammal and bee mortality.

40. The notification states that all use of products containing carbofuran is prohibited by the final regulatory action, and that is expected to lead to a significant decrease in the quantity of the chemical used, resulting in a significant reduction of risk to human health and the environment.

**(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;*

41. Canada undertook a re-evaluation of carbofuran prior to the regulatory action. This led to publication of a proposed re-evaluation decision (Proposed Re-evaluation Decision, Carbofuran (PRVD2009-11)) for public review and comment.

42. The re-evaluation programme considers potential risks as well as the value of pesticide products to ensure that they meet modern standards established to protect human health and the environment. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available. An evaluation of available scientific information found that, under current conditions of use, carbofuran products posed an unacceptable risk to human health and the environment and therefore do not meet Health Canada's current standards for human health and environmental protection.

43. The "Science Evaluation" section of the proposed re-evaluation decision cites toxicity data, eco-toxicity data, modelled exposure levels and field studies.

44. The Committee confirms that in the supporting documentation provided by Canada data were generated according to scientifically recognized methods and that data reviews were performed and documented according to generally recognized scientific principles and procedures.

45. Consequently, the Committee confirms that the criteria in subparagraphs (b) (i) and (b) (ii) are met.

46. Thus, the Committee established that the data underlying the risk evaluation were generated according to scientifically recognized methods and also that the data reviews were performed according to generally recognized scientific principles and procedures.

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

47. The final regulatory action to ban carbofuran was based on a risk evaluation. The risk analysis considered the label directions of carbofuran products that were registered in Canada at the time of the review.

48. Use of the pesticide carbofuran posed an unacceptable risk to workers conducting certain mixing, loading, applying and post-application activities even when engineering controls or personal protective equipment were used. Post-application risks for workers were of concern for certain scenarios; mitigation measures that would diminish the risk were considered, but the mitigation measures calculated to reduce post-application risk may be agronomically unfeasible (UNEP/FAO/RC/CRC/11/6, sections 2.4.2.1 and 2.4.2.2 of the Canadian notification, UNEP/FAO/RC/CRC/11/INF/12, page 45).

49. A dietary risk assessment demonstrated that exposure to carbofuran from food was unacceptable. Since acute dietary exposure exceeds the ARfD for food alone, there is concern about any additional exposure through drinking water. An aggregate risk assessment combining exposure from food and drinking water was not conducted, as exposure from food alone is of concern. Therefore, carbofuran does not meet Health Canada's current standards for human health protection (UNEP/FAO/RC/CRC/11/6, sections 2.4.2.1 and 2.4.2.2 of the Canadian notification, UNEP/FAO/RC/CRC/11/INF/12, pages 45, 46).

50. Also based on the label directions of carbofuran products that were registered in Canada at time of the review, its use posed an unacceptable risk to terrestrial and aquatic organisms and therefore does not meet Health Canada's current standards for environmental protection. The risk assessment of carbofuran indicates adverse effects on non-target terrestrial invertebrates and vertebrates and aquatic organisms, some of which cannot be mitigated. There is potential that carbofuran may appear in surface water through runoff and in groundwater through leaching. Additionally, thirty-three environmental incident reports from the United States and Canada were considered during the review of carbofuran, indicating that exposure to carbofuran under the registered use pattern resulted in avian, small wild mammal and bee mortality (UNEP/FAO/RC/CRC/11/6, sections 2.4.2.1 and 2.4.2.2 of the Canadian notification, UNEP/FAO/RC/CRC/11/INF/12, page 46).

51. Based on the risks to human health and the environment that were identified during the review of the available data, the Committee established that a risk evaluation involving prevailing conditions in Canada had been the basis for the final regulatory action.

52. Consequently, the Committee confirms that the criterion in subparagraph (b) (iii) is met.

53. The Committee confirms that the criteria in paragraph (b) 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;*

54. The final regulatory action prohibits all uses of carbofuran as a plant protection product (UNEP/FAO/RC/CRC.11/6, section 2.3.3 of the Canadian notification).

55. The estimated quantity of carbofuran produced, imported exported and used in Canada prior to the regulatory action was not provided. Nevertheless, since the regulatory action bans the use of carbofuran (UNEP/FAO/RC/CRC.11/6, section 2.3.3 of the Canadian notification), it is expected that the quantity used in Canada as a plant protection product will be reduced to zero.

56. Therefore the Committee confirms that the criterion in subparagraph (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;*

57. It is expected that since the regulatory action bans the use of carbofuran, the risks to the environment and to human health will be significantly reduced.

58. Therefore the Committee confirms that the criterion in subparagraph (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;*

59. The concerns expressed regarding risks to workers, terrestrial and aquatic organisms, as well as the incident reports citing avian, small wild mammal and bee mortality as determined by use patterns, field studies and modelled behavior, could be encountered in other countries using carbofuran.

60. Therefore the Committee confirms that the criterion in subparagraph (c) (iii) is met.

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

61. The Committee confirms that, based on the information in the notifications from Europe, North America and Africa and supporting documentation, ongoing international trade of carbofuran may be expected (UNEP/FAO/RC/CRC.11/6, UNEP/FAO/RC/CRC.11/INF/11, UNEP/FAO/RC/CRC.11/INF/12 and UNEP/FAO/RC/CRC.11/INF/13).

62. Information in document UNEP/FAO/RC/CRC.11/INF/5 confirms that international trade in carbofuran is ongoing.

63. Therefore the Committee confirms that the criterion in subparagraph (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.*

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

65. Based on the above point the Committee confirms that the criterion in paragraph (d) is met.

**(f) Conclusion**

66. The Committee concluded that the notification of final regulatory action by Canada met the criteria set out in Annex II to the Convention.

### **III. Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo**

**(a) Scope of the notified regulatory action**

67. The regulatory action notified by Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo (hereafter referred to as the CILSS countries) relates to the use of carbofuran as a pesticide. Use of carbofuran pesticides was prohibited effective 8 April 2015 (UNEP/FAO/RC/CRC.11/6, section 2.2.1 of the CILSS notifications).

68. 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;*

69. The Committee confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.11/6, section 2.4.2 of the CILSS notifications).

70. Pesticide formulations containing carbofuran were authorized in the CILSS countries between 1995 and 2002. In 2006 a review of the authorizations of a group of pesticides including carbofuran-containing pesticides was performed. The review committee (composed of experts from the Sahelian Pesticides Committee and the Sahel Institut) recommended the withdrawal of authorization of pesticides containing active ingredients classified as highly hazardous (class Ib) by the World Health Organization (including carbofuran) because such pesticides are used by inadequately trained small farmers who don't respect the safety recommendations, specifically by not wearing appropriate personal protective equipment, and as a result suffer high levels of exposure to the pesticides. The Sahelian Pesticides Committee withdrew the registration of carbofuran-based pesticides in 2006 taking into account the following reasons (UNEP/FAO/RC/CRC.11/INF/13):

(a) The fragile ecology of CILSS countries, already characterized by an imbalance of ecosystems and the disappearance of organisms useful to the environment;

- (b) Non-compliance with recommended measures for safe use of carbofuran by users in CILSS countries;
- (c) Non-compliance with pre-harvest intervals (PHI) in particular, resulting in the presence of pesticide residues in harvested foodstuffs;
- (d) The low utilization rate of protective equipment by growers;
- (e) The existence of alternatives to the use of carbofuran.

71. In 2015, on the recommendation of the Sahelian Pesticides Committee, carbofuran was banned by decision of the CILSS Coordinating Minister due to unacceptable risk to the health of populations and unacceptable risk to non-target organisms in the environment, as well as the difficulty faced by users in Sahel countries in using carbofuran without unacceptable risk. The ban on carbofuran in several other countries such as the States of the European Union is also mentioned (UNEP/FAO/RC/CRC/11/INF/13.)

72. In the notifications, the following hazards to human health are reported: non-compliance with recommended measures for a safe use of carbofuran by users in CILSS countries; the presence of pesticide residues in harvested crops and the behavior of local people make the risk unacceptable; non-compliance with pre-harvest intervals in particular, entailing the presence of pesticide residues in harvested foodstuffs; the low utilization rate of protective equipment by growers (UNEP/FAO/RC/CRC/11/6, section 2.4.2.1 of the CILSS notifications, UNEP/FAO/RC/CRC/11/INF/13)

73. In the notification, the following hazards to the environment are reported: The fragile ecology of CILSS countries already characterized by an imbalance of ecosystems and the disappearance of organisms useful to the environment, the pollution of Sahel ground water which constitutes the main drinking water resource with open wells. High toxicity to birds, freshwater invertebrates and freshwater fish were also cited. (UNEP/FAO/RC/CRC/11/6, section 2.4.2.2 of the CILSS notifications).

74. The notifications state that carbofuran is banned by the final regulatory action; this is expected to lead to a significant decrease in the quantity of the chemical used, resulting in significant reduction of risk to human health and the environment.

75. The Committee confirms that the criterion in paragraph (a) 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;*

76. The notifications from the CILSS countries took into account scientific information from a variety of sources. Toxicity data was obtained from the Pesticide Properties Database, ExToxNet and sagepesticides.qc.ca (which draws its information from the proposed re-evaluation decision PRVD2009-11 supplied by Canada in UNEP/FAO/RC/CRC/11/INF/12, the Interim Reregistration Eligibility Decision for carbofuran published by the United States Environmental Protection Agency (EPA) and other publications by EPA and the Food and Agriculture Organization of the United Nations).

77. The Committee confirms that the data in the supporting documentation provided by CILSS countries were generated according to scientifically recognized methods and that data reviews were performed and documented according to generally recognized scientific principles and procedures.

78. Consequently, the Committee confirms that the criteria in subparagraphs (b) (i) and (b) (ii) are met.

79. Thus, the Committee established that the data underlying the risk evaluation were generated according to scientifically recognized methods and also that the data reviews were performed according to generally recognized scientific principles and procedures.

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

80. The final regulatory action to ban carbofuran was based on a risk evaluation. The CILSS countries found that carbofuran presented risks to human health and especially to non-target organisms in the environment that was making it very difficult for users in Sahel countries to handle carbofuran without unacceptable risk. The risk to human health (in particular due to the high acute toxicity of carbofuran) and non-target organisms as well as the risk of contamination of groundwater make it very difficult to use carbofuran safely in the Sahel countries. The notifications cited the following risks to human health and the environment: non-compliance with recommended measures for safe use of carbofuran; non-compliance with pre-harvest intervals in particular, resulting in the presence of pesticide residues in harvested foodstuffs; the low rate of utilization of protective equipment by growers.

81. In reference [6] of the supporting documentation (UNEP/FAO/RC/CRC/11/INF/13, page 11) the use of a carbofuran-containing pesticide (Grinox, Spinox: powder formulation containing 15 per cent thiram, 7 per cent benomyl and 10 per cent carbofuran, already listed as a severely hazardous pesticide formulation in Annex III to the Rotterdam Convention) in the planting of groundnut seeds by Senegalese farmers is described: during planting the farmers use a seeder to spread groundnut seeds. The equipment is drawn by a traction animal. During the loading of the powder in the container and the mixing of the product with seeds, the operators are exposed to the product by inhalation and contact. No protective measures (i.e., gloves and masks) are used. According to the direction of the wind, the operators who handle the powder sometimes inhale quantities of the product during the filling of the seeder. In August 2000 several cases of a disease characterized mainly by effort dyspnea, thoracic pain and edemas of the lower limbs and face were observed in the area of the village of Tankon (South Senegal). The signs and the symptoms of the disease suggested intoxication by carbamates and clinical manifestations indicated a mixture of effects of carbofuran and thiram.

82. The acceptable operator exposure level (AOEL) of 0.0003 mg/kg bw/day for carbofuran is mentioned in the supporting documentation (UNEP/FAO/RC/CRC/11/INF/13, page 55). The Committee noted that the AOEL was a qualitative measure, but due to the high toxicity of carbofuran concluded that it represented a risk analysis.

83. Also cited is the fragile ecology of CILSS countries, already characterized by an imbalance of ecosystems and the disappearance of organisms useful to the environment (UNEP/FAO/RC/CRC/11/6, sections 2.4.2.1 and 2.4.2.2 of the CILSS notifications).

84. The groundwater ubiquity score (GUS) index of carbofuran is 3.02, which represents a high risk of ground water pollution through leaching. Because of its high mobility, carbofuran presents a risk of surface water pollution in sandy areas. Other countries have noted that, following its percolation into soil, carbofuran leaches into soil and has been detected in ground waters after it had been used in agriculture (UNEP/FAO/RC/CRC/11/INF/13, page 15).

85. The risk evaluation took into account the conditions within the notifying Parties.

86. Consequently, the Committee confirms that the criterion in subparagraph (b) (iii) is met.

87. The Committee confirms that the criteria in paragraph (b) 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;*

88. The final regulatory action prohibits all uses of carbofuran as plant protection products (UNEP/FAO/RC/CRC.11/6, section 2.3.3 of the CILSS notifications).

89. The estimated quantity of carbofuran produced, imported exported and used in the CILSS countries prior to the regulatory action was not provided. Nevertheless, since the regulatory action bans the use of carbofuran (UNEP/FAO/RC/CRC.11/6, section 2.3.3 of the CILSS notifications), it is expected that the quantity of carbofuran used in the CILSS countries will be reduced to zero.

90. Therefore the Committee confirms that the sub-criterion in subparagraph (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;*

91. It is expected that since the regulatory action bans the use of carbofuran, the risks to the environment and to human health will be significantly reduced.

92. Therefore the Committee confirms that the criterion in subparagraph (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;*
93. The concerns expressed regarding risks to groundwater pollution and crop residues could be encountered in other countries using carbofuran.
94. Therefore the Committee confirms that the criterion is met.
- (iv) *Whether there is evidence of ongoing international trade in the chemical;*
95. The Committee confirms that, based on the information in the notifications from Europe, North America and Africa and supporting documentation, ongoing international trade of carbofuran may be expected (UNEP/FAO/RC/CRC/11/6, UNEP/FAO/RC/CRC/11/INF/11, UNEP/FAO/RC/CRC/11/INF/12 and UNEP/FAO/RC/CRC/11/INF/13). Specifically, supporting information from the African countries notes that the pesticide is still registered for use in some countries.
96. Information in document UNEP/FAO/RC/CRC.11/INF/5 confirms that international trade in carbofuran is ongoing.
97. Therefore the Committee confirms that the criterion in subparagraph (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.*
98. There is no indication in the notification that concerns for intentional misuse prompted the regulatory action.
99. Based on the above point the Committee confirms that the criterion in subparagraph (d) is met.

**(f) Conclusion**

100. The Committee concludes that the notifications of final regulatory action by Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo met the criteria set out in Annex II to the Convention.

## **IV. Conclusion**

101. The Committee concludes that the notifications of final regulatory action by the European Union, Canada, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo meet the criteria set out in Annex II to the Convention. The Committee also concludes that the final regulatory actions taken by the European Union, Canada, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo provide a sufficient basis to merit including carbofuran 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-11/4: Carbosulfan

*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 carbosulfan submitted by the European Union and by Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo 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;

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

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

6. *Also decides*, in accordance with the process for drafting decision guidance documents set out in decision RC-2/2, that the composition of the intersessional drafting group to prepare the draft decision guidance document for carbosulfan and the workplan of the group shall be as set out in annexes II and III to the report of the Committee's eleventh meeting, respectively.

### Annex to decision CRC-11/4

#### **Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by the European Union, Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo in respect of carbosulfan meet the criteria of Annex II to the Rotterdam Convention**

1. In reviewing the notifications of final regulatory action by the European Union, Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo to ban carbosulfan as a pesticide, together with the supporting documentation provided by those parties, the Committee was able to confirm that the final regulatory actions had been taken to protect human health and the environment. The notifications from those parties were found to meet the information requirements of Annex I to the Rotterdam Convention.

2. The notifications and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.11/4, UNEP/FAO/RC/CRC.11/7, UNEP/FAO/RC/CRC.11/INF/5, UNEP/FAO/RC/CRC.11/INF/14 and UNEP/FAO/RC/CRC.11/INF/15.

### I. European Union

#### (a) Scope of the notified regulatory action

3. The regulatory action notified by the European Union relates to the use of carbosulfan as a pesticide. The marketing or use of carbosulfan is banned by the final regulatory action, which states that it is prohibited to place on the market or use plant protection products containing carbosulfan and that the substance is not included in the list of approved active ingredients under Regulation (EC) No. 1107/2009, which replaces Council Directive 91/414/EEC. The authorizations for plant protection products containing carbosulfan had to be withdrawn by 13 December 2007. As of 16 June 2007 no authorizations for plant protection products containing carbosulfan were allowed to be granted or renewed by the member States and all uses of plant protection products containing carbosulfan were prohibited as from 13 December 2008 (UNEP/FAO/RC/CRC.11/7, section 2.2.1 of the European Union notification).

4. Entry into force of all provisions of Commission Decision 2007/415/EC of 13 June 2007 pertaining to the non-inclusion of carbosulfan in Annex I to Council Directive 91/414/EEC and the withdrawal of authorizations for plant protection products containing that substance occurred on 13 December 2008, since all uses of plant protection products containing carbosulfan were prohibited as from that date at the latest (UNEP/FAO/RC/CRC.11/7, section 2.2.3 of the European Union notification).

5. 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;*

6. The Committee confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.11/7, section 2.4.2 of the European Union notification).

7. Carbosulfan was used in the European Union as a systemic insecticide. It was used for incorporation into soil (at drilling) at sites where maize and sugar beets were grown, as well as on citrus and cotton. The substance can be used as insecticide and nematicide (UNEP/FAO/RC/CRC.11/7, section 2.3.1 of the European Union notification).

8. The risk evaluation concluded that carbosulfan was not shown to meet the safety requirements of Article 5 (1) (a) and (b) of Directive 91/414/EEC. Certain metabolites with hazardous profiles (some of which are potentially genotoxic) result from the use of carbosulfan, which leads to concerns about the exposure of consumers and the possible risk of groundwater contamination. In addition, impurities, of which at least one is carcinogenic (N-nitrosodibutylamine), have been found in the active substance as sold on the market (technical material) at levels raising concerns. The presence of unknown carcinogenic impurities in the technical substance may increase during storage, but the data submitted by the notifiers were not sufficient to address this concern and adequately assess the related risks for operators.

9. A further review in 2009 noted that intake by toddlers might exceed the acceptable daily intake and that consumption of a number of crops might pose an acute risk to children and adults. The risk evaluation raised concerns regarding a possible risk to groundwater due to potential contamination by the parent substance and a number of relevant metabolites. Concerns remained regarding the risk for birds and mammals, aquatic organisms, bees and earthworms (UNEP/FAO/RC/CRC.11/7, section 2.4.2 of the European Union notification; UNEP/FAO/RC/CRC.11/INF/14). The results of this second review from 2009, however, have not resulted in another regulatory action (see introduction to chapter 2.3).

10. The notification describes that the final regulatory action prohibits all uses of carbosulfan as a plant protection product; this is expected to lead to a significant decrease in the quantity of the chemical used, resulting in a significant reduction of risk to human health and the environment.

11. Therefore the Committee confirms that the criterion in paragraph (a) 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;*

12. Prior to the regulatory action, a risk assessment was carried out on the basis of Directive 91/414/EEC, replaced by Regulation (EC) 1107/2009, which provided for the European Commission to issue a work programme for the examination of existing active substances used in plant protection products with a view to their possible inclusion in Annex I to the Directive in accordance with the provisions of Article 8 (7) of Regulation (EC) No 451/2000.

13. A member State (Belgium) was designated to undertake the risk assessment based on the information submitted by the notifiers and to establish a draft assessment report, which was subject to peer review organized by the European Food Safety Authority (EFSA). The conclusions provided by EFSA were reviewed by the member States and the Commission and submitted to the Standing Committee on the Food Chain and Animal Health.

14. The evaluation of carbosulfan was based on a review of scientific data taking into account the conditions prevailing in the European Union, including intended uses, recommended application rates and good agricultural practices. Only data 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 (UNEP/FAO/RC/CRC.11/7, section 2.4.1 of the European Union notification).

15. The conclusions on the effects of carbosulfan on human health and the environment were reached on the basis of the evaluation of representative uses of carbosulfan as an insecticide as proposed by the applicant, including incorporation into soil (at drilling) to control soil insects where maize and sugar beets were grown. Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that at least limited quality control measurements of the plant protection product are possible. Analytical methods for the data provided are summarized in the supporting documentation from the European Union. Data includes toxicity endpoints, no observed adverse effect levels, acceptable daily intake, acceptable operator exposure levels and determinations and comparisons to expected exposure of humans and various organisms (UNEP/FAO/RC/CRC/11/INF/14).

16. Thus, the Committee established that the data reviewed for the risk evaluation were generated according to scientifically recognized methods and that the data reviews were performed according to generally recognized scientific principles and procedures.

17. Consequently, the Committee confirms that the criteria in subparagraphs (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;*

18. The final regulatory action to ban carbosulfan was based on a risk evaluation, in which the proposed conditions of use within the European Union, including intended uses, recommended application rates and good agricultural practices, were taken into account. The risk analysis considered the representative insecticide uses as proposed by the applicant for incorporation into soil (at drilling) to control soil insects, where maize and sugar beets would be grown. The conclusions of EFSA were reached on the basis of the evaluation of the representative uses in the European Union.

19. Assessments made on the basis of the data on carbosulfan submitted by the applicant did not demonstrate that it might be expected that, under the proposed conditions of use, plant protection products containing carbosulfan would satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC. In particular, concerns were identified with regard to:

(a) The toxicity of the substance and the presence of unknown levels of carcinogenic impurities in the technical substance, which might increase during storage;

(b) Worker exposure, which remains inconclusive due to uncertainties regarding the presence of the above impurities;

(c) Consumer exposure, which remains inconclusive due to uncertainties regarding the effects of certain metabolites, some of which could be genotoxic;

(d) Possible contamination of groundwater by the parent substance and by a number of relevant metabolites;

(e) A substantial lack of data for almost all groups with regard to ecotoxicology (UNEP/FAO/RC/CRC/11/INF/14, p. 91), including in particular for birds, mammals, aquatic organisms and bees (except in sugar beets), for which a first tier high risk was identified (UNEP/FAO/RC/CRC/11/INF/14, p. 49).

20. Consequently, the Committee confirms that the criterion in subparagraph (b) iii) is met.

21. The Committee confirms that the criteria in paragraph (b) 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 final regulatory action prohibits all uses of carbosulfan as a plant protection product (UNEP/FAO/RC/CRC.11/7, section 2.3.3 of the European Union notification).

23. The estimated quantity of carbosulfan produced, imported, exported and used in the European Union prior to the regulatory action was not provided. Nevertheless, since the regulatory action prohibits the use of carbosulfan, it is expected that the use of carbosulfan as a plant protection product within the European Union will be reduced to zero.

24. Therefore the Committee confirms that the criterion in subparagraph (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. It is expected that since the regulatory action prohibits the use of carbosulfan the risks to the environment and to human health will be significantly reduced.
26. Therefore, the Committee confirms that the criterion in subparagraph (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;*
27. The concerns expressed regarding the acute exposure of vulnerable groups of consumers, risk of groundwater contamination and risks for birds, mammals, aquatic organisms, bees and earthworms, as determined by use patterns and modelled behaviour, could be encountered in other countries with similar climatic conditions using carbosulfan (UNEP/FAO/RC/CRC.11/7, sections 2.4.2. and 2.5.2 of the European Union notification).
28. Therefore the Committee confirms that the criterion in subparagraph (c) (iv) is met.
- (iv) *Whether there is evidence of ongoing international trade in the chemical;*
29. The notification from the European Union provides no information on the estimated quantity of carbosulfan produced, imported, exported and used. The information gathered by the Secretariat (UNEP/FAO/RC/CRC.11/INF/5), however, indicates that carbosulfan was exported from the European Union to two countries in 2012 and 2013. In the same document, CropLife International confirms that there is ongoing international trade of carbosulfan.
30. Therefore the Committee confirms that the criterion in subparagraph (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.*

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

32. Based on the above point the Committee confirms that the criterion in subparagraph (d) is met.

**(f) Conclusion**

33. Therefore, the Committee concludes that the notification of final regulatory action by the European Union meets all the criteria set out in Annex II to the Convention.

**II. Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo**

**(a) Scope of the notified regulatory action**

34. The regulatory action notified by Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo (hereafter referred to as the CILSS countries), relates to the use of carbosulfan as a pesticide. All uses of carbosulfan-based pesticides were prohibited effective 8 April 2015. The final regulatory action states that all products containing carbosulfan were banned due to its extremely high toxic potential to human health and especially the environment (UNEP/FAO/RC/CRC.11/7, section 2.2.1 of the CILSS notifications).

35. 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;*

36. The Committee confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.11/7, section 2.4.2 of the CILSS notifications).

37. Four carbosulfan-based formulations were granted temporary sales authorization in 1996. Two other formulations have been under review since 2005. However, no carbosulfan-based formulation

has been registered by the Sahelian Pesticides Committee since 2006 (SPC) (SPC, 2011; Toe, 2007). The Sahelian Pesticides Committee stopped the registration of carbosulfan-based pesticides in 2006 taking into account the following reasons (UNEP/FAO/RC/CRC/11/INF/15, page 15):

- (a) The fragile ecology of CILSS countries, already characterized by an imbalance of ecosystems and the disappearance of organisms useful to the environment;
- (b) Non-compliance with recommended measures for the safe use of carbosulfan by users in CILSS countries;
- (c) The low rate of utilization of protective equipment by growers;
- (d) The existence of alternatives to the use of carbosulfan.

38. In April 2015, on the recommendation of the Sahelian Pesticides Committee, carbosulfan was banned by decision of the CILSS Coordinating Minister (Minister of Agriculture and Environment) due to unacceptable risk to human health (arising from difficulty in handling carbosulfan by users in Sahelian countries without unacceptable risk) and non-target organisms in the environment. The ban of carbosulfan in several other countries such as the States of the European Union is also mentioned (UNEP/FAO/RC/CRC/11/INF/15, page 15).

39. In the notifications, the following hazards to human health are reported: carbosulfan belongs to WHO Class II (moderately hazardous) (Footprint, 2011; WHO, 2008); it is a cholinesterase inhibitor (FAO, 003) (UNEP/FAO/RC/CRC/11/INF/15, page 15). Furthermore, the notification states that during a pilot study carried out in Burkina Faso in June 2010, through both retrospective and prospective surveys, one carbosulfan-based formulation was involved in a poisoning case: PROCOT 40 WS, a tertiary formulation containing carbosulfan (250 g/kg), carbendazim (100 g/kg) and metalaxyl-M (50 g/kg) (UNEP/FAO/RC/CRC/11/7, section 2.4.2.1 of the CILSS notifications, UNEP/FAO/RC/CRC/11/INF/15).

40. In the notifications, the following hazards to the environment are reported: carbosulfan is highly toxic to birds ( $LD_{50}$  *Anas platyrhynchos* = 10 mg/kg), fish ( $LC_{50}$  96h *Lepomis macrochirus* = 0.015 mg/L), aquatic invertebrates ( $EC_{50}$  48h *Daphnia magna* = 0.0032 mg/L) and bees ( $LD_{50}$  48h = 0.18 µg/bee) (Footprint PPDB, 2014) (UNEP/FAO/RC/CRC/11/7, section 2.4.2.2 of the CILSS notifications).

41. The notifications state that carbosulfan is banned by the final regulatory action; this is expected to lead to a significant decrease in the quantity of the chemical used, resulting in significant reduction of risk to human health and the environment.

42. Therefore, the Committee confirms that the criterion in paragraph (a) 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;

43. The risk evaluation is based on scientific data from several internationally recognized sources (the Food and Agriculture Organization of the United Nations, the World Health Organization, Pesticide Action Network, Pesticide Properties Database) and reports from the Sahelian Pesticides Committee, the United States Environmental Protection Agency (for carbofuran), the European Commission, the Australian Pesticides and Veterinary Medicines Authority and the National Institute of Industrial Environment and Risk (L'Institut National de l'Environnement Industriel et des Risques) (UNEP/FAO/RC/CRC.11/INF/15, pages 17-18, 110-134). The notifications from the CILSS countries took into account scientific information from these sources.

44. The Committee concludes that the data in the above sources were generated according to scientifically recognized methods and that data reviews were performed and documented according to generally recognized scientific principles and procedures.

45. Consequently, the Committee confirms that the criteria in subparagraphs (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;*

46. The final regulatory action to ban carbosulfan was based on a risk evaluation. The risk to human health and non-target organisms, as well as the risk of contamination of groundwater, makes it very difficult to handle carbosulfan safely in Sahel countries. The decision takes into account information from a pilot study on agricultural pesticide poisoning in Burkina Faso. The full report on this pilot study is included in the supporting documentation (UNEP/FAO/RC/CRC.11/INF/15, page 19). Burkina Faso is in the same geographical region as the rest of the notifying Parties. The notifications cited the following risks to human health and the environment: cases of poisoning due to the use of a carbosulfan-based pesticide formulation; the fragile ecology of CILSS countries, already characterized by an imbalance of ecosystems and disappearance of organisms useful to the environment; non-compliance with recommended measures for the safe use of carbosulfan, including the low rate of utilization of protective equipment by growers (UNEP/FAO/RC/CRC.11/INF/15, page 17).

47. The annex to the decision to ban carbosulfan further specifies the risks to human health and the environment in the notifying Parties. These risks result from the use of pesticides and the use of pesticides containing carbosulfan specifically. Growers do not follow good agricultural practices, in particular regarding the use of appropriate personal protective equipment. Protective equipment (dust masks, boots and gloves in particular) is sold to growers by distributors in 20 per cent of cases. The equipment is not specifically designed for field treatments. During plant treatment, growers mainly wear dust masks (39.08 per cent of cases) and boots (28.8 per cent of cases), whereas overalls are the least used (4.5 per cent of cases).

48. More than half of growers (67.5 per cent) had a water source in their fields or nearby. The majority of water points were less than 100 metres from fields, and that proximity may result in water pollution by pesticides. Water was drunk in 50 per cent of cases, was used for the preparation or dilution of pesticides in 29.26 per cent of cases and was used for watering animals 26.96 per cent of cases (UNEP/FAO/RC/CRC.11/INF/15, page 16).

49. Consequently, the Committee confirms that the criterion in subparagraph (b) (iii) is met.

50. Therefore, the Committee confirms that the criteria in paragraph (b) 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;*

51. The use of carbosulfan is banned by the final regulatory action, which entered into force on 8 April 2015. The final regulatory action states that all plant protection products (insecticide-nematicide) containing carbosulfan are banned due to its highly toxic potential for human health and mainly the environment (UNEP/FAO/RC/CRC.11/5, section 2.2.1).

52. The final regulatory action is therefore expected to lead to a significant decrease in the quantity of the chemical used, resulting in a significant reduction of the risk to human health and the environment.

53. Therefore the Committee confirms that the criterion in subparagraph (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;*

54. It is expected that since the regulatory action bans the use of carbosulfan the risks to the environment and to human health will be significantly reduced.

55. Therefore the Committee confirms that the criterion in subparagraph (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;*

56. The notifications state that the final regulatory action will be of great interest to other Sahel countries using the product under the same conditions (UNEP/FAO/RC/CRC.11/7, section 2.5.2).

57. The Committee concluded that the considerations that led to the final regulatory action being taken are applicable to a wide geographical area and a broad range of circumstances.

58. Therefore the Committee confirms that the criterion in subparagraph (c) (iii) is met.

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

59. The notifications give no information on the estimated quantity of carbosulfan produced, imported, exported and used. The information gathered by the Secretariat (UNEP/FAO/RC/CRC.11/INF/5), however, indicates that carbosulfan was exported from the European Union to two countries in 2012 and 2013. In the same document, CropLife International confirms that there is ongoing international trade of carbosulfan.

60. Therefore the Committee confirms that the criterion in subparagraph (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.*

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

62. Based on the above point the Committee confirms that the criterion in paragraph (d) is met.

**(f) Conclusion**

63. The Committee concludes that the notifications of final regulatory action by Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo meet the criteria set out in Annex II to the Convention.

### **III. Conclusion**

64. The Committee concludes that the notifications of final regulatory action by the European Union, Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo meet the criteria set out in Annex II to the Convention. The Committee also concludes that the final regulatory actions taken by the European Union, Burkina Faso, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo provides a sufficient basis to merit including carbosulfan 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.

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## Annex II

### Composition of intersessional drafting groups (2015–2016)

#### Drafting group on carbofuran

Chair: Mr. Jack Holland (Australia)  
 Vice-Chair: Ms. Leonarda Christina van Leeuwen (Netherlands)  
 Members: Mr. Malverne Spencer (Antigua and Barbuda)  
           Mr. Gilberto Fillman (Brazil)  
           Ms. Parvoleta Angelova Luleva (Bulgaria)  
           Mr. Peter Ayuk Enoh (Cameroon)  
           Mr. Jeffery R. Goodman (Canada)  
           Ms. Jinye Sun (China)  
           Mr. Omar S. Bah (The Gambia)  
           Ms. Mirijam Seng (Germany)  
           Mr. Ram Niwas Jindal (India)  
           Mr. Mohd Fauzan Yunus (Malaysia)  
           Ms. Magdalena Frydrych (Poland)  
           Mr. Jung-Kwan Seo (Republic of Korea)  
           Mr. Jürgen Helbig (Spain)  
           Ms. Sarah Maillefer (Switzerland)  
           Ms. Nuansri Tayaputch (Thailand)  
           Mr. N'Ladon Nadjo (Togo)

#### Drafting group on carbosulfan

Chair: Mr. Jeffery R. Goodman (Canada)  
 Vice-Chair: Ms. Parvoleta Angelova Luleva (Bulgaria)  
 Members: Mr. Jack Holland (Australia)  
           Ms. Jinye Sun (China)  
           Ms. Elsa Ferreras (Dominican Republic)  
           Mr. Omar S. Bah (The Gambia)  
           Ms. Mirijam Seng (Germany)  
           Ms. Ana Gabriela Ramírez Salgado (Honduras)  
           Mr. Ram Niwas Jindal (India)  
           Mr. Mohd Fauzan Yunus (Malaysia)  
           Mr. Gaoussou Kanouté (Mali)  
           Ms. Amal Lemsioui (Morocco)  
           Ms. Magdalena Frydrych (Poland)  
           Mr. Jung-Kwan Seo (Republic of Korea)  
           Ms. Tatiana Tugui (Republic of Moldova)  
           Mr. Jürgen Helbig (Spain)  
           Ms. Sarah Maillefer (Switzerland)  
           Ms. Nuansri Tayaputch (Thailand)  
           Mr. N'Ladon Nadjo (Togo)

## 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 Vice-Chair	15 December 2015
Send the draft internal proposal to the drafting group members for comments via e-mail	Chair Vice-Chair	15 December 2015
Replies	Drafting group members	20 January 2016
Update the internal proposal based on comments from drafting group members	Chair Vice -Chair	20 February 2016
Send the updated internal proposal to the Committee members and observers for comments via e-mail	Chair Vice -Chair	20 February 2016
Replies	Committee members and observers	31 March 2016
Draft a decision guidance document based on the comments of the Committee members and observers	Chair Vice -Chair	28 April 2016
Send the draft decision guidance document to the drafting group members for comments via e-mail	Chair Vice -Chair	28 April 2016
Replies	Drafting group members	9 May 2016
Finalize the draft decision guidance document based on the comments of the drafting group members	Chair Vice -Chair	30 May 2016
Send the draft decision guidance document to the Secretariat	Chair Vice-Chair	30 May 2016
Present the draft decision guidance document to the Committee at its twelfth meeting		September 2016