

## **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>1</sup> meet the criteria set out in Annex II to the Convention;
2. *Adopts* the rationale for the Committee's conclusion set out in the annex to the present decision;
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;
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).

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<sup>1</sup> UNEP/FAO/RC/CRC.11/6.

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 American 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 (Granox, 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 American 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.