CRC-17/2: Terbufos

The Chemical Review Committee,

Recalling Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

1. *Concludes* that the notifications of final regulatory action for terbufos submitted by Canada and Mozambique[1] meet the criteria set out in Annex II to the Convention;

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

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

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

5. *Also decides*, in accordance with the process for drafting decision guidance documents set out in decision RC-2/2 and amended by decision RC-6/3, that the composition of the intersessional drafting group to prepare the draft decision guidance document for terbufos and the workplan of the group shall be as set out in annexes II and III, respectively, to the report of the Committee on the work of its seventeenth meeting.

Annex to decision CRC-17/2

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

1. The notifications on terbufos from Canada and Mozambique have been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. These notifications underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notifications appeared to meet the requirements of the Convention.

2. The notifications and supporting documentation were made available to the Chemical Review Committee for its consideration (UNEP/FAO/RC/CRC.17/8/Rev.1, UNEP/FAO/RC/CRC.17/INF/18, UNEP/FAO/RC/CRC.17/INF/19/Rev.1). Information on trade was available in document UNEP/FAO/RC/CRC.17/INF/5.

I. Canada

(a) Scope of the regulatory action notified by Canada

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

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

regulatory action was taken as a result of the unacceptable risk to the environment posed by the registered uses of pesticides containing terbufos in Canada (UNEP/FAO/RC/CRC.17/8/Rev.1, sects. 2.2.1 and 2.2.3 of the Canada notification).

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

(b) Annex II paragraph (a) criterion

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

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

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

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

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

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

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

(c) Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

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

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

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

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

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

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

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

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

10. The Proposed Acceptability for Continuing Registration (PACR 2003-02) document includes a human health assessment, an environmental assessment and information on the value of terbufos to pest management in Canada. This document specifies that the toxicology database

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

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

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

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

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

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

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

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

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

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

19. Risk quotients determined for applications of the end-use terbufos formulations Counter 5-G and Counter 15-G indicate risks for all groups of organisms (i.e., birds, mammals, fish and

aquatic invertebrates) for all application scenarios. Based on the available toxicity data, risk is classified as high to extremely high for aquatic organisms and in most cases high to extremely high for birds. Similarly, risk to mammals is classified from low for large mammals to high for small mammals (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 3.2.3 of the Canada notification).

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

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

(d) Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

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

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

24. The Committee therefore confirms that the criterion in paragraph (c) (i) is met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

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

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

27. The Committee confirms that the criterion in paragraph (c) (ii) is met.

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

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

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

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

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

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

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

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

(e) Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

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

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

(f) Conclusion

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

II. Mozambique

(a) Scope of the regulatory action notified by Mozambique

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

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

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

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

(b) Annex II paragraph (a) criterion

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

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

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

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

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

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

46. The Committee therefore confirms that the criterion in paragraph (a) of Annex II is met.

(c) Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

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

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

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

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

(c) FAO/WHO, “Report of the second Joint Meeting on Pesticide Management and the fourth session of the FAO Panel of Experts on Pesticide Management” (pp. 14–18), Geneva (2008). Available at: www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Report.pdf;

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

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

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

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

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

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

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

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

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

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

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

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

54. The notification states that the final regulatory action was based on a risk or hazard evaluation involving the prevailing conditions within the Party in order to protect human health (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 2.4 of the Mozambique notification). With the goal of reducing the greatest risks associated with pesticide use in Mozambique, the project on reducing risks of highly hazardous pesticides in Mozambique was initiated by the Government of Mozambique, with the technical support of the FAO Pesticide Management Unit, and funded by the SAICM Quick Start Programme Trust Fund. Its ultimate goal was to develop and implement an HHP risk reduction action plan in Mozambique for the most dangerous pesticides and use situations, resulting over time in the implementation of a variety of risk reduction measures based on a review of use conditions. These could include the cancellation of specific registrations of HHPs, implementation of risk mitigation measures, appropriate use restrictions, development of alternative pest management strategies, promotion of good agricultural practices, and possible phase-out of specific pesticides (UNEP/FAO/RC/CRC.17/INF/18, p. 11).

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

56. The terbufos formulations registered at the time in Mozambique included Moz Terbufos 15% GR, Rotam Terbufos 15% GR, and Bongo (UNEP/FAO/RC/CRC.17/8/Rev.1, sect. 1.3 of the Mozambique notification; UNEP/FAO/RC/CRC.17/INF/18, p. 203). These formulations were assessed against the following FAO/WHO JMPM criterion for identification of HHPs: pesticide formulations that meet the criteria of classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard. The oral and dermal LD_{50} value of the formulations, as provided in the

registration dossier, were used as the basis for the classification. LD_{50} values for the formulations were available or could be estimated. The terbufos formulations were identified as extremely hazardous (class Ia) according to the JMPM criteria for HHPs based on the WHO Recommended Classification of Pesticides by Hazard, and therefore considered and shortlisted as HHP.

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

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

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

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

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

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

63. Although specific information related to actual or measured terbufos exposure of agricultural workers in Mozambique was not included as part of the risk evaluation, the notification and supporting documentation provide an assessment of the prevailing conditions of use of pesticides in Mozambique. While no imports of terbufos formulations were recorded in the four years (2010–2013) prior to and including the period when the survey of users was carried out, registrations of those formulations remained in place and therefore future use could not be precluded (UNEP/FAO/RC/CRC.17/INF/18, p. 33). The registered uses for terbufos formulations were for maize, sorghum, potato and beans. These cropping systems were included in the survey of users conducted, and were the predominant crops in three of the regions of Mozambique surveyed. In addition, vegetable crops were reported as being the crops most frequently oversprayed by HHPs, which poses a risk to human health given the local conditions of use (application as many as 14 times per growing season) (UNEP/FAO/RC/CRC.17/INF/18, pp. 52–77). The notification and

supporting documentation indicate that the use of pesticides in general, and of HHPs (such as terbufos) in particular, was likely to result in excessive exposure of farmers given the availability, knowledge and use of PPE among farmers, and was evidenced by a high level of reporting of adverse health effects. The final regulatory action was taken as a result of the national objective of Mozambique of reducing the greatest risks associated with pesticide use.

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

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

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

(d) Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

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

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

69. The Committee therefore confirms that the criterion in paragraph (c) (i) is met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

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

71. The Committee therefore confirms that the criterion in paragraph (c) (ii) is met.

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

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

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

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

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

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

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

(e) Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

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

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

(f) Conclusion

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

III. Conclusion

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

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