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

Chemical Review Committee
Seventh meeting
Rome, 28 March–1 April 2011

Report of the Chemical Review Committee on the work of its seventh 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 in Annex III to the Convention of chemicals notified as banned or severely restricted or as severely hazardous pesticide formulations; 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 seventh meeting was held at the headquarters of the Food and Agriculture Organization of the United Nations (FAO) in Rome from 28 March to 1 April 2011. The meeting was opened at 10:20 a.m. on Monday, 28 March 2011, by Mr. Peter Kenmore, Co-Executive Secretary of the Secretariat of the Rotterdam Convention.

4. Mr. Kenmore, speaking also on behalf of his Co-Executive Secretary, Mr. Donald Cooper, welcomed the new members of the Committee and thanked those whose terms of office would come to an end following the current meeting for their hard work. He spoke of the tasks that the Committee would face during the week, stressing the importance of applying the criteria of the Convention to ensure that the basis for decisions was clearly explained for the benefit of the Conference of the Parties and others not taking part in the current meeting. He said that, in recommending to the Conference of the Parties that a chemical should be made subject to the prior informed consent (PIC) procedure, and should accordingly be listed in Annex III, the Committee confirmed that a final regulatory action had been taken in order to protect human health or the environment, thus ensuring that trade flourished within a safe and sustainable framework. He noted that the meeting would be the Committee's first, and the first ever at FAO, to be conducted in paperless format.

5. Recent events, he suggested, had reminded the world of the vital importance of the Committee's mission to protect human life and the environment from natural hazards and the risks inherent in modern industrial societies. He expressed sympathy to the people of Japan following the recent earthquake and tsunami that had afflicted that country, saying that their concerted action and fortitude should strengthen the resolve of others to protect human health and the environment from hazards, including chemical hazards. In the field and in developing countries he had personally

witnessed the harmful effects of four of the candidate chemicals before the Committee. Noting that evidence of the long-term negative effects of exposure to chemicals of all kinds was mounting, he expressed his personal gratitude to the Committee for helping to avoid unnecessary exposure for billions of people around the world. In conclusion, he wished the participants a successful meeting.

6. Ms. Marit E. Randall (Norway), Chair of the Committee, welcomed the Committee members and observers to the meeting. Briefly outlining the main tasks and key issues that the Committee was to consider during the course of the meeting and the objectives that were to be achieved, she expressed optimism that the meeting would be successful given the experience of the previous meeting and the important contributions that all had made to the Committee's intersessional work.

II. Organizational matters

A. Officers

7. The following officers served on the Bureau of the Committee for the meeting:

Chair: Ms. Marit E. Randall (Norway – Western European and others region)

Vice-Chairs: Mr. Idris Adamu Goji (Nigeria – African region)
Ms. Hala Sultan Saif Al-Easa (Qatar – Asian and Pacific region)
Ms. Magdalena Balicka (Poland – Central and Eastern European region)[1]
Ms. Jacqueline Arroyo (Ecuador – Latin American and Caribbean region)

Ms. Al-Easa served also as rapporteur.

B. Attendance

8. The following 29 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. Jacqueline Arroyo (Ecuador), Ms. Mirijam Kristina Brigitta Seng (France), Mr. Hubert Binga (Gabon), Mr. Manoranjan Hota (India), Mr. Mehdi Ghaemian (Islamic Republic of Iran), Mr. Michael Frank Ramsay (Jamaica), Mr. Masayuki Ikeda (Japan), Mr. Peter Opiyo (Kenya), Mr. Sidi Ould Aloueimine (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).

9. Following the resignation from the Committee of Mr. Hesameddin Nasirzadeh and Mr. Shoki Al-Dobai prior to the current meeting, Mr. Mehdi Ghaemian and Mr. Abdullah Mohammed Abdullah Shamlan had been designated by the Governments of the Islamic Republic of Iran and Yemen, respectively, as members in their place, subject to confirmation of their appointment by the Conference of the Parties at its fifth meeting.

10. Observers from the following countries and regional economic integration organizations were present: Argentina, Australia, Azerbaijan, Brazil, Bulgaria, Canada, China, Colombia, Croatia, Cyprus, Democratic People's Republic of Korea, Estonia, European Union, Gabon, Hungary, India, Indonesia, Iran (Islamic Republic of), Italy, Japan, Malaysia, Mexico, Netherlands, Norway, Oman, Paraguay, Qatar, Romania, Russian Federation, Slovakia, South Africa, Switzerland, Syrian Arab Republic, Turkey, Ukraine, United States of America.

11. The Inter-States Pesticides Committee for Central Africa was also represented.

12. The following non-governmental organizations were also represented: Berne Declaration, CropLife International, Indian Chemical Council, International Alliance of Trade Union Organizations "Chrysotile", Pesticide Action Network, Sindicato Nacional da Indústria de Produtos para Defesa Agrícola, Women in Europe for a Common Future.

13. A complete list of participants was circulated as document UNEP/FAO/RC/CRC.7/INF/12.

1 Ms. Balicka was elected to replace Ms. Darina Liptáková (Czech Republic), who was unable to attend the current meeting.

C. Adoption of the agenda

14. At its opening session, the Committee adopted the following agenda on the basis of the provisional agenda (UNEP/FAO/RC/CRC.7/1):

1. Opening of the meeting.
2. Organizational matters:
   (a) Adoption of the agenda;
   (b) Organization of work.
3. Operational issues:
   (a) Rotation of the membership in October 2011;
   (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.
2. Technical work:
   (a) Report of the Bureau on the preliminary review of notifications and the proposal for a severely hazardous pesticide formulation, and proposed priorities for chemicals scheduled for review by the Committee;
   (b) Consideration of the draft decision guidance document for azinphos-methyl;
   (c) Review of notifications of final regulatory action:
      (i) Amitraz;
      (ii) Carbaryl;
      (iii) Endosulfan;
      (iv) Perfluorooctane sulfonate, its salts and its precursors;
      (v) Pentabromodiphenyl ether commercial mixtures;
      (vi) Pentachlorobenzene;
      (vii) Octabromodiphenyl ether commercial mixtures;
   (d) Review of the proposal to list Gramoxone Super as a severely hazardous pesticide formulation in Annex III to the Rotterdam Convention.
3. Other matters.
4. Dates and venue of the Committee's eighth meeting.
5. Adoption of the report.
6. Closure of the meeting.

D. Organization of work

15. At its opening session, 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 adjustment as appropriate. It also decided that task groups and drafting groups would be formed as necessary.

16. 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. The meeting would be conducted in paperless format, with all documents distributed electronically.

17. Referring to a scenario note for the meeting that she had prepared (UNEP/FAO/RC/CRC.7/INF/2), the Chair explained that the main tasks before the Committee were to review the notifications of final regulatory action and relevant supporting documentation for seven chemicals (amitraz, carbaryl, endosulfan, perfluorooctane sulfonate, its salts and its precursors, pentabromodiphenyl ether commercial mixtures, pentachlorobenzene and octabromodiphenyl ether commercial mixtures) to determine whether they met the requirements of the Convention, and to review the proposal to list Gramoxone Super as a severely hazardous pesticide formulation. Lastly, the

Committee was to review and finalize the draft decision guidance document for azinphos-methyl that had been prepared following discussions at the Committee's sixth meeting. She also explained that the Committee would consider, in the light of experience at the current meeting, whether to amend any of the Committee's policy guidance or working procedures.

18. None of the Committee members indicated that they had any conflicts of interest relating to the Chemical Review Committee process.

III. Operational issues

A. Rotation of the membership in October 2011

19. The Chair referred to a conference room paper that listed the experts who would continue to serve as members of the Committee until 2013, in conformity with decision RC-4/3 of the Conference of the Parties, and those whose terms would expire at the end of September 2011.

20. The representative of the Secretariat explained that the terms of office of 14 members would expire at the end of September 2011 and that the Conference of the Parties would need to decide on a list of parties that were to nominate members to the Committee whose terms would run from the beginning of October 2011 to the end of September 2015. Each region should therefore be ready to provide, at the fifth meeting of the Conference of the Parties, a list of parties that would nominate new members for their regions.

21. The representative of the Secretariat also confirmed that the Committee had to elect three new Bureau members, including the Chair, as the current meeting was the last for the members representing the African, Central and Eastern European and Western European and others regions. Upon confirmation of the new Bureau members by the Committee, the revised Bureau would have to nominate one of its members to serve as the acting Chair pending the election of a Chair by the Conference of the Parties at its fifth meeting.

22. The Chair therefore invited the African, Central and Eastern European, and Western European and others regions to consult and to be prepared to nominate members from their regions to become Bureau members when the matter was taken up again under agenda item 5 (Other matters).

23. The Committee took note of the information.

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 reported on joint workshops that had been held in Egypt, Mexico and Sri Lanka for designated national authorities, official contact points, national government officials, national and regional stakeholders and members of the Chemical Review Committee and the Persistent Organic Pollutants Review Committee of the Stockholm Convention on Persistent Organic Pollutants, which had been organized by the secretariats of the Rotterdam and Stockholm Conventions. The workshops were aimed at enhancing the understanding of parties and stakeholders of the operation of the committees and the process for listing chemicals under the conventions; at increasing awareness and promoting opportunities for exchanging information under the conventions and between the two conventions; and at exploring an integrated approach to chemicals management at the national level.

25. At the joint workshops, representatives had expressed interest in increasing the number of notifications and import responses under the Rotterdam Convention, in addition to improving chemicals management as a whole at the national level through increased information exchange, empowerment of communities and more informed decision-making based on a greater understanding of the social and economic considerations arising in the context of chemicals management and other environmental issues. They had also noted that they would like to participate more actively in the work of the two committees through a better understanding of the work of the committees and the conventions in general.

26. In the ensuing discussion, several members said that they had found the workshops to be very useful in equipping them to provide input into chemicals management decision-making at the national level, including in the development of integrated chemicals management policies and the promotion of synergies in the implementation of the chemicals-related conventions. The knowledge gained had also contributed to advocacy at the national level, helping to convince stakeholders of the need to cooperate in taking action on hazardous chemicals. Another member said that the workshop that he had attended had assisted in raising awareness of what other countries in his region were doing, and another that sharing of experiences between designated national authorities had been useful in helping to resolve

problematic issues, including how to fulfil obligations under the chemicals-related conventions. In response to a question from an observer, the representative of the Secretariat said that the attendance of observers at joint workshops on effective participation in the work of the Committee and the Persistent Organic Pollutants Review Committee was encouraged.

27. One member said that an orientation workshop for new members of the Committee had also proved very valuable, and the Committee encouraged the Secretariat to hold similar events in the future, including for the new members of the Committee who would begin their terms in October 2011.

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

28. In considering the item, the Committee had before it the working procedures and policy guidance developed by the Committee to facilitate its work (UNEP/FAO/RC/CRC.7/INF/4). Two of the guidance documents, guidance to intersessional task groups on reviewing notifications of final regulatory action and supporting documentation for chemicals scheduled for consideration by the Committee, and the working paper on the application of criteria (b) of Annex II to the Convention, had been revised by an intersessional drafting group to reflect the experience gained at the Committee's sixth meeting. Those revised documents were presented separately in documents UNEP/FAO/RC/CRC.7/13 and UNEP/FAO/RC/CRC.7/14, respectively.

29. Ms. Seng, coordinator of the intersessional drafting group, introduced the revised guidance to intersessional task groups. She recalled that the Committee had developed the paper to provide guidance to intersessional task groups in reviewing candidate chemicals and pesticide formulations. Comments on the guidance had been provided at the Committee's sixth meeting and had been taken into account in revising the document. The guidance had also been revised since the sixth meeting to take into account editorial comments and to emphasize that the text of task group reports should contain all information and details regarding the analysis of notifications. The analysis tables that were prepared as Excel spreadsheets would henceforth only be used by task groups to assist in the preliminary work of organizing the often voluminous supporting information provided with the notifications.

30. She also introduced the working paper on the application of the criteria in paragraph (b) of Annex II (UNEP/FAO/RC/CRC.7/14), noting that the Committee had originally developed that working paper to assist it in judging whether notifications of final regulatory action met those criteria. Comments on the guidance had been provided at the Committee's sixth meeting and taken into account in revising the document. As tasked by the Committee at its sixth meeting, an intersessional drafting group had revised the working paper to add information on the understanding of the term "risk evaluation" in the context of the Convention; to explain further the idea that the criteria in paragraphs (b) (i), (b) (ii) and (b) (iii) of Annex II should be considered as a single cluster, meaning that criterion (b) as a whole could be met only if all the sub-criteria were met; and to indicate clearly that, to establish whether criteria (b) (i) and (b) (ii) were met, information on both hazard and exposure should be taken into account.

31. Two new examples had also been included to assist the Committee in its work. The first related to the notification from Norway on azinphos-methyl. The second related to the discussion at the Committee's sixth meeting on the notification from Sweden for paraquat.

32. In the ensuing discussion, one member stressed that the documents before the Committee were fundamental to its work and said that there was a need to take a holistic view when evaluating candidate chemicals and to conform to both the letter and the spirit of the Convention. He informed the Committee that he intended to submit two conference room papers on the subject.

33. One observer drew attention to the expression "risk evaluation is an evaluation of intrinsic toxicological and ecotoxicological properties and actual or expected relevant exposure" set out in the working paper on the application of the criteria in paragraph (b) of Annex II to the Convention, suggesting that such language was insufficient. He proposed that a reference to the causal relationship between hazardous properties and actual or expected relevant exposure should be added at the end of the sentence. He undertook to submit more comments in writing to the Secretariat.

34. Another observer referred to the addition of the following text in the guidance to intersessional task groups on reviewing notifications of final regulatory action and supporting documentation for chemicals scheduled for consideration by the Committee:

> "This extra line has been inserted to indicate whether the entire criterion (b) or (c) has been met. The whole criterion has only been met if all of the sub-criteria have been met".

35. She said that while criterion (b) should be considered as a single cluster the same was not true of criterion (c) because the Convention provided only that the subparagraphs of that provision were to be "taken into account" and therefore did not constitute independent criteria that had to be met in every case.

36. In subsequent discussion of improvements that could be made to the working procedures and policy guidance developed by the Committee, one observer said that, in the interests of transparency, every effort should be made to ensure that comments and other documentation submitted by observers and Committee members were made freely available to all concerned in a timely manner.

37. Another observer said that, in the light of the experience at the current meeting in dealing with the first proposal for a severely hazardous pesticide formulation to be discussed by the Committee since the Convention entered into force, the Committee should develop further guidance and working procedures related specifically to building capacity to assist parties in submitting proposals on such formulations, particularly with regard to the development of incident reporting systems, taking advantage of the expertise of the FAO Pesticide Management Unit.

38. A third observer said that his organization would submit written comments to the Committee on a number of elements of document UNEP/FAO/RC/CRC.7/14.

39. The Committee agreed to establish an intersessional drafting group, chaired by Ms. Seng, to undertake further work on the guidance document.

IV. Technical work

A. Report of the Bureau on the preliminary review of notifications and the proposal for a severely hazardous pesticide formulation, and proposed priorities for chemicals scheduled for review by the Committee

40. Introducing the item the Vice-Chair recalled that the Bureau, in consultation with the Secretariat, had in December 2010 undertaken a preliminary review of notifications of final regulatory action for seven chemicals and one proposal relating to a severely hazardous pesticide formulation. The results of that preliminary analysis were described in document UNEP/FAO/RC/CRC.7/3, which also detailed the Bureau's proposed priorities for intersessional work relating to the chemicals and the formulation. Following the preliminary reviews, and on the recommendation of the Bureau, an intersessional task group was established for each chemical and formulation and tasked with undertaking an initial review and preparing an analysis of whether it met the applicable criteria of the Convention.

41. Following the priorities proposed by the Bureau in the above-mentioned document, the seven chemicals for consideration by the Committee had been clustered into two proposed groups. Endosulfan, perfluorooctane sulfonate, its salts and its precursors, pentabromodiphenyl ether commercial mixtures and octabromodiphenyl ether commercial mixtures had been placed in the first group, comprising chemicals for which it was possible that notifications from at least two PIC regions would meet the criteria in the Convention. Amitraz, carbaryl and pentachlorobenzene 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 criteria in the Convention.

42. The Committee agreed to consider the notifications before it in line with the priorities recommended by the Bureau in document UNEP/FAO/RC/CRC.7/3.

B. Consideration of the draft decision guidance document for azinphos-methyl

43. Introducing the sub-item the Chair recalled that at its fifth and sixth meetings the Committee had reviewed notifications of final regulatory action for azinphos-methyl from Canada and Norway, along with 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.

44. Accordingly, the Committee had agreed at its sixth meeting to recommend to the Conference of the Parties that azinphos-methyl should be listed in Annex III to the Convention. In addition, the Committee had adopted a rationale for that recommendation, agreed to establish an intersessional drafting group to produce a draft decision guidance document for azinphos-methyl and agreed on

a detailed workplan for the development of the decision guidance document, in line with the process adopted by the Conference of the Parties in decision RC-2/2. The rationale, recommendation and workplan were annexed to the report of the Committee's sixth meeting (UNEP/FAO/RC/CRC.6/16, annex II). The workplan had subsequently been modified and an updated version posted on the Convention website.

45. At the current meeting the Committee had before it a draft decision guidance document on azinphos-methyl prepared by the drafting group established at the Committee's sixth meeting (UNEP/FAO/RC/CRC.7/12), together with a tabular summary of comments thereon received under step 4 of the procedure for developing decision guidance documents and how they were addressed (UNEP/FAO/RC/CRC.7/INF/6).

46. Ms. Al-Easa presented the work of the drafting group, which comprised her and Mr. Helbig as co-chairs, and Mr. Abdelbagi, Mr. Al-Dobai, Ms. Arroyo, Ms. Balicka, Mr. Goji, Ms. Gwayi, Mr. Opiyo, Ms. Randall and Ms. Tang as members.

47. Following the Chair's presentation an observer maintained that the notifications had been made well after the 90-day time limit. The Chair, stating that the issue needed to be clear for all, explained that the UNEP legal office had advised that paragraph 1 of Article 5 of the Convention did not have any bearing on the Committee's mandate. The Committee was a technical body bound to follow the provisions of the Convention that governed its operations and it was for the Conference of the Parties to decide on issues such as that raised by the observer.

48. As there were no further comments, the Chair requested the Secretariat to prepare a draft decision on forwarding the draft decision guidance document and associated comments to the Conference of the Parties for consideration at its sixth meeting.

49. Subsequently, the Committee adopted a recommendation in which it agreed upon the text of the draft decision guidance document, as contained in document UNEP/FAO/RC/CRC.7/12, and decided to forward it for consideration by the Conference of the Parties. The recommendation is set out in annex I to the present report.

C. Review of notifications of final regulatory action

1. Presentation by the Chair of the Persistent Organic Pollutants Review Committee

50. Mr. Reiner Arndt, Chair of the Persistent Organic Pollutants Review Committee, gave a presentation on the work of that committee, focusing on its consideration of proposals to list perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride, pentabromodiphenyl ether, octabromodiphenyl ether, pentachlorobenzene and endosulfan in the annexes to that Convention.

51. A number of questions were raised following Mr. Arndt's presentation. In response to a question from a member, he said that once the Persistent Organic Pollutants Review Committee had considered a substance before it and found it to meet the requirements for listing in the annexes to the Stockholm Convention it should, based on a risk profile and a risk management evaluation, recommend whether the chemical should be considered by the Conference of the Parties for listing in Annexes A, B and/or C to the Convention. At the Committee's sixth meeting, however, the Committee had recommended to the Conference of the Parties that it should consider listing technical endosulfan, its related isomers and endosulfan sulfate in Annex A to the Convention and had also recommended that it should consider allowing exemptions because developing countries would require time and assistance in phasing out the use of those chemicals. It remained to be seen how the Conference of the Parties at its fifth meeting would react, given that the Convention did not explicitly authorize the Committee to recommend the consideration of exemptions.

52. Responding to an observer who had thanked him for acknowledging that the procedures employed by the Committee in considering whether to recommend the listing of endosulfan under the Stockholm Convention had followed twists and turns, he noted that the Committee had applied those same procedures to all nine chemicals that the Conference of the Parties had agreed to list under the Convention at its fourth meeting. By deciding to list the nine chemicals under the Convention, he suggested, the Conference of the Parties had endorsed those procedures.

2. Chemicals for which, following a preliminary review, at least two notifications appeared to meet the criteria in Annex II

(a) Endosulfan

53. Introducing the sub-item the Chair recalled that at its third meeting the Committee had reviewed a notification of final regulatory action on endosulfan from the European Community and

had concluded that it met the criteria of Annex II to the Convention. At its fifth and sixth meetings the Committee had reviewed additional notifications from eight Sahelian parties and concluded that they too met the criteria of Annex II, and at its sixth meeting the Committee had finalized a draft decision guidance document based on those notifications and forwarded it to the Conference of the Parties for consideration at its fifth meeting, together with a recommendation that it should list endosulfan in Annex III to the Convention.

54. At the current meeting the Committee had before it one additional verified notification of final regulatory from each of two PIC regions, which were set out in document UNEP/FAO/RC/CRC.7/6. One notification had been submitted by Benin (African region) and the other by New Zealand (Southwest Pacific region). The supporting documentation submitted by New Zealand was provided in document UNEP/FAO/RC/CRC.7/6/Add.1, while the supporting documentation submitted by Benin was provided in documents UNEP/FAO/RC/CRC.7/6/Add.2 and Add.3.

55. The Chair recalled that the notification submitted by New Zealand had been discussed by the Committee at its sixth meeting. An intersessional task group had concluded that the notification had met all the criteria of Annex II but one member of the Committee at the sixth meeting had raised concerns about the notification, which were then discussed by a drafting group that also concluded that the notification satisfied the criteria of Annex II. The member had nevertheless maintained his objections and the Committee had therefore decided to defer its consideration of the notification to the current meeting. She said that as no new information had been received since the sixth meeting, however, there was no need to reopen the debate that had taken place at that meeting.

56. The Chair also noted that the notification submitted by Benin was based on the same technical grounds as were those submitted by the Sahelian countries that had been found to satisfy the criteria of Annex II.

57. Ms. Seng presented the work of the intersessional task group that had undertaken a preliminary assessment of the new notification and its supporting documentation, which had also undertaken to review the findings of the earlier intersessional task group on the notification submitted by New Zealand. The group had comprised her and Mr. Figueroa-Cornejo as co-chairs and Ms. Bartels, Ms. Collier, Mr. Lanciné and Mr. Linders as members.

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

59. With regard to Annex II to the Convention she said that the notification submitted by Benin was nearly identical to those submitted by the eight parties from the Sahel, and was based on the same supporting documentation, including risk evaluations, which demonstrated that the uses, ranges of concentration and trade names of preparations were substantially the same. The risks to human health and the environment were also the same, and the conditions in the cotton-growing area of Benin were comparable to those in the Sahelian States. The task group was of the view that the notification submitted by Benin was substantially identical to those submitted by the Sahelian States and that, like them, it therefore satisfied the criteria of Annex II.

60. Turning to the notification from New Zealand she reiterated that, since the Committee's consideration of the notification at its sixth meeting, no new information had been received from the notifying party, nor from the Committee member who had raised concerns. The task group had nevertheless reviewed the notification once again. Reviewing the elements of the notification for the Committee, she reported that the task group had confirmed that the notification satisfied the criteria of Annex II (outlined in paragraph 72 of the report of the Committee's sixth meeting (UNEP/FAO/RC/CRC.6/16)).

61. Following the presentation of the task group's findings one member said that he wished to reiterate, without detailing them as he had detailed them in conference room papers submitted at the current meeting, the concerns that he had expressed at the Committee's sixth meeting regarding the notifications from the Sahelian countries, which he said applied with equal force to the notification from Benin. He said that as set out in his conference room papers the notification from Benin, along with that from New Zealand, did not meet the criteria of paragraph (b) of Annex II. He also indicated that the Benin notification was flawed because the risk evaluation was based on data that had not been generated in Benin and had been based on bridging information, the use of which was not provided for under the Convention.

62. An observer, endorsing the member's comments regarding the use of bridging information, echoed the view that the Convention did not provide for its use. He also said that the notification from Benin did not include supporting documentation demonstrating a link between the statement by the

National Committee of Accreditation and Control, the risk evaluations and the decree to ban endosulfan in Benin.

63. Several other members expressed strong disagreement with the notion that bridging information could not be used, and a representative of the Secretariat noted that while the Convention itself did not provide for it the Conference of the Parties had taken note of the Committee's working procedures and policy guidelines. As to arguments raised at the Committee's sixth meeting, several members argued vigorously that all such issues had been discussed extensively and that no further time should be spent on them. One member indicated that he believed that no outstanding issues remained. Regarding the lack of a documentary trail to establish that the final regulatory action had been based on the risk evaluation, Ms. Seng stated that the notification indicated that the action had indeed been based on the risk evaluations with local conditions taken into account and that there had been nothing to cast doubt on that statement.

64. In response to the above mentioned observer, the representative of the Secretariat clarified that decree No. 447 banning endosulfan referred to Benin's phytosanitary regulation law (law N91-004 of 11 February 1991). The National Committee of Accreditation and Control had been established pursuant to Article 17 of that law and the decree referred to that law.

65. A drafting group was established to draft a rationale as to how the notifications from Benin and New Zealand met the criteria in Annex II to the Convention.

66. Subsequently, the coordinator of the drafting group presented the draft rationale. One member recalled the conference room papers that he had submitted, saying that he wished to reiterate, again without detailing them as he had detailed them in conference room papers, the views set forth therein. Many other members voiced strong support for the draft rationale and said that they saw no reason to delay the adoption of the rationale as the member's concerns had already been addressed. The Chair suggested to the member that he should accept the adoption of the rationale and indicated that the member's views would be reflected in the report. The member agreed.

67. The Committee adopted the rationale for endosulfan and requested the drafting group to prepare a workplan for preparing a decision guidance document for endosulfan and the Secretariat to prepare a draft recommendation to the Conference of the Parties for the inclusion of endosulfan in Annex III.

68. The Committee subsequently took up the draft workplan prepared by the drafting group and the draft recommendation prepared by the Secretariat.

69. One member objected to the consideration of the two documents, saying that he renewed, again without detailing them as he had detailed them in conference room papers, the views that he had set out in conference room papers and said that he had never consented to the adoption of the rationale for endosulfan. He said that the rationale could be adopted, so long as it was made clear that it had been adopted by all the Committee members except him.

70. The Chair reminded the member that the Committee had already adopted the rationale, with the member's participation and agreement, on the condition that the member's expression of his concerns should be reflected in the present report. She also pointed out that the member's conference room papers had been taken into account prior to the adoption of the rationale.

71. Numerous other members expressed support for the statement by the Chair, saying that the Committee had indeed adopted the rationale on the understanding that the member's concerns would be reflected in the report of the meeting and that the member had agreed to that procedure. They observed that the member had had ample opportunity to comment in the drafting group but had failed to do so orally, and affirmed the Chair's statement that the drafting group had considered the member's conference room papers in preparing the rationale. They argued strongly that the Committee should spend no more time on the member's views and should move on with its business.

72. The Chair concluded the discussion by indicating that the draft recommendation and the draft workplan would be appended as annexes to the present report and that the member's concerns would also be reflected. The rationale, the recommendation and the timetable for endosulfan are set out in chapter I of annex II to the present report.

(b) Perfluorooctane sulfonate, its salts and its precursors

73. The Committee had before it four notifications and supporting documentation on perfluorooctane sulfonate, its salts and its precursors submitted by Canada, the European Union and Japan, set out in documents UNEP/FAO/RC/CRC.7/7 and Add.1–3. One of the notifications submitted by Japan was for perfluorooctane sulfonyl fluoride, which the Committee was considering since perfluorooctane sulfonyl fluoride was a precursor of perfluorooctane sulfonate.

74. Ms. Al-Easa presented the work of the intersessional task group that had undertaken a preliminary assessment of the notifications and their supporting documentation. The group had comprised her and Mr. Helbig as co-chairs and Mr. Abdelbagi, Mr. Binga, Mr. Ikeda and Mr. Shan as members.

(i) Notification from Canada

75. She said that the notification from Canada related to a severe restriction on the industrial use of perfluorooctane sulfonate, its salts and its precursors. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

76. With regard to Annex II to the Convention, she said that the notification from Canada 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 Canada. Accordingly, the task group had concluded that the criteria in paragraph (b) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, she said that Canada had severely restricted the substance; thus, the expected quantities and risks would be significantly reduced. As the basis for the regulatory action included environmental concerns relating to persistent organic pollutants, 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.

(ii) Notification from the European Union

77. Ms. Al-Easa said that the notification from the European Union related to a severe restriction on the industrial use of perfluorooctane sulfonates. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

78. With regard to Annex II to the Convention, she said that the notification from the European Union 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 Union. Accordingly, the task group had concluded that the criteria in paragraph (b) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, she said that the European Union had severely restricted the substance; thus, the expected quantities and risks would be significantly reduced. As the basis for the regulatory action included environmental concerns relating to persistent organic pollutants, 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.

(iii) Notifications from Japan

79. Ms. Al-Easa said that the notifications from Japan related to a severe restriction on the industrial use of perfluorooctane sulfonate and a ban on perfluorooctane sulfonyl fluoride (a precursor of perfluorooctane sulfonate). The task group had concluded that the notifications had met the information requirements in Annex I to the Convention.

80. With regard to Annex II to the Convention, she said that the notifications from Japan explained that the regulatory action had been taken to protect human health; thus, the criterion in paragraph (a) of Annex II had been met. The referenced hazard data had been taken from internationally recognized sources and, in particular, from the work of the Persistent Organic Pollutants Review Committee of the Stockholm Convention, and the risk evaluation had been performed in accordance with recognized

scientific principles and procedures, taking into account prevailing conditions in Japan. Accordingly, the task group had concluded that the criteria in paragraph (b) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, she said that Japan had banned the substance; thus, use would be eliminated and risks significantly reduced. As the basis for the regulatory action included human health concerns relating to persistent organic pollutants, 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.

(iv) Discussion of the notifications

81. In the ensuing discussion, one member suggested that, as the Committee had agreed that it was no longer required to append analysis tables to task group reports, the reference to such tables in the report should be deleted. The Committee agreed to take the suggestion into account for the task group reports to be prepared for its eighth meeting.

82. One member intimated that the risk evaluation underlying the Canadian notification was inadequate, suggesting that the notification should have been based on a risk assessment.

83. Responding, one member said that the risk evaluation undertaken was complicated and involved both hazard and risk assessments that went beyond what was required by the Convention. It was entirely acceptable for a country to perform a risk assessment if it so desired, but was not obligatory under the Convention. An observer representing the Canadian Government clarified that the Canadian notification was indeed a full-blown risk assessment that took into account hazard and exposure data from multiple sources. While terminology often varied by country, the aim was to provide the Committee with the information that it needed to make its decision on a valid risk evaluation.

84. The member who had asked the original question also suggested that, as the Canadian notification had been delayed and had exceeded the 90-day period mentioned in Article 5 of the Convention, it should be time barred. In response, the representative of the Secretariat recalled that, 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. At the Committee's sixth meeting, the UNEP Senior Legal Officer had 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. Thus a notification, even if submitted after the applicable deadline, once verified by the Secretariat and submitted to the Committee, remained valid. Issues of compliance with the deadlines for submitting notifications of final regulatory action were to be discussed by the Conference of the Parties, not the Committee. At that same meeting, the representative of the Secretariat had said that the notifications in question had been verified and had been submitted within the 90-day period.

85. An observer asked whether, if the Committee agreed to recommend the chemicals for listing in Annex III to the Convention, perfluorooctane sulfonate and its salts and perfluorooctane sulfonyl fluoride would be listed as a single chemical entity, noting that the definition of "chemical" in Article 2 of the Convention did not refer to precursors. The representative of the Secretariat said that that issue would be taken into account when preparing a draft decision on the subject.

(v) Next steps

86. The Committee agreed that, as the notifications from Canada, the European Union and Japan had been found to meet the criteria of Annex I and Annex II to the Convention, the Committee should recommend to the Conference of the Parties that perfluorooctane sulfonate, its salts and its precursors should be included in Annex III to the Convention.

87. A drafting group was established to draft a rationale as to how the notifications from Canada, Japan and the European Union met the criteria in Annex II to the Convention, to prepare a timetable for the development of a 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 perfluorooctane sulfonate, its salts and its precursors in Annex III to the Convention.

88. Subsequently, one member reiterated concerns that he had expressed earlier about the use of the terms "ecological screening assessment" and "risk evaluation" in the Canadian and Norwegian notifications, respectively. He suggested that the text of the rationale should be amended to reflect the fact that the screening assessments and risk assessments were in substance of the same type. Several

members opposed such an amendment. The Committee agreed that the member's concerns would be further discussed during the preparation of the decision guidance document.

89. An observer asked, if the Committee agreed to list perfluorooctane sulfonate and its salts and perfluorooctane sulfonyl fluoride as a single chemical entity in Annex III to the Convention. He also said that only one notification had been submitted pertaining to perfluorooctane sulfonyl fluoride. The Chair noted in response that the CAS numbers of the relevant chemicals, including the precursor, were specified in the rationale; the representative of the Secretariat pointed out that the Japanese and Canadian notifications included perfluorooctane sulfonate precursors and consequently perfluorooctane sulfonyl fluoride.

90. The Committee adopted a recommendation on perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride, 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 chapter II of annex II to the present report.

(c) Pentabromodiphenyl ether commercial mixtures

91. The Committee had before it five notifications and supporting documentation on pentabromodiphenyl ether commercial mixtures submitted by Canada, the European Community,[2] Norway and Japan, set out in documents UNEP/FAO/RC/CRC.7/8 and Add.1–4.

92. For the discussion of the notification from Norway, Ms. Al-Easa took the Chair in place of Ms. Randall in consideration of the fact that Ms. Randall was a national of the submitting party.

93. Ms. Arroyo 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 her and Mr. Abdelbagi as co-chairs and Mr. Helbig, Mr. Ikeda, Ms. Morales and Ms. Randall as members.

(i) Notification from Canada

94. She said that the notification from Canada related to a ban on pentabromodiphenyl ether commercial mixtures and their industrial use. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

95. With regard to Annex II to the Convention, she said that the notification from Canada 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 Canada. Accordingly, the task group had concluded that the criteria in paragraph (b) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, she said that Canada had prohibited the substance; thus, use would be eliminated and risks significantly reduced. As the basis for the regulatory action included environmental concerns relating to persistent organic pollutants, 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.

(ii) Notification from the European Community

96. Ms. Arroyo said that the notification from the European Community related to a severe restriction on the industrial use of pentabromodiphenyl ether commercial mixtures. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

97. With regard to Annex II to the Convention, she said that the notification from the European Community explained that the regulatory action had been taken to protect human health and the

2 As indicated by the Depositary of the Convention in a notification dated 31 March 2010 (reference: C.N.182.2010.TREATIES-2), which was in turn based on a communication from the Council of the European Union dated 8 March 2010, following the entry into force of the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, with effect from 1 December 2009 the European Union replaced the European Community (Article 1, third paragraph, of the Treaty of Lisbon) and took over all rights and obligations of the European Community. The former European Community has accordingly been replaced by the European Union in respect of all conventions or agreements for which the Secretary-General of the United Nations is the depositary and to which the European Community is a signatory or a contracting party.

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 paragraph (b) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, she said that the European Community had severely restricted the substance; thus, use would be eliminated and risks significantly reduced. As the basis for the regulatory action included environmental concerns relating to persistent organic pollutants, 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.

98. An observer noted that the European Community had submitted a notification on pentabromodiphenyl ether to the interim secretariat of the Rotterdam Convention in 2003, and asked whether the notification currently before the Committee should therefore be considered a resubmission. The representative of the Secretariat said that, according to paragraph 2 of Article 5 of the Convention, notifications submitted to the interim secretariat remained valid.

(iii) Notification from Japan for pentabromodiphenyl ether

99. Ms. Arroyo said that the notification from Japan related to a ban on the industrial use of pentabromodiphenyl ether. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

100. With regard to Annex II to the Convention, she said that the notification from Japan explained that the regulatory action had been taken to protect human health; thus, the criterion in paragraph (a) of Annex II had been met. As no data had been provided on exposure and there was insufficient evidence of a risk evaluation under prevailing conditions in Japan, the task group had concluded that the criteria in paragraph (b) of Annex II had not been met. Turning to the criteria in paragraph (c) of Annex II, she said that Japan had prohibited the substance; thus, use would be eliminated and risks significantly reduced. As the basis for the regulatory action included human health concerns relating to persistent organic pollutants, 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.

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

(iv) Notification from Japan for tetrabromodiphenyl ether

102. Ms. Arroyo said that the notification from Japan related to a ban on the industrial use of tetrabromodiphenyl ether. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

103. With regard to Annex II to the Convention, she said that the notification from Japan explained that the regulatory action had been taken to protect human health; thus, the criterion in paragraph (a) of Annex II had been met. As no data had been provided on exposure and there was insufficient evidence of a risk evaluation performed under prevailing conditions in Japan, the task group had concluded that the criteria in paragraph (b) of Annex II had not been met. Turning to the criteria in paragraph (c) of Annex II, she said that Japan had prohibited the substance; thus, use would be eliminated and risks significantly reduced. As the basis for the regulatory action included human health concerns for persistent organic pollutants, 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.

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

(v) Notification from Norway

105. Ms. Arroyo said that the notification from Norway related to a ban on the industrial uses of pentabromodiphenyl ether commercial mixtures. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

106. 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 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 Norway. Accordingly, the task group had concluded that the criteria in paragraph (b) 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, use would be eliminated and risks significantly reduced. As the basis for the regulatory action included environmental concerns relating to persistent organic pollutants, 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.

(vi) Other issues and next steps

107. One member asked whether the use of the terms “ecological screening assessment” and “risk evaluation” in the Canadian and Norwegian notifications, respectively, reflected a difference in approach. Ms. Arroyo said that, while the vocabulary might differ, both countries had used scientifically valid methods and procedures to evaluate the chemical against the criteria laid out in the Convention.

108. One member asked whether the wording “commercial mixtures” would be retained should those mixtures be accepted for inclusion in Annex III to the Convention. The Chair responded that that issue would be addressed at a later stage in drafting groups, along with the related issue of consistency in the treatment of pentabromodiphenyl ether commercial mixtures and octabromodiphenyl ether commercial mixtures.

109. In response to a query from a member on the listing of chemicals in the annexes to the Stockholm Convention and the Rotterdam Convention, the representative of the Secretariat said that the listing of a chemical in Annex A, B or C to the Stockholm Convention reflected the fact that the goal was the ultimate elimination of the chemical, but if there were no safe cost-effective alternatives currently available, exemptions for use were allowed until such alternatives were identified; the Rotterdam Convention, on the other hand, was concerned only with trade in chemicals subject to the PIC procedure.

110. The Committee agreed that, as the notifications from Canada, the European Community and Norway had been found to meet the criteria of Annex I and Annex II to the Convention, the Committee should recommend to the Conference of the Parties that pentabromodiphenyl ether commercial mixtures should be included in Annex III to the Convention.

111. A drafting group was established to draft a rationale as to how the notifications from Canada, the European Community and Norway met the criteria in Annex II to the Convention, to prepare a timetable for the development of a 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 pentabromodiphenyl ether commercial mixtures in Annex III to the Convention.

112. Subsequently, one member called for care to be taken during the intersessional work in respect of CAS numbers and exact chemical compositions to ensure consistency with the work on the substance undertaken by the Persistent Organic Pollutants Review Committee.

113. The Committee adopted the recommendation on tetrabromodiphenyl ether and pentabromodiphenyl ether, which are components of pentabromodiphenyl ether commercial mixtures, 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 chapter III of annex II to the present report.

(d) Octabromodiphenyl ether commercial mixtures

114. The Committee had before it five notifications and supporting documentation on octabromodiphenyl ether commercial mixtures, submitted by Canada, the European Community, Norway and Japan, set out in documents UNEP/FAO/RC/CRC.7/10 and Add.1–4. Additional information from the Persistent Organic Pollutants Review Committee was also provided in document UNEP/FAO/RC/CRC.7/INF/11.

115. For the discussion of the notification from Norway, Ms. Al-Easa took the Chair in place of Ms. Randall in consideration of the fact that Ms. Randall was a national of the submitting party.

116. Mr. Goji presented the work of the intersessional task group that had undertaken a preliminary assessment of the notifications and their supporting documentation. The group had comprised him and Mr. Linders as co-chairs and Mr. Aloueimine, Ms. Gwayi and Mr. Khan as members.

(i) Notification from Norway

117. He said that the notification from Norway related to a ban on octabromodiphenyl ether commercial mixtures and their industrial uses. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

118. With regard to Annex II to the Convention, he said that the notification from Norway 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 Norway. Accordingly, the task group had concluded that the criteria in paragraph (b) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, he said that Norway had prohibited the substance; thus, use would be eliminated and risks significantly reduced. As the basis for the regulatory action included environmental concerns relating to persistent organic pollutants, 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.

119. In response to a concern raised by one member regarding the abbreviations used in task group reports, Mr. Goji stated that the usage of the abbreviations had been consistent with the language of the notifications.

120. The Committee agreed that the notification from Norway had been found to meet the criteria of Annex I and Annex II to the Convention.

(ii) Notification from the European Community

121. Mr. Goji said that the notification from the European Community related to a severe restriction on the industrial use of octabromodiphenyl ether. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

122. 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 paragraph (b) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, he said that the European Community had severely restricted the substance; thus, use would be eliminated and risks significantly reduced. Since the basis for the regulatory action included environmental concerns relating to persistent organic pollutants, 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.

(iii) Notification from Canada

123. Mr. Goji said that the notification from Canada related to a ban on the industrial use of octabromodiphenyl ether commercial mixtures. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

124. With regard to Annex II to the Convention, he said that the notification from Canada 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 Canada. Accordingly, the task group had concluded that the criteria in paragraph (b) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, he said that Canada had prohibited the substance; thus, use would be eliminated and risks significantly reduced. Since the basis for the regulatory action included environmental concerns relating to persistent organic pollutants, 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.

(iv) Notification from Japan for heptabromodiphenyl ether

125. Mr. Goji said that the notification from Japan related to a ban on the industrial use of heptabromodiphenyl ether. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

126. With regard to Annex II to the Convention, he said that the notification from Japan explained that the regulatory action had been taken to protect human health; thus, the criterion in paragraph (a) of Annex II had been met. As no data had been provided on local exposure nor a valid risk evaluation performed under prevailing conditions in Japan, the task group had concluded that the criteria in paragraph (b) of Annex II had not been met. Turning to the criteria in paragraph (c) of Annex II, he said that Japan had prohibited the substance; thus, use would be eliminated and risks significantly reduced. As the basis for the regulatory action included environmental concerns relating to persistent organic pollutants, 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.

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

(v) Notification from Japan for hexabromodiphenyl ether

128. Mr. Goji said that the notification from Japan related to a ban on the industrial use of hexabromodiphenyl ether. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

129. With regard to Annex II to the Convention, he said that the notification from Japan explained that the regulatory action had been taken to protect human health; thus, the criterion in paragraph (a) of Annex II had been met. As no data had been provided on exposure nor a valid risk evaluation performed under prevailing conditions in Japan, the task group had concluded that the criteria in paragraph (b) of Annex II had not been met. Turning to the criteria in paragraph (c) of Annex II, he said that Japan had prohibited the substance; thus, it could be considered that the expected quantities and risks would be significantly reduced. Since the basis for the regulatory action included human health concerns relating to persistent organic pollutants, 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.

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

(vi) Next steps

131. The Committee agreed that, as notifications from Canada, the European Community and Norway had been found to meet the criteria of Annex I and Annex II to the Convention, the Committee should recommend to the Conference of the Parties that octabromodiphenyl ether commercial mixtures should be included in Annex III to the Convention.

132. A drafting group was established to draft a rationale as to how the notifications from Canada, the European Community and Norway met the criteria in Annex II to the Convention, to prepare a timetable for the development of a 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 octabromodiphenyl ether commercial mixtures in Annex III to the Convention.

133. Subsequently, the Committee adopted a recommendation on hexabromodiphenyl ether, heptabromodiphenyl ether, octabromodiphenyl ether, nonabromodiphenyl ether and decabromodiphenyl ether, which were components of octabromodiphenyl ether commercial mixtures, the rationale for that recommendation and a workplan for preparing a decision guidance document for the substances, as amended. The rationale, the recommendation and the timetable are set out in chapter IV of annex II to the present report.

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

(a) Amitraz

134. The Committee had before it a notification and supporting documentation on amitraz submitted by the Syrian Arab Republic, set out in documents UNEP/FAO/RC/CRC.7/4 and UNEP/FAO/RC/CRC.7/4/Add.2, together with the notification from the European Community that it had reviewed at its sixth meeting, for which it had prepared a rationale for its decision that the notification had met the requirements of the Convention. That rationale was available in document UNEP/FAO/RC/CRC.7/4/Add.1.

135. Mr. Opiyo 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 him and Ms. Tang as co-chairs and Ms. Aleksandryan, Ms. Collier, Mr. Ghaemian, Mr. Linders and Ms. Seng as members.

136. He said that the notification from the Syrian Arab Republic 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.

137. With regard to Annex II to the Convention, he said that the notification from the Syrian Arab Republic explained that the regulatory action had been taken to protect human health; thus, the criterion in paragraph (a) of Annex II had been met. The referenced hazard data had been taken from internationally recognized sources and a risk or hazard evaluation had been performed. It appeared, however, that the basis for the final regulatory action was the banning of the substance by the European Union, meaning that the final regulatory action had not been taken as a consequence of a risk evaluation that took into account the prevailing conditions in the Syrian Arab Republic. Accordingly, the task group had concluded that the criteria in paragraph (b) of Annex II had not been met. Turning to the criteria in paragraph (c) of Annex II, he said that the Syrian Arab Republic 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.

138. In the ensuing discussion, one observer said that the text displayed during the presentation by Mr. Opiyo did not conform exactly to the text of Annex II to the Convention, particularly with regard to the criteria of paragraphs (b) (i) and (b) (ii). He cautioned against possible misinterpretations of the criteria. In response, the Chair suggested that further details on the task group's findings could be found in the task group's report.

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

140. As only one notification of final regulatory action from one of the two PIC regions had met the criteria in Annex II, the Committee agreed that no further action would be taken at the current time.

(b) Carbaryl

141. The Committee had before it a notification and supporting documentation on carbaryl submitted by the Syrian Arab Republic, set out in documents UNEP/FAO/RC/CRC.7/5 and UNEP/FAO/RC/CRC.7/5/Add.2, together with the notification from the European Community that it had reviewed at its fourth meeting, for which it had prepared a rationale for its decision that the notification had met the requirements of the Convention. That rationale was available in document UNEP/FAO/RC/CRC.7/5/Add.1.

142. Ms. Tang 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 her and Ms. Arroyo as co-chairs and Ms. Balicka, Ms. Cedillo, Mr. Helbig, Mr. Hota, Ms. Marasinghe, Mr. Opiyo and Mr. Ramsay as members.

143. She said that the notification from the Syrian Arab Republic related to a ban on the use of carbaryl as a pesticide. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

144. With regard to Annex II to the Convention, she said that the notification from the Syrian Arab Republic 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 or hazard evaluation had been performed. It appeared, however, that the basis for the final regulatory action was the ban of the substance by the European Union, meaning that the final regulatory action had not been taken as a consequence of a risk evaluation that took into account the prevailing conditions in the Syrian Arab Republic. Accordingly, the task group had concluded that the criteria in paragraph (b) of Annex II had not been met. Turning to the criteria in paragraph (c) of Annex II, she said that the Syrian Arab Republic 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.

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

146. As only one notification of final regulatory action from one of the two PIC regions had met the criteria in Annex II, the Committee agreed that no further action would be taken at the current time.

(c) Pentachlorobenzene

147. The Committee had before it two notifications and supporting documentation on pentachlorobenzene submitted by Canada and Japan, set out in documents UNEP/FAO/RC/CRC.7/9 and Add.1 and Add.2.

148. Ms. Balicka presented the work of the intersessional task group that had undertaken a preliminary assessment of the notifications and their supporting documentation. The group had comprised her and Ms. Seng as co-chairs and Ms. Bartels and Mr. Linders as members.

(i) Notification from Canada

149. She said that the notification from Canada related to a severe restriction on the industrial use of pentachlorobenzene. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

150. With regard to Annex II to the Convention, she said that the notification from Canada 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 Canada. Accordingly, the task group had concluded that the criteria in paragraph (b) of Annex II had been met. Turning to the criteria in paragraph (c) of Annex II, she said that Canada had severely restricted the substance; thus, use would be eliminated and risks significantly reduced. As the basis for the regulatory action included environmental concerns the regulatory action would be broadly applicable to other countries. Although there were no indications of ongoing international trade above laboratory

scale, reintroduction of the chemical on international markets was possible. 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.

(ii) Notification from Japan

151. She said that the notification from Japan related to a ban on the industrial and agricultural use of pentachlorobenzene. The task group had concluded that the notification had met the information requirements in Annex I to the Convention.

152. With regard to Annex II to the Convention, she said that the notification explained that the regulatory action had been taken to protect human health; thus, the criterion in paragraph (a) of Annex II had been met. Insufficient data had been generated using scientifically recognized methods, the review of data had been unsatisfactory and there was no information available on exposure under prevailing conditions in Japan; the task group had therefore concluded that the criteria in paragraph (b) of Annex II had not been met. Turning to the criteria in paragraph (c) of Annex II, she said that Japan had prohibited the substance; thus, use would be eliminated and risks significantly reduced. As the basis for the regulatory action included human health concerns, the regulatory action would be broadly applicable to other countries. Although there were no indications of ongoing international trade above laboratory scale, reintroduction of the chemical on international markets was possible. 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.

153. Following the presentation, one member recalled that at its sixth meeting the Committee had decided to forward new information on unintentional releases of pentachlorobenzene to the Persistent Organic Pollutants Review Committee for its consideration. That information might be relevant should the Chemical Review Committee decide at a future meeting that a further notification on pentachlorobenzene from another PIC region met the criteria of Annex II, leading to the drafting of a decision guidance document.

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

(iii) Next steps

155. The Committee agreed that the notification from Canada met all the criteria in Annex II to the Convention and established a drafting group to prepare a rationale for that conclusion.

156. Subsequently, the Committee adopted a rationale for the conclusion that the notification by Canada 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.

157. Accordingly, as only one notification of final regulatory action from one of two PIC regions met the criteria in Annex II, the Committee agreed that no further action would be taken at the current time.

D. Review of the proposal to list Gramoxone Super as a severely hazardous pesticide formulation in Annex III to the Rotterdam Convention

158. The Committee had before it a proposal and supporting documentation for the pesticide formulation Gramoxone Super submitted by Burkina Faso (UNEP/FAO/RC/CRC.7/11, Corr.1 and Add.1). In addition, and in line with part 2 (d) of Annex IV to the Convention, information submitted by other parties, international organizations, non-governmental organizations and other relevant sources, which had been compiled by the Secretariat, was also available to the Committee. That information was presented in documents UNEP/FAO/RC/CRC.7/11/Add.2–6.

159. Ms. Bartels presented the work of the intersessional task group that had undertaken a preliminary assessment of the proposal and its supporting documentation. The group had comprised her as chair and Ms. Al-Easa, Ms. Marasinghe, Mr. Moudachirou, Mr. Ramsay, Ms. Randall and Ms. Seng as members.

160. She said that the proposal from Burkina Faso related to incidents involving the use of Gramoxone Super, a pesticide formulation containing 200 g/L of paraquat. The task group concluded that the proposal included adequate documentation, as required in part 1 of Annex IV. The task group

noted that the Secretariat had collected relevant information relating to the formulation, as outlined in part 2 of Annex IV, and had provided it to the intersessional task group and the Committee.

161. With regard to part 3 of Annex IV to the Convention, she indicated that the task group found that the evidence indicating that the use of the formulation resulted in the reported incidents was reliable, thereby meeting criterion (a) of part 3. As to criterion (b) of part 3, it had been found that the incidents involving the formulation were relevant to other States in the Sahel and possibly also to other States with similar climate, conditions and patterns of use of the formulation. Regarding criterion (c) of part 3, she indicated that the proposal submitted by Burkina Faso clearly outlined the common pattern of use of pesticides in the country. She reported a list of known application restrictions and indicated that they could not be respected in Burkina Faso. The reported effects of the formulation in relation to the quantity used were significant, thereby satisfying criterion (d) of part 3. There was no evidence that intentional misuse had been the basis for the proposal; thus, the criterion in paragraph (e) had been met. She concluded that all the criteria in Annex IV had been met.

162. In the ensuing discussion one member said that while he supported the conclusions of the task group he was concerned at the lack of information on the professional standing of those who had diagnosed the incidences of poisoning. Another member said that the questionnaire survey on which the proposal was based had yielded insufficient data, in terms of both quantity and quality, to justify the listing of a severely hazardous pesticide formulation. Further toxicological data needed to be gathered based on sound research methodologies, sufficient to permit the determination of a quantifiable toxicological impact. He also said that the registration for Gramoxone Super in Burkina Faso had been cancelled in 2006, which meant that any further quantities of the chemical still in circulation were illegal and therefore did not fall under the purview of the Committee.

163. Responding to the points raised Ms. Bartels said that the Convention did not specify the qualifications of those who reported incidents of poisoning and suggested that there was no reason to mistrust the information reported by Burkina Faso. She expressed surprise that the second member had not raised his objections during the previous day's task group meeting, at which he had been present and at which all participants had been given the opportunity to express any concerns that they had. With regard to the quality of the data, she said that it was very difficult for developing countries to carry out rigorous toxicological research and that the Convention did not require them to do so. She also said that the Convention did not require that a chemical proposed for listing in Annex III should be registered for use in the proponent country. Another member said that Article 6 of the Convention contained no obligation for a developing country to take regulatory action against a formulation that was causing problems under conditions of use in its territory. The Chair confirmed that the questionnaire survey was identified as a method in the working guidelines and policy procedures established by the Committee.

164. Another member voiced support for Ms. Bartels' comments. Recalling the legal opinion of UNEP on what constituted intentional misuse, discussed at the Committee's sixth meeting, she said that the fact that Gramoxone Super was not registered did not mean that its use constituted intentional misuse within the meaning of the Convention.

165. An observer said that comments by his organization on the task group report on Gramoxone Super had not been made available to the task group prior to its meeting immediately preceding the current Committee meeting, which he said contravened the Committee's working procedures. His organization had concluded that Gramoxone Super neither met the definition of a severely hazardous pesticide formulation nor satisfied the criteria set out in paragraphs 3 (a) and 3 (d) of Annex IV to the Convention. Noting that Article 2 (d) of the Convention defined a severely hazardous pesticide formulation as one producing "severe health or environmental effects", he said that, if judged according to the widely applied scoring scheme used by the European Association of Poisons Centres and Clinical Toxicologists and the International Programme on Chemical Safety of the World Health Organization to assess the severity of poisoning incidents, none of the reported incidents in Burkina Faso was severe, a fact that had not been taken into account by the task group at its recent meeting.

166. He also said that the reliability of the causal relationship between reported incidents and the alleged exposure to Gramoxone Super had not been estimated; such an evaluation should have been done to discount confounding factors, and was especially necessary for a survey documenting incidents occurring over a long time period, as had been used in the present case. In addition, several of the survey questions on Gramoxone Super had asked specifically about certain brand name formulations, an approach that was well known to encourage respondent bias. Due to such factors, many of the data reported were not reliable. Lastly, he said, the task group had not considered the significance of the reported effects in relation to the volume of the formulation used. In conclusion, his organization was of the opinion that the results of the Burkina Faso survey did not demonstrate that

Gramoxone Super met the definition of a severely hazardous pesticide formulation. Another observer echoed the earlier member comments about the registration of Gramoxone Super, asking whether the Convention applied to a chemical that was the subject of illegal trade. Another suggested that the use of personal protective equipment needed for the preparation and use of Gramoxone Super was probably typical of other chemicals used in Burkina Faso.

167. Responding, the Chair noted that the Committee was not considering a final regulatory action, to which trade was relevant as specified in Annex II to the Convention; the relevant inquiry in the present case was whether incidents of poisoning had been reported, as specified in Annex IV; a number of such incidents had been reported and in fact several had occurred prior to the registration of Gramoxone Super being cancelled. Another member added that it was not part of the Committee's remit to query the legality of trade in a chemical. In response to the observer's concern regarding the lack of availability of comments for the recent task group meeting, the representative of the Secretariat clarified that all comments on the task group's analysis of Gramoxone Super had in fact been made available at the most recent task group meeting, as required by the guidance to intersessional task groups outlined in document UNEP/FAO/RC/CRC.7/13.

168. Another observer said that the symptoms described in the Burkina Faso report were typical of the symptoms of paraquat poisoning, which were well known, and added that the adverse effects documented were among those listed in the Severely Hazardous Pesticide Formulation Incident Report Form of the Rotterdam Convention as symptoms of severe poisoning.

169. A drafting group was established to draft a rationale as to how the proposal from Burkina Faso had met the criteria in Annex IV to the Convention and to report to the Committee on its work.

170. Subsequently, one member drew attention to editorial comments on the draft rationale that he had submitted. The Committee undertook to take those comments into account when finalizing the rationale.

171. One member, noting that the Conference of the Parties would not consider until 2013 Gramoxone Super if recommended for listing at the current meeting, drew attention to the issues that he had raised in a conference room paper. Those issues were whether Gramoxone Super had been registered in Burkina Faso at the time the notification had been submitted to the Secretariat; whether a chemical that was the subject of illegal trade (illegal export or import) could be subjected to the Convention; and whether the listing in the Convention of a severely hazardous pesticide formulation could contribute to the environmentally sound use of the formulation. Such information should be obtained to facilitate a decision before 2013.

172. Several members expressed surprise that the member was raising concerns, given that he had been present in the group that had drafted the rationale for Gramoxone Super and had not done so there. One member asked why the member was insisting on repeating questions that had been clearly answered. In response, the member said that he had indeed tabled some of his concerns during the meeting of the drafting group, and had also done so at the Committee's first plenary session. He said that he had raised questions regarding various notifications, in addition to the current proposal under discussion, which he felt merited a response. If, however, the Committee did not wish to take them up, that was the Committee's decision. It was suggested that the rationale should be adopted and that the concerns of the member should be reflected in the present report. The member agreed.

173. The Chair noted that a party proposing the listing of a severely hazardous pesticide formulation was not required to take a final regulatory action in respect of that formulation.

174. The Committee adopted a rationale for Gramoxone Super and requested the drafting group to prepare a recommendation relating to that rationale and a workplan for preparing a decision guidance document for the substance.

175. Following the Committee's adoption of the rationale, several observers questioned the Committee's decision. One expressed his disappointment that extensive input from an observer on the draft task group report that had been submitted to the Secretariat early the previous week had not been distributed to the Committee members. He also said that the proposal raised three issues that should be the subject of input from the Conference of the Parties: the definition of severe, the standard for reliablity of evidence relating to incidents and the application of the criterion in part 3 (d) in the absence of volume information from the proposing country. In response, the Chair explained that the issue of the non-distribution had been discussed and resolved at the Committee's plenary session on Monday, while the issue of the criterion in part 3 (d) was addressed in the rationale prepared by the drafting group.

176. Another observer drew attention to paragraph 5 of the rationale, which included a list of symptoms that were linked to exposure to paraquat. He suggested, however, that many of the symptoms were not actually attributable to paraquat at all. Eleven cases of hospitalization were mentioned in the rationale but could not be found in the final report of the survey prepared by Burkina Faso. When taken in conjunction with the other information provided, it showed that there was a need for the Committee to review the reliability of the information set forth in paragraph 5 of the rationale. He suggested that there was evidence to show that the cases had been misclassified as the result of reliance on individual summaries of the incident in response to Ms. Bartels' clarification that the 11 cases of hospitalization were presented in the original proposal submitted by Burkina Faso.

177. A third observer said that the Committee's decision sent the signal that a particular formulation did not even have to be legally registered in a country before it could be proposed for listing as a severely hazardous pesticide formulation. He called for an explanatory note to be included to make that clear, especially as the Convention did not explicitly state that a pesticide had to be legally registered to qualify for notification under Annex IV.

178. One member suggested that there was a lack of consistency in the naming of the substance and other substances already listed in the Convention, saying that attention should be paid to that issue in the preparation of the decision guidance document. The Chair said that the Secretariat would deal with editorial comments and would take into account the naming inconsistency. The name "Gramoxone Super" would not be used for listing.

179. Another member reiterated the concerns that he had raised previously under the item in conference room papers, asking whether they had been taken into account. The Chair and a number of members explained that the concerns had indeed been taken into account, but had not proved sufficient to change the members' views.

180. The Committee adopted a recommendation to list paraquat dichloride (formulated as emulsifiable concentrate of 276 g active ingredient/L or above, corresponding to paraquat ion at or above 200 g/L) in Annex III to the Convention as a severely hazardous pesticide formulation and a workplan for drafting a decision guidance document for the chemical, as amended. The rationale, the recommendation and the workplan are set out in annex IV to the present report.

V. Other matters

Nomination of new Bureau members and Chair

181. The following Vice-Chairs were elected to serve on the Bureau of the Committee, with terms of office to begin at the end of the current meeting:

Mr. Azhari Omer Abdelbagi (Sudan – African region)

Ms. Anahit Aleksandryan (Armenia – Central and Eastern European region)

Mr. Jürgen Helbig (Spain – Western European and others region)

182. Ms. Hala Sultan Saif Al-Easa (Qatar – Asian and Pacific region) was selected to serve as Acting Chair of the Committee pending the election of a Chair by the Conference of the Parties at its fifth meeting.

183. The Chair thanked the outgoing Bureau members, Mr. Goji and Ms. Balicka, for their valuable contributions to the Committee's work.

VI. Dates and venue of the Committee's eighth meeting

184. The Committee agreed to hold its next meeting in Geneva from 18 to 23 March 2012.

VII. Adoption of the report

185. 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 the finalization of the report would be entrusted to the Rapporteur, working in consultation with the Secretariat.

VIII. Closure of the meeting

186. At the time of the closure of the meeting the member who had submitted a number of conference room papers said that, contrary to assurances from the Chair, there had been no opportunity for the Committee to discuss the issues raised therein at the current meeting. Other members of the

Committee disagreed, saying that the member's issues had been taken into account by the Committee in task and drafting groups and in the Committee's plenary sessions.

187. The Chair noted that while the Committee had indeed considered the member's technical arguments the conference room papers also referred to a number of procedural issues that were for consideration by the Conference of the Parties. Following consultation with the Secretariat she therefore suggested that the relevant issues raised by the member at the current meeting could be subject to an information document and made available to the Conference of the Parties at its fifth meeting.

188. Several members questioned the approach suggested. The Chair then clarified that the information document would be submitted by the Government of India through its delegate at the fifth meeting of the Conference of the Parties. On that understanding it was agreed that the Secretariat would facilitate such a request.

189. There then ensued the customary exchange of courtesies, following which the meeting was declared closed at 2.30 p.m. on Friday, 1 April 2011.

Annex I

Recommendation to the Conference of the Parties on the decision guidance document for azinphos-methyl

The Chemical Review Committee,

Recalling its decision, adopted by consensus 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 azinphos-methyl (CAS No. 86-50-0) in Annex III to the Rotterdam Convention,

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

Decides to agree upon the draft text of the decision guidance document on azinphos-methyl and to forward it to the Conference of the Parties for its consideration.

Annex II

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

I. Endosulfan

A. Rationale for the recommendation by the Chemical Review Committee to list endosulfan (CAS No. 115-29-7) in Annex III to the Rotterdam Convention

In reviewing the notifications of final regulatory action by Benin and New Zealand to ban endosulfan as a pesticide, together with the supporting documentation provided by those parties, the Committee was able to confirm that those actions had been taken to protect human health and the environment. The notifications from those parties were found to meet the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.

The notification and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.7/6, and UNEP/FAO/RC/CRC.7/6/Add.1–3.

As the notification from Benin was almost identical to the notifications from the Sahelian States, which had been considered to fulfil the information requirements of Annex I and the criteria of Annex II by the Committee at its fifth meeting, the corresponding rationale was also taken into consideration (UNEP/FAO/RC/CRC.5/16, annex II).

Benin

1. Scope of the notified regulatory action

The final regulatory action to ban the import, distribution and utilization of all formulations containing endosulfan in Benin was taken for the category "pesticide" to protect human health and the environment. Before the ban, endosulfan was used in Benin as an insecticide and/or acaricide in cotton. The National Committee for Certification and Testing (Le Comité National d'Agrément et de Contrôle, CNAC), the body in charge of pesticides registration in Benin, considered the risk of using endosulfan in Benin to be unacceptable. The decision to ban endosulfan was proposed by CNAC. The corresponding regulatory action was taken by inter-ministerial decree No. 447/MAEP/MEPN/MC/DC/SGM/SA of 5 November 2009 and took effect on that date.

2. Criterion Annex II (a)

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

The final regulatory action of Benin was to ban all use, import and sales of endosulfan by 5 November 2009. The action was taken to protect human health and the environment. The action was based on a risk evaluation taking into account local exposure conditions for pesticide operators and of the aquatic environment. It was found that endosulfan posed an unacceptable risk to operators, to bystanders (families who had their habitations in or near cotton fields) and to aquatic ecosystems (fish and certain aquatic invertebrates in surface water). The notification and supporting documentation describe the specific risks.

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;

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

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

The risk evaluation performed by Benin included assessments of the hazards to human health (high acute toxicity) and human exposure (occupational exposure) that were performed by Australia and the United States of America involving comparable use patterns and took into account the

prevailing conditions in Benin (use rates, application techniques with even higher concentration of the spray solution than in Australia and the United States, farmers' lack of training, little or no use of personal protective equipment owing to lack of financial means and a hot climate rendering use of personal protective equipment impossible).

In Benin, endosulfan is used at dose rates between 300 and 750 g a.i./ha, generally twice during the cotton-growing season. The product is applied with handheld sprayers (rotary disk sprayers or sometimes pneumatic backpack sprayers) by farmers themselves, generally without adequate protection. Endosulfan is sprayed in very low volumes, at about 10 litres of diluted product per ha, using preferably rotary disk sprayers. These spray volumes are considerably more concentrated than those used in Australia or the United States. generally use little if any personal protective equipment, because of limited financial resources or because the climate is too hot to wear it. The use of personal protective equipment as required in Australia or the United States can at present not be guaranteed in Benin. Furthermore, the level of training of farmers in Benin in judicious pesticide use is much more limited than in Australia or the United States. Consequently, the occupational risk of using endosulfan in cotton in Benin is undoubtedly much higher than in Australia or the United States. The presence of habitations within the cotton fields increases the risk of exposure to bystanders. In conclusion, the poisoning risk of users under local conditions is considered to be unacceptable (UNEP/FAO/RC/CRC.7/6, annex to section 2.4.2.1 of the notification).

The risk evaluation also contains an assessment of hazards to aquatic organisms (high toxicity to fish and invertebrates) and exposure in surface water. Two argumentation lines were presented. First, a pesticide risk evaluation for surface water carried out in Burkina Faso was reported and documented. Burkina Faso is a country neighbouring Benin with similar environmental conditions. This evaluation used an Australian computer model (PIRI) and land-use data including application rates in Benin (which are identical to application rates in the Sahelian countries) that was applied to 14 pesticides that were used on cotton in the Sahel. Five exposure scenarios of surface water were evaluated, including buffer zones and rain events. The result of the evaluation was that endosulfan was the only substance which posed a high or very high risk to aquatic ecosystems under all five scenarios, even taking into account buffer zones of up to 1,000 m.

In the second approach, assessments performed by Australia and the United States involving comparable-use patterns that were based on recognized scientific methods and principles were taken into account by Benin. The Australian and United States authorities had concluded that the risk to aquatic organisms was acceptable only if mitigation measures such as large vegetated and general buffer zones were respected. In Australia, no endosulfan applications may take place if heavy rains or storms are forecast within two days or under hot weather conditions. In the United States, endosulfan is not authorized for the use on cotton in states in which surface water bodies are abundant.

Taking into account the results of these two approaches and given the prevailing conditions in the cotton-growing areas of Benin, where surface water is abundant and treatments take place in the rainy season, which is characterized by rainstorms that are heavy and difficult to predict, it was virtually impossible to guarantee that risk reduction measures such as those required in Australia or the United States could be applied in Benin.

In conclusion, CNAC considered the risk to aquatic ecosystems of using endosulfan in Benin to be unacceptable (UNEP/FAO/RC/CRC.7/6, annex to section 2.4.2.2 of the notification).

The Chemical Review Committee established that the final regulatory action had been taken on the basis of a risk evaluation and that the evaluation had been based on reviews of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognized methods and that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures. Data were generated from internationally recognized sources such as the United States Environmental Protection Agency and the Australian National Registration Authority for Agricultural and Veterinary Chemicals reviews of endosulfan. The review process took into account existing use patterns and environmental conditions in Benin. Overall, the available documents showed that the final regulatory action had been based on a chemical-specific risk evaluation, involving prevailing conditions of exposure within Benin.

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;

The Committee noted that, as the regulatory action in Benin was to ban all use, import and sales of endosulfan as a pesticide, and that there was no indication of any industrial uses of endosulfan in Benin, a significant decrease (to zero) in the quantity of endosulfan used was to be expected.

(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;

As a consequence of the expected decrease in the quantity of endosulfan used, there would be a significantly reduced risk of human and environmental exposure to the toxic effects of endosulfan for all uses.

(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;

The Committee also noted that the considerations underlying the final regulatory action were not of limited applicability since concerns similar to those identified in Benin could occur in other countries, in particular developing countries.

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

On the basis of information provided to the Committee in document UNEP/FAO/RC/CRC.7/INF/3, there was evidence of ongoing international trade in endosulfan.

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.

There was no indication in the notification from Benin that concerns about intentional misuse were the reason for the regulatory action. Instead, the final regulatory action from Benin was based on concerns for human health and for the environment resulting from registered agricultural use of endosulfan.

New Zealand

1. Scope of the notified regulatory action

The notified regulatory action relates to endosulfan and its pesticidal use as an insecticide on certain vegetable, citrus and berry fruit crops, on ornamentals and for earthworm control on turf on golf courses, sports fields, airports, etc. No industrial uses were reported. The decision revoked all existing approvals for the import, manufacture or use of endosulfan and endosulfan products (complete ban).

The revocation of approvals followed a reassessment carried out under the provisions of section 63 of the Hazardous Substances and New Organisms Act 1996, which included a determination that the environmental and human health risks associated with the use of the products outweighed the benefits obtained from its use (UNEP/FAO/RC/CRC.7/6, section 2.2.1 of the notification). The risk evaluation undertaken was based on New-Zealand-specific data on human health and environmental exposure.

2. Criterion Annex II (a)

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

The Chemical Review Committee confirmed that the notification from New Zealand indicated that the final regulatory action was taken to protect human health and the environment. On 15 December 2008, the Environmental Risk Management Authority of New Zealand, under the Hazardous Substances and New Organisms Act 1996, announced the revocation of all approvals for the import, manufacture or use of endosulfan and endosulfan products. This revocation of approvals followed a reassessment carried out under the provisions of section 63 of the Hazardous Substances and New Organisms Act, which included a determination that the environmental and human health risks associated with the use of the products outweighed the benefits obtained from its use.

Unacceptable risks were identified to operators for turf and citrus applications, as well as for bystanders and residents from air-blast applications in citrus, as well as for aquatic organisms.

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;

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

Reference 2 of the notification (UNEP/FAO/RC/CRC.7/6/Add.1: Application for reassessment of a hazardous substance under section 63 of the Hazardous Substances and New Organisms Act 1996: Endosulfan and formulations containing endosulfan (ERMA, June 2008)) contains an extensive list of more than 100 references. All references are cited in the text and a bibliography is added. Most of these references are publications in international, peer-reviewed scientific journals and books. In addition, data from internationally recognized scientific sources such as the World Health Organization Intergovernmental Programme for Chemical Safety was used. Most of the hazard data are from international sources which had been screened for relevance to, among others, scientific rigour. (UNEP/FAO/RC/CRC.7/6/Add.1, Ref. 2, App. A, p. 161). The review results were documented in summary tables. Any doubts as to data availability or quality for some items are mentioned in the review. Since New-Zealand-specific exposure data was not available, the evaluation largely used environmental and human health models to estimate exposure, as the use of models is common scientific practice in risk evaluations made by regulatory agencies worldwide.

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

The revocation of all approvals for the import, manufacture or use of endosulfan and endosulfan products was the consequence of a reassessment carried out under the provisions of section 63 of the Hazardous Substances and New Organisms Act, which included a determination that the environmental and human-health risks associated with the use of the products outweighed the benefits obtained from its use. This assessment considered New-Zealand-specific use patterns and application rates. The risk evaluation included an identification of the risks associated with the substance (= hazard evaluation), a determination of potentially significant effects (pathways for exposure, areas of impact), and the likelihood and magnitude of effect (= risk). Among the areas of impact were human health and safety, the environment, society and community.

Risks to operators for turf and citrus applications, even if full personal protective equipment (including respiratory protection) is used, were considered high by New Zealand. This is due to the application rates being higher than the current label uses for both turf and citrus and the different application method for citrus only. Risks to bystanders and residents from air-blast application to citrus were estimated as very high at current application rates and procedures (UNEP/FAO/RC/CRC.7/6/Add.1, Ref. 2, p. 11, 12, 136).

Since New-Zealand-specific exposure data was not available, the evaluation largely used environmental and human health models to estimate exposure. Although these models are conservative and may overestimate risks, they were used for the evaluation in accordance with the precautionary principle, consistent with the legal basis for dealing with uncertainty (UNEP/FAO/RC/CRC.7/6/Add.1, Ref. 2, executive summary, page 8 and section 4.1, pages 56 and following.).

New-Zealand-specific use patterns and application rates were also used to evaluate the risk to the environment. Preliminarily, data gaps identified by first-tier modelling using GENEEC2 (GENeric Estimated Environmental Concentration) had been publicly announced to collect additional available information. In the meantime, the notifier submitted higher-tier environmental modelling data based on application rates typical for New Zealand, but with United States soil and weather data (Pesticide Root Zone Model 3.12 (PRZM) and Exposure Analysis Modeling System EXAMS models) which resulted in the same level of risk. After that, a New-Zealand-developed higher tier model (SPASMO/CREAMS) was applied using New-Zealand-specific soil characteristics, a set of 34 years' climate data, crop types and application rates to estimate leaching and run-off and the resulting exposure of the environment. This modelling also showed a high risk for the environment. (UNEP/FAO/RC/CRC.6/7/Add.5: page 6 summarizes the process for the environmental exposure modelling; details can be found on pages 32 and 33 (pages 34 and 35 and Appendix A of the same document). The results of the refined assessment confirmed the initially determined high risk for aquatic organisms.

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;

The notification from New Zealand is based on the revocation of all existing approvals for the import, manufacture or use of endosulfan and endosulfan products (complete ban). Therefore, a significant decrease (to zero) of the quantity used and the number of uses can be expected.

(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;

As a consequence of the expected decrease in the quantity of endosulfan used, the actual risks to human health and/or the environment that result from endosulfan use can also be expected to decrease significantly.

(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;

New Zealand considers in its notification that much of the data and analysis used in its reassessment of endosulfan and products was taken from overseas sources. The risk evaluation identified the highest risks to human health for some uses that may have been unique to New Zealand (earthworm control on airfields and sports fields). Uses in citrus using air blast sprayers, however, may certainly be relevant in other countries and similar concerns to those identified in the reassessment are likely to be encountered in other countries in which endosulfan is used (UNEP/FAO/RC/CRC.7/6, section 2.5.2 of the notification).

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

New Zealand confirmed that endosulfan products had been imported and used at least until 2008. In addition, on the basis of information provided to the Committee in documents UNEP/FAO/RC/CRC.6/INF/2 and UNEP/FAO/RC/CRC.7/INF/3, there was evidence of ongoing international trade in endosulfan.

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.

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

The “off-label uses” mentioned in UNEP/FAO/RC/CRC.7/6/Add.1, Ref. 1 to the notification refer to uses on citrus and for earthworm control on turf at golf courses, bowling clubs, parks, sports grounds and airports. These uses were not assessed and approved when the product was registered under the Agricultural Compounds and Veterinary Medicines Act, but they were lawful (as long as the product as such was registered) provided that the user took precautions to avoid violating residue standards for crops for human consumption.

Section 3.5.10 of UNEP/FAO/RC/CRC.7/6/Add.1, Ref. 2 explains that “off-label use” refers to the use of a product in a manner and/or on a species of animal or plant that was not assessed and approved when the product was issued its official marketing approval. In New Zealand the official marketing approval is a product registration from the Approvals and Agricultural Compounds and Veterinary Medicines Group of the New Zealand Food Safety Authority or a prescribed exemption from registration. The uses recommended by the registrant of the product and approved by the Group are always provided on the label. Consequently, any use not listed on the label is called an off-label use. The Group (has) addressed the problem (of minor use/minor species) by providing a general registration condition that allows off-label uses, provided that the user takes proper precautions to avoid violating residue standards.

Considering the working paper on the application of criterion (d) of Annex II devised by the Committee and the amended legal opinion from the UNEP legal office (UNEP/FAO/RC/CRC.6/10), the “off-label use” mentioned in the notification from New Zealand does not fulfil the criterion for “intentional misuse”.

Recommendations

The Committee concluded that the notifications of final regulatory action by Benin and New Zealand met the information requirements of Annex I and the criteria set out in Annex II to the Convention. The Committee also concluded that the final regulatory actions taken by Benin and New Zealand provided a sufficient basis to merit including endosulfan in Annex III to the Convention in the pesticide category and that a decision guidance document should be drafted on the basis of the notifications.

B. 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,

Concluding that the notifications of final regulatory action relating to endosulfan from Benin and New Zealand 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 Rotterdam Convention as a pesticide.

C. Workplan for the intersessional drafting group on endosulfan

The drafting group comprises the following members:

Chair:	Ms. Mirijam Seng
Co-Chair:	Mr. Ignacio Figueroa Cornejo
Members:	Mr. Azhari Abdelbagi
	Mr. Sidi Ould Aloueimine
	Ms. Susan Collier
	Mr. Idris Goji
	Mr. Goné Droh Lanciné
	Mr. Jan Linders

The drafting group agreed to the following workplan:

Task	*Responsible persons*	*Deadline*
Draft an internal proposal on endosulfan based on the information available to the Chemical Review Committee (CRC)	Chair Co-chair	10 May 2011
Send draft internal proposal to drafting group members for comments via e-mail	Chair Co-chair	10 May 2011
Replies	All drafting group members	10 June 2011
Update internal proposal based on comments from drafting group members	Chair Co-chair	12 July 2011
Send updated internal proposal to CRC and observers for comments via e-mail	Chair Co-chair	12 July 2011
Replies	All CRC members and observers	27 August 2011
Draft a decision guidance document (DGD) based on the comments from CRC and observers	Chair Co-chair	22 September 2011
Send draft DGD to drafting group members for comments via e-mail	Chair Co-chair	22 September 2011
Replies	All drafting group members	18 October 2011
Finalize draft DGD based on the comments of the drafting group	Chair Co-chair	15 November 2011
Send draft DGD to Secretariat	Chair Co-chair	15 November 2011
Present draft DGD to CRC at its eighth meeting		March 2012

II. Perfluorooctane sulfonate, its salts and precursors

A. Rationale for the recommendation by the Chemical Review Committee to list Perfluorooctanesulphonic acid (PFOS) (CAS No. 1763-23-1), PFOS potassium salt (CAS No. 2795-39-3), PFOS ammonium salt (CAS No. 29081-56-9), PFOS lithium salt (CAS No. 29457-72-5), PFOS diethanolamine salt (CAS No. 70225-14-8), Perfluorooctane sulfonyl fluoride (PFOSF or POSF) (CAS No. 307-35-7) in Annex III to the Rotterdam Convention

In reviewing the notifications of final regulatory action by Canada, the European Union and Japan to ban perfluorooctane sulfonate (PFOS), its salts and precursor (CAS No 1763-23-1 (acid), 29081-56-9 (ammonium salt), 70225-14-8 (diethanolamine (DEA) salt), 2795-39-3 (potassium salt), 29457-72-5 (lithium salt), 307-35-7 (perfluorooctane sulfonyl fluoride or PFOSF)) as industrial chemicals, together with the supporting documentation provided by those parties, the Committee was able to confirm that those actions had been taken to protect the environment and human health. The notifications from those parties were found to meet the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.

The notification and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.7/7 and Add.1–3, UNEP/FAO/RC/CRC.7/INF/3 and UNEP/FAO/RC/CRC.7/INF/8.

Canada

1. Scope of the notified regulatory action

The final regulatory action was taken for PFOS and its salts and precursors in the category industrial chemicals to protect the environment. The manufacture, use, sale, offer for sale or import of PFOS, its salts and its precursor are prohibited with a limited number of exemptions (UNEP/FAO/RC/CRC.7/7).

The principal applications of PFOS and its salts and precursor before the regulatory action were as water, oil, soil and grease repellents for use on surface and paper-based applications such as rugs and carpets, fabric and upholstery and food packaging. PFOS, its salts and its precursor also had specialized chemical applications, for example as firefighting foams, hydraulic fluids, carpet spot removers, mining and oil well surfactants, fume suppressant and other specialized chemical formulations (UNEP/FAO/RC/CRC.7/7).

2. Criterion Annex II (a)

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

The regulatory action was taken to protect the environment. It was based on a risk evaluation taking into account ecological and environmental behaviour. PFOS has been detected in fish and in Canadian wildlife located far from known sources or manufacturing facilities, indicating that PFOS may undergo long-range transport. Unlike many other persistent organic pollutants, some perfluorinated substances, such as PFOS, are present as ions in environmental media and partition preferentially to proteins in the liver and blood rather than to lipids. Therefore, the bioaccumulation potential of PFOS may not be related to the typical mechanisms associated with bioaccumulation in lipid-rich tissues (UNEP/FAO/RC/CRC.7/7).

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;

The stated data upon which the hazard identification and risk assessment were based were generated according to recognized testing methods or taken from peer-reviewed literature (Canadian Environmental Protection Act, 1999 (CEPA 1999)).

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

The physicochemical data are published in scientific peer-reviewed literature, which shows that they are based on scientifically recognized testing methods. The environmental risk evaluation has been carried out by Canadian authorities according to recognized scientific principles and procedures (UNEP/FAO/RC/CRC.7/7).

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

The risk evaluation took into account the conditions prevailing in Canada since it was based on both hazard and exposure data collected in Canada on a variety of aquatic and terrestrial species, including aquatic plants, invertebrates and vertebrates and terrestrial invertebrates, birds and mammals (UNEP/FAO/RC/CRC.7/7).

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;

The regulatory action severely restricts the use of PFOS and its salts and precursors in Canada. It is estimated that the regulatory action would substantially reduce the release of PFOS into the environment (UNEP/FAO/RC/CRC.7/7 and UNEP/FAO/RC/CRC.7/INF/8).

(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;

The notification outlines that the prohibition on the manufacture, use, sale and import of PFOS and its salts and precursors works towards the objective of virtual elimination of the substance. Therefore the prohibition is expected significantly to reduce exposure, which will result in a reduction of risk for Canada's environment (UNEP/FAO/RC/CRC.7/7 and UNEP/FAO/RC/CRC.7/INF/8).

(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;

The considerations that led to the final regulatory action are applicable to other countries and regions and are not limited to specific circumstances, in particular since PFOS is a persistent organic pollutant and represents a risk to the environment worldwide.

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

Canada reported that the whole quantity used in 2006 had been imported. This indicates that there is still international trade (UNEP/FAO/RC/CRC.7/7).

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.

The notification does not mention any involvement of intentional misuse in the regulatory decision-making process (UNEP/FAO/RC/CRC.7/7).

European Union

1. Scope of the notified regulatory action

The major use of PFOS and its salts in consumer applications was to provide grease, oil and water resistance to materials such as carpets, leather/apparel, textiles/upholstery, paper and packaging and coatings, and in industrial and household cleaning products.

Industrial/professional use of PFOS in smaller volumes, which is continuing after the regulatory action, has been confirmed in the following sectors in the European Union: metal (chromium) plating, firefighting foams, photographic industry, semiconductor industry and aviation industry (UNEP/FAO/RC/CRC.7/7).

The use of perfluorooctonate sulfonates has been severely restricted by the regulatory action taken in the European Union. The placing on the market and the use of PFOS as a substance or in mixtures in concentrations equal to or higher than 0.005 per cent by weight is prohibited. Furthermore,

PFOS may not be placed on the market in semi-finished products or articles, or parts thereof, if the concentration of PFOS is equal to or higher than 0.1 per cent by weight. Firefighting foams placed on the market before 27 December 2006 are also allowed, until 27 June 2011, in order to limit emissions to those of existing stocks (UNEP/FAO/RC/CRC.7/7).

2. Criterion Annex II (a)

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

The regulatory action was taken to protect human health and the environment. The toxicity associated with oral route exposure was confirmed, as was the high persistency of PFOS. It bioconcentrates in fish and it has been detected in tissue of wild birds and fish, in surface water and sediment, wastewater treatment plant effluent, sewage sludge and landfill leachate. (UNEP/FAO/RC/CRC.7/7).

Data on the exposure revealed that levels of PFOS in the blood serum of workers were significantly higher than in the serum of the general population. In addition, levels of PFOS in the blood serum of populations living in the neighbourhood of industrial plants were found to be higher compared to the general population (UNEP/FAO/RC/CRC.7/7).

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;

The stated data upon which the hazard identification and risk assessment were based originate from recognized testing methods, peer-reviewed literature and peer-reviewed scientific reports (UNEP/FAO/RC/CRC.7/7/Add.2).

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

The data were reviewed in scientific reports and by scientific committees according to recognized scientific principles and procedures (UNEP/FAO/RC/CRC.7/7/Add.2).

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

The final regulatory action was based on an evaluation of the risks arising from the use of PFOS in the European Union. Data on the exposure of workers and of the general population were considered. In addition, levels of PFOS in the blood serum of populations living in the neighbourhood of industrial plants were compared with data from the general population. Furthermore, risks to fish, mammals, birds and bees were considered under the prevailing conditions in the European Union (UNEP/FAO/RC/CRC.7/7).

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;

The use of PFOS has been severely restricted in the European Union and it is therefore expected that the quantity used will significantly decrease (UNEP/FAO/RC/CRC.7/7).

(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;

As a result of the expected reduction of the quantity of PFOS used in the European Union it is expected that exposure of humans and the environment will decrease, which will lead to a significant reduction of risk for human health and the environment (UNEP/FAO/RC/CRC.7/7).

(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;

The considerations that led to the final regulatory action are not limited to a geographical area or to specific circumstances (UNEP/FAO/RC/CRC.7/7).

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

The Organization for Economic Cooperation and Development (OECD) report referenced in the notification showed that PFOS has been imported into OECD countries, which indicates that there is still international trade (UNEP/FAO/RC/CRC.7/7).

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.

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 (UNEP/FAO/RC/CRC.7/7).

Japan

1. Scope of the notified regulatory action

Prior to the regulatory action PFOS was used in metal plating, photo masks in semiconductors, etching agents, photo resists, firefighting foams and other applications. PFOSF was used as a precursor for the production of PFOS (UNEP/FAO/RC/CRC.7/7).

The final regulatory action taken by Japan prohibits all manufacture, import and uses of PFOS and PFOSF. The following uses remain allowed: etching agents for voltage filters or high-frequency compound semiconductors, photo resists for semiconductor production, photo films for industrial purposes and firefighting foams (UNEP/FAO/RC/CRC.7/7).

2. Criterion Annex II (a)

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

PFOS is persistent, highly bioaccumulative and chronically toxic to humans. PFOS fulfils the criteria for adverse effects. It has demonstrated toxicity for mammals in repeated dose studies at low concentrations, in addition to rat reproductive toxicity, with mortality of pups occurring shortly after birth (UNEP/FAO/RC/CRC.7/7/Add.3).

The Japanese Government designates chemical substances that are persistent and highly bioaccumulative and show chronic toxicity for humans as Class I Specified Chemical Substances to be banned under the Chemical Substances Control Law (CSCL). As a result of internal evaluation using the scientific data found in the risk profile prepared by the Persistent Organic Pollutants Review Committee of the Stockholm Convention on Persistent Organic Pollutants, the Japanese authorities concluded that the chemical met the criteria for designation as a Class I Specified Chemical Substance under CSCL. Class I Specified Chemical Substances are banned under CSCL to protect human health and the environment (UNEP/FAO/RC/CRC.7/7).

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;

The data were used under the Stockholm Convention and are considered to be scientifically sound, which means that they were generated according to scientifically recognized methods and that data reviews were performed and documented according to generally recognized scientific principles and procedures (UNEP/FAO/RC/CRC.7/INF/8). In addition the exposure data were generated in Japan according to scientifically recognized methods (UNEP/FAO/RC/CRC.7/7/Add.3).

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

The data were used under the Stockholm Convention and are considered to be scientifically sound, which means that they were generated according to scientifically recognized methods and that data reviews have been performed and documented according to generally recognized scientific principles and procedures (UNEP/FAO/RC/CRC.7/INF/8). In addition the exposure data were generated in Japan according to scientifically recognized methods (UNEP/FAO/RC/CRC.7/7/Add.3).

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

The notification and the supporting documentation provide sufficient evidence that the final regulatory action was based on a risk evaluation involving prevailing conditions in the notifying party (UNEP/FAO/CRC/7/7/Add.3).

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;

Since the manufacture, import and most uses have been prohibited, it can be expected that the regulatory action will lead to a significant decrease of the chemical used (UNEP/FAO/RC/CRC.7/7).

(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;

As a result of the significant reduction in the quantity of the chemical used it can be expected that exposure will be reduced, which will also lead to a reduction of risks to human health (UNEP/FAO/RC/CRC.7/7).

(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;

The considerations that led to the final regulatory action are not limited to a geographical area or to specific circumstances since they are linked to the inherent characteristics of PFOS and PFOSF (UNEP/FAO/RC/CRC.7/7).

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

The notification does not provide evidence of international trade. Evidence of international trade is, however, presented in document UNEP/FAO/RC/CRC.7/INF/3.

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.

The notification does not include any indication that intentional misuse was involved in the decision to adopt the final regulatory action (UNEP/FAO/RC/CRC.7/7).

Recommendations

The Committee concluded that the notifications of final regulatory action by Canada, the European Union and Japan met the information requirements of Annex I and the criteria set out in Annex II to the Convention. The Committee also concluded that the final regulatory actions taken by Canada, the European Union and Japan provided a sufficient basis to merit including PFOS, its salts and its precursor PFOSF in Annex III to the Rotterdam Convention in the industrial chemical category and that a decision guidance document should be drafted on the basis of the notifications.

B. Recommendation to the Conference of the Parties on the inclusion of perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride 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 final regulatory action relating to perfluorooctane sulfonate and its salts and precursors from Canada, the European Union and Japan 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:

Perfluorooctanesulphonic acid (PFOS) (CAS No. 1763-23-1)

PFOS potassium salt (CAS No. 2795-39-3)

PFOS ammonium salt (CAS No. 29081-56-9)

PFOS lithium salt (CAS No. 29457-72-5)

PFOS diethanolamine salt (CAS No. 70225-14-8)

Perfluorooctane sulfonyl fluoride (PFOSF or POSF) (CAS No. 307-35-7)

in Annex III to the Convention as industrial chemicals.

C. Workplan for the intersessional drafting group on perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride

The drafting group comprises the following members:

Chair: Ms. Hala Sultan Saif Al-Easa

Co-Chair: Mr. Jürgen Helbig

Members: Mr. Azhari Abdelbagi
Ms. Jacqueline Arroyo
Ms. Magdalena Balicka
Mr. Idris Goji
Mr. Masayuki Ikeda
Mr. Peter Opiyo
Ms. Mirijam Seng
Ms. Hang Tang

The drafting group agreed to the following workplan:

Tasks to be carried out	*Responsible persons*	*Deadlines*
Draft an internal proposal on perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) based on the information available to the Chemical Review Committee (CRC)	Chair Co-chair	10 May 2011
Send draft internal proposal to drafting group members for comments via e-mail	Chair Co-chair	10 May 2011
Replies	All drafting group members	4 June 2011
Update internal proposal based on comments from drafting group members	Chair Co-chair	12 July 2011
Send updated internal proposal to CRC and observers for comments via e-mail	Chair Co-chair	12 July 2011
Replies	All CRC members and observers	27 August 2011
Draft a decision guidance document (DGD) based on the comments from CRC and observers	Chair Co-chair	22 September 2011
Send draft DGD to drafting group members for comments via e-mail	Chair Co-chair	22 September 2011
Replies	All drafting group members	30 September 2011
Finalize draft DGD based on the comments of the drafting group	Chair Co-chair	15 October 2011
Send draft DGD to Secretariat	Chair Co-chair	15 October 2011
Present draft DGD to CRC at its eighth meeting		March 2012

III. Pentabromodiphenyl ether commercial mixtures

A. Rationale for the recommendation by the Chemical Review Committee to list tetrabromodiphenyl ether (tetraBDE) (CAS No. 40088-47-9, CAS No. 5436-43-1) and pentabromodiphenyl ether (pentaBDE) (CAS No. 32534-81-9, CAS No. 60348-60-9) as contained in pentabromodiphenyl ether commercial mixtures in Annex III to the Rotterdam Convention

Introduction

In reviewing the notifications of final regulatory action by Canada, the European Community and Norway to ban and/or severely restrict pentabromodiphenyl ether commercial mixtures as industrial chemicals, together with the supporting documentation provided by those parties, the Committee was able to confirm that those actions had been taken to protect the environment and human health. The notifications from those parties were found to meet the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.

The notification and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.7/8/Add.1–4 and UNEP/FAO/RC/CRC.7/INF/3.

Canada

1. Scope of the notified regulatory action

The notified regulatory action relates to pentabromodiphenyl ether commercial mixtures (pentaBDE) and their industrial use as flame retardants. The notification from Canada states that pentaBDE is predominantly a mixture of tetrabromodiphenyl ether (tetraBDE), pentabromodiphenyl ether (pentaBDE) and hexabromodiphenyl ether (hexaBDE) congeners. The final regulatory action by Canada for polybrominated diphenyl ethers (PBDE) covers pentaBDE.

The decision made was to ban the use, manufacture, sale, offer for sale and import of PBDE congeners that met the criteria for virtual elimination under the Canadian Environmental Protection Act 1999 (CEPA 1999). The decision does not apply to PBDE in pest control products, or to polymers, resins or other mixtures containing PBDE congeners for use in a laboratory for analysis, in scientific research or as laboratory analytical standards or those present as contaminants (Polybrominated Diphenyl Ethers Regulations (SOR/2008-218) under CEPA 1999.

The notification included the properties, identification and uses of PBDE mixtures and the social and economic effects of the final regulatory action. The final regulatory action was taken to protect the environment, based on a risk evaluation by Environment Canada (Ecological Screening Assessment Report on Polybrominated Diphenyl Ethers, as required under CEPA 1999). The notification was found to comply with the information requirements of Annex I.

2. Criterion Annex II (a)

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

The regulatory action was taken to protect the environment. Pentabromodiphenyl ether commercial mixtures have been used as flame retardants that slow the ignition and spread of fire of plastics, which are the primary end use for flame retardants as a result of the inherent flammability of many polymers. As such, PBDEs can be found in many items, including building and automobile materials, carpet underlay, furniture polyurethane foam and electronic equipment, and are released to the environment during the product's manufacture (UNEP/FAO/RC/CRC.7/8 and Add.1).

Environment Canada, under CEPA 1999, proceeded to implement a hazard and risk assessment on PBDEs. The result was published in June 2006 in the Ecological Screening Assessment Report, in which it was concluded that PBDEs were entering the environment in concentrations or under conditions that had or might have an immediate or long-term harmful effect on the environment or its biological diversity. Environment Canada's Ecological Screening Assessment Report indicated that the greatest potential risks from PBDEs in the Canadian environment were the secondary poisoning of wildlife from the consumption of prey containing elevated concentrations of PBDEs and effects on benthic organisms, which might result from elevated concentrations of certain PBDE congeners in sediments (UNEP/FAO/RC/CRC.7/8 and Add.1).

The notification describes the specific risks and outlines that the ban on the use of PBDEs significantly reduces the exposure of aquatic organisms and wildlife: therefore, the final regulatory action constitutes a preventative approach to ensure that pentabromodiphenyl ether mixtures are not reintroduced in Canada.

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;

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

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

Data relevant to the ecological screening assessment of PBDEs were identified in original literature, review documents and commercial and government databases and indices. In addition to retrieving the references from a literature database search, contacts were made with researchers, academics, industry and other government agencies to obtain relevant information on PBDEs (UNEP/FAO/RC/CRC.7/8 and Add.1).

The Canadian regulations on PBDE assure the quality of data gathered based on the use of an accredited laboratory under the International Organization for Standardization (standard ISO/IEC 17025: 2005), with all data acquired under these conditions generated according to scientifically recognized methods. The notification stated that the ecological screening assessment examined various supporting information that presented the most critical studies and lines of evidence supporting the conclusions.

The data and the assessment of the ecological screening assessment report were generated according to scientifically recognized methods, and the data reviews, as reflected in the reports, were performed according to generally recognized scientific principles and procedures.

The final regulatory action was taken as a consequence of a risk evaluation. This evaluation was based on screening assessments of substances that present or may present a risk to the environment or to human health and examined supporting information and developed conclusions based on a weight-of-evidence approach as required under section 76.1 of CEPA 1999.

The final regulatory action was based on the ecological screening assessment in Canada. The notification indicates that seven PBDEs were identified in a screening assessment under CEPA 1999 on the basis of their potential persistence and/or bioaccumulation in the environment and inherent toxicity to organisms. In addition, an industry survey on PBDEs was conducted in 2000 under CEPA 1999. The industry survey collected data on the Canadian manufacture, import, uses and releases of PBDEs (Environment Canada 2003) and also provided toxicological studies under section 70 of CEPA 1999.

In Environment Canada's Ecological Screening Assessment Report, risk quotients were used to identify potential for ecological effects and potential risks, such as persistence, bioaccumulation, chemical transformation and trends in ambient concentrations. The report indicates that the greatest potential risks from PBDEs, including tetra-BDE and penta-BDE, in the Canadian environment are the secondary poisoning of wildlife from the consumption of prey containing elevated concentrations of tetra-BDE and penta-BDE and the deleterious effects on benthic organisms, which may result from elevated concentrations of certain congeners in sediments that meet the criteria for persistence and bioaccumulation. The screening assessment also concluded that their presence in the environment was primarily the result of human activity (that is, releases from product manufacturing and processing, throughout the product life cycle).

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;

All uses as industrial chemicals are banned, as stated in document UNEP/FAO/RC/CRC.7/8 and Add.1. The regulatory action covers the manufacture, use, sale, offer for sale and import of PBDEs. This is expected to result in a significant reduction of the quantity of chemical used and 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;

The significant reduction of the quantity of chemical used is expected to cause an actual reduction of the risk to the environment, especially wildlife and benthic organisms.

(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;

The considerations that led to the regulatory action are generally expected to be applicable to other countries and regions.

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

There is ongoing international trade in the chemical (UNEP/FAO/RC/CRC.7/INF/3) and the chemical is subject to transboundary movement (UNEP/FAO/RC/CRC.7/8 and Add.1).

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.

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 deleterious effects on benthic organisms was the main reason for the final regulatory action.

European Community

1. Scope of the notified regulatory action

The notification from the European Community states that pentabromodiphenyl ether commercial mixture (pentaBDE) is predominantly a mixture of tetrabromodiphenyl ether (tetraBDE), pentabromodiphenyl ether (pentaBDE) and hexabromodiphenyl ether (hexaBDE) congeners. PentaBDE was used in the European Community as a flame retardant additive for polyurethane (principally flexible foam for use in car seats, furniture and packaging) at typical loading of 10 per cent w/w. Several other uses have been reported in the literature (e.g., in textiles and electronics) but it is not known whether these currently occur in the European Community. The decision was to severely restrict previous uses and to prohibit all applications of pentaBDE as a substance and articles containing the substance in concentrations higher than 0.1 per cent by mass. The European Community member States were to apply the laws, regulations and administrative provisions necessary to comply with the Directive from 15 August 2004. Concentrations lower than 0.1 per cent remain allowed thereafter (UNEP/FAO/RC/CRC.7/8 and Add.2). The notification was found to comply with the information requirements of Annex I.

2. Criterion Annex II (a)

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

The regulatory action was taken to protect both human health and the environment as indicated in UNEP/FAO/RC/CRC.7/8 and Add.2. PentaBDE has been used as a flame retardant additive. The decision was based on a risk assessment covering emissions and consequent environmental impact and human exposures at each stage of the life cycle of the chemical, from production through processing, formulation and use, to recycling and disposal. Protection goals for the environment included the atmosphere, aquatic organisms, sediment-dwelling organisms, soil-dwelling organisms, microorganisms in wastewater treatment plants, and mammals and birds exposed via accumulation through the food chain. Exposure of humans from all relevant sources was considered, including exposure from consumer products, through air, food and drinking water (humans exposed via environment) and exposure at the workplace. It was concluded that, although available data were

insufficient in some respects, there were unacceptable risks to human health and the environment that necessitated regulatory action. The risks to workers were that the estimated body burden of pentaBDE arising from occupational exposure, mainly via dermal contact, was approximately four times greater than the no observable adverse effect level derived from the rodent study (liver effects). Unacceptable risks to humans were identified, including humans exposed through the environment and infants exposed through breast milk. Concerns for the aquatic and terrestrial environment were also identified from the production and/or use of polyurethane foams. This information is provided in UNEP/FAO/RC/CRC.7/8 and Add.2.

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;

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

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

The final regulatory action was taken as a consequence of a risk evaluation performed by one member State of the European Community, in the framework of Regulation (EEC) No 793/93. The evaluation was based on the review of scientific data generated for pentaBDE derivatives in the context of the conditions prevailing in the European Community (including current practices related to the life cycle of the substance). The results were then subject to peer review within the European Community by experts from member States and the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment, an independent expert body, was obtained. Data reviews were performed and documented according to scientifically recognized principles and procedures (UNEP/FAO/RC/CRC.7/8 and Add.2).

The notification from the European Community (UNEP/FAO/RC/CRC.7/8 and Add.2) indicated that the final regulatory action was based on a risk evaluation under conditions prevailing in the European Community.

Based on this evaluation, concerns were identified with regard to unacceptable risks to human health and the environment that necessitated regulatory action. The risks to workers were that the estimated body burden of pentaBDE arising from occupational exposure, mainly via dermal contact, was approximately four times greater than the no observable adverse effect level derived from the rodent study (liver effects). Other unacceptable risks were identified, including risks for humans exposed through the environment and infants exposed through breast milk. Concerns for the aquatic and terrestrial environment were also identified from production and/or use of polyurethane foams.

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;

PentaBDE has been used in the European Community as a flame retardant additive for polyurethane (principally flexible foam for use in car seats, furniture and packaging) at typical loading of 10 per cent w/w. The decision prohibited all applications of pentaBDE where concentrations exceeded 0.1 per cent by mass, from 15 August 2004. Concentrations lower than 0.1 per cent remained allowed thereafter. Since the use of the chemical was severely restricted it can be assumed that this regulatory action will result in a significant reduction of quantities of the chemical and 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;

The chemical was severely restricted, which will result in a significant reduction of risk to human health and the environment from exposure to pentaBDE at the local and regional levels within the European Community.

(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;

Similar health and environmental concerns could arise in other countries in which the substance is used, particularly in developing countries.

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

Evidence of ongoing international trade was made available to the Committee in document UNEP/FAO/RC/CRC.7/INF/3.

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.

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 risks to workers from occupational exposure, in addition to the aquatic and terrestrial environment, were identified in connection with the production and/or use of polyurethane foams and were the main reasons for the final regulatory action.

Norway

1. Scope of the notified regulatory action

The final regulatory action relates to pentabromodiphenyl ether (pentaBDE) commercial mixtures and their industrial use. Pentabromodiphenyl ether commercial mixtures have been used in Norway as a flame retardant in electrical and electronic equipment, polyurethane foam, textiles and means of transportation. The final regulatory action bans all uses of these chemicals at concentrations equal to or greater than 0.1 per cent by weight (UNEP/FAO/RC/CRC.7/8 and Add.4). The notification was found to comply with the information requirements of Annex I.

2. Criterion Annex II (a)

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

The regulatory action was taken to protect both human health and the environment, as indicated in UNEP/FAO/RC/CRC.7/8 and Add.4. Norway's risk evaluation of pentaBDE was based on risk assessments undertaken by the European Community and a report by the Nordic Council of Ministers (UNEP/FAO/RC/CRC.7/8 and Add.4), in addition to scientific data that were considered particularly relevant to Norwegian conditions, as given in documents UNEP/FAO/RC/CRC.7/8 and Add.4. The national evaluation took into account production, use, environmental fate and behaviour, exposure and toxicity to humans and wildlife. Social and economic factors were also considered. All data evaluated indicated that pentaBDE was an important contaminant of the Norwegian environment and of sufficient concern for human health and wildlife to warrant a national ban.

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;

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

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

The evaluation was based on the review of scientific data generated for pentaBDE in the context of the conditions prevailing in Norway. The national evaluation took into account production, use, environmental fate and behaviour, exposure and toxicity to humans and wildlife. Data reviews were performed and documented according to generally recognized scientific principles and procedures.

The notification from Norway indicated that the final regulatory action was based on a risk evaluation under conditions prevailing in Norway.

In Norway, congeners of pentaBDE have been detected in a variety of biotic samples. They have been detected in, for example, human samples and in cod liver and mussels. High levels of pentaBDEs were detected in fish from the Norwegian lake Mjøsa. Further studies detected significant amounts of pentaBDEs in sediments and fish at various locations in Norway.

Based on this evaluation, there are concerns for serious damage to human health from prolonged exposure and concerns for breastfed babies. PentaBDE was found in most compartments of the Norwegian environment, mainly in fish, which is regarded as an important source of exposure to humans in Norway. This was considered alarming, especially for populations that depend on fish for their diet (e.g., indigenous people).

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;

PentaBDE has been used in Norway as a flame retardant in electrical and electronic equipment, polyurethane foam, textiles and means of transportation. The final regulatory action bans all uses of pentaBDE at concentrations equal to or greater than 0.1 per cent by weight. This will cause 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;

The banning of the chemical will result in a significant reduction of risk to 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;

The notification gave no indication of any geographical limitations to the final regulatory action. Similar concerns to those identified are likely to be encountered in other countries where the substance is used.

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

Since concentrations lower than 0.1 per cent remain allowed, this can be considered as evidence of ongoing international trade.

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.

There was no indication in the notification that concern about intentional misuse was the reason for the final regulatory action. Instead, concerns for human health and wildlife are mentioned as the main reasons for the action.

Recommendations

The Committee concluded that the notifications of final regulatory action by Canada, the European Community and Norway met the information requirements of Annex I and the criteria set out in Annex II to the Convention. The Committee also concluded that the final regulatory actions taken by Canada, the European Community and Norway provided a sufficient basis to merit including pentaBDE commercial mixtures in Annex III to the Rotterdam Convention in the industrial chemical category, and that a decision guidance document should be drafted on the basis of the notifications.

B. Recommendation to the Conference of the Parties on the inclusion of tetrabromodiphenyl ether and pentabromodiphenyl ether contained in pentabromodiphenyl ether commercial mixtures 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 final regulatory action relating to pentabromodiphenyl ether commercial mixtures from Canada, the European Community 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 tetrabromodiphenyl ether (CAS No. 40088-47-9, CAS No. 5436-43-1[3]) and pentabromodiphenyl ether (CAS No. 32534-81-9, CAS No. 60348-60-9[3]), which are components of pentabromodiphenyl ether commercial mixtures, in Annex III to the Convention as industrial chemicals.

C. Workplan for the intersessional drafting group on pentabromodiphenyl ether commercial mixtures

The drafting group comprises the following members:

Chair:	Ms. Jacqueline Arroyo
Co-Chair:	Mr. Azhari Abdelbagi
Members:	Mr. Jürgen Helbig
	Ms. Hala Al-Easa
	Ms. Magdalena Balicka
	Mr. Idris Goji
	Ms. Noluzuko Gwayi
	Mr. Masayuki Ikeda
	Mr. Muhammed Bashir Khan
	Mr. Jan Linders
	Mr. Peter Opiyo
	Ms. Mirijam Seng
	Ms. Hang Tang
	Mr. Ignacio Figueroa Cornejo

The drafting group agreed to the following workplan:

Tasks to be carried out	*Responsible persons*	*Deadlines*
Draft an internal proposal on pentabromodiphenyl ether commercial mixtures based on the information available to the Chemical Review Committee (CRC)	Chair Co-chair	10 May 2011
Send draft internal proposal to drafting group members for comments via e-mail	Chair Co-chair	10 May 2011
Replies	All drafting group members	4 June 2011
Update internal proposal based on comments from drafting group members	Chair Co-chair	12 July 2011
Send updated internal proposal to CRC and observers for comments via e-mail	Chair Co-chair	12 July 2011
Replies	All CRC members and observers	27 August 2011
Draft a decision guidance document (DGD) based on the comments from CRC and observers	Chair Co-chair	22 September 2011

3 CAS number from the Stockhom Convention listing.

Tasks to be carried out	*Responsible persons*	*Deadlines*
Send draft DGD to drafting group members for comments via e-mail	Chair Co-chair	22 September 2011
Replies	All drafting group members	30 September 2011
Finalize draft DGD based on the comments of the drafting group	Chair Co-chair	15 October 2011
Send draft DGD to Secretariat	Chair Co-chair	15 October 2011
Present draft DGD to CRC at its eighth meeting		March 2012

IV. Octabromodiphenyl ether commercial mixtures

A. Rationale for the recommendation by the Chemical Review Committee to list hexabromodiphenyl ether (hexaBDE)) (CAS No. 36483-60-0, CAS No. 68631-49-2, CAS No. 207122-15-4); heptabromodiphenyl ether (heptaBDE)) (CAS No. 68928-80-3, CAS No. 446255-22-7, CAS No. 207122-16-5); octabromodiphenyl ether (octaBDE)) (CAS No. 32536-52-0); nonabromodiphenyl ether (nonaBDE)) (CAS No. 63936-56-1); and decabromodiphenyl ether (decaBDE)) (CAS No. 1163-19-5)) contained in commercial mixtures of OctaBDE in Annex III to the Rotterdam Convention

Introduction

In reviewing the notifications of final regulatory action by Canada, the European Community and Norway to ban (Canada and Norway) and to severely restrict (European Community) the use of commercial mixtures of octaBDE congeners as industrial chemicals, together with the supporting documentation provided by those parties, the Committee confirmed that those actions had been taken to protect the environment and human health. The notifications from those parties were found to meet the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.

The notification and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.7/10 and Add.1–4, UNEP/FAO/RC/CRC.7/13, UNEP/FAO/RC/CRC.7/14, UNEP/FAO/RC/CRC.7/INF/3, UNEP/FAO/RC/CRC.7/INF/4 and UNEP/FAO/RC/CRC.7/INF/11.

Canada

1. Scope of the notified regulatory action

The final regulatory action was taken for the category “industrial chemicals” to protect the environment. The decision made was to ban the uses of octaBDE commercial mixtures in Canada (UNEP/FAO/RC/CRC.7/10 and Add.1) as flame retardants that slow down the ignition and spread of fire.

2. Criterion Annex II (a)

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

The notification sets out the final regulatory action, which is a ban to protect the environment, and was based on a risk evaluation. Polybrominated diphenyl ethers are a group of chemical flame retardants that slow the ignition and spread of fire. In general, plastics are the primary end use for flame retardants due to the inherent flammability of many polymers. As such, octaBDE commercial mixtures can be found in many items such as building and automobile materials, carpet underlay, furniture foam and electronic equipment.

OctaBDE commercial mixtures were predominantly used in Canada in acrylonitrile butadiene styrene to provide flame retardance for business-equipment housings (UNEP/FAO/RC/CRC.7/10).

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;

Data relevant to the ecological screening assessment of octaBDE commercial mixtures were identified by the Canadian Environment Protection Act (CEPA) 1999, in peer-reviewed literature and commercial and government databases and indices. An industry survey on octaBDE commercial mixtures was conducted for the year 2000 through a Canada Gazette notice issued pursuant to section 71 of CEPA 1999. This survey collected data on the Canadian manufacture, import, uses and releases of octaBDE commercial mixtures (Environment Canada 2003). Toxicological studies were also submitted by industry under section 70 of CEPA 1999 (section 2.4.2.2). Linkages with Stockholm Convention assessments are also made in the notification (UNEP/FAO/RC/CRC.7/10).

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

Canada undertook an ecological screening assessment and examined supporting information and developed conclusions on the risks of octaBDE commercial mixtures in the environment based on a weight-of-evidence approach as required under section 76.1 of CEPA 1999 (section 2.4.2.2 of the notification). The Canadian notification also includes evidence of information on octaBDE commercial mixtures from scientifically published documents (UNEP/FAO/RC/CRC.7/10).

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

The risk evaluation took into account exposure based on measured total (dissolved and particulate phases) octaBDE commercial mixtures mono- to hepta-BDE congeners in concentrations of approximately 6 pg/L in Lake Ontario and 158 pg/L in Lake Michigan waters (section 3.2.3 of the notification) to warrant virtual elimination from the environment in Canada. OctaBDE commercial mixtures have been detected in sediment and soil samples collected in North America, and high concentrations have been measured in sewage sludge. A study carried out in 2004 determined levels of octaBDE commercial mixtures in sediments from Lake Ontario. The total octaBDE commercial mixtures measured in sediment samples taken from 14 tributary sites ranged from approximately 12 to 430 µg/kg dw (section 3.2.3 of the notification).

The risk evaluation took into account these exposure data and the ecotoxicological endpoints for octaBDE commercial mixtures and the result was an unacceptable risk to aquatic organisms such as fish, molluscs and other invertebrates.

The assessment by the Canadian authorities in relation to the environment carried out in the context of the prevailing conditions in Canada resulted in the conclusion that octaBDE commercial mixtures were entering the environment in quantities or concentrations or under conditions that had or might have an immediate or long-term harmful effect on the environment or its biological diversity. The screening assessment also concluded that their presence in the environment resulted primarily from human activity (i.e., releases from product manufacturing and processing, and throughout the product life cycle). As a result, congeners of octaBDE commercial mixtures meet the conditions for virtual elimination, as set out in subsection 77(3) of CEPA 1999 (section 2.4.2.2 of the notification).

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;

The final regulatory action prohibited the manufacture, use, sale, offer for sale or importation of octaBDE commercial mixtures as flame retardants, which was the main use of octaBDE commercial mixtures. It therefore led to a significant decrease in the quantity of octaBDE commercial mixtures in use. The final regulatory action does not apply to any octaBDE commercial mixture that is present as a contaminant in a chemical feedstock used in a process from which it is not released, provided that the octaBDE commercial mixture is destroyed or completely converted in that process to a substance that is not an octaBDE commercial mixture (UNEP/FAO/RC/CRC.7/10).

(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;

Since the regulatory action is a ban, the source of octaBDE commercial mixtures to the environment will be removed, which will lead to a significant reduction of risk to the environment. Although persistence in the environment at some locations will cause elevated levels to be maintained

for some time, removing this source of input will allow the gradual elimination of octaBDE commercial mixtures from the environment (UNEP/FAO/RC/CRC.7/10).

(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;

OctaBDE commercial mixtures could pose a risk to the environment wherever octaBDE commercial mixtures are used, particularly in developing countries, meaning that the relevance of the final regulatory action is not limited to Canada.

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

Evidence of ongoing international trade was made available to the Committee through the notifications, which show various quantities of octaBDE commercial mixtures being produced, imported, or used (in the case of the submission of the European Community) for various years. The focused summary provided by Norway also gives useful information on export, import and uses of this chemical in Norway.

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.

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

European Community

1. Scope of the notified regulatory action

The notified regulatory action relates to octaBDE commercial mixtures and their industrial use as a flame retardant that slows the ignition and spread of fire. The decision made was to severely restrict the use of octaBDE commercial mixtures in the European Community to protect human health and the environment (UNEP/FAO/RC/CRC.7/10 and UNEP/FAO/RC/CRC.7/10/Add.2).

2. Criterion Annex II (a)

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

The notification sets out the basis for the final regulatory action, which severely restricts the use of octaBDE commercial mixtures to protect human health and the environment and states that it was based on a risk or hazard evaluation (UNEP/FAO/RC/CRC.7/10).

OctaBDE commercial mixtures are used in the Community as flame retardants. These flame retardants are added to plastics and textiles to reduce flammability and improve fire safety. Further information provided by industry indicates that octaBDE commercial mixtures are primarily used in Europe in acrylonitrile-butadiene-styrene (ABS) polymers at 12–18 per cent weight loadings in the final product.

Other uses that have been reported for octaBDE commercial mixtures include nylon and low-density polyethylene, polycarbonate, phenol-formaldehyde resins and unsaturated polyethers and in adhesives and coatings (UNEP/FAO/RC/CRC.7/10).

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;

The evaluation was based on the review of scientific data generated for octaBDE commercial mixtures in the context of the conditions prevailing in the European Community (including current practices related to the life cycle of the substance) (UNEP/FAO/RC/CRC.7/10).

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

The documentation provided was evaluated and only data that were generated according to scientifically recognized methods were validated and used for the assessment. Data reviews were performed and documented according to generally recognized scientific principles and procedures (UNEP/FAO/RC/CRC.7/10).

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

A risk assessment was conducted covering emissions and consequent environmental impact and human exposures at each stage of the life cycle of the chemical, from production through processing, formulation and use to recycling and disposal. Protection goals for the environment included the atmosphere, aquatic organisms, sediment-dwelling organisms, soil-dwelling organisms, microorganisms in waste water treatment plants, and mammals and birds exposed via accumulation through the food chain. The exposure of humans from all relevant sources was considered, including exposures from consumer products, through air, food and drinking water and exposure at the workplace (UNEP/FAO/RC/CRC.7/10).

Two member States were designated to undertake the evaluation. The results were then subject to peer review during which the European Commission consulted experts in member States and obtained the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment, an independent expert body.

It was concluded that there were unacceptable risks to human health and the environment that necessitated regulatory action (UNEP/FAO/RC/CRC.7/10).

Information on evaluations regarding human exposure, worker health, breast and cow milk contamination, in addition to risks related to the environment and the resulting danger of secondary poisoning, particularly through earthworms, was provided (UNEP/FAO/RC/CRC.7/10). Of particular concern was secondary poisoning as a result of the hexaBDE component in octaBDE commercial mixtures (via earthworms) from use in polymer applications. A combination of uncertainties, particularly linked to the risk assessment approach at the time for secondary poisoning and debromination, warranted regulatory action (UNEP/FAO/RC/CRC.7/10).

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;

The final regulatory action prohibited the placing on the market and use of octaBDE commercial mixtures in concentrations higher than 0.1 per cent by mass (UNEP/FAO/RC/CRC.7/10). It will therefore lead to a significant decrease in the quantity of the chemical in 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;

It is expected that, since the regulatory action has restricted the source of octaBDE commercial mixtures to the environment, it will lead to a significant reduction of risk to human health and the environment from exposure to octaBDE commercial mixtures (UNEP/FAO/RC/CRC.7/10).

(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;

Similar health and environmental concerns could arise in other countries where the substance is used, particularly developing countries (UNEP/FAO/RC/CRC.7/10).

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

Evidence of ongoing international trade was made available to the Committee through the notifications, which show various quantities of octaBDE commercial mixtures being produced, imported, or used in various years (UNEP/FAO/RC/CRC.7/10). The focused summary provided by Norway also gives useful information on export, import and uses of this chemical in Norway.

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.

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

Norway

1. Scope of the notified regulatory action

The notified regulatory action relates to octaBDE commercial mixtures and the industrial use of the chemical as flame retardant in polymers (ABS), high-impact polystyrene (HIPS) and in electrical and electronic equipment. The decision made was to ban the uses of octaBDE commercial mixtures in Norway (UNEP/FAO/RC/CRC.7/10 and Add.4).

2. Criterion Annex II (a)

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

The notification sets out the basis for the final regulatory action, which is a ban on octaBDE commercial mixtures to protect human health and the environment, and states that it was based on a risk or hazard evaluation (UNEP/FAO/RC/CRC.7/10).

OctaBDE commercial mixtures were used in Norway as flame retardants in polymers (ABS), high-impact polystyrene (HIPS) and in electrical and electronic equipment (UNEP/FAO/RC/CRC.7/10).

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;

Norway made use of the European Union risk assessment report, in which data were generated according to scientifically recognized methods (UNEP/FAO/RC/CRC.7/10).

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

In a Norwegian study, investigation of 66 hobby fisherfolk showed clear associations between the concentrations of octaBDE commercial mixtures (BDE-153, BDE-154, BDE-138 and BDE-183) in serum and the subjects' age and intake of freshwater fish (UNEP/FAO/RC/CRC.7/10). The notification (section 2.4.2.2) further states that reviewed temporal trends of octaBDE commercial mixtures in eggs from three bird species, three locations and three sampling times (from 1983 to 2003) from northern Norway indicated that spatial differences were only observed for hexaBDE (BDE-153), and increases in the measured concentration from 1983 to 2003 were observed for hexaBDE (153 and 154) and heptaBDE (BDE-183). A detailed review conducted concluded that hexaBDE had much higher bioconcentration potential than the other components of octaBDE commercial mixtures and so was likely to have a higher potential to have adverse effects on organisms in the environment (UNEP/FAO/RC/CRC.7/10).

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

The notification states that research was carried out in Norway to determine human and environmental exposure to octaBDE commercial mixtures. Certain components of octaBDE commercial mixtures have been found in samples from the Norwegian population, and congeners of octaBDE have also been found in polar cod, ringed seals and mussels (UNEP/FAO/RC/CRC.7/10). The notification and the supporting documentation conclude that the final regulatory action was taken to protect human health and the environment and aims to reduce the risks identified based on assessments linked to local exposure (UNEP/FAO/RC/CRC.7/10).

In Norway, congeners of octaBDE commercial mixtures have been found in a variety of samples. They have been detected in human samples (section 2.4.2.1 of the notification) and in polar cod, ringed seals and mussels. In a study from Svalbard, congeners of octaBDE commercial mixtures were found to bioaccumulate in zooplankton, polar cod and ringed seals. Evidence was also found in the study that hexaBDE (BDE-153) biomagnified in the Arctic food chain (ringed seal to polar bear).

OctaBDE commercial mixtures are classified as "toxic" as a result of their effects on human health, with the risk phrases "may cause harm to unborn child", and "possible risk of impaired fertility". Studies and assessments provide evidence that octaBDE commercial mixtures may cause adverse effects, such as effects on reproductive organs and development. The effects of repeated exposure to octaBDE commercial mixtures consistently indicate that the liver is the key target organ,

and liver effects have been observed in animal studies. It is assumed that in humans components of octaBDE commercial mixtures bioaccumulate in adipose tissue.

The notification states that the final regulatory action was based on a risk or hazard evaluation. According to data from the notification, congeners of octaBDE commercial mixtures resist degradation and thus have the potential to persist in the environment for a long time. These congeners have the potential to bioaccumulate and there is monitoring evidence of biomagnification. OctaBDE commercial mixtures have shown potential for long-range environmental transport. The analysis of chemical properties of octaBDE commercial mixtures appears to support this conclusion, as the Henry's law constant for these chemicals is very similar to those of acknowledged persistent organic pollutants. It is therefore expected that octaBDE commercial mixtures are subject to long-range environmental transport.

The notification also states that available monitoring data indicate that some heptaBDEs, in addition to hexaBDEs, have recently been found in organisms in the environment. This shows that uptake of some of the main components of the octaBDE commercial mixtures is occurring in the environment.

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;

The final regulatory action is a ban (UNEP/FAO/RC/CRC.7/10), and therefore has led to a significant decrease in the quantity of the chemical in 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;

It is expected that, since the regulatory action is a ban, the source of octaBDE commercial mixtures to the environment will be removed, leading to a significant reduction of risk to human health and the environment (UNEP/FAO/RC/CRC.7/10).

(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;

Similar concerns to those identified are likely to be encountered in other countries where the substance is used (UNEP/FAO/RC/CRC.7/10).

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

Evidence of ongoing international trade was made available to the Committee through the notifications, which show various quantities of octaBDE commercial mixtures being produced, imported, or used (in the case of the submission by the European Community) for various years. The focused summary provided by Norway also gives useful information on export, import and uses of octaBDE in Norway.

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.

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

Recommendations

The Committee concluded that the notifications of final regulatory action by Canada, the European Community and Norway met the information requirements of Annex I and the criteria set out in Annex II to the Rotterdam Convention. The Committee also concluded that the final regulatory actions taken by Canada, the European Community and Norway provided a sufficient basis to merit including octaBDE commercial mixtures in Annex III to the Rotterdam Convention in the industrial chemicals category and that a decision guidance document should be drafted on the basis of the notifications.

B. Recommendation to the Conference of the Parties on the inclusion of octabromodiphenyl ether commercial mixtures 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 final regulatory action relating to octabromodiphenyl ether commercial mixtures from Canada, the European Community 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 hexabromodiphenyl ether (CAS No. 36483-60-0), heptabromodiphenyl ether (CAS No. 68928-80-3), octabromodiphenyl ether (CAS No. 32536-52-0), nonabromodiphenyl ether (CAS No. 63936-56-1) and decabromodiphenyl ether (CAS No. 1163-19-5), which are components of octabromodiphenyl ether commercial mixtures, in Annex III to the Convention as industrial chemicals.

C. Workplan for the intersessional drafting group on octabromodiphenyl ether commercial mixtures

The drafting group comprises the following members:

Chair:	Mr. Jan Linders
Co-Chair:	Mr. Peter Opiyo
Members:	Mr. Jürgen Helbig
	Mr. Azhari Abdelbagi
	Ms. Jacqueline Arroyo
	Mr. Idris Goji
	Ms. Noluzuko Gwayi
	Mr. Peter Opiyo
	Mr. Muhammed Bashir Khan
	Mr. Masayuki Ikeda
	Ms. Mirijam Seng
	Ms. Hala Al-Easa
	Ms. Magdalena Balicka
	Ms. Hang Tang

The drafting group agreed to the following workplan:

Tasks to be carried out	*Responsible persons*	*Deadlines*
Draft an internal proposal on octabromodiphenyl ether commercial mixtures based on the information available to the Chemical Review Committee (CRC)	Chair Co-chair	10 May 2011
Send draft internal proposal to drafting group members for comments via e-mail	Chair Co-chair	10 May 2011
Replies	All drafting group members	4 June 2011
Update internal proposal based on comments from drafting group members	Chair Co-chair	12 July 2011

Tasks to be carried out	*Responsible persons*	*Deadlines*
Send updated internal proposal to CRC and observers for comments via e-mail	Chair Co-chair	12 July 2011
Replies	All CRC members and observers	27 August 2011
Draft a decision guidance document (DGD) based on the comments from CRC and observers	Chair Co-chair	22 September 2011
Send draft DGD to drafting group members for comments via e-mail	Chair Co-chair	22 September 2011
Replies	All drafting group members	30 September 2011
Finalize draft DGD based on the comments of the drafting group	Chair Co-chair	15 October 2011
Send draft DGD to Secretariat	Chair Co-chair	15 October 2011
Present draft DGD to CRC at its eighth meeting		March 2012

Annex III

Rationale for the chemical for which only one notification met the criteria of Annex II: rationale for the conclusion that the notification for pentachlorobenzene (QCB or PeCB) (CAS No. 608-93-5) submitted by Canada meets the criteria of Annex II to the Rotterdam Convention

In reviewing the notification of final regulatory action by Canada to ban pentachlorobenzene as an industrial chemical, together with the supporting documentation provided by that party, the Committee was able to confirm that that action had been taken to protect the environment. The notification from that party was found to meet the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.

The notification and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.7/9, and Add.1 and Add.2.

Canada

1. Scope of the notified regulatory action

The notified regulatory action relates to pentachlorobenzene and its use as an industrial chemical. The decision made was to severely restrict the use of pentachlorobenzene. The regulatory action prohibits the manufacture, use, sale, offer for sale or import of pentachlorobenzene, with the exception of any use of pentachlorobenzene with any chlorobiphenyls that have the molecular formula $C_{12}H_{10-n}Cl_n$ in which "n" is greater than 2.

The Prohibition of Certain Toxic Substances Regulations, 2005 (SOR/2005-41), as amended in 2006 (SOR/2006-279), prohibit the manufacture, use, sale and offer for sale of toxic substances listed in schedules 1 and 2 to the regulations. Pentachlorobenzene is found in schedule 2, which lists substances that are subject to prohibitions related to concentration or use.

The final regulatory action entered into force on 9 February 2007.

2. Criterion Annex II (a)

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

The regulatory action was taken to protect the environment.

Before the regulatory action, pentachlorobenzene had been used in Canada in combination with polychlorinated biphenyls (PCBs) in dielectric fluids and as a laboratory reagent (UNEP/FAO/RC/CRC.7/9/Add.1: document No. 2, p. 4). Pentachlorobenzene has been found in products as impurities and to be unintentionally produced through waste incineration, but the regulatory action does not apply to products that incidentally contain pentachlorobenzene. Pentachlorobenzene may be released into the environment through accidental spillage of industrial chemicals, including dielectric fluids containing PCBs, waste incineration, deposition after long-range transport, the use of pentachloronitrobenzene (the pesticide quintozene, according to UNEP/POPS/POPRC.6/INF/21) or through waste streams of a range of industrial production sites, especially chemical plants and iron and steel mills (UNEP/FAO/RC/CRC.7/9/Add.1: document No. 2, pp. 5–6; 3, pp. 4–5).

The notification describes the specific risks: Pentachlorobenzene is considered to be persistent in soil, sediment and in air, bioaccumulative and toxic according to the criteria stipulated in the Canadian Environmental Protection Act (CEPA) 1999. In addition, pentachlorobenzene is subject to atmospheric transport from its sources to remote areas.

Pentachlorobenzene was found to be entering the environment in quantities or concentrations or under conditions that had or might possibly have had an immediate or long-term harmful effect on the environment (especially on sediment-dwelling benthic organisms) or its biological diversity.

The Canadian federal Government therefore proposed that pentachlorobenzene should be subjected to the virtual elimination provisions of CEPA 1999. The prohibition on the manufacture, use, sale, offer for sale, or import of pentachlorobenzene (except for its use in liquid for transformer maintenance with some chlorobiphenyls as specified in section 2.3.2 of the notification) is expected to

work towards the objective of virtual elimination (document UNEP/FAO/RC/CRC.7/9: Canadian notification, chapters 2.3.2 and 2.4.2, UNEP/FAO/RC/CRC.7/9/Add.1: document No. 2, p. 4).

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;

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

Before the regulatory action, Canada undertook a first assessment of pentachlorobenzene (UNEP/FAO/RC/CRC.7/9/Add.1: document No. 2, published in 1993) to clarify whether pentachlorobenzene was entering the Canadian environment in quantities or under conditions that might be harmful to the environment or constitute a danger for human health and thus met the definition of "toxic" under paragraph 11 (a) of the CEPA.

This first assessment report was based on original data relevant to the assessment of risks to health associated with exposure to chlorinated benzenes. These data were reviewed during 1984–1987 by staff of Health Canada in the preparation of a draft IPCS environmental health criteria document (EHC). That assessment had been updated and expanded to emphasize data most relevant to the assessment of the risks associated with exposure to pentachlorobenzene in the general environment in Canada (UNEP/FAO/RC/CRC.7/9/Add.1: document No. 2, p. 1).

Information considered relevant to the assessment of whether PeCB was toxic to the environment was identified from online searches in scientific literature databases completed in November 1990 (ASFA, BIOSIS, CAB Abstracts, Chemical Abstracts, CESARS, CIS, ENVIROLINE, Hazardous Substances, and IRPTC). Literature searches were repeated in 1995 and 1999 to prepare a follow-up report (UNEP/FAO/RC/CRC.7/9/Add.1: document No. 3). The National Pollutant Release Inventory (NPRI) and Accelerated Reduction/Elimination of Toxics databases supported by Environment Canada were also reviewed.

Both reports cite many references, more than half of which have been published in peer-reviewed scientific journals. They provide a summary and table of contents and explain the scientific methods used for generating and reviewing the data, along with possible limitations and uncertainties with regard to the issue to be clarified. Although the reports themselves were not published in peer-reviewed journals, they have been reviewed by scientific staff of Canadian authorities.

The Chemical Review Committee established that the scientific data on hazard and exposure used for the risk evaluation of pentachlorobenzene had been generated in accordance with scientifically recognized methods and that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures.

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

The 2003 report, on which the regulatory action was based, evaluates the risks for sediment-dwelling and soil-dwelling organisms by comparing exposure data (reported pentachlorobenzene concentrations observed in Canadian soils and sediments) to hazard data (information on toxicity for these groups of organisms). Exposure of the Canadian environment to pentachlorobenzene was assessed by evaluating release paths in Canada, environmental fate and environmental concentrations, in addition to a characterization of its effects on sediment-dwelling and soil-dwelling organisms.

The 2003 report concluded that pentachlorobenzene was entering the Canadian environment in a quantity or concentration or under conditions that had or might have an immediate or long-term harmful effect on the environment or its biological diversity.

Concentrations of pentachlorobenzene in Canadian soil are unlikely to be causing harm to populations of soil-dwelling organisms. Pentachlorobenzene has, however, occurred in sediments from the St. Clair River, Ontario, Canada, near a waste disposal site at a chemical plant and an effluent outfall from an industrial area of Sarnia in concentrations that may have been harming benthic organisms.

The risk quotient of maximum exposure value versus estimated no-effects value for pentachlorobenzene in freshwater sediments exceeded a value of 1 in 23 per cent (9 of 39) of samples collected from the St. Clair River (UNEP/FAO/RC/CRC.7/9/Add.1: document No. 2, page 10 and document No. 3, pp. 15, 29 and 36).

The Chemical Review Committee established that the final regulatory actions had been taken on the basis of a risk evaluation involving prevailing conditions in Canada.

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;

The Committee considered that, by prohibiting the manufacture, use, sale, offer for sale, or import of pentachlorobenzene, with the exemption of uses with chlorobiphenyls, the final regulatory action would work towards the objective of virtual elimination of the substance (UNEP/FAO/RC/CRC.7/9, chapter 2.4.2.2 of the Canadian notification).

(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;

As a consequence of the expected significant decrease in the use of pentachlorobenzene, the Committee considered that the associated risks would also be significantly reduced.

(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;

The follow-up report concludes that pentachlorobenzene is persistent in soil, sediment and in air, is bioaccumulative and is “toxic” according to the criteria of CEPA 1999. Furthermore, pentachlorobenzene is subject to long-range transport to remote areas, which results in low-level, widespread contamination (UNEP/FAO/RC/CRC.7/9/Add.1: document No. 3, page 18). Pentachlorobenzene may therefore cause problems also in other countries or regions.

The Committee concluded that the considerations that led to the regulatory action were applicable also to other regions.

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

The Committee concluded that, although there were no indications of ongoing international trade in pentachlorobenzene above laboratory scale, its reintroduction on international markets was possible (UNEP/FAO/RC/CRC.7/INF/10, p. 4).

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.

Although the accidental spillage of dielectric fluids was cited as the main source of contamination with pentachlorobenzene in Canada (UNEP/FAO/RC/CRC.7/9/Add.1: document No. 3, page 4), there is no indication in the notification or supporting documentation that concerns for intentional misuse prompted the regulatory action.

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

Annex IV

Rationales, draft decisions and workplans for severely hazardous pesticide formulations for which proposals met the criteria of Annex IV

I. Rationale for the recommendation by the Chemical Review Committee to list paraquat dichloride (formulated as emulsifiable concentrate of 276 g active ingredient/L or above, corresponding to paraquat ion at or above 200 g/L) in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation

1. Scope of the notified regulatory action

1. The proposal submitted by Burkina Faso referred to the formulation Gramoxone Super (200 g/L emulsifiable concentrate (EC)). This is an emulsifiable concentrate of 276 g paraquat dichloride/L (CAS No. 1910-42-5), corresponding to paraquat ion at 200 g/L (CAS No. 4685-14-7).

2. The proposal and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.7/11, Corr.1 and Add.1–6.

3. Gramoxone Super (200 g/L EC) was used in Burkina Faso as a total herbicide in cotton, rice and maize once at the beginning of the season with a dosage of 2 to 3 litres/hectare.

4. Incidents were reported (survey of farmers) involving 53 males between 29 and 65 years old who had applied the product in the field. The incidents occurred from 1996 to 2010 in three provinces of Burkina Faso (Boucle du Mouhoun, Cascades and Hauts Bassins).

5. The product was applied using backpack sprayers. In many cases, little or no personal protective equipment (PPE) was worn as a result of various factors, such as a lack of financial means to acquire it, the inappropriateness of PPE for local climatic conditions and an underestimation of the dangers of pesticides.

6. The adverse effects appeared immediately to several hours after the application of the pesticide. Symptoms reported included headaches, excessive sweating, itching, tingling, burning of the skin, skin rashes and sores, complete destruction of contaminated areas, fever, dizziness, bone pain, loss of consciousness, breathing difficulties, cough, vision troubles, eye pain, ringing in the ears, abdominal pain, nausea, vomiting and lockjaw. In 15 cases, the treatment was unknown, whereas treatment was administered in 26 cases, and in an additional 11 cases hospitalization was required. A detailed report of the survey undertaken in three regions of Burkina Faso on intoxications due to agricultural pesticides is available.[4]

7. The documentation required according to part 1 of Annex IV to the Convention was submitted by Burkina Faso in its proposal and published in PIC Circular XXXII (12, Dec. 2010).

8. The information collected by the Secretariat according to part 2 of Annex IV to the Convention was submitted by parties and observers and was made available to the Committee in document UNEP/FAO/RC/CRC.7/11/Add.1–6.

2. Criterion Annex IV, part 3 (a)

In reviewing the proposals forwarded by the Secretariat pursuant to paragraph 5 of Article 6, the Chemical Review Committee shall take into account:

(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;

9. The Pilot Study on Agricultural Pesticide Poisoning in Burkino Faso clearly describes the common and recognized pesticide application practices in the field in Burkina Faso. Gramoxone Super is reported to be used in the field on cotton, rice and maize once at the beginning of the season and is applied by means of backpack sprayers at rates of 2 to 3 L/ha. The average duration of the operator's

4 www.pic.int/mbg.php?sid=2&pf=3&Mtype=99999&Regn=0&Ctry=75.

exposure during agricultural use as found in the Pilot study was 3½ hours/hectare on an average area of 2 hectares/farm, for a total of 7 hours of exposure during an average of 1½ to 2 days of treatment.

10. The common practices regarding use of PPE (personal protective equipment) in Burkina Faso were as follows: Only 20 per cent of pesticide distributors also sell protective equipment (dust masks, boots and gloves in particular) to the farmers; limited use of PPE by farmers: dust masks (39 per cent), boots (29 per cent), suits (5 per cent). Around 13 per cent use both dust masks and boots, whereas around 1 per cent use gloves, boots, suits, dust masks and glasses at the same time. The combination of chemical cartridge respirator, gloves, boots, suit and glasses was used in 0.3 per cent of cases.

11. Most farmers in Burkina Faso are illiterate and not able to read instructions printed on labels. In addition, pesticide distributors and vendors lack the necessary knowledge and training and are therefore unable to provide proper advice to customers. There is also a lack of financial means to buy PPE. PPE is often not available on local markets and is generally not adapted to local weather conditions.

12. With regard to Gramoxone Super, incidents were reported involving 53 farmers who had applied the product in the field using backpack sprayers. In many cases, little or no PPE was worn as a result of various factors explained above, such as a lack of financial means to acquire it, the inappropriateness of PPE for local climatic conditions and an underestimation of the dangers of pesticides.

13. The Committee concluded that evidence indicating that the use of Gramoxone Super, in accordance with common and recognized practices within Burkina Faso, resulted in the reported incidents was reliable and, taking into account this criterion, concluded that it was met.

3. Criterion Annex IV, part 3 (b)

The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;

14. Abundant documentation was available to the Committee demonstrating that the above-listed conditions for Burkina Faso were similar to the conditions prevailing in other States and regions. For example, a study was reported from Senegal presenting information on chemical pesticide poisoning incidents. Data were analysed from 166 poisoning incidents, 59 per cent of which were related to pesticide applications in the field. Inappropriate application practices (lack of PPE) were identified as the main reason for those incidents. A report from the Niger identified the following operator exposure risks with respect to pesticide use in that country (among others): lack of use of PPE, illiteracy, attitude, application under inappropriate conditions such as excessive wind. The conditions of pesticide use and the climate in neighbouring countries the Niger and Senegal can be considered to be similar to those of Burkina Faso. Documentation is available from other regions, including on intoxications from occupational exposure in Costa Rica, attributable to leaking backpack sprayers among other causes. Especially in Costa Rica`s banana plantations, Gramoxone is reported as a frequent cause of occupational accidents. In a contribution from Chile, 43 acute occupational poisoning incidents with paraquat formulations from 2004 to 2009 were reported, although full PPE is mandatory in that country. In El Salvador between 289 and 402 (average 344) intoxications due to Gramoxone are reported per year from 2005 to 2010. Further examples are provided in document UNEP/FAO/RC/CRC.7/11/Add.2 and 3.

15. The Committee concluded that there was convincing evidence that the incidents reported by Burkina Faso were relevant to other States with similar climate, conditions and patterns of use of the formulation, and therefore that the criterion was met.

4. Criterion Annex IV, part 3 (c)

The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;

16. Handling or applicator restrictions for the use of paraquat products have been provided by various parties (UNEP/FAO/RC/CRC.7/11/Add.2 and 3). They include, for example, such instructions as “Wear coveralls over a long-sleeved shirt and long pants during application with a backpack sprayer” and “Do not use damaged sprayers”. The product label contains precautionary advice to keep the product under lock and key, not to use mist blowers, to use only backpack or draw sprayers, not to smoke, eat or drink during use of the product, to wear glasses, boots and synthetic rubber gloves, to avoid entering a treated plot within 24 hours after application of the product and to avoid any contact with spray mixture.

17. Evidence is provided by Burkina Faso and other parties that the majority of farmers in many developing countries do not use PPE (see also paragraphs 10–12), are illiterate and are unaware of the risks posed by pesticides. Reports are available about defective sprayers: more than half of the sprayers in use in Cameroon, for example, are damaged. In Brazil 80 per cent of sprayers are reported to have deficiencies, while in Costa Rica the figure stands at 58 per cent. Frequently leaking sprayers are also reported from China. A survey in Cameroon revealed that 85 per cent of the farmers there do not use PPE, and in particular 80 per cent of operators wear no boots. In Zimbabwe, the use of PPE was reported to be low, partly because the benefits of such equipment did not seem overwhelming and use of the equipment was associated with discomfort, high cost and maintenance. In Nicaragua, field workers usually get no appropriate instructions (UNEP/FAO/RC/CRC.7/11/Add.3).

18. Taking into account the information available, the Committee concluded that the criterion was met.

5. Criterion Annex IV, part 3 (d)

The significance of reported effects in relation to the quantity of the formulation used;

19. In Burkina Faso, Gramoxone Super is reported to be used in the field on cotton, rice and corn once at the beginning of the season at rates of 2 to 3 L/hectare. The average duration of exposure was 3½ hours/hectare on an average area of 2 hectares/farm, for a total of 7 hours of exposure during an average of 1½ –2 days of treatment. With regard to incident frequency rate, Gramoxone Super alone has been implicated in 53 intoxication incidents and is the product that has caused the greatest number of health problems among agricultural producers in Burkina Faso. Of 153 pesticide formulations identified in the survey and 296 poisoning incidents from field application, Gramoxone Super was responsible for 20 per cent of intoxications. This is due to the high toxicity of paraquat. Exposure through dermal or ocular contact, inhalation or ingestion may readily lead to systemic intoxication. Exposure to small amounts of paraquat, for example through ingestion of inhaled spray droplets, eating food that has been in contact with contaminated hands, or absorption through damaged skin when insufficient PPE is used, can cause systemic intoxication. In case of intoxication, no antidote or cure exists.

20. In a study performed in Costa Rica, 11 knapsack spray operators using Gramoxone Super at four banana plantations were studied. Between 22 litres with a concentration of 0.2 per cent and 42 litres with a concentration of 0.1 per cent spray solution were sprayed per working hour. Of the 11 spray operators under study, seven reported having had one or more health problems in the preceding 12 months that were thought to have been related to paraquat exposure. Dermal and respiratory exposure was measured with skin pads and personal air sampling, and internal exposure by urine sampling. In Costa Rica in 2001, paraquat was identified as the causal agent in 127 cases out of 544 notified pesticide poisonings. Seventeen of the cases were attributable to occupational exposure (24 unknown). Paraquat was also the leading active ingredient for severe and moderate poisonings. In Costa Rica, the total actual dermal exposure of operators to paraquat in banana plantations, assessed by skin pads in 1995, varied between 35 and 1130 mg/kg or 2–57 mg/h. The number of pesticide poisonings and incidents per million inhabitants are reported for several countries in document UNEP/FAO/RC/CRC.7/11/Add.3. In El Salvador, approximately 2 million litres of paraquat formulations are imported each year and between 289 and 402 (average 344) incidents were reported each year from 2005 to 2010. This corresponds to 172 incidents per 1 million litres.

21. Taking into account the information available, the Committee concluded that the criterion was met.

6. Criterion Annex IV, part 3 (e)

That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.

22. The reason for the proposal to list Gramoxone Super in Annex III was the occurrence of a number of poisoning incidents during the agricultural use of Gramoxone Super (operator exposure) in the field under conditions of use that are reported to be common in Burkina Faso. Intentional misuse was not reported to be a reason for the proposal.

23. Taking into account the information available, the Committee concluded that the criterion was met.

24. The Committee concluded at its seventh session that the proposal from Burkina Faso to list Gramoxone Super (paraquat dichloride formulated as emulsifiable concentrate of 276 g active ingredient/L, corresponding to paraquat ion at 200 g/L) in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of part 1 of Annex IV and all

criteria set out in part 3 of Annex IV to the Convention, considering the information collected by the Secretariat in accordance with part 2 of Annex IV.

25. The Committee therefore recommends that paraquat dichloride formulated as emulsifiable concentrate of 276 g active ingredient/L or above, corresponding to paraquat ion at or above 200 g/L (CAS No. 1910-42-5, CAS No. 4685-14-7), be included in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation.

II. Recommendation to the Conference of the Parties on the inclusion of paraquat dichloride (formulated as emulsifiable concentrate of 276 g active ingredient/L or above, corresponding to paraquat ion at or above 200 g/L) as a severely hazardous pesticide formulation in Annex III to the Rotterdam Convention

The Chemical Review Committee,

Recalling Article 6 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

Concluding that the proposal from Burkina Faso to list Gramoxone Super[5] in Annex III to the Convention as a severely hazardous pesticide formulation meets the criteria set forth in Part 3 of Annex IV to the Convention,

Decides, in accordance with paragraph 5 of Article 6 of the Convention, to recommend to the Conference of the Parties that it should list Gramoxone Super in Annex III to the Rotterdam Convention in the category of severely hazardous pesticide formulation as follows:

Paraquat dichloride (formulated as emulsifiable concentrate of 276 g active ingredient/L or above, corresponding to paraquat ion at or above 200 g/L) (CAS No. 1910-42-5 and CAS No. 4685-14-7).

III. Workplan for the intersessional drafting group on Gramoxone Super[5]

The drafting group comprises the following members:

Chair:	Ms. Anja Bartels
Co-Chair:	Ms. Hala Al-Easa
Members:	Ms. Magdalena Balicka
	Mr. Jürgen Helbig
	Mr. Masayuki Ikeda
	Mr. Peter Opiyo
	Ms. Jeevani Marasinghe
	Mr. Michael Ramsay
	Ms. Marit Randal
	Mr. Mirijam Seng

5 The proposal submitted by Burkina Faso referred to the formulation Gramoxone Super (200 g/L EC). This is an emulsifiable concentrate of 276 g paraquat dichloride/L (CAS No. 1910-42-5), corresponding to paraquat ion at 200 g/L (CAS No. 4685-14-7).

The drafting group agreed to the following workplan:

Tasks to be carried out	*Responsible persons*	*Deadlines*
Draft an internal proposal on Gramoxone Super based on the information available to the Chemical Review Committee (CRC)	Chair Co-chair	24 May 2011
Send draft internal proposal to drafting group members for comments via e-mail	Chair Co-chair	24 May 2011
Replies	All drafting group members	13 June 2011
Update internal proposal based on comments from drafting group members	Chair Co-chair	8 July 2011
Send updated internal proposal to CRC and observers for comments via e-mail	Chair Co-chair	8 July 2011
Replies	All CRC members and observers	27 August 2011
Draft a decision guidance document (DGD) based on the comments from CRC and observers	Chair Co-chair	22 September 2011
Send draft DGD to drafting group members for comments via e-mail	Chair Co-chair	22 September 2011
Replies	All drafting group members	18 October 2011
Finalize draft DGD based on the comments of the group	Chair Co-chair	15 November 2011
Send draft DGD to Secretariat	Chair Co-chair	15 November 2011
Present draft DGD to CRC at its eighth meeting		March 2012