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**Rotterdam Convention on the Prior  
Informed Consent Procedure for Certain  
Hazardous Chemicals and Pesticides in  
International Trade  
Conference of the Parties  
Fifth meeting  
Geneva, 20–24 June 2011  
Item 5 (b) of the provisional agenda\*  
Matters related to the implementation of the  
Convention: Chemical Review Committee**

## **Reports of the Chemical Review Committee**

### **Note by the Secretariat**

### **Addendum**

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

1. The annex to the present note contains the report of the Chemical Review Committee on the work of its sixth meeting.

#### **Possible action by the Conference of the Parties**

2. The Conference of the Parties may wish to take note of the report and consider any particular requests therein.

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\* UNEP/FAO/RC/COP.5/1/Rev.1.

## Annex

# Report of the Chemical Review Committee on the work of its sixth meeting

## Introduction

1. The Chemical Review Committee, hereinafter referred to as the Committee, was established pursuant to decision RC-1/6 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, adopted in September 2004 at the first meeting of the Conference of the Parties to the Convention, with a membership of 31 government-designated experts.
2. In accordance with paragraph 13 of decision RC-1/6 and pursuant to the provisions of Articles 5, 6, 7 and 9 of the Convention, the Committee's functions and responsibilities are to make recommendations on the listing of chemicals notified as banned or severely restricted or as severely hazardous pesticide formulations in Annex III to the Convention; to prepare, as appropriate, relevant draft decision guidance documents; and to make recommendations on the removal of chemicals from Annex III to the Convention.

## I. Opening of the meeting

3. The Committee's sixth meeting was held at the Varembe Conference Centre in Geneva from 15 to 19 March 2010. The meeting was opened at 10 a.m. on Monday, 15 March 2010, by Ms. Marit E. Randall (Norway), Chair of the Committee.
4. Mr. Donald Cooper, Co-Executive Secretary of the Secretariat of the Rotterdam Convention, speaking also on behalf of his fellow Co-Executive Secretary, Mr. Peter Kenmore, welcomed all those attending the meeting. He spoke of the tasks facing the Committee during the week and urged the members to ensure that, in applying the criteria set out in the Convention to the chemicals before them, the basis for decisions was clearly described in the rationales developed, so as to inform those who were unable to participate and the deliberations of the Conference of the Parties itself. Drawing attention to the working papers and policy guidance developed by the Committee over its past meetings based on the lessons learned, he encouraged participants to continue that process of, as he termed it, "learning by doing" as they worked through the candidate chemicals over the coming week. The Committee's best judgement on the chemicals before it would provide a firm scientific and technical basis for decisions, which were the purview of the Conference of the Parties, a body in which political, social and economic factors must prevail. He stressed that listing a chemical in Annex III was not a ban, but a means to help Parties to make informed decisions, share information and cooperate in the promotion of safe international trade in chemicals, with a view to protecting human health and the environment. He invited the members and other participants to avail themselves fully of the services provided by the capable Secretariat team assembled to assist the Committee.

## II. Organizational matters

### A. Officers

5. The following officers served on the Bureau of the Committee for the meeting:  
Chair: Ms. Marit E. Randall (Norway – Western Europe and others region)  
Vice-Chairs: Mr. Idris Adamu Goji (Nigeria – African region)  
Ms. Hala Sultan Saif Al-Easa (Qatar – Asian and Pacific region)<sup>1</sup>  
Ms. Darina Liptáková (Czech Republic – Central and Eastern European region)  
Ms. Jacqueline Arroyo (Ecuador – Latin American and Caribbean region)<sup>2</sup>  
  
Ms. Al-Easa agreed to serve as rapporteur.

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1 Elected to replace Mr. Manuweera, who had resigned during the intersessional period.

2 Elected to replace Mr. Yarto, who had resigned from the Committee.

## B. Attendance

6. The following 30 experts attended the session: Ms. Anahit Aleksandryan (Armenia), Ms. Anja Bartels (Austria), Mr. Mansourou Moudachirou (Benin), Ms. Hang Tang (Canada), Mr. Ignacio Figueroa-Cornejo (Chile), Mr. Shan Zhengjun (China), Mr. Goné Droh Lanciné (Côte d'Ivoire), Ms. Darina Liptáková (Czech Republic), Ms. Jacqueline Arroyo (Ecuador), Ms. Mirijam Kristina Brigitta Seng (France), Mr. Hubert Binga (Gabon), Mr. Manoranjan Hota (India), Mr. Michael Frank Ramsay (Jamaica), Mr. Masayuki Ikeda (Japan), Mr. Peter Opiyo (Kenya), Mr. Sidi Ould Alouéimine (Mauritania), Ms. Leonor Alicia Cedillo Becerril (Mexico), Mr. Jan B. H. J. Linders (Netherlands), Ms. Susan Jane Collier (New Zealand), Mr. Idris Adamu Goji (Nigeria), Ms. Marit E. Randall (Norway), Mr. Muhammad Bashir Khan (Pakistan), Ms. Vilma Morales Quillama (Peru), Ms. Magdalena Balicka (Poland), Ms. Hala Sultan Saif Al-Easa (Qatar), Ms. Noluzuko Gwayi (South Africa), Mr. Jürgen Helbig (Spain), Ms. Jeevani Prasadika Marasinghe (Sri Lanka), Mr. Azhari Omer Abdelbagi (Sudan), Mr. Shoki Abdulwali A. Al-Dobai (Yemen).

7. Mr. Hesameddin Nasirzadeh (Islamic Republic of Iran) was unable to attend.

8. Following the resignation from the Committee of Mr. Gopal Krishna Pandey (India), Mr. Mario Yarto (Mexico) and Mr. Gamini Manuweera (Sri Lanka), Mr. Hota, Ms. Cedillo Becerril and Ms. Marasinghe had been designated by the Governments of India, Mexico and Sri Lanka, respectively, as members in their place, subject to confirmation of their appointment by the Conference of the Parties at its next meeting.

9. Observers from the following countries were present: Argentina, Australia, Brazil, Bulgaria, Canada, China, Colombia, France, Iraq, Israel, Japan, Kenya, New Zealand, Nigeria, Norway, Oman, Panama, Philippines, Portugal, Qatar, Romania, Sweden, Switzerland, Trinidad and Tobago, United Arab Emirates, United States of America, Zambia, Zimbabwe.

10. The Central Africa Inter-State Pesticides Committee was also represented.

11. The following non-governmental organizations were also represented: CropLife International, Indian Chemical Council, International Council of Chemical Associations, International Stewardship Centre, Pesticide Action Network Asia and the Pacific, Swiss Association of the Chemical and Pharmaceutical Industry, Women in Europe for a Common Future.

12. A complete list of participants was circulated as document UNEP/FAO/RC/CRC.6/INF/15/Rev.1.

## C. Adoption of the agenda

13. At its opening meeting, the Committee adopted the following agenda on the basis of the provisional agenda (UNEP/FAO/RC/CRC.6/1):

1. Opening of the session.
2. Organizational matters:
  - (a) Adoption of the agenda;
  - (b) Organization of work.
3. Review of the outcome of the fourth meeting of the Conference of the Parties to the Rotterdam Convention.
4. Operational issues:
  - (a) Review of the Committee's role and mandate;
  - (b) Report on activities undertaken or planned for the effective participation of members and Parties in the Committee's work;
  - (c) Working procedures and policy guidance developed to facilitate the Committee's work.
5. Listing of chemicals in Annex III to the Rotterdam Convention:
  - (a) Report of the Bureau on the preliminary review of notifications and proposed priorities for chemicals scheduled for review by the Chemical Review Committee;
  - (b) Review of notifications of final regulatory actions to ban or severely restrict a chemical:

- (i) Amitraz;
  - (ii) Azinphos-methyl;
  - (iii) Endosulfan;
  - (iv) Methyl bromide;
  - (v) Paraquat;
- (c) Consideration of the draft decision guidance document for endosulfan.
6. Other matters.
  7. Adoption of the report.
  8. Closure of the meeting.

#### **D. Organization of work**

14. At its opening meeting, the Committee decided to conduct its work in plenary session each day from 9 a.m. to 12.30 p.m. and from 2 p.m. to 5 p.m., subject to adjustments as appropriate. It also decided that task groups and drafting groups would be formed as necessary.

15. The representative of the Secretariat drew the Committee's attention to the meeting documents, which had been circulated to participants prior to the meeting and made available on the Convention website.

16. The Chair explained that the main tasks before the Committee were to review the new notifications of final regulatory action and relevant supporting documentation for five chemicals – amitraz, azinphos-methyl, endosulfan, methyl bromide and paraquat – to determine whether they met the requirements of the Convention and should be recommended to the Conference of the Parties for listing in Annex III, and also to review and finalize the draft decision guidance documents for endosulfan that had been prepared following discussions at the Committee's previous meetings.

### **III. Review of the outcome of the fourth meeting of the Conference of the Parties to the Rotterdam Convention**

17. In considering the item, the Committee had before it a note by the Secretariat on issues arising out of the fourth meeting of the Conference of the Parties (UNEP/FAO/RC/CRC.6/4) and an information note containing additional information relevant to the implementation of decision RC-4/11 on enhancing cooperation and coordination among the Basel, Rotterdam and Stockholm conventions (UNEP/FAO/RC/CRC.6/INF/11).

18. The representative of the Secretariat presented the outcome of the fourth meeting of the Conference of the Parties, highlighting the elements relevant to the Committee's work at the current meeting. He drew attention to decision RC-4/2, by which the Conference had confirmed the appointment of new government-designated experts to the Committee for a period of four years, commencing on 1 October 2007, and decision RC-4/3, by which the Conference had nominated 17 Governments eligible to designate experts to the Committee for a period of four years, commencing on 1 October 2009, to replace those whose terms expired in September 2009. The experts appointed by those Governments were participating in the current meeting for the first time, along with those experts who were continuing their terms with the Committee, as identified in decisions RC-4/2 and RC-4/3.

19. He also recalled that the Conference had been unable to reach consensus on a decision to include endosulfan in Annex III to the Convention because a small number of representatives had opposed the inclusion on the grounds that the notification of final regulatory action from Thailand was based on intentional misuse of the chemical. The Conference had agreed, by its decision RC-4/6, that a further legal opinion on the application of the "intentional misuse" criterion in paragraph (d) of Annex II to the Convention should be made available to the Committee at its sixth meeting. That opinion was before the Committee in documents UNEP/FAO/RC/CRC.6/10 and Corr.1.

20. Another representative of the Secretariat recalled that, by section C of part II of decision RC-4/11 on enhancing cooperation and coordination among the Basel, Rotterdam and Stockholm conventions, the Conference had requested the secretariats of the three conventions to facilitate the exchange of relevant information between the technical and scientific bodies of the three conventions through the sharing of information with one another, with the secretariat of the Strategic Approach to International Chemicals Management and with other relevant intergovernmental bodies concerning the procedures developed and the chemicals being discussed under the three conventions.

The Conference had also requested the three secretariats to maintain or establish cooperation on technical issues that related to more than one of the three conventions, involving other bodies and institutions beyond the three conventions as appropriate. In that regard, she explained that a number of initiatives were under way among the secretariats regarding the sharing of information among the three technical committees. Thus, during the planning process for meetings of the technical and scientific bodies of the conventions, the secretariat that was organizing the meeting would inform the other two chemicals and wastes convention secretariats, the Strategic Approach secretariat and other appropriate bodies of issues relevant to them.

21. The Committee took note of the outcome of the fourth meeting of the Conference of the Parties and the implementation of decision RC-4/11.

#### **IV. Operational issues**

##### **A. Review of the Committee's role and mandate**

22. The representative of the Secretariat gave an overview of the Convention, putting the Committee's work in the context of the prior informed consent (PIC) procedure.

23. Another representative of the Secretariat gave a presentation on the Committee's role and mandate as set out in the Convention and decided by the Conference of the Parties.

##### **B. Report on activities undertaken or planned for the effective participation of members and Parties in the Committee's work**

24. The representative of the Secretariat gave details of an orientation workshop for new Committee members held in Budapest from 8 to 10 December 2009 in which 20 members had participated. The workshop had provided an opportunity for members to familiarize themselves with the Committee's work, in particular the working procedures and policy guidance that had been developed.

25. Another representative of the Secretariat gave details of a joint workshop held in November 2009 in Cairo comprising designated national authorities, official contact points and some members of the Chemical Review Committee and the Persistent Organic Pollutants Review Committee, organized by the secretariats of the Rotterdam and Stockholm conventions, to enhance the effectiveness of those committees. The workshop had provided an opportunity for members to hold detailed discussions and acquire practical experience of issues related to the committees' work, and also to explore ways of increasing cooperation at various levels. The next such workshop was expected to take place in Latin America and the Caribbean.

26. The orientation workshop would enable new members to participate more effectively in the Committee's work and intersessional task groups. For its part, the joint workshop of the Rotterdam and Stockholm conventions for effective participation in the review committees' work had brought experts together with designated national authorities and had illustrated different approaches taken to managing various chemicals and identified implementation issues common to the Basel, Rotterdam and Stockholm conventions. Several members expressed appreciation for the workshops and requested more such opportunities to learn by doing. They recommended that comparable workshops should be organized in other regions.

##### **C. Working procedures and policy guidance developed to facilitate the Committee's work**

27. In considering the item, the Committee had before it notes by the Secretariat on revised guidance to intersessional task groups (UNEP/FAO/RC/CRC.6/13), on revised policy guidance regarding the working paper on the application of the criteria in paragraphs (b) (i), (b) (ii) and (b) (iii) of Annex II to the Convention (UNEP/FAO/RC/CRC.6/14) and on a supplementary legal opinion on intentional misuse and the application of the criterion in paragraph (d) of Annex II (UNEP/FAO/RC/CRC.6/10 and Corr.1), together with information notes containing a compilation of the Committee's working procedures and policy guidance (UNEP/FAO/RC/CRC.6/INF/3), a letter from CropLife International on the legal opinion (UNEP/FAO/RC/CRC.6/INF/10) and views from Parties and observers on the application of the criterion in paragraph (d) of Annex II (UNEP/FAO/RC/CRC.6/INF/13).

28. Mr. Goji introduced the revised guidance to intersessional task groups, explaining that the process for drafting decision guidance documents set out in decision RC-2/2 provided for the creation of task groups to work intersessionally. The Committee had developed a paper to provide guidance to such groups in reviewing candidate chemicals on the understanding that it was a work in progress that could

be amended in the light of experience gained. The guidance had since been revised to define more precisely the roles and tasks of the intersessional task groups, to ensure that the task groups' reports were sufficiently detailed and clearly documented why criteria were considered to have been met or not met, and to stress communication between task group members and the need to make available draft task group reports prior to Committee meetings. The revised guidance also emphasized that the main part of the task group report should be the analysis that explained the basis for the task group's conclusions. For each notification a detailed analysis reviewing the criteria in Annex II to the Convention should be prepared, clearly stating whether the information available was sufficient to satisfy those criteria and, if so, how. Where a notification was determined by the Committee to meet the requirements of the Convention, the analysis would form the basis for the preparation of the rationale, which would be included in the report of the meeting.

29. Following that presentation, a number of issues were raised and comments made by both members and observers.

30. The Chair introduced the revised working paper on the application of the criteria in paragraphs (b) (i), (b) (ii) and (b) (iii) of Annex II to the Convention, noting that the Committee had originally developed that working paper to assist it in judging whether a notification of final regulatory action met those criteria. The working paper had been developed on the understanding that it could be amended in the light of experience gained. It had since been revised to indicate clearly that, to determine whether the criteria in paragraphs (b) (i) and (b) (ii) of Annex II were met, both hazard and exposure information should be taken into account and to emphasize that the criteria in paragraphs (b) (i), (b) (ii) and (b) (iii) of Annex II should be considered as a single cluster. Should additional information for a notification be submitted in the future, the notification and all supporting documentation would be made available to the Committee to be revisited. The Committee would then take into account all available information, including that reviewed at previous meetings and new information, to reach a conclusion.

31. One member, while endorsing the idea that the criteria in paragraphs (b) (i), (b) (ii) and (b) (iii) of Annex II should be considered as a single cluster, said that the document in question appeared to be intermingling the criteria rather than keeping them separate, citing paragraph 11 as an example. Referring to the phrase "prevailing conditions in the notifying country" in that paragraph, he said that, under the criterion in paragraph (b) (ii), of Annex II, in-country generation of data was not always needed, pointing out that most data were generated by international sources. The Chair responded that the data themselves did not have to be generated in the country in question; rather, the evaluation had to be based on a review in the context of the conditions prevailing in that country. In response to the member's assertion that her explanation pertained more to the criterion in paragraph (b) (iii) of Annex II, the Chair suggested that the subparagraphs of paragraph (b) had to be read in conjunction with its chapeau.

32. An observer drew attention to paragraph (iii) of page 6 of the document, suggesting that the wording should be amended to bring it into line with the language of the Convention. The Chair said that the wording could be amended to read "specific quantitative information".

33. In the light of the foregoing comments on the working procedure and policy guidance, the Chair suggested that a task group should be established to collect suggestions and examples from Committee members and observers that would serve as the basis for revision of the two papers by an intersessional drafting group.

34. Subsequently, the chair of the task group reported back that she had gathered a number of comments during the task group's meetings and plenary sessions and that the group would continue its work during the intersessional period. The revised guidance documents would be made available to the Committee at its seventh meeting.

35. The UNEP Senior Legal Officer introduced the supplementary legal opinion on intentional misuse and the application of the criterion in paragraph (d) of Annex II (document UNEP/FAO/RC/CRC.6/10 and Corr.1), saying that, pursuant to decision RC-4/6, the original legal advice on the matter (document UNEP/FAO/RC/CRC.3/INF/7) had been reviewed to clarify further the meaning of the term "intentional misuse". He invited the Committee to take the legal opinion into account when considering the application of the criterion in paragraph (d) of Annex II. The document containing the views submitted by Parties and observers on the application of the criterion provided further background information.

36. The Committee, in particular its new members, expressed appreciation of the light shed on the term "intentional misuse" by the supplementary legal opinion and the guidance that it offered for the appropriate application of the term by the Committee. Many members said that the supplementary legal

opinion made the issue clear. All the Committee members who took the floor confirmed that they understood the legal opinion.

37. In response to the concerns raised by one observer regarding the submission from Argentina in the document containing the views of Parties and observers, which had not been translated from Spanish into English, the UNEP Senior Legal Officer explained that the Secretariat made available submissions from Parties exactly as they had been received, for information purposes only, and that such views were not for discussion by the Committee. It was not for the Committee to debate legal issues; that was the role of the Conference of the Parties.

38. Some observers drew attention to the relationship between the corrigendum and the two legal opinion documents. The UNEP Senior Legal Officer said that a generic approach had been adopted in the original opinion paper in making reference to “misuse” and other terms, while the purpose of the corrigendum was to explain, in the light of the drafting history, what was meant by the term “misuse” in view of the meaning of the term “use” as defined in the Convention. He also explained that the UNEP legal office had not acted on its own initiative in preparing the legal opinion: it had been requested to do so by the Conference of the Parties itself.

39. A number of observers suggested that the matter, which constituted a complex and important legal issue, should be referred to the Conference of the Parties with a view to reaching a correct interpretation.

40. The Chair noted that the Committee had expressed appreciation of the clarity of the legal opinion and agreed that it understood that opinion and how to apply it.

## **V. Listing of chemicals in Annex III to the Rotterdam Convention**

### **A. Report of the Bureau on the preliminary review of notifications and proposed priorities for chemicals scheduled for review by the Chemical Review Committee**

41. In considering the item, the Committee had before it a note by the Secretariat setting out the results of the Bureau’s preliminary review of notifications and proposed priorities for chemicals scheduled for review by the Committee at its sixth meeting (UNEP/FAO/RC/CRC.6/3).

42. The representative of the Secretariat said that, following the priorities proposed by the Bureau, as set out in the above-mentioned document, the five chemicals for consideration by the Committee had been clustered into the three proposed groups. Thus, azinphos-methyl had been placed in the first group, which included chemicals for which it was possible that notifications from at least two PIC regions would meet the criteria in the Convention. Amitraz, endosulfan and methyl bromide had been placed in the second group of chemicals, for which there might only be a notification from a single PIC region that would meet the Convention criteria. Based on the information available at the time of the preliminary review, paraquat had been placed in the third group of chemicals, for which there did not appear to be any notifications that met the criteria in Annex II.

43. The Committee agreed to consider the notifications before it in line with the priorities recommended by the Bureau in document UNEP/FAO/RC/CRC.6/3.

### **B. Review of notifications of final regulatory actions to ban or severely restrict a chemical**

#### **1. Chemicals for which, following a preliminary review, at least two notifications appeared to meet the criteria in Annex II: azinphos-methyl**

44. The Committee had before it a new notification and supporting documentation on azinphos-methyl submitted by Norway, contained in documents UNEP/FAO/RC/CRC.6/6 and UNEP/FAO/RC/CRC.6/6/Add.2, together with the notification from Canada that it had reviewed at its fifth meeting, for which it had prepared a rationale for its decision that the notification had met the requirements of the Convention. That rationale was set out in annex III to the report of the Committee’s fifth meeting (UNEP/FAO/RC/CRC.5/16, annex III, paras. 1–10) and had been reproduced in document UNEP/FAO/RC/CRC.6/6/Add.1.

45. Ms. Al-Easa presented the work of the intersessional task group that had undertaken a preliminary assessment of the new notification and its supporting documentation. The group had comprised herself and Ms. Balicka as co-chairs and Ms. Arroyo, Mr. Droh Lanciné, Mr. Goji, Mr. Helbig, Mr. Hota, Ms. Marasinghe, Mr. Opiyo and Ms. Randall as members.

46. She said that the notification from Norway related to a ban on the use of azinphos-methyl as a pesticide. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

47. With regard to Annex II to the Convention, she said that the notification from Norway explained that the regulatory action had been taken to protect the environment: thus, the criterion in paragraph (a) of Annex II had been met. The referenced hazard data had been taken from internationally recognized sources and the risk evaluation had been performed in accordance with recognized scientific principles and procedures, taking into account prevailing conditions in Norway. Accordingly, the task group had concluded that the criteria in paragraphs (b) (i), (b) (ii) and (b) (iii) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, she said that Norway had prohibited the substance: thus, it could be considered that the expected quantities and risks would be significantly reduced. As the basis for the regulatory action included environmental concerns, the regulatory action would be broadly applicable to other countries. There was evidence of ongoing international trade. Accordingly, the task group had concluded that the criteria in paragraphs (c) (i), (c) (ii), (c) (iii) and (c) (iv) of Annex II had been met. There was no evidence that intentional misuse had been the basis for the final regulatory action: thus, the criterion in paragraph (d) of Annex II had been met. The task group had therefore concluded that the notification had met all the criteria in Annex II.

48. The Committee agreed that the notification from Norway met all the criteria in Annex II to the Convention, and that, as the notification from Canada had previously been found to meet those criteria, the Committee should recommend to the Conference of the Parties that azinphos-methyl should be included in Annex III to the Convention.

49. A drafting group was established to draft a rationale as to how the notification from Norway had met the criteria in Annex II to the Convention, to prepare a timetable for the development of the decision guidance document and to report to the Committee on its work. The Secretariat was requested to draft a recommendation to the Conference of the Parties on the inclusion of azinphos-methyl in Annex III to the Rotterdam Convention.

50. Subsequently the Committee adopted a recommendation on azinphos-methyl, the rationale for that recommendation and a workplan for preparing a decision guidance document for the substance, as amended. The rationale, the recommendation and the timetable are set out in annex II to the present report.

## **2. Chemicals for which, following a preliminary review, only one notification appeared to meet the criteria in Annex II**

### **(a) Amitraz**

51. The Committee had before it new notifications and supporting documentation on amitraz, submitted by the European Community and the Islamic Republic of Iran, contained in documents UNEP/FAO/RC/CRC.6/5, Add.1, Add. 2 and Add.3/Rev.1.

52. Mr. Abdelbagi presented the work of the intersessional task group that had undertaken a preliminary assessment of the new notifications and their supporting documentation. The group had comprised himself and Mr. Ikeda as co-chairs and Ms. Bartels, Mr. Helbig, Mr. Linders, Mr. Moudachirou, Mr. Opiyo, Mr. Ramsay, Ms. Randall, Mr. Shan and Mr. Yarto as members.

53. He said that the notification from the Islamic Republic of Iran related to a ban on the use of amitraz as a pesticide. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

54. With regard to Annex II to the Convention, he said that the notification from the Islamic Republic of Iran explained 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. While the referenced hazard data had been taken from internationally recognized sources and data reviews had been performed and documented according to generally recognized scientific principles and procedures, meeting the criteria in paragraphs (b) (i) and (b) (ii) of Annex II, the notification stated that the final regulatory action had not been based on a risk evaluation. Accordingly, the task group had concluded that the notification from the Islamic Republic of Iran had not met the criterion in paragraph (b) (iii) of Annex II. Turning to the criteria in paragraph (c) of Annex II, he said that the Islamic Republic of Iran had prohibited the substance as from 20 March 2012: thus, it could be considered that the expected quantities and risks would be significantly reduced. As the basis for the regulatory action included human health concerns, the regulatory action would be broadly applicable to other countries. There was evidence of ongoing international trade. Accordingly, the task group had concluded that the criteria in paragraphs (c) (i), (c) (ii), (c) (iii) and (c) (iv) of Annex II had been met. There was no evidence that intentional misuse

had been the basis for the final regulatory action: thus, the criterion in paragraph (d) of Annex II had been met.

55. The Committee agreed that, since the criteria in paragraph (b) of Annex II had not been met, the notification from the Islamic Republic of Iran had not met all the criteria in Annex II to the Convention.

56. Turning to the notification from the European Community, he said that the notification related to a ban on all uses of amitraz as a pesticide. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

57. With regard to Annex II to the Convention, he said that the notification from the European Community explained 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. The referenced hazard data had been taken from internationally recognized sources and the risk evaluation had been performed in accordance with recognized scientific principles and procedures, taking into account prevailing conditions in the European Community. Accordingly, the task group had concluded that the criteria in paragraphs (b) (i), (b) (ii) and (b) (iii) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, he said that the European Community had prohibited the substance: thus, it could be considered that the expected quantities and risks would be significantly reduced. As the basis for the regulatory action included human health and environmental concerns, the regulatory action would be broadly applicable to other countries. There was evidence of ongoing international trade. Accordingly, the task group had concluded that the criteria in paragraphs (c) (i), (c) (ii), (c) (iii) and (c) (iv) of Annex II had been met. There was no evidence that intentional misuse had been the basis for the final regulatory action: thus, the criterion in paragraph (d) of Annex II had been met. The task group had therefore concluded that the notification had met all the criteria in Annex II.

58. The Committee agreed that the notification from the European Community had met all the criteria in Annex II to the Convention and established a drafting group to draft a rationale for amitraz.

59. Subsequently the Committee adopted a rationale for the conclusion that the notification by the European Community had met the information requirements of Annex I and the criteria in Annex II to the Convention. The rationale is set out in annex III to the present report.

60. As only one notification of final regulatory action from one PIC region had met the criteria in Annex II, it was agreed that amitraz could not be proposed for inclusion in Annex III to the Rotterdam Convention at the current time.

## **(b) Methyl bromide**

61. The Committee had before it a new notification and supporting documentation on methyl bromide submitted by Malawi, contained in documents UNEP/FAO/RC/CRC.6/8 and UNEP/FAO/RC/CRC.6/8/Add.2/Rev.1, together with the notification from the Netherlands that it had reviewed at its first meeting, for which it had prepared a rationale for its decision that the notification had met the requirements of the Convention. That rationale was set out in annex V to the report of the Committee's first meeting (UNEP/FAO/RC/CRC.1/28, annex V, paras. 1–7) and had been reproduced in document UNEP/FAO/RC/CRC.6/8/Add.1.

62. Mr. Goji presented the work of the intersessional task group that had undertaken a preliminary assessment of the new notification and its supporting documentation. The group had comprised himself and Ms. Tang as co-chairs and Ms. Al-Easa, Ms. Aleksandryan, Ms. Arroyo, Mr. Hota, Mr. Khan and Ms. Liptáková as members.

63. He said that the notification from Malawi related to a severe restriction of the uses of methyl bromide as a pesticide. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

64. With regard to Annex II to the Convention, he said that the notification from Malawi explained that the regulatory action had been taken to protect the environment: thus, the criterion in paragraph (a) of Annex II had been met. As no applicable hazard and exposure data had been included in the notification and it did not take into account a risk evaluation in the conditions prevailing in Malawi, the task group considered that the criteria in paragraphs (b) (i), b (ii) and (b) (iii) of Annex II had not been met. Turning to the criteria in paragraph (c) of Annex II, he said that Malawi had severely restricted the substance: thus, it could be considered that the expected quantities and risks would be significantly reduced. As the basis for the regulatory action included environmental concerns, the regulatory action would be broadly applicable to other countries. There was evidence of ongoing international trade. Accordingly, the task group had concluded that the criteria in paragraphs (c) (i), (c) (ii), (c) (iii) and (c)

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

65. The Committee agreed that, since the criteria in paragraph (b) of Annex II had not been met, the notification from Malawi had not met all the criteria in Annex II to the Convention.

66. Accordingly, as only one notification of final regulatory action from one PIC region, reviewed at the Committee's first meeting, had met the criteria in Annex II, the Committee concluded that methyl bromide could not be proposed for inclusion in Annex III to the Rotterdam Convention at the current time.

**(c) Endosulfan**

67. The Committee had before it new notifications and supporting documentation on endosulfan, submitted by Guinea-Bissau, New Zealand, the Islamic Republic of Iran and Malaysia, contained in documents UNEP/FAO/RC/CRC.6/7 and Add.1-5.

68. Mr. Figueroa presented the work of the intersessional task group that had undertaken a preliminary assessment of the new notifications and their supporting documentation. The group had comprised himself and Ms. Seng as co-chairs and Mr. Aloueimine, Ms. Collier, Ms. Gwayi, Mr. Linders and Mr. Nasirzadeh as members.

**(i) Notification from Guinea-Bissau**

69. Mr. Figueroa said that the task group had concluded that the notification from Guinea-Bissau referred to the same final regulatory action as the notifications from the seven African countries (Burkina Faso, Cape Verde, the Gambia, Mali, Mauritania, the Niger and Senegal) reviewed by the Committee at its fifth meeting.

70. The Committee confirmed the findings of the task group and decided to add Guinea-Bissau as one of the notifying countries in the draft decision guidance document on endosulfan.

**(ii) Notification from New Zealand**

71. Mr. Figueroa said that the notification from New Zealand related to a ban on the use of endosulfan as a pesticide. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

72. With regard to Annex II to the Convention, he said that the notification from New Zealand explained 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. The referenced hazard data had been taken from internationally recognized sources and the risk evaluation had been performed in accordance with recognized scientific principles and procedures, taking into account prevailing conditions in New Zealand. Accordingly, the task group had concluded that the criteria in paragraphs (b) (i), (b) (ii) and (b) (iii) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, he said that New Zealand had prohibited the substance: thus, it could be considered that the expected quantities and risks would be significantly reduced. As the basis for the regulatory action included human health concerns, the regulatory action would be broadly applicable to other countries. There was evidence of ongoing international trade. Accordingly, the task group had concluded that the criteria in paragraphs (c) (i), (c) (ii), (c) (iii) and (c) (iv) of Annex II had been met. On the criterion in paragraph (d) of Annex II, the task group had concluded that, considering the Committee's working paper on the application of the criterion in paragraph (d) of Annex II and the amended legal opinion, the "off-label use" mentioned in the notification from New Zealand did not meet the definition of "intentional misuse": thus, the criterion in paragraph (d) of Annex II had been met. The task group had therefore concluded that the notification had met all the criteria in Annex II.

73. In the ensuing discussion, one member said that there was an absence of data as acknowledged by the New Zealand authorities in their notification and that the data used in the notification from New Zealand had not been generated in the country but had been extrapolated through modelling. The use of modelling was unacceptable, as the technique was hypothetical and precautionary in nature, failing to take into consideration other factors, such as social and economic aspects and the use of personal protective equipment. If the only data available had been acquired through modelling, the notification could not be deemed to meet the requirement of paragraph (b) (iii) of Annex II that the final regulatory action should be based on a risk evaluation involving prevailing conditions within the Party taking the action. In addition, many risks had been identified in the supporting documentation, but a number of them were deemed to be within acceptable limits. He also questioned whether off-label use could be regarded as intentional misuse. In response, another member said that modelling was a recognized and

scientifically acceptable tool suitable for use in such scenarios. Off-label use varied by country and could not be construed as misuse.

74. One observer said that there was no evidence of manifested risks in the notification submitted by New Zealand. He stressed that the initial decision of the New Zealand authorities had been to continue the use of endosulfan with minor modifications in its use pattern, but subsequently, considering other factors, the authorities had banned endosulfan as a precautionary measure. While New Zealand enjoyed the right to use or ban any chemical within its territory, when such national regulatory decisions came before the Convention, its decision must necessarily meet the provisions of the Convention. The Convention carried no explicit reference to accepting national decisions based exclusively on laboratory models and, with that and other issues in mind, the notification deserved to be set aside. Another observer said that the notification had been based on models that did not appear to have been validated or peer-reviewed and called for the objections voiced to be given the fullest possible consideration.

75. In response to the issues raised by one member, the Chair noted that they were of a procedural and technical nature. The Chair invited the member to explain in detail his concerns in a conference room paper and established that a drafting group could be set up to consider those technical concerns. The Committee would consider the procedural concerns as a separate matter.

76. One member asked whether, given that the Committee had found that the notifications from the Sahelian countries and the European Community met the criteria for inclusion in Annex III to the Convention, there was any need to consider the notification from New Zealand further. The Chair clarified that, since the substance had yet to be included in Annex III by the Conference of the Parties and at least one notification had been received from each of two PIC regions, the Committee was bound to follow the procedures for reviewing notifications, as outlined in paragraph 5 of Article 5 of the Convention.

77. The member who had raised the issues outlined the following technical concerns: New Zealand having taken a final regulatory action based on a precautionary approach when banning endosulfan; off-label uses of the substance in the Party; the ruling by the World Trade Organization appellate body on risk evaluation matters; and the observations by the New Zealand authorities.

78. One member, supported by another, said that the data gaps identified by the member voicing concerns pertained to topics that did not influence the risk evaluation and were therefore irrelevant to the Committee's consideration of the notification. The Chair established a drafting group to consider those technical concerns.

79. Subsequently, the chair of the drafting group, reporting on its deliberations, drew attention to a conference room paper reflecting the discussion of 39 issues raised by the member who had voiced concerns. A core issue was whether the alleged lack of data in the New Zealand notification should preclude its consideration. The drafting group had taken the view that many of the data gaps related to areas that the New Zealand authorities deemed to be irrelevant. It had concluded that the analysis reflected in the earlier task group report and its own responses to the issues raised by the member confirmed that the notification from New Zealand met all the criteria in Annex I and Annex II to the Convention.

80. In response to a question from the Chair, the member said that, while he was grateful to the drafting group for its painstaking consideration of the questions that he had raised, he continued to feel that they had not been adequately addressed on account of their complexity. He reiterated his view that the lack of exposure data and the reliance on modelling invalidated the notification. He suggested that the Committee should request further data from the regulatory authority. One member noted that the member who had raised concerns had failed to identify any essential missing data that could have nullified the notification. Another member, referring to that member's comment on the lack of ecotoxicological data for marine mammals, pointed out that such data would never be generated both on ethical grounds and because of the enormous challenge that testing would present. Other issues identified were, in his view, equally irrelevant.

81. The Chair noted that the position of the member who had raised concerns remained unchanged, regardless of the drafting group's conclusion that the New Zealand notification met the criteria of Annex I and Annex II.

82. Subsequently, the same member tabled a further conference room paper setting out, in consolidated form, the primary concerns that he had raised during the meeting. Taking note of the paper, the Chair affirmed that, throughout the meeting, the Committee had endeavoured to create an open and cooperative environment to facilitate discussion and to enable members to express their views. In that process all members, including the member who had raised concerns, had been given every

opportunity to express their views, in the discussions in plenary session and the drafting groups and through the submission of conference room papers.

83. The Chair, noting that member's concerns, suggested that the discussion of the notification should be deferred until the Committee's seventh meeting to allow the Committee more time to consider it. Several members opposed deferral on the ground that all the questions raised had already been thoroughly addressed. One member maintained that the questions raised were not scientific in nature and were only delaying the process. Another member questioned whether the lack of agreement was due to conflicting interests and noted that, if such interests were allowed to prevail, the Convention itself would be undermined. Yet another member made the point that, in the event of a deferral of the discussion, the member who had raised the concerns should specify the critical issues to be addressed well in advance, thereby averting the need to invest a comparable amount of time in the process at the Committee's seventh meeting.

84. The Committee agreed to defer its consideration of the notification from New Zealand until its seventh meeting.

**(iii) Notifications from the Islamic Republic of Iran and Malaysia**

85. Mr. Figueroa said that the notification from the Islamic Republic of Iran related to a ban on the use of endosulfan as a pesticide. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

86. With regard to Annex II to the Convention, he said that the notification from the Islamic Republic of Iran explained 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. While the referenced hazard data had been taken from internationally recognized sources and data reviews had been performed and documented according to generally recognized scientific principles and procedures, meeting the criteria in paragraph (b) (i) and (b) (ii) of Annex II, the notification stated that the final regulatory action had not been based on a risk or hazard evaluation. Accordingly, the task group had concluded that the notification from the Islamic Republic of Iran had not met the criterion in paragraph (b) (iii) of Annex II. Turning to the criteria in paragraph (c) of Annex II, he said that the Islamic Republic of Iran had prohibited the substance: thus, it could be considered that the expected quantities and risks would be significantly reduced. As the basis for the regulatory action included human health concerns, the regulatory action would be broadly applicable to other countries. There was evidence of ongoing international trade. Accordingly, the task group had concluded that the criteria in paragraphs (c) (i), (c) (ii), (c) (iii) and (c) (iv) of Annex II had been met. There was no evidence that intentional misuse had been the basis for the final regulatory action: thus, the criterion in paragraph (d) of Annex II had been met.

87. Turning to the notification from Malaysia, he said that it related to a ban on the use of endosulfan as a pesticide. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

88. With regard to Annex II to the Convention, he said that the notification from Malaysia explained 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. The task group considered that the criteria in paragraphs (b) (i) and (b) (ii) of Annex II had been met for international references on hazard information, but no national data had been provided with the notification or supporting documentation. Turning to the criterion in paragraph (b) (iii) of Annex II, he said that the notification had indicated that the final regulatory action was based on a risk and hazard evaluation, but no supporting documentation had been received. The task group had therefore concluded that the notification from Malaysia had not met the criterion in paragraph (b) (iii) of Annex II. Turning to the criteria in paragraph (c) of Annex II, he said that Malaysia had prohibited the substance: thus, it could be considered that the expected quantities and risks would be significantly reduced. As the basis for the regulatory action included human health concerns, the regulatory action would be broadly applicable to other countries. There was evidence of ongoing international trade. Accordingly, the task group had concluded that the criteria in paragraphs (c) (i), (c) (ii), (c) (iii) and (c) (iv) of Annex II had been met. There was evidence of misuse in Malaysia but no evidence that it had been the only reason for the final regulatory action: in the light of the revised legal opinion, the task group considered that the criterion in paragraph (d) of Annex II had been met.

89. In response to a question from one member as to the use of the word "restricted" in the task group report to refer to some of the Malaysian documentation, the representative of the Secretariat explained that the Secretariat had endeavoured on multiple occasions to obtain supporting

documentation, but it had not been forthcoming. In the notification, the documentation had been marked as internal and confidential, and “restricted” should be so interpreted.

90. One member, supported by several others, expressed his opinion that the criteria in paragraphs (b) (i) and (b) (ii) of Annex II had been met for all three notifications, given that the prevailing conditions should only be considered when looking at the criterion in paragraph (b) (iii) of Annex II. Another member disagreed with that assertion. A third member, while endorsing the Chair’s statement that the notifications from the Islamic Republic of Iran and Malaysia had not met the criteria, said that it would be useful for notifying countries if the Committee were to make it clear which criteria had not been met. An overall conclusion would provide insufficient information. The Chair drew attention to the text of paragraph (b) of Annex II, pointing out that the subparagraphs of the criteria in paragraph (b) of Annex II had to be read in conjunction with the chapeau to that subparagraph.

91. The Committee agreed that, since the criteria in paragraph (b) of Annex II had not been met, the notification from the Islamic Republic of Iran had not met all the criteria in Annex II to the Convention.

92. The Committee agreed that, since the criteria in paragraph (b) of Annex II had not been met, the notification from Malaysia had not met all the criteria in Annex II to the Convention.

**(iv) Notification from Thailand**

93. In considering the item, the Committee had before it a notification and supporting documentation on endosulfan from Thailand that it had previously considered at its second meeting, concluding that the submitted material met the requirements of Annex II to the Convention (reissued as documents UNEP/FAO/RC/CRC.6/15 and Add.1), and also the rationale (Add.2). Given the supplementary legal opinion made available to the Committee, the Committee was to revisit the application of the criterion in paragraph (d) of Annex II.

94. The Chair drew attention to paragraphs 8–10 of the rationale (UNEP/FAO/CRC.6/15/Add.2), confirming the Committee’s observation that the Thai authorities’ decision to restrict the chemical had been prompted by its misuse by farmers and concluding that, while intentional misuse was not in itself an adequate reason to list a chemical in Annex III, the Thai regulatory action had been directly linked to the chemical’s adverse environmental effects and that the notification met all the information requirements of Annex I and the listing criteria in Annex II to the Convention.

95. She recalled that, by its decision RC-4/6, the Conference of the Parties had noted with appreciation the work of the Committee in its consideration of endosulfan, in particular the technical quality and comprehensiveness of the draft decision guidance document. In response to concerns raised during the meeting relating to the criterion in paragraph (d) of Annex II, however, the Conference had requested the Committee to take into account the legal opinion which the UNEP legal office had been requested to provide so as to clarify the meaning of “intentional misuse” when considering the application of the criterion in paragraph (d) of Annex II. She recalled that only the criterion in paragraph (d) of Annex II remained under consideration: all the others were not questioned.

96. A number of members took the floor to affirm that, in their view, guided by their understanding of the supplementary legal opinion furnished by the UNEP legal office, the Thai notification met the criterion in paragraph (d) of Annex II.

97. One member disagreed, maintaining that the issue of misuse was not a chemical matter but a problem of human behaviour and that misuse of a chemical in one country was not an appropriate trigger for regulatory action concerning a chemical in international trade, and suggested that the matter should be left to the Conference of the Parties to consider further at its fifth meeting.

98. The Chair reiterated that the legal opinion would be discussed by the Conference of the Parties at its fifth meeting and that the Committee’s task was merely to determine whether it understood the legal opinion and how to apply it to the Thai notification in meeting the criterion in paragraph (d) of Annex II.

99. One member pointed out that the Committee had been directed by the Conference of the Parties as to what it was required to do. The member who had disagreed was asking it to reverse a decision that all members had clearly understood. If that were allowed to occur, she said, the Committee would be setting an undesirable precedent. Another member pointed out that the interpretation of intentional misuse was a legal exercise, which lay outside the Committee’s remit. The Committee, he insisted, should focus on revisiting the Thai notification. Consideration of the legal opinion was the job of the Conference of the Parties.

100. Several observers supported that position, pointing out that the Conference of the Parties had directed the Committee to take into account and apply the legal opinion, not to discuss it. Two,

however, opposed that position. One pointed out that understanding the legal opinion was not tantamount to accepting it, while the other argued that the legal opinion applied two quite distinct standards for the interpretation of intentional misuse and that it was unclear which interpretation was being applied in the case of the Thai notification. The Conference of the Parties had requested the Committee to take the legal opinion into account but had stated that it would revisit it at its fifth meeting: accordingly, it was not imperative that the problem posed by the Thai notification should be resolved at the current meeting.

101. Summing up the discussion, the Chair said that, in line with decision RC-4/6, the UNEP legal office had furnished the Committee with its supplementary legal opinion, so that it could be taken into account by the Committee in considering the application of the criterion in paragraph (d) of Annex II. She reiterated that it was not the Committee's mandate to debate the legal opinion but to ensure that it had been understood by all members. She said that she had heard no disagreement from the Committee, in the light of the supplementary legal opinion, as to the conclusion that it had reached at its second meeting on the application of the criterion in paragraph (d) of Annex II to the Thai notification.

102. Noting, however, that one member maintained his concerns relating to the issue of intentional misuse and had a different view in respect of the supplementary legal opinion, she proposed that the legal opinion and the Committee's conclusion at its current meeting should be forwarded to the Conference of the Parties for its consideration and that the views of members should be recorded in the present report and brought to the attention of the Conference of the Parties.

**3. Chemicals for which, following a preliminary review, there appeared to be no notifications that met the criteria in Annex II: paraquat**

103. The Committee had before it a notification and supporting documentation on paraquat submitted by Sweden, contained in documents UNEP/FAO/RC/CRC.6/9, Add.1/Rev.1 and Add.2-4.

104. At its fifth meeting, the Committee had reviewed the Swedish notification and concluded that it did not meet the criteria in Annex II to the Convention on the basis of the information available at that time. One member had said that, being conversant with Swedish, he had reviewed the information on prevailing conditions submitted by Sweden and had found that it did contain data confirming that the risk evaluation had been made in accordance with prevailing conditions in the country. Accordingly, the Committee had invited Sweden to submit an English translation of its supporting information so that the notification could be revisited by the Committee at the current meeting.

105. Ms. Bartels presented the work of the intersessional task group that had undertaken a preliminary assessment of the notification and its supporting documentation. The group had comprised herself and Mr. Ramsay as co-chairs and Mr. Abdelbagi, Mr. Al-Dobai, Mr. Binga, Mr. Goji, Mr. Helbig, Mr. Ikeda, Mr. Linders, Ms. Liptáková, Ms. Marasinghe, Ms. Morales Quillama, Mr. Opiyo, Ms. Randall, Mr. Shan and Ms. Tang as members.

106. She said that the notification from Sweden related to a ban on the use of paraquat as a pesticide. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

107. With regard to Annex II to the Convention, she said that the notification from Sweden explained 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. The referenced hazard data had been taken from internationally recognized sources and the risk evaluation had been performed in accordance with recognized scientific principles and procedures, taking into account prevailing conditions in Sweden. Accordingly, the task group had concluded that the criteria in paragraphs (b) (i), (b) (ii) and (b) (iii) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, she said that Sweden had prohibited the substance: thus, it could be considered that the expected quantities and risks would be significantly reduced. As the basis for the regulatory action included human health and environmental concerns, the regulatory action would be broadly applicable to other countries. There was evidence of ongoing international trade. Accordingly, the task group had concluded that the criteria in paragraphs (c) (i), (c) (ii), (c) (iii) and (c) (iv) of Annex II had been met. There was no evidence that intentional misuse had been the basis for the final regulatory action: thus, the criterion in paragraph (d) of Annex II had been met. The task group had therefore concluded that the notification had met all the criteria in Annex II. She noted, however, that members had subsequently raised certain concerns during the pre-meeting held on Sunday, 14 March 2010, as to whether all the criteria in paragraph (b) of Annex II had been met.

108. In the ensuing discussion, several members queried on a number of grounds whether the criteria in paragraph (b) of Annex II had been met. It appeared that the regulatory action had been preventive in

nature, given the toxicity of the chemical, and that there was no antidote in the event of poisoning as a result of equipment failure.

109. Some members said that they were unsure that the regulatory action had been taken relative to conditions prevailing in Sweden, as insufficient information had been provided. Some members said that the link between exposure and prevailing conditions was unclear, while others disagreed, pointing out that events in other countries had been considered in the context of the prevailing conditions in Sweden and that the link was clear.

110. On the issue of the presence of the product in the soil and its potential risk to the environment, one member said that the documentation provided did not clearly show the link between presence and risk.

111. The Committee took note of some concerns raised by observers about the notification. The Chair suggested that a small drafting group comprising those members who had expressed concerns about the notification and members of the intersessional task group should consider the issue further.

112. Subsequently, reporting back to the Committee on the outcome of the drafting group's work, the chair of that group said that it was recognized that a sound decision had been taken by the Swedish Government to protect the population from the risk of accidents but that the group had failed to reach consensus that a risk evaluation had been carried out involving prevailing conditions within the Party. Accordingly, there had been no agreement that the criteria in paragraph (b) of Annex II had been met. The group had also recognized that the decision by Sweden indicated concerns about the environment, specifically the build-up of paraquat in the soil that could affect soil organisms. It appeared, however, that no risk evaluation had been undertaken for the prevailing conditions in Sweden. The group had therefore agreed that the criterion in paragraph (b) (iii) of Annex II had not been met for the environment. The group had suggested that guidance should be further developed on the minimum information required to meet the criterion in paragraph (b) (iii) of Annex II, possibly based on the example of paraquat.

113. The Chair proposed that the intersessional drafting group should take account of the discussions under the present agenda item when revisiting the guidance on the application of the criteria in paragraph (b) of Annex II.

114. The Committee agreed that, since the criteria in paragraph (b) of Annex II had not been met, the notification from Sweden had not met all the criteria in Annex II to the Convention.

### **C. Consideration of the draft decision guidance document for endosulfan**

115. At its third meeting, the Committee had reviewed the notification of final regulatory action for endosulfan from the European Community, including the supporting documentation referenced therein, and, taking into account each of the specific requirements set out in Annex II to the Convention, had concluded that the requirements of that Annex had been met.

116. At its fifth meeting, the Committee had reviewed the notifications of final regulatory actions for endosulfan by Burkina Faso, Cape Verde, the Gambia, Mali, Mauritania, the Niger and Senegal, including the supporting documentation referenced therein, and, taking into account each of the specific requirements set out in Annex II to the Convention, had adopted a rationale as to how the notifications had met those criteria. The Committee had decided, in the light of past practice in drafting decision guidance documents, to establish a drafting group to develop a decision guidance document for endosulfan for consideration at the current meeting on the understanding that responses to the outstanding questions regarding the notifications from the above-mentioned Sahelian countries would be made available at the same time.

117. A draft decision guidance document for endosulfan, based on the eight notifications, had been prepared by the intersessional drafting group and was before the Committee as document UNEP/FAO/RC/CRC.6/11, together with a table of comments received thereon and a description of how those comments had been taken into account (UNEP/FAO/RC/CRC.6/INF/5), and additional comments from an observer (UNEP/FAO/RC/CRC.6/INF/5/Add.1). The Committee also had before it additional information provided by Australia and Burkina Faso (UNEP/FAO/RC/CRC.6/12); comments by an observer on the notification on endosulfan (UNEP/FAO/RC/CRC.6/INF/7/Rev.1); the final version of the risk profile adopted by the Persistent Organic Pollutants Review Committee at its fifth meeting, in October 2009 (UNEP/FAO/RC/CRC.6/INF/8); and initial thoughts on tackling the outstanding questions raised at the Committee's fifth meeting prepared by the Bureau (UNEP/FAO/RC/CRC.6/INF/9).

118. The Committee agreed to conduct the discussion on endosulfan in three segments: first, to consider the work of the intersessional drafting group and the draft decision guidance document and the extent to which all the comments had been addressed; second, to consider the outstanding questions regarding the African notifications on endosulfan; and, third, to review the comments made by an observer on the notifications.

**1. Consideration of the work of the drafting group and of the draft decision guidance document**

119. Ms. Bartels presented the work of the drafting group, which comprised herself and Ms. Gwayi as co-chairs and Ms. Amala Jayasekara, Mr. Manuweera, Mr. Moudachirou, Mr. Mario Nichelatti, Mr. Pandey, Mr. Ramsay, Ms. Randall, Mr. Ousmane Sow and Ms. Tang as members. She confirmed that the drafting group had followed the procedure for the preparation of draft decision guidance documents and introduced the documentation under the item.

120. With regard to the additional comments submitted by an observer, Ms. Bartels made a proposal on how to address them, which was accepted by the Committee and incorporated in the table of comments.

121. With regard to the risk profile adopted by the Persistent Organic Pollutants Review Committee, the Committee agreed that it was not appropriate to reopen the draft decision guidance document and that it would suffice to include a cross-reference to the risk profile in the introduction to annex I to the decision guidance document, so that readers were aware of that additional source of information.

122. The Committee adopted a recommendation in which it agreed on the draft text of the decision guidance document, contained in UNEP/FAO/RC/CRC.6/11, as amended, and decided to forward it to the Conference of the Parties for its consideration. The recommendation is contained in annex I to the present report.

123. In line with decision RC-2/2, the Committee also agreed to forward to the Conference of the Parties for its consideration the tabular summary of comments received and a description of how those comments had been addressed, contained in UNEP/FAO/RC/CRC.6/INF/5; the recommendation on the decision guidance document for endosulfan; and the rationales contained in annex II to the report of the Committee's third meeting (UNEP/FAO/RC/CRC.3/15) and in annex II to the report of the Committee's fifth meeting (UNEP/FAO/RC/CRC.5/16).

124. Subsequently, one member introduced a conference room paper setting out his concern that the Committee had acted prematurely by approving the preparation of the decision guidance document on endosulfan before agreement had been reached on a decision to recommend the inclusion of the chemical in Annex III. Accordingly, he requested the Chair to set aside the Committee's earlier action concerning the adoption of the decision guidance document. The UNEP Senior Legal Officer explained that, pursuant to the provision of rule 43 of the rules of procedure, when a proposal had been adopted or rejected, it could not be reconsidered at the same meeting unless the Committee, by a two-thirds majority of the members present and voting, so decided.

**2. Consideration of the outstanding questions regarding the African notifications on endosulfan**

125. Following the introduction of the draft decision guidance document, the Chair turned to the outstanding questions regarding the African notifications on endosulfan. Initial thoughts on tackling those questions had been prepared by the Bureau and were before the Committee in document UNEP/FAO/RC/CRC.6/INF/9. The Chair proposed that the Committee should take up the five outstanding questions, as set out in the document, in sequence.

126. With regard to the first question, concerning the selective use of information from risk evaluations carried out in circumstances with different application methods, frequency of applications, formulations used, soil and weather conditions and size of land holdings, the Committee agreed that the response provided in the document was satisfactory.

127. Similarly, with regard to the second question, concerning whether the model used had been peer-reviewed, the Committee agreed that the response in the document was satisfactory.

128. On the third question, regarding whether the model used by the Sahelian countries had been validated, the Committee agreed that the response in the document was satisfactory.

129. In the discussion of the fourth question, that there were no actual field measurements, one member drew attention to what he considered a lack of actual field measurements in the African notifications on endosulfan.

130. In response, one member noted that field measurements from Burkina Faso had been reported to the Committee at its fifth meeting in the supporting documentation provided by the Sahelian countries (UNEP/FAO/RC/CRC.5/5/Add.2). The threat to surface water by endosulfan revealed by the Pesticide Impact Rating Index (PIRI) model had been confirmed by the presence of endosulfan residues in water samples in the cotton-producing region in Burkina Faso in which the chemical was used. In response to the objection raised by one member that the data obtained through a single set of measurements could not yield a conclusive result, the Chair, supported by several members, emphasized that the answer to the specific question raised was clearly in the affirmative since there were in fact actual field measurements.

131. The Committee agreed that the issue had been satisfactorily addressed.

132. Lastly, the Chair drew attention to the fifth and final outstanding question, which indicated that modelling was not considered an acceptable substitute for field measurements. The Chair said that, as she saw it, in the present case modelling was not a substitute for field measurements since, according to the supporting documentation provided by the Sahelian countries, the results of the field measurements had confirmed those of the modelling. Several members concurred with the view that modelling had not served as a substitute for measurements in the case before the Committee.

133. The Committee agreed that all outstanding questions identified at the Committee's fifth meeting regarding the Sahelian notifications had been sufficiently answered.

### **3. Consideration of comments on the notifications**

134. Following that discussion of the outstanding questions, the Chair turned to the comments on the notification on endosulfan submitted to the Secretariat by an observer, which had been reproduced in document UNEP/FAO/RC/CRC.6/INF/7/Rev.1.

135. The Chair introduced the comments and the manner in which they had been addressed. The Committee agreed that satisfactory responses had been provided to all the comments.

### **4. Way forward**

136. Subsequently, the Chair sought the Committee's approval to request the Secretariat to prepare a draft recommendation to list endosulfan in Annex III to the Convention. One member, however, objected to the idea, pointing out that, in his opinion, numerous outstanding questions had yet to be resolved, such as compliance with the 90-day period within which final regulatory action should be submitted under paragraph 1 of Article 5 of the Convention.

137. The Chair responded that a legal opinion had been given on the 90-day issue and, at its fifth meeting, the Committee had requested that the question about the consequences of not respecting the 90-day period referred to in paragraph 1 of Article 5 of the Convention should be brought to the attention of the Conference of the Parties. The UNEP Senior Legal Officer reiterated that the Convention contained no provision to invalidate a notification of a final regulatory action by a Party on the grounds of its late submission. Thence, a notification, even if submitted after the deadline of the required period, once verified by the Secretariat and submitted to the Committee, remained valid. Issues of compliance were to be discussed by the Conference of the Parties. The representative of the Secretariat said that the notifications in question had been verified and had been submitted within the 90-day period.

138. Several members said that the conduct of the member who had raised objections during the discussions on endosulfan was of grave concern to them and therefore should be examined, suggesting that ulterior motives lay behind his concerns about the chemical. Reiterating that Committee members were serving in their individual capacities as experts and not as country representatives, they called upon the member in question to outline his concerns at the technical level and not bring other matters into the equation. One member pointed out that all members had signed conflict-of-interest declarations before beginning their terms on the Committee and that the conduct of the member who had raised objections could lead to the work of the Committee as a scientific body being called into question.

139. Given the continued disagreement on the matter, the Chair invited the Secretariat to prepare a draft recommendation to include endosulfan in Annex III to the Convention and the member who had raised objections to submit his concerns on the matter in writing. She assured the member that his concerns would be reflected in the present report.

140. Subsequently, the Committee considered the draft recommendation. At that time, one member again voiced his disagreement, reiterating the issues set out above. He again sought clarification of the consequences if the recommendation were rejected. He repeated that the term "recommendation" was unsuitable in the case of endosulfan, suggesting that the Committee should instead use "observation".

The Legal Officer clarified that in accordance with the provisions of the Convention no term other than “recommendation” could be used.

141. The majority of members having expressed their support for the recommendation as it stood, the Committee agreed that a small drafting group would work with the member who had raised objections in an effort to modify the text of the recommendation and reach consensus on it.

142. Subsequently, the chair of the drafting group entrusted with reaching consensus on the text of the recommendation to the Conference of the Parties on the inclusion of endosulfan in Annex III reported back to the Committee that one member of the group had raised concerns about the recommendation and had proposed amending it in such a way as to indicate that the notifications had not met the criteria and that the Conference of the Parties was not to recommend the inclusion of endosulfan. The member with the concerns was informed that, in cases in which the Committee considered that the criteria had not been met, no recommendation was prepared. Instead, it was suggested that his concerns could be recorded in a footnote to the recommendation. The member did not, however, accept the insertion of a footnote and opposed the forwarding of the recommendation to the Conference of the Parties.

143. Subsequently, the Committee resumed its consideration of the recommendation to the Conference of the Parties on the inclusion of endosulfan in Annex III. Several members, considering that all efforts to reach consensus on the text and substance of the recommendation had been exhausted, proposed that the Committee should move to a vote. Therefore, in conformity with paragraph 6 (c) of Article 18 of the Convention, the Committee referred the decision to a vote.

144. Pursuant to paragraph 2 of rule 45, on voting on matters of procedure, the Committee first voted on the holding of a vote and by a majority vote of the members present and voting, the Committee agreed to move forward on a vote on the substantive matter that the Committee should recommend to the Conference of the Parties the inclusion of endosulfan in Annex III.

145. Accordingly, in conformity with paragraph 6 (c) of Article 18 of the Convention, the Committee moved to the second vote on the substantive matter and adopted, by a two-thirds majority of the members present and voting, the text of the recommendation, in which it recommended to the Conference of the Parties that it should list endosulfan in Annex III to the Convention. The recommendation is set out in annex I to the present report.

146. Subsequently, the Committee returned to the text of the recommendation to the Conference of the Parties on the decision guidance document for endosulfan, adopted as outlined in section 1 above, and amended it, removing the phrase “by consensus”, thereby reflecting the recommendation on the inclusion of endosulfan in Annex III to the Rotterdam Convention adopted by a two-thirds majority vote. The recommendation to the Conference of the Parties on the decision guidance document for endosulfan, which the Committee adopted as amended, is set out in annex I to the present report.

## **D. General issues raised during the consideration of the chemicals**

### **1. Modelling**

147. During the Committee’s deliberations, the issue of the acceptability of modelling as a tool for risk evaluation in relation to the notifications for candidate chemicals was raised.

148. One member stated that modelling alone was not a sufficient basis for a risk evaluation. Several members noted that modelling was an internationally recognized scientific tool that was widely used. An observer pointed out that the Conference of the Parties had adopted decision guidance documents based on several notifications including data generated through modelling. Another observer said that modelling was particularly applicable to developing countries with limited resources as it reduced costs and saved time.

## **2. Procedural issues**

149. One member raised issues relating to procedure and policy. Those issues were: first, that a separate Committee meeting was required to finalize the Committee's operational and working procedures; second, that the Committee should identify the required parameters or uniform benchmarks for risk evaluations to ensure consistency and transparency in its work; third, that there was a need for a manual on how notifications of final regulatory action were to be prepared and submitted to the Secretariat; fourth, that information in support of a notification of final regulatory action submitted under Article 5 should be provided to the Secretariat together with the notification and, where necessary, clarifications of the new submissions might be provided in response to a Committee request, but no substantial new information should be accepted; fifth, that Parties that notified national regulatory actions to ban a chemical should be required to comply with such decisions and not continue to import such chemicals; and, sixth, that technical assistance could be provided to interested Parties to develop their capacity for risk assessment. The Committee took note of the concerns.

## **VI. Other matters**

### **A. Correspondence with the Indian Chemical Council**

150. The Chair drew the Committee's attention to correspondence between the Secretariat and the Indian Chemical Council, as set out in documents UNEP/FAO/RC/CRC.6/INF/6 and Add.1.

151. The Committee took note of the information.

### **B. Dates and venue of the Committee's seventh meeting**

152. The Committee agreed to hold its next meeting in Rome from 28 March to 1 April 2011.

## **VII. Adoption of the report**

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

## **VIII. Closure of the meeting**

154. Following the customary exchange of courtesies, the meeting was declared closed at 1 p.m. on Friday, 19 March 2010.

## Annex I

### Recommendations to the Conference of the Parties: Endosulfan

#### A. Recommendation to the Conference of the Parties on the inclusion of endosulfan in Annex III to the Rotterdam Convention

*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,

*Recalling also* the conclusion at its third meeting that the notification of final regulatory action relating to endosulfan by the European Community had met the criteria set forth in Annex II to the Convention,<sup>1</sup>

*Concluding* that the notifications of final regulatory actions from Burkina Faso, Cape Verde, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger and Senegal meet the criteria set forth in Annex II to the Convention,

*Decides*, in accordance with paragraph 6 of Article 5 of the Convention, to recommend to the Conference of the Parties that it should list endosulfan (CAS No.115-29-7) in Annex III to the Convention as a pesticide.

#### B. Recommendation to the Conference of the Parties on the decision guidance document for endosulfan

*The Chemical Review Committee,*

*Recalling* its decision, at its sixth meeting, in accordance with paragraph 6 of Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, to recommend to the Conference of the Parties that it should include endosulfan in Annex III to the Convention,

*Recalling also* paragraphs 1 and 2 of Article 7 of the Convention,

*Decides* to agree on the draft text of the decision guidance document on endosulfan and to forward it to the Conference of the Parties for its consideration.

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1 UNEP/FAO/RC/CRC.3/15, Annex II.

## Annex II

### Rationales, recommendations and workplans for chemicals for which two notifications met the criteria of Annex II

#### A. Rationale for the recommendation that azinphos-methyl (CAS No. 86-50-0) should become subject to the prior informed consent procedure and an intersessional drafting group be established to prepare a draft decision guidance document

1. A notification from Norway for azinphos-methyl has been determined to meet the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.
2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.6/6 and Add.1 and 2 and UNEP/FAO/RC/CRC.6/INF/2.

#### 1. Scope of the notified regulatory action

3. The final regulatory action was taken for the category "pesticide" to protect the environment. The use prior to the ban was as an insecticide for pome fruit, stone fruit, garden blueberries, strawberries, cabbages and ornamentals. The decision was made to ban all uses of plant protection products containing azinphos-methyl.
4. Gusathion (a product containing azinphos-methyl) was allowed to be imported until 31 December 2003 and allowed to be distributed until 31 December 2004. All use of Gusathion was strictly prohibited after 31 December 2005.

#### 2. Criterion Annex II (a)

*Confirm that the final regulatory action has been taken in order to protect human health or the environment*

5. The regulatory action was taken to protect the environment. It was based on a risk evaluation and took into account toxicology, environmental fate and behaviour, ecotoxicology, residues and availability of alternatives. The review concluded that azinphos-methyl was extremely toxic to most aquatic organisms tested. Even a 30-metre buffer zone to surface water was not sufficient to protect the aquatic environment. By repeated use of azinphos-methyl, it was possible that some populations of invertebrates were adversely affected for a longer period.

#### 3. Criteria Annex II (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*

6. The scientific data on hazards and exposure used for the risk evaluation of azinphos-methyl have been generated according to scientifically recognized methods. Moreover, data reviews were performed and documented according to generally recognized scientific principles and procedures. Documents supporting this were made available in document UNEP/FAO/RC/CRC.6/6/Add.2.

*(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures*

7. Scientific data have been reviewed in the context of the conditions prevailing in Norway. The data reviews were performed and documented according to generally recognized scientific principles and procedures. Documents supporting this were made available in document UNEP/FAO/RC/CRC.6/6/Add.2.

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

8. The regulatory action was based on a risk evaluation conducted by the Norwegian Agricultural Inspection Service and a review by the Council for Pesticides. The risk evaluation took into account toxicology, environmental fate and behaviour, ecotoxicology, residues and availability of alternatives.

9. Under the Agricultural and Environmental Monitoring Programme of Pesticides in Norway (JOVÅ), Norway's pesticide laboratory (Planteforsk Pesticidlaboratoriet) carried out a spectrum analysis for the catchments that represent agricultural areas in Norway from 1996 to 2002 on the presence of azinphos-methyl. The findings of the study exceeded the limit for environmental damage, which is 0.01 µg/L.

10. In ecotoxicological studies, the no observed effect concentrations (NOECs) for fish (rainbow trout) range from 0.18 to 0.39 µg/L, the NOEC for invertebrates (*Daphnia magna*) is established at 0.25 µg/L, and EC15 for *Chironomus riparius* is established at 0.3 µg/L.

11. Employing the calculation method used at the time of the evaluation (Ganzelmeier et al, 1995), a maximum predicted environmental concentration (PEC) in surface water, taking into account a 30-metre buffer zone, of 1.53 µg/L was calculated. This was based on the application rate for apple fruit moths. This value was then compared to the NOEC of 0.32 µg/L established from a microcosm study. The ratio of these two figures is 5, indicating that the expected concentration in surface water is 5 times higher than an acceptable concentration for the protection of aquatic species. This conclusion was also supported by actual concentrations in Norway, in that concentrations detected in the monitoring programme were twice as high as the acceptable concentration for the protection of aquatic species.

#### 4. Criteria Annex II (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;*
- (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;*
- (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;*
- (iv) *Whether there is evidence of ongoing international trade in the chemical*

12. All uses of azinphos-methyl as a pesticide were banned in Norway as provided in UNEP/FAO/RC/CRC6/6/Add.2. Hence the final regulatory action led to a reduction of the released quantities of azinphos-methyl used, meeting the criterion in paragraph (c) (i) of Annex II, and in consequence to an actual reduction of the risk to the aquatic environment, meeting the criterion in paragraph (c) (ii) of Annex II. The considerations which led to the regulatory action were generally expected to be applicable to other countries and regions and are related to the intended use of azinphos-methyl as a pesticide, meeting the criterion in paragraph (c) (iii) of Annex II.

13. There was evidence of ongoing international trade in the chemical as outlined in document UNEP/FAO/RC/CRC.6/INF/2, meeting the criterion in paragraph (c) (iv) of Annex II.

#### 5. Criterion Annex II (d)

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

14. There was no indication in the notification that concern about intentional misuse was the reason for the regulatory action. It is clearly stated that concern about environmental exposure such as contamination of surface water and exposure of aquatic organisms was the main reason for the final regulatory action.

#### 6. Conclusion

15. The Committee concluded that the notification of final regulatory action from Norway met the information requirements of Annex I and the criteria set out in Annex II to the Convention. The Committee also concluded that a decision guidance document should be drafted on the basis of the notifications from Norway and Canada, which at the Committee's fifth meeting were found to meet the

requirements of Annex I and the criteria of Annex II (as set out in the rationale in document UNEP/FAO/RC/CRC.6/6/Add.1).

**B. Recommendation to the Conference of the Parties on the inclusion of azinphos-methyl in Annex III to the Rotterdam Convention**

*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,

*Concluding* that the notifications of the final regulatory actions relating to azinphos-methyl by Canada and Norway meet the criteria set forth in Annex II to the Convention,

*Decides*, in accordance with paragraph 6 of Article 5 of the Convention, to recommend to the Conference of the Parties that it should include azinphos-methyl (CAS No. 86-50-0) in Annex III to the Convention as a pesticide.

**C. Workplan for the intersessional drafting group on azinphos-methyl**

The drafting group comprises the following members:

- Chair: Ms. Hala Sultan Saif Al-Easa
- Co-Chair: Mr. Jürgen Helbig
- Members: Mr. Azhari Abdelbagi  
 Mr. Shoki Al-Dobai  
 Ms. Jacqueline Arroyo  
 Ms. Magdalena Balicka  
 Mr. Idris Goji  
 Ms. Noluzuko Gwayi  
 Mr. Peter Opiyo  
 Ms. Marit Randall  
 Ms. Hang Tang

The group agreed to the following workplan:

**Tasks to be carried out, responsible persons and deadlines**

<i>Task</i>	<i>Responsible persons</i>	<i>Deadline</i>
Draft an internal proposal on azinphos-methyl based on the information available to CRC	Chair Co-chair	10 May 2010
Send draft internal proposal to drafting group members for comments via e-mail	Chair Co-chair	10 May 2010
Replies	All DG members	4 June 2010
Update internal proposal based on comments from drafting group members	Chair Co-chair	12 July 2010
Send updated internal proposal to CRC and observers for comments via e-mail	Chair Co-chair	12 July 2010
Replies	All CRC members and observers	27 August 2010
Draft a decision guidance document (DGD) based on the comments from CRC and observers	Chair Co-chair	27 September 2010
Send draft DGD to drafting group members for comments via e-mail	Chair Co-chair	27 September 2010
Replies	All DG members	18 October 2010
Finalize draft DGD based on the comments of the group	Chair Co-chair	15 November 2010
Send draft DGD to secretariat	Chair Co-chair	15 November 2010
CRC meeting		March 2011

## Annex III

### Rationales for those chemicals for which only one notification met the criteria of Annex II

#### Rationale for the conclusion that the notification for amitraz (CAS No. 33089-61-1) submitted by the European Community meets the information requirements of Annex I and the criteria of Annex II to the Rotterdam Convention

1. The notification from the European Community for amitraz has been determined to meet the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.
2. The notification and the supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.6/5 and Add.1 and UNEP/FAO/RC/CRC.6/INF/2.

#### 1. Scope of the notified regulatory action

3. The notified regulatory action relates to amitraz and its pesticidal use. Uses within the European Community included plant protection uses relating to apples, pears, stone fruits, strawberries, tomatoes, aubergines, peppers, hops, ornamentals, empty glasshouses, tree nurseries and public greens in Northern Europe and citrus fruits, apples, pears, stone fruits, bananas, grapes, strawberries, tomatoes, aubergines, peppers, cucurbits, cotton and ornamentals in Southern Europe, respectively. In addition the notification reports animal health uses: amitraz is used on mammalian domestic pets to control ticks, mites, lice and other animal pests.
4. The decision made was to ban all uses of amitraz in plant protection products, with the exception of certain essential uses in specific member States that were allowed to use amitraz until 30 June 2007. The notifier classified the prohibition of the use of plant protection products that contain amitraz as severe restriction.

#### 2. Criterion Annex II (a)

*Confirm that the final regulatory action has been taken in order to protect human health and the environment*

5. The regulatory action was taken to protect human health and the environment. It was taken to protect consumers from the potential neurological effects of acute exposure to amitraz. Some environmental concerns were also identified with regard to non-target organisms, in particular birds and mammals eating treated insects.

#### 3. Criteria Annex II (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*

6. The scientific data on hazards and exposure used for the risk evaluation of amitraz were generated according to scientifically recognized methods. Moreover, data reviews were performed and documented according to generally recognized scientific principles and procedures. The following supporting documents were made available: report of the Standing Committee on the Food Chain and Animal Health for the active substance amitraz, finalized at its meeting on 4 July 2003 (SANCO/10363/2003 – final of 6 June 2003) and other supporting documentation (Dossier, Monograph and Peer Review Report under the Peer Review Programme – ECCO, March 2000).

(ii) *Data reviews have been performed and documented according to generally recognized scientific principles and procedures*

7. The scientific data were reviewed in the context of the conditions prevailing in the European Community (intended uses, recommended application rates, good agricultural practices). The data reviews were performed and documented according to generally recognized scientific principles and procedures. The following supporting documents were made available: report of the Standing Committee on the Food Chain and Animal Health for the active substance amitraz, finalized at its meeting on 4 July 2003 (SANCO/10363/200 – final of 6 June 2003) and other supporting documentation (Dossier, Monograph and Peer Review Report under the Peer Review Programme – ECCO, March 2000).

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

8. The final regulatory action was based on a risk evaluation in the context of conditions prevailing within the European Community, taking into account the expected use patterns, i.e., the intended uses, the recommended application rates and good agricultural practices. The following supporting documents were made available: report of the Standing Committee on the Food Chain and Animal Health for the active substance amitraz, finalized at the Committee's meeting on 4 July 2003 (SANCO/10363/2003 – final of 6 June 2003) and other supporting documentation (Dossier, Monograph and Peer Review Report under the Peer Review Programme – ECCO, March 2000).

9. On the basis of this evaluation, concerns were identified with regard to the acceptability of possible neurological effects caused by acute exposure of consumers to the active substance. The final regulatory action was taken to protect consumers from the potential neurological effects of acute exposure to amitraz. Some environmental concerns were also identified with regards to non-target organisms, in particular birds and mammals eating treated insects.

#### 4. **Criteria Annex II (c)**

*Consider whether the final regulatory action provides a sufficiently broad basis to merit the 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*

10. Uses of amitraz within the European Community included plant protection uses relating to apples, pears, stone fruits, strawberries, tomatoes, aubergines, peppers, hops, ornamentals, empty glasshouses, tree nurseries and public greens in Northern Europe and citrus fruits, apples, pears, stone fruits, bananas, grapes, strawberries, tomatoes, aubergines, peppers, cucurbits, cotton and ornamentals in Southern Europe, respectively.

11. Amitraz is also used on mammalian domestic pets to control ticks, mites, lice and other animal pests. Since the decision made was to ban all uses of plant protection products containing amitraz, it was concluded that the regulatory action would lead to significant reduction in the quantity of the chemical used as well as the number of its use.

(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*

12. Since all uses of plant protection products containing amitraz were banned within the European Community, it can be expected that the exposure of consumers and of the environment will be significantly reduced. This reduction of exposure is expected to lead to a significant reduction of risk for human health and the environment.

(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*

13. The notification gave no indication of any geographical limitations or circumstances to the decision. Similar concerns could arise in other countries where the substance is used, particularly in developing countries.

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

14. Sufficient information on evidence of ongoing international trade in amitraz was made available in document UNEP/FAO/RC/CRC.6/INF/2.

**5. Criterion Annex II (d)**

*Take into account that international misuse is not itself an adequate reason to list a chemical in Annex III*

15. There is no indication in the notification that concerns about intentional misuse prompted the regulatory action.

**6. Conclusion**

16. The Committee concluded that the notification from the European Community regarding amitraz met the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.

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