CRC-17/1: Iprodione

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 iprodione submitted by Mozambique and the European Union[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 iprodione 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 iprodione;

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 iprodione 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-17/1

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

1. The notifications on iprodione from Mozambique and the European Union 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 in documents UNEP/FAO/RC/CRC.17/5, UNEP/FAO/RC/CRC.17/INF/11 and UNEP/FAO/RC/CRC.17/INF/12. Information on trade was made available in document UNEP/FAO/RC/CRC.17/INF/5.

I. Mozambique

(a) Scope of the regulatory action notified by Mozambique

3. The regulatory action notified by Mozambique relates to iprodione (CAS No. 36734-19-7) as a pesticide. Iprodione 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 iprodione in the country were decided due to the toxic nature and hazardous properties of this active substance

[1] See UNEP/FAO/RC/CRC.17/5.

which, combined with improper use in the country due to the local specific conditions of use, can damage human and animal health.

4. The decision to ban the registration of iprodione was taken as the last step in the project on reducing risks of highly hazardous pesticides, which identified highly hazardous pesticides (HHPs) that are registered in Mozambique. After consultations with different actors (public sector, private sector, civil society and others) the cancellation of registrations and consequent ban and non-approval of its use in Mozambique was approved.

5. 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;

6. The Committee confirms that the regulatory action was taken to reduce the risk from iprodione to human health (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification).

7. The notification states that the ban of all uses and the cancellation of the products containing iprodione 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 damage human and animal health.

8. Iprodione and products containing iprodione were considered to be harmful to human health, taking into consideration the local conditions of use in Mozambique requiring risk mitigation measures. The notification refers to a consultancy report entitled "Shortlisting highly hazardous pesticides" (Come and van der Valk, 2014, see full reference below), which identified iprodione as carcinogenic equivalent or similar to GHS category 1A and 1B. The conclusion was based on the United States Environmental Protection Agency (EPA) and European Food Safety Authority (EFSA) assessments, according to which iprodione was classified as likely to be carcinogenic or in category 2 of the carcinogenicity classification.

9. The final conclusion of the HHP assessment in Mozambique identified iprodione as carcinogenic equivalent or similar to GHS category 1A and 1B, and it was therefore considered as "coming close" to being an HHP (Come and van der Valk, 2014).

10. 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;

11. 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) Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (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: ww.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Report.pdf.

12. The available consultancy reports and hazard assessment criteria by the FAO/WHO Joint Meeting on Pesticide Management (JMPM) are considered scientifically sound and generated according to scientifically recognized methods and reported according to generally recognized scientific principles and procedures.

13. Iprodione was shortlisted as a pesticide "coming close" to being an HHP based on the following criteria:

(a) Pesticides for which carcinogenicity evaluations by different registration/assessment authorities did not lead to consistent classification as GHS category 1A or 1B, but which were, based on the evidence of one of these authorities, considered of particular concern for use in Mozambique (Come and van der Valk, 2014);

(b) Iprodione was classified by the United States EPA as likely to be carcinogenic. It was registered in the United States. However, all residential uses were cancelled due to cancer risk concerns and the remaining backpack sprayers and mixers were required to wear double-layer personal protective equipment, masks and gloves. Iprodione was registered in the European Union. The European Union review of 2004 classified iprodione in category 2 of the carcinogenicity classification. The Mozambican authorities considered that the risk mitigation measures of the United States could not be achieved in Mozambique.

14. The final conclusion of the HHP assessment in Mozambique identified iprodione as carcinogenic equivalent or similar to GHS category 1A and 1B, and it was therefore considered as "coming close" to being an HHP (Come and van der Valk, 2014).

15. Iprodione and products containing it were considered harmful to human health, taking into consideration the local conditions of use in Mozambique requiring risk mitigation measures (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification).

16. The available reports developed under the reducing risks of highly hazardous pesticides in Mozambique project and included in the supporting documentation provide a detailed methodology that specifies that internationally recognized criteria established by the FAO/WHO JMPM for the identification of HHPs, together with the additional criterion used by Mozambique, were utilized for the identification of iprodione as "coming close" to being an HHP (UNEP/FAO/RC/CRC.17/INF/11, p.15). Also, the report on the survey of pesticide use practices in selected cropping systems indicates that its 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/11, pp.57–58).

17. 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;

18. 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.17/5, sect. 2.4 of the Mozambique notification). With the goal of reducing the greatest risks associated with pesticide use in Mozambique, the reducing risks of highly hazardous pesticides in Mozambique project was initiated by the Government of Mozambique, with the technical support of the FAO Pesticide Management Unit, and funded by the Strategic Approach to International Chemicals Management (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/11).

19. 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), and additional criteria for pesticides with characteristics coming close to JMPM criteria.

20. The iprodione formulation registered at the time in Mozambique was Iprodione 25.5% SC (UNEP/FAO/RC/CRC.17/5, sect. 1.3 of the Mozambique notification and UNEP/FAO/RC/CRC.17/INF/11, p. 49). This formulation was assessed against the FAO/WHO JMPM criteria for identification of HHPs and the following additional criterion used by Mozambique for identifying pesticides with characteristics which "come close" to being an HHP: pesticides for which carcinogenicity evaluations by different registration/assessment authorities did not lead to consistent classification as GHS category 1A or 1B, but which were, based on the evidence of one of these authorities, considered of particular concern for use in Mozambique. As a result, iprodione was on the shortlist as a pesticide "coming close" to being an HHP.

21. 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 are being used in the country and their contribution to potential risks for human health and the environment.

22. 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 pesticides 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 interviewed farmers used HHPs).

23. In addition, almost none of the farmers (93 per cent) owned or wore adequate personal protective equipment (PPE), having only one or no protective items at all. Only 2 per cent of those applying HHPs wore adequate full-body-protection 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 battery-operated electric sprayers (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.

24. 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.

25. 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.

26. Iprodione and the products containing this active ingredient were considered harmful to human health taking into consideration the local conditions of use in Mozambique requiring risk mitigation measures. Therefore, the authorities decided to ban the active ingredient iprodione from

future use in the country and to cancel the registration of all products containing it (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification, with a focus on iprodione-specific information as included in the supporting documentation).

27. Although specific information related to actual or measured exposure of agricultural workers to iprodione 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. Iprodione was imported into Mozambique in 2013 and registrations of the formulation remained in place; future use could not therefore be precluded (UNEP/FAO/RC/CRC.17/INF/11, p. 35). The registered uses for iprodione formulations were for vines, fruit trees and vegetables. Vegetable cropping systems were included in the survey of users conducted, and vegetables were the predominant crops in two of the regions of Mozambique surveyed (UNEP/FAO/RC/CRC.17/INF/11, pp. 52–77). The notification and supporting documentation indicate that the use of pesticides in general 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 Mozambique's national objective of reducing the greatest risks associated with pesticide use.

28. Mozambique's goal to develop and implement an HHP risk reduction action plan could be considered a national policy that HHPs should not be registered based on the understanding that the prevailing conditions of use in Mozambique will result in unacceptable risks to agricultural workers. Iprodione was included in the shortlist of HHPs as "coming close" to being an HHP based on the following criteria: pesticides for which carcinogenicity evaluations by different registration/assessment authorities did not lead to consistent classification as GHS category 1A or 1B, but which were, based on the evidence of one of these authorities, considered of particular concern for use in Mozambique (Come and van der Valk, 2014). Iprodione was classified by the United States EPA as likely to be carcinogenic. The European Union review of 2004 classified iprodione in category 2 of carcinogenicity classification (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification).

29. Iprodione was registered in the United States. However, all residential uses were cancelled due to cancer risk concerns. In addition, backpack sprayers and mixers were required to wear double-layer PPE, including masks and gloves (UNEP/FAO/RC/CRC.17/INF/11, p. 327).

30. According to the survey, similar pesticide uses and application techniques to those in the United States (use on field, fruit and vegetable crops) were used in Mozambique. The Mozambican authorities considered that the risk mitigation measures required in the United States could not be achieved in Mozambique.

31. 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 registered iprodione uses), which included the identification of inadequate availability and use of PPE and iprodione's likely carcinogenicity, and noting the bridging information to the PPE requirements in the United States, it is concluded that the final regulatory action was based on a risk evaluation involving the prevailing conditions within the Party taking the action.

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

33. 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;

34. Before the regulatory action, iprodione was used in Mozambique as a fungicide in vines, fruit trees and vegetables. There was one pesticide formulation on the market (UNEP/FAO/RC/CRC.17/5, sect. 1.3 of the Mozambique notification). The supporting documentation reported 12 litres of import in 2013 for the registered pesticide formulation (UNEP/FAO/RC/CRC.17/5, sect. 2.5.1 of the Mozambique notification and Come and van der Valk, 2014, table 6).

35. The final regulatory action banned the import and use of iprodione in Mozambique and cancelled the registration of all products containing iprodione. Although information on registration and imported amounts was available for only one formulation and for a short period of time, it is expected that the regulatory action will remove exposure to this chemical in Mozambique.

36. 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;

37. Iprodione was identified as carcinogenic equivalent or similar to GHS category 1A and 1B (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification). A follow-up survey (Come et al., 2014) found that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers in Mozambique. Iprodione and the products containing it were considered harmful to human health, taking into consideration the local conditions of use in Mozambique requiring risk mitigation measures (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification). The enforcement of risk mitigation measures that depended solely on wearing the appropriate PPE under the local conditions of use was considered to be difficult and unlikely to produce results.

38. The ban of all iprodione formulations in Mozambique can be considered to reduce the risk from exposure to iprodione as much as possible.

39. 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;

40. The final regulatory action was based on information on use of and exposure to pesticides during application (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification) as well as international information on hazards. As no specific exposure values for iprodione in Mozambique were derived, the considerations are not geographically limited.

41. The survey on pesticide use in Mozambique revealed poor use of protective equipment (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 of the Mozambique notification). The notification notes that 93 per cent of farmers did not own or wear adequate PPE, having only one or no protective items at all. Approximately half of the farmers surveyed reported that they had noticed getting pesticide on their clothes, bare skin or eyes during use. Almost half of the farmers declared they did not read pesticide labels, including use instructions such as proper dosage and protective measures, with the main reason being illiteracy. This information was not related to the use of iprodione specifically, but pesticides use in general. Similar conditions could be found elsewhere.

42. 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;

43. According to the notification and the supporting documentation, iprodione was imported into the Mozambican market in 2013. Recent communications from the European Union and CropLife International submitted to the Secretariat confirm the ongoing trade in iprodione (UNEP/FAO/RC/CRC.17/INF/5).

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

45. 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.

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

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

(f) Conclusion

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

II. European Union

(a) Scope of the regulatory action notified by the European Union

49. The regulatory action notified by the European Union relates to iprodione (CAS No. 36734-19-7) as a pesticide. Iprodione is not included in the list of approved active substances under Regulation (EC) No 1107/2009.[2] It was concluded that no plant protection product containing the active substance iprodione is expected to satisfy in general the requirements laid down in Article 29 (1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EC) 546/2011. As a consequence, it is prohibited to place on the market or use plant protection products containing iprodione in the European Union as of 6 March 2018. Disposal, storage, placing on the market and use of existing stocks of plant protection products containing iprodione is prohibited as of 6 June 2018.

50. 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;

51. The Committee confirms that the regulatory action was taken to reduce the risk from iprodione to human health and the environment (UNEP/FAO/RC/CRC.17/5, sect. 2.4.2.1 and 2.4.2.2 of the European Union notification, respectively).

52. According to the evaluation by the European Union related to human health the following concerns were identified:

(a) The genotoxic potential of metabolite RP 30228 (found as a residue and impurity in the technical material). It is noted that metabolite RP 30228 is predicted to occur in groundwater above 0.1 µg/L in one groundwater scenario developed by the European Commission Forum for the coordination of pesticide fate models and their use (FOCUS) according to the representative uses;

(b) lprodione currently has a harmonized classification (GHS) as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council;

(c) For the representative uses considered, residue levels exceed the default value for maximum residue levels of pesticides in or on food and feed of plant and animal origin;

(d) An acute consumer risk that cannot be excluded based on a preliminary risk assessment.

[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Available at: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32009R1107.

53. According to the evaluation by the European Union related to the environment the following concerns were identified:

(a) The predicted concentrations in groundwater that exceed 0.1 µg/L for relevant metabolites RP 35606 and RP 30181. Metabolite RP 35606 also exceeds 0.75 µg/L in acidic soils, and metabolite RP 30181 exceeds 0.75 µg/L in both acidic and slightly acidic to alkaline soils for both intended uses (carrots and lettuce);

(b) The high long-term risk of iprodione to aquatic organisms.

54. Furthermore, in respect of one metabolite, found as a residue in plants and as an impurity in the technical material, the pesticide authority concluded that the genotoxic potential cannot be excluded and therefore the setting of reference values for that metabolite cannot be confirmed based on the information available. Moreover, based on the available information, the dietary risk assessment could not be finalized as it is not possible to establish residue definitions for risk assessment; nevertheless, an acute consumer risk could not be excluded. Finally, the long-term risk assessment for wild mammals for all the relevant routes of exposure could not be finalized, based on the information submitted in the dossier.[3]

55. 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;

56. The notification refers to a hazard and risk assessment based on the information submitted by the pesticide registration applicant. The assessment report was peer-reviewed together with consultation between EFSA, European Union member States experts and the applicant (UNEP/FAO/RC/CRC.17/5, sect. 2.4.1 of the European Union notification).

57. The procedure for the renewal of the approval of active substances is contained in Commission Implementing Regulation (EU) No 844/2012.[4] The assessment has been outlined in chapter 2 to the regulation: "The rapporteur member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge. It shall take into account the supplementary dossiers, and, where appropriate, the dossiers submitted for the approval and subsequent renewals of approval."

58. The supporting documentation contains the following reports:

(a) European Commission Directorate-General For Health and Food Safety, "Final renewal report for the active substance iprodione", SANTE/10627/2017 Rev. 21 (6 October 2017);

(b) EFSA, "Conclusion on the peer review of the pesticide risk assessment of the active substance iprodione", EFSA Journal 2016;14(11):4609 (2016a). Available at: https://doi.org/10.2903/j.efsa.2016.4609;

[3] See https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R2091&qid=1619436102485&from=EN#ntr6-L_2017297EN.01002501-E0006.

[4] Commission Implementation Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

(c) EFSA, “Conclusion on the peer review of the pesticide risk assessment of the active substance iprodione”, EFSA Journal 2016;14(11):4609 (2016b). Available at: https://doi.org/10.2903/j.efsa.2016.4609.

59. The supporting material (EFSA, 2016a) notes that EFSA organized a consultation of technical experts from the European Union member States to review the renewal assessment report prepared by a member State and the comments received thereon (peer review).

60. While the conclusions have been published (EFSA, 2016b, appendix A), the information in the renewal report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009, and cannot be verified in the context of the task group’s work. Nevertheless, considering the process outlined in the regulation, consultancies and peer review, it can be considered that data have been generated according to scientifically recognized methods and data reviews have been performed and documented according to generally recognized scientific principles and procedures.

61. 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;

62. The data used in the risk evaluation are considered relevant. According to the evaluation related to human health the following information was identified:

(a) lprodione currently has a harmonized classification (GHS) as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council;

(b) Given the GHS classification and the representative uses considered, residue levels exceed the default value for maximum residue levels of pesticides in or on food and feed of plant and animal origin;

(c) An acute consumer risk that cannot be excluded based on a preliminary risk assessment.

63. According to the evaluation related to the environment the following information was identified: the high long-term risk of iprodione to aquatic organisms.

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

65. 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;

66. Prior to the final regulatory action, iprodione was registered as a fungicide (UNEP/FAO/RC/CRC.17/5, sect. 2.3.1 of the European Union notification). According to the supporting documentation, iprodione was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2003/31/EC in 2003. This approval expired in December 2013. One pesticide formulation was registered in the European Union: Rovral WG (BAS 610 06 F) (UNEP/FAO/RC/CRC.17/5, sects. 1.3 and 2.4.2.1 of the European Union notification).

67. The final regulatory action prohibits all applications of iprodione as a plant protection product within the European Union.

68. 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;

69. According to the notification, the expected outcome of the final regulatory action is the reduction of risk to human health and the environment from the use of plant protection products containing iprodione (UNEP/FAO/RC/CRC.17/5, sects. 2.4.2.1 and 2.4.2.2 of the European Union notification).

70. The concerns regarding the use of iprodione, as identified in the evaluation (UNEP/FAO/RC/CRC.17/5, sects. 2.4.2.1 and 2.4.2.2 of the European Union notification), were considered not acceptable to allow its approval as a pesticide in accordance with Regulation (EC) No 1107/2009.

71. The ban of all iprodione formulations in the European Union can therefore be considered to result in a significant reduction of risk to human health and the environment.

72. 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;

73. The human health and environmental hazards identified in the evaluation are also applicable to regions outside the European Union. The exposure assessment was based on simulation modelling with models and scenarios developed for and representative of European conditions. However, similar conditions can also be found outside the European Union.

74. 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;

75. Recent communications from the European Union and CropLife International submitted to the Secretariat confirm the ongoing trade in iprodione (UNEP/FAO/RC/CRC.17/INF/5).

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

77. 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.

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

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

(f) Conclusion

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

III. Conclusion

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

82. The Committee also concludes that the final regulatory actions taken by Mozambique and the European Union provide a sufficient basis for including iprodione 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.