CRC-19/3: Chlorpyrifos

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 chlorpyrifos submitted by the European Union, Malaysia and Sri Lanka[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 chlorpyrifos 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 chlorpyrifos;

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 chlorpyrifos 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 nineteenth meeting.

[1] See UNEP/FAO/RC/CRC.19/8.

Annex to decision CRC-19/3

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

1. The notifications on chlorpyrifos from the European Union, Malaysia and Sri Lanka 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 notification and supporting documentation were made available to the Chemical Review Committee for its consideration in UNEP/FAO/RC/CRC.19/8, UNEP/FAO/RC/CRC.19/INF/15/Rev.2, UNEP/FAO/RC/CRC.19/INF/13 and UNEP/FAO/RC/CRC.19/INF/14. Information on trade was made available in document UNEP/FAO/RC/CRC.19/INF/6.

I. European Union

A. Scope of the regulatory action notified by the European Union

3. The regulatory action notified by the European Union relates to chlorpyrifos (CAS No. 2921-88-2) in the pesticide category.

4. The regulatory action is notified as a ban. It is prohibited to place on the market or use plant production products containing chlorpyrifos under Commission implementing regulation (EU) 2020/18 dated 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos, in accordance with regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of the plant products on the market, amending the annex to Commission implementing regulation (EU) No. 540/2011 (*Official Journal of the European Union*, L 7, 13 January 2020, p.14). Disposal, storage, placing on the market and use of existing stocks of plant protection products containing chlorpyrifos are prohibited as of 16 April 2020.

5. The ban on chlorpyrifos was based on the evaluation of the hazards and risk to human health (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4 of the European Union notification).

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. Before the final regulatory action, chlorpyrifos was used as an acaricide and insecticide. The pesticide formulations in the European Union were Pyrinex 250 CS, Pyrinex, EF-1551 EC, RIMI 101 RB, Chlorpyrifos-ethyl 5G GR, SAP250 CS, Dursban, OMS 0971, Lorsban, Brodan, Killmaster, Suscon, Coroban, Terial, Danusban, Durmet, Eradex (UNEP/FAO/RC/CRC.19/8, annex, sect. 1.3 of the European Union notification).

7. In the recitals to the final regulatory action, the following concerns were identified as a result of the chlorpyrifos assessment:

(a) It cannot be excluded that chlorpyrifos has a genotoxic potential;

(b) Consequently, it is not possible to establish health-based reference values for chlorpyrifos or to conduct the relevant consumer and non-dietary risk assessments;

(c) Furthermore, developmental neurotoxicity (DNT) effects were observed in rats and epidemiological evidence exists showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children;

(d) It is appropriate to classify chlorpyrifos as toxic for reproduction, category 1B.

8. Therefore, the Committee concludes that the final regulatory action was taken in order to protect human health; accordingly, 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;

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

9. The overall conclusion of the European Union risk assessment of chlorpyrifos in relation to impacts on human health, based on the information available and the proposed conditions of use, is that the EU approval criteria for active ingredients and plant protection products are not satisfied.

10. The supporting documentation (UNEP/FAO/RC/CRC.19/INF/15/Rev.2) contains the main results of the risk assessment. As a first step, the risk evaluation of the active substance chlorpyrifos was done by a rapporteur member State, taking into account proposed uses and exposure conditions that prevail in the EU. The rapporteur member State then submitted its renewal assessment report (RAR) to the European Food Safety Authority (EFSA). After the commenting period for member States, the applicants and the public, in April 2019, the EFSA convened an expert discussion related to chlorpyrifos impacts to mammalian toxicology and human health. On 31 July 2019, EFSA issued a statement on the outcome of the risk assessment for human health for chlorpyrifos. Concerns were raised with regard to chromosome aberration and DNA damage (oxidative stress and topoisomerase II inhibition), resulting in an unclear genotoxic potential. Consequently, the experts determined that it was not possible to establish health-based reference values for chlorpyrifos or to conduct relevant consumer and non-dietary risk assessments. Therefore, the experts also determined that it cannot be excluded that there is a probability of adverse effects to human health at any level of exposure.

11. The renewal report, which summarizes the results of the evaluation process, concludes that from the assessments made on the basis of the available information (RAR, comments thereon, EFSA statement, applicant comments on the EFSA statement and draft renewal report), no plant protection product containing the active substance chlorpyrifos is expected to satisfy the requirements laid down in article 29(1) of regulation (EC) No. 1107/2009 and the uniform principles laid down in regulation (EU) No. 546/2011.

12. Because the European Union approval criteria related to the effects of chlorpyrifos on human health were not satisfied, the results of other risk assessment components, such as the initial environmental risk assessment, could not alter this conclusion. This is the reason why only concerns for human health are listed as reasons for the final regulatory action.

13. Summarizing the above, the final regulatory action was based on a risk evaluation which identified concerns for human health under the foreseen conditions of use of chlorpyrifos as an active ingredient in pesticides in the European Union.

14. Based on the above, the Committee concludes that the criteria in paragraph (b) (i), (ii) and (iii) of Annex II are met.

15. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole 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;

16. The European Union reported on notified export of chlorpyrifos to 22 countries in 2022 (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.5.1 of the European Union notification).

17. The final regulatory action is a total ban of all uses of chlorpyrifos in plant protection products in the European Union.

18. Consequently, it is expected that the regulatory action will lead to a reduction of risk for human health from use of plant protection products containing chlorpyrifos in the European Union.

19. Hence, the Committee concludes 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;

20. Since the final regulatory action cancelled the registration and banned all applications of chlorpyrifos as a plant protection product, a significant reduction of the health risk can be expected.

21. Hence, the Committee concludes 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;

22. The notification stated that the similar human health problems are likely to be encountered in other regions where the chlorpyrifos is used, particularly in developing countries.

23. Therefore, the Committee concludes that the criterion in paragraph (c) (iii) is met.

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

24. In response to the Secretariat request to provide information on ongoing international trade in candidate chemicals for nineteenth meeting of the Chemical Review Committee, UNEP/FAO/RC/CRC.19/INF/6 confirmed ongoing international trade in chlorpyrifos. The notification gives information on notified export to 22 countries in 2022.

25. Therefore, the Committee concludes that the criterion in paragraph (c) (iv) is met.

E. Annex II paragraph (d) criterion

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

26. The notification does not refer to the data of intentional misuses of chlorpyrifos in the European Union.

27. Based on the above point, the Committee concludes that the criterion in paragraph (d) is met**.**

F. Conclusion

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

II. Malaysia

A. Scope of the regulatory action notified by Malaysia

29. The regulatory action notified by Malaysia relates to chlorpyrifos (CAS No. 2921-88-2) in the pesticide category.

30. The regulatory action is notified as a severe restriction. Based on the circular from the Pesticides Board dated 28 April 2021 informing of the Pesticides Board's decision dated 9 April 2021, the registration of chlorpyrifos pesticides for use in agriculture is cancelled. The regulatory action entered into force on 1 May 2023 (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.2 of the Malaysia notification and UNEP/FAO/RC/CRC.19/INF/13, annex, pp. 4–7).

31. The ban on the use of all types of chlorpyrifos formulations in agriculture in Malaysia as of 1 May 2023 was decided due to the risks of adverse effects to human health, ecology and the environment through agricultural use of chlorpyrifos, as well as food safety risks due to the maximum residue limit (MRL) violations of chlorpyrifos residues in agricultural commodities (UNEP/FAO/RC/CRC.19/8, annex, sect. 3 of the Malaysia notification and UNEP/FAO/RC/CRC.19/INF/13, annex, p.8).

32. Chlorpyrifos may still be used in public health to control urban pests, such as cockroaches, termites, mosquitoes, ants, flies and bugs (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.2 of the Malaysia notification and UNEP/FAO/RC/CRC.19/INF/13, annex, pp. 4–7).

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;

33. Before the final regulatory action, chlorpyrifos was registered as a plant protection product for use to control pests in various types of crops and for use in public health to control urban pests, such as cockroaches, termites, mosquitoes, ants, flies and bugs (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.3 of the Malaysia notification). The pesticide formulations registered in Malaysia were CHEMITOX 75, G-505, STARFOS 505, LORSBAN 40EC, NURELLE-D505 EC, DURSBAN 75+, ECLIPSE 505, PEST-BAN 100, FIGHTER 505, TRICEL 21.2EC, TRICEL 38.7 EC, ZA 505 (UNEP/FAO/RC/CRC.19/8, annex, sect. 1.3 of the Malaysia notification). According to the internal report from the Department of Agriculture's Pesticides Monitoring Program, chlorpyrifos residues consistently exceeded national MRLs in recommended crops, including crops intended for export. In addition, according to data generated by the National Poison Centre Malaysia over a 10-year period (2006–2015), 40 per cent of reported cases of insecticide poisoning involved pesticides from the organophosphate group, with chlorpyrifos being the most commonly reported pesticide. The data from 2016–2019 recorded that 24 per cent of insecticide poisoning cases (1,374 cases) involved chlorpyrifos (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4.1 of the Malaysia notification and UNEP/FAO/RC/CRC.19/INF/13, annex, p. 8).

34. Therefore, the Committee concludes that the final regulatory action was taken in order to protect human health; accordingly, 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;

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

35. The notification states that the final regulatory action was based on a risk evaluation to protect human health (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4.1 of the Malaysia notification). The scope of the review considered the assessment of risks for humans and socioeconomic impacts (UNEP/FAO/RC/CRC.19/8, annex, sects. 2.4.2.1 and 2.5.3.1 of the Malaysia notification and UNEP/FAO/RC/CRC.19/INF/13, annex, pp. 4–7). The Pesticides Board reviewed and scrutinized many research information documents and publications related to chlorpyrifos from within and outside the country (UNEP/FAO/RC/CRC.19/INF/13, annex).

36. The following topics were covered by the chlorpyrifos pesticide review:

(a) Physico-chemical, toxicological and ecotoxicological information;

(b) Assessment of chlorpyrifos poisoning cases in Malaysia;

(c) Evaluation of the studies conducted by other regulatory bodies such as the European Food Safety Authority (EFSA), the Department of Pesticide Regulation in California, and the United States Environmental Protection Agency;

(d) Evaluation of the study of the exposure of chlorpyrifos among paddy farmers in Malaysia;

(e) Evaluation of alternative pesticides to chlorpyrifos;

(f) Impact assessment on the agriculture sector.

37. In the supporting documentation (UNEP/FAO/RC/CRC.19/INF/13), the national and international risk evaluations are presented, including the study conducted by Rozita Hod and others (2011) on the relationship between the chlorpyrifos blood level among paddy farmers in Selangor and exposure symptoms, the assessment of carbofuran and chlorpyrifos by the National Poison Centre Malaysia (unpublished report, 2021), the conclusion on the peer review of the pesticide risk assessment of the active substance chlorpyrifos by EFSA (2011), the Human health risk assessment (2020) and Ecological risk assessment (2021) of chlorpyrifos by United States Environmental Protection Agency, and the justification of cancellation of chlorpyrifos registrations in California by the California Department of Pesticide Regulation (2020).

38. In a study conducted by Rozita Hod and others (2011), the presence of chlorpyrifos and the pesticides exposure symptoms of paddy farmers in Sabak Bernam, Malaysia were investigated. The study involved 100 respondents and showed that 7 per cent of the respondents had chlorpyrifos in their blood, with a mean value of 7.29 nanograms per millilitre blood (SD 5.84 nanograms per millilitre). The percentage of farmers who experienced at least one pesticide exposure symptom was 75 per cent. The farmers had low scores on safe practice of pesticide use, despite their high scores for knowledge and attitude.

39. Assessment of carbofuran and chlorpyrifos by the National Poison Centre of Malaysia concludes that based on 10 years of data (2006–2015), 40 per cent of reported cases of insecticide poisoning involved pesticides from the organophosphate group, with chlorpyrifos having the highest number of cases. Data on poisoning cases received by the National Poison Centre from 2016 to 2019 showed that chlorpyrifos accounted for 24 per cent of all reported cases of insecticide poisoning (n = 1,374), and contributed more to intentional poisoning cases than unintentional cases. Acute poisoning caused by chlorpyrifos can have severe effects and can lead to long-term neurological disorders. Scientific evidence shows that exposure to chlorpyrifos in pregnant women and children can cause neurotoxic effects that can affect children's growth and development.

40. The EFSA initial statement, dated 31 July 2019, and its updated statement, dated 11 November 2019, confirmed the EFSA conclusions on the peer review of the pesticide risk assessment of the active substance chlorpyrifos (UNEP/FAO/RC/CRC.19/INF/13, annex, p. 592). In Commission implementing regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, in accordance with regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection

products on the market, and amending the annex to Commission implementing regulation (EU) No. 540/2011, concerns were identified concerning developmental neurotoxicity (DNT) for which epidemiological evidence exists, showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children. It was concluded that the concerns raised for chlorpyrifos with regard to chromosome aberration and DNA damage (oxidative stress and topoisomerase II inhibition) may apply to chlorpyrifos-methyl, resulting in an unclear genotoxicity potential, developmental neurotoxicity (DNT) effects observed at the lowest dose tested in the DNT study with chlorpyrifos, decreased cerebellum height corrected by brain weight, indicating a health concern, as well as concluding that the epidemiological evidence supports the developmental neurological outcomes in children for both chlorpyrifos and chlorpyrifos-methyl.

41. The California Department of Pesticide Regulation (DPR) evaluated the strengths and uncertainties associated with the use of the available database for deriving critical endpoints for chlorpyrifos. Following the recommendation of the Scientific Review Panel (SRP), DPR thoroughly evaluated developmental neurotoxicity as the critical endpoint for the chlorpyrifos risk assessment. Based on the evaluation of the toxicity database and exposure analyses, this assessment supports the finding that chlorpyrifos meets the criteria to be listed as a toxic air contaminant, pursuant to the law of California.

42. According to the supporting documentation, Malaysia used findings from the international risk assessments and compared these with local conditions of use of chlorpyrifos in plant protection products. Malaysia anticipated that the risks to human health under Malaysian conditions are much higher than in the European Union and California. Malaysia said that the hot and humid conditions in the tropics can make wearing proper protective clothing sometimes impossible, and if the proper protective equipment is available, the cost might be an issue for poor farmers (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4.1 of the Malaysia notification).

43. Summarizing the above, the final regulatory action was based on a risk evaluation, which included health hazard evaluation of chlorpyrifos and the prevailing conditions of the use of pesticides in Malaysia (application doses, methods, protective measures, agricultural practices).

44. Based on the above, the Committee concludes that the criteria in paragraph (b) (i), (ii) and (iii) of Annex II are met.

45. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole 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;

46. Malaysia reported that significant quantities of chlorpyrifos were imported in 2020, while the imported quantities in 2021 were lower (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.5.1 of the Malaysia notification). Consequently, it is expected that the regulatory action will lead to a significant reduction of the quantity of the chemical used.

47. Hence, the Committee concludes 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;

48. Since the final regulatory action cancelled the registration and banned the use of all pesticides containing chlorpyrifos in the agricultural sector, it can be expected that this will reduce poisoning cases and MRL violations, which will represent a significant reduction of the health risk for farmers and consumers.

49. Hence, the Committee concludes 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;

50. The notification stated that the hot and humid conditions in the tropics can make wearing proper protective clothing impossible, and if the proper protective equipment is available, the cost might be an issue for poor farmers. The same concerns are considered to be relevant for countries with similar conditions, as well as where the farmers use pesticides without protective equipment.

51. Therefore, the Committee concludes that the criterion in paragraph (c) (iii) is met.

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

52. In response to the Secretariat request to provide information on ongoing international trade in candidate chemicals for nineteenth meeting of the Chemicals Review Committee, UNEP/FAO/RC/CRC.19/INF/6 confirmed ongoing international trade in chlorpyrifos. The notification gives information on quantities of chlorpyrifos imported in 2020 and 2021.

53. Therefore, the Committee concludes that the criterion in paragraph (c) (iv) is met.

E. Annex II paragraph (d) criterion

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

54. The Pesticides Board's decision to ban the use of chlorpyrifos pesticides in the agricultural sector was based on concerns over its potential risk to human health, ecology and the environment through agricultural activities, as well as food safety risks due to the high content of pesticide residues in the products. Malaysia noted that chlorpyrifos residues consistently exceeded national residue limits in recommended crops, and dietary risk assessments showed the risk to consumers from long-term exposure to chlorpyrifos residue exceeding legal limits. The National Poison Centre over a 10-year period (2006–2015) recorded that 40 per cent of reported cases of insecticide poisoning involved pesticides from the organophosphate group, with chlorpyrifos being the most commonly reported pesticide. Chlorpyrifos contributed more to intentional poisoning cases than unintentional cases. The notification or supporting documentation mention variable reasons for severely restricting chlorpyrifos such as MRL exceedance and poisoning cases including unintentional poisoning cases. Consequently, intentional misuse was not the sole reason for severely restricting chlorpyrifos.

55. Based on the above point, the Committee concludes that the criterion in paragraph (d) is met**.**

F. Conclusion

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

III. Sri Lanka

A. Scope of the regulatory action notified by Sri Lanka

57. The regulatory action notified by Sri Lanka relates to chlorpyrifos (CAS No. 2921-88-2) in the pesticide category.

58. The regulatory action is notified as a ban. Sri Lanka, by this action, prohibited all applications of chlorpyrifos pesticides as well as its production, trade and import. The ban was introduced by the decision of the Pesticide Technical & Advisory Committee of Sri Lanka dated 5 April 2013. As a result of the decision, the registration of all products and formulations containing the active ingredient chlorpyrifos was cancelled on 28 December 2016 (UNEP/FAO/RC/CRC.19/8,

annex, sect. 2.2. of the Sri Lanka notification). The ban entered into force on 28 December 2016 but dealers and farmers were given a grace period to finish off the old stock of chlorpyrifos products by 28 December 2018.

59. The ban on chlorpyrifos was based on the evaluation of the hazards and risk to human health and to the environment (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4. of the Sri Lanka notification).

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;

60. Before the final regulatory action, the residential indoor use of chlorpyrifos for termite controls was prohibited. However, all uses of chlorpyrifos for agricultural pest control remained allowed. More than 21 trade products containing chlorpyrifos, e.g., Pyrinex, Vltashield, Pyrimac, Pyriban, Lidorban, Unifos 400, Cyren 40, Mackfos (UNEP/FAO/RC/CRC.19/8, annex, sect. 1.3 of the Sri Lanka notification) were used in Sri Lanka.

61. The ban on all use of chlorpyrifos formulations was based on a risk and hazards evaluation related to human health (excessive occupational exposure of farmers and poisoning cases among the farming communities) and to the environment (risks to indigenous fish communities).

62. Therefore, the Committee concludes that the final regulatory action was taken in order to protect human health and the environment; accordingly, 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;

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

63. The notification states that the final regulatory action was based on a risk evaluation to protect human health (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4.2.1 of the Sri Lanka notification) and the environment (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.4.2.2 of the Sri Lanka notification). The scope of the review considered the assessment of risks relevant to human health and to the environment as well as socioeconomic impacts (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.5.3.1 of the Sri Lanka notification). The final regulatory action was based on review of many research information documents and publications related to chlorpyrifos from within and outside the country (UNEP/FAO/RC/CRC.19/INF/14, annex).

64. The following topics were covered by the chlorpyrifos pesticide review:

(a) Physico-chemical, toxicological and ecotoxicological information;

(b) Human health assessment conducted by the United States Environmental Protection Agency (EPA);

(c) Evaluation of studies collected by Annals of the Sri Lanka Department of Agriculture;

(d) Study on use of chlorpyrifos pesticides related to the environment;

(e) Evaluation of alternative pesticides to chlorpyrifos;

(f) Impact assessment on the agriculture sector.

65. In the supporting documentation (UNEP/FAO/RC/CRC.19/INF/14), the national and international risk evaluations are presented, including the human health assessment on chlorpyrifos conducted by EPA in 2000 on exposure to chlorpyrifos by children in the USA due to increasing susceptibility of children occurring at high doses in the developmental neurotoxicity study. This study had been used as a basis for Sri Lanka's 2004 decision to ban the use of chlorpyrifos for indoor termite control (UNEP/FAO/RC/CRC.19/8, sect. 2.4.1 of the notification).

66. The study by Aponso and others (2002) on exposure and risk assessment for farmers occupationally exposed to chlorpyrifos in Sri Lanka showed that farmers using chlorpyrifos on cucurbits (grows on trellises = canopies) can be exposed to unnecessarily high levels of chlorpyrifos via dermal exposure. It was revealed that wearing long pants during spraying did not necessarily reduce the exposure. More than 30 per cent of the farmers in the study used more than the officially recommended dose of chlorpyrifos to achieve better pest control. Many of the knapsack spray tanks were old and about 30 per cent were leaking. Many of the workers did not use a head cover despite the fact that the curcurbit crops grow and are sprayed on over-head canopies. Most farmers did not use gloves when mixing concentrated pesticides (UNEP/FAO/RC/CRC.19/INF/14, pp. 197–205). All except three farmers showed a hazard quotient higher than 1, which indicates a risk to the applicator. The margin of safety values were greater than 1 in all cases. It is clear that the amount of compound applied is the deciding factor. However, the use of sound equipment and long-sleeved shirts can reduce exposure by 6–10 per cent. The farmers received an occupational dose higher than the reference dose (RfD) for chlorpyrifos, but it was below the no-observed-effect level (NOEL) (UNEP/FAO/RC/CRC.19/INF/14, pp. 225 and 227). Although the study concludes that under conditions of this worst-case scenario, farmers experience a minimal risk despite taking limited precautions, this might be due to the fact that in this study only small areas were sprayed (UNEP/FAO/RC/CRC.19/INF/14, p. 293). The study was interpreted by the notifying country to indicate the high occupational risk of chlorpyrifos to the farmers under use conditions in Sri Lanka.

67. The study by Aponso and others (2003) on "Analysis of water for pesticides in two major agricultural areas of the dry zone" showed that in the Polonnaruwa and Dambulla areas of Sri Lanka 83 per cent of the farming community was reported to have clinical symptoms related to acute toxicity, but 21 per cent of the group surveyed had confirmed effects related to pesticide exposure. It was stated that pesticides usage statistics in Sri Lanka indicate that about 60 per cent of total insecticides were organophosporus pesticides – major organophosporus pesticides used in agriculture are chlorpyrifos 40 per cent emulsifiable concentrate. The study concludes that farmers take minimal precautions when handling pesticides and 70 per cent do not apply the recommended dosage. It also reports that unwarranted practices such as washing spray equipment in streams and disposal of empty containers close to water bodies would have a high potential to contaminate internal water bodies such as water wells and small water reservoirs. Furthermore, it concludes that there are strong indications of acute pesticide poisoning potential among the farmers. (UNEP/FAO/RC/CRC.19/INF/14, p. 320).

68. The results of the study by Sumith and others (2012) on potential impact of agricultural pesticides on widely distributed fishes (Teleostei, family: Cyprinidae) in agricultural areas in Sri Lanka showed that chlorpyrifos, diazinon and carbosulfan had the greatest number of agricultural applications and identified as dominant pollutants. The study revealed dynamic impact of agricultural pollutants (including chlorpyrifos) on indigenous fish communities and their existence. Stringent pesticide management options and good agricultural practices are recommended to protect fish in agricultural catchments in Sri Lanka (UNEP/FAO/RC/CRC.19/INF/14, p. 336).

69. According to the supporting documentation, the list of chemical alternatives was considered sufficient for all uses of chlorpyrifos (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.5.3.2 of the Sri Lanka notification). Integrated pest management has been practised as government policy over the years in Sri Lanka.

70. Summarizing the above, the final regulatory action was based on an evaluation of risks to human health and to the environment, taking into account the prevailing conditions of the use of

pesticides, especially chlorpyrifos, in Sri Lanka (application doses, methods, protective measures, agricultural practices).

71. The notification (sect. 2.5.3.3) refers to the study of Eddleston and others (2005) on self-poisonings with organophosphorous pesticides, including chlorpyrifos, in Sri Lanka, as an additional basis for the final regulatory action, other than a hazard or risk evaluation.

72. Based on the above, the Committee concludes that the criteria in paragraph (b) (i), (ii) and (iii) of Annex II are met.

73. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole 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;

74. Sri Lanka reported on reducing the import of chlorpyrifos during the period 2011–2013 (UNEP/FAO/RC/CRC.19/8, annex, sect. 2.5.1 of the Sri Lanka notification). Consequently, it is expected that the regulatory action will lead to zero exposure, as no quantity of chlorpyrifos could be used in the country.

75. Hence, the Committee concludes 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;

76. Since the final regulatory action cancelled the registration and banned the use of chlorpyrifos, a significant reduction of the health risk and chemical burden to the environment can be expected.

77. Hence, the Committee concludes 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;

78. The notification stated that similar human health and environmental risks associated with the use of chlorpyrifos are anticipated in other states and regions, in particular under similar cultural and agro-climatic conditions in developing countries.

79. Therefore, the Committee concludes that the criterion in paragraph (c) (iii) is met.

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

80. In response to the Secretariat request to provide information on ongoing international trade in candidate chemicals for nineteenth meeting of the Chemicals Review Committee, UNEP/FAO/RC/CRC.19/INF/6 confirmed ongoing international trade in chlorpyrifos. The notification gives information on quantities of chlorpyrifos imported in 2011, 2012 and 2013.

81. Therefore, the Committee concludes that the criterion in paragraph (c) (iv) is met.

E. Annex II paragraph (d) criterion

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

82. The notification refers to the studies on the misuse of chlorpyrifos formulations for suicide. However, since the risk evaluation was based on many other considerations, intentional misuse was only one of several aspects considered before taking the final regulatory action. The

studies were not reported in the notification form in the sections concerning the risk or hazard evaluation. They are mentioned in the section which cites them as an additional basis for the final regulatory action, other than a hazard or risk evaluation.

83. In addition, in the CRC Working Paper on the Application of Criterion (d) of Annex II, the United Nations legal opinion states that criterion (d) only takes effect if not all Annex II criteria (a) to (c) are met. Only if intentional misuse is the sole reason for the final regulatory action might it be considered that there is no adequate reason for listing the chemical in Annex III.

84. Based on the above point, the Committee concludes that the criterion in paragraph (d) is met.

F. Conclusion

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

III. Conclusion

86. The Committee concludes that the notifications of final regulatory action from the European Union, Malaysia and Sri Lanka meet all the criteria set out in Annex II to the Convention.