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

Chemical Review Committee
Fourteenth meeting
Rome, 11–14 September 2018
Item 7 of the provisional agenda*
Other matters

Collection of examples of severely hazardous pesticide formulations proposals reviewed by the Chemical Review Committee

Note by the Secretariat

The Chemical Review Committee at its thirteenth meeting requested the Secretariat to collect past experience cases to support its future work on severely hazardous pesticide formulations, and to provide that information to the Committee at its fourteenth meeting. The Secretariat prepared, as set out in the annex to the present note, a summary of proposals for severely hazardous pesticide formulations reviewed by the Chemical Review Committee. The present note, including its annex, has not been formally edited.

* UNEP/FAO/RC/CRC.14/1.

Annex

Collection of examples of severely hazardous pesticide formulations proposals reviewed by the Chemical Review Committee

1. Under Article 6 of the Rotterdam Convention, any Party that is a developing country or country with an economy in transition and that is experiencing problems caused by a severely hazardous pesticide formulation under conditions of use in its territory may propose to the Secretariat the listing of the formulation in Annex III to the Convention. The proposal shall contain the information required by part 1 of Annex IV to the Convention.

2. Once the Secretariat has received such a proposal, it shall verify whether it contains the information required under part 1 of Annex IV. If the proposal contains the information required, the Secretariat shall forthwith forward to all Parties a summary of the information received and collect the additional information set out in part 2 of Annex IV. Thereafter, the Secretariat shall forward the proposal and related information to the Chemical Review Committee. The Committee shall review the information provided in the proposal and the additional information collected and, in accordance with the criteria set out in part 3 of Annex IV, recommend to the Conference of the Parties whether the severely hazardous pesticide formulation in question should be listed in Annex III to the Convention.

3. Part A of this document contains a tabular summary of proposals reviewed by the Chemical Review Committee. Part B contains the discussion and conclusion of the Committee when applying the criteria of part 3 of Annex IV to the Convention.

A. Summary of proposals for severely hazardous pesticide formulations reviewed by the Chemical Review Committee (CRC)

Proposal	Pesticide formulations	Proposing Parties	Review and conclusions by the CRC	Further actions of the CRC
1	Gramoxone Super (200 g/L Paraquat EC)	Burkina Faso	CRC-7 (2011) concluded that all criteria of Annex IV part 3 had been met	CRC-7 decided to recommend to the Conference of the Parties that liquid formulations (emulsifiable concentrate and soluble concentrate) containing paraquat dichloride at or above 276 g/L, corresponding to paraquat ion at or above 200 g/L, be listed in Annex III to the Convention as a severely hazardous pesticide formulation, adopted a rationale for its conclusion, and proceeded to develop a draft decision guidance document. CRC-8 finalized the text of the draft decision guidance document
2	Fenthion 640 ULV	Chad	CRC-9 (2013) concluded that all criteria of Annex IV part 3 had been met	CRC-9 decided to recommend to the Conference of the Parties that fenthion (ultra low volume (ULV) formulations at or above 640 g active ingredient/L) be listed in Annex III to the Convention as a severely hazardous pesticide formulation, adopted a rationale for its conclusion, and proceeded to develop a draft decision guidance document. CRC10 finalized the text of the draft decision guidance document.
3	Dimethoate emulsifiable concentrate 400 g/L	Georgia	CRC-11 (2015) agreed that criteria (a), (b) and (d) of Annex IV had not been met	No further action.

Proposal	Pesticide formulations	Proposing Parties	Review and conclusions by the CRC	Further actions of the CRC
4	Carbofuran suspension concentrate (SC) 330 g/L	Colombia	CRC-12 (2016) concluded that all criteria of Annex IV part 3 had been met	CRC-12 decided to recommend to the Conference of the Parties that carbofuran (suspension concentrate (SC) at or above 330 g active ingredient/L) be listed in Annex III to the Convention as a severely hazardous pesticide formulation and adopted a rationale for its conclusion. COP-8 decided to list carbofuran in Annex III in the category of pesticide, also decided that the CRC should discontinue its consideration of the proposal from Colombia as the formulation at issue fell within the scope of the listing of carbofuran in Annex III at the current meeting.
5	Lambda-cyhalothrin emulsifiable concentrate 50g/L	Georgia	CRC-13 (2017) was not in a position to determine whether the proposal met all the criteria in part 3 of Annex IV based on the available information	CRC-13 agreed to take up the issue at a future meeting only if new information was submitted to the Committee for consideration.
6	Lambda-cyhalothrin capsule suspension 50 g/L	Georgia	CRC-13 (2017) concluded that the proposal did not meet the criteria of part 3 of Annex IV	No further action.

B. Application of criteria of part 3 of Annex IV to the Convention

1. Rationale for the recommendation by the Chemical Review Committee to list paraquat dichloride (formulated as emulsifiable concentrate of 276 g active ingredient/L or above, corresponding to paraquat ion at or above 200 g/L) in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation[1]

Scope of the notified regulatory action

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

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

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

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

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

9. The adverse effects appeared immediately to several hours after the application of the pesticide. Symptoms reported included headaches, excessive sweating, itching, tingling, burning of the skin, skin rashes and sores, complete destruction of contaminated areas, fever, dizziness, bone pain, loss of consciousness, breathing difficulties, cough, vision troubles, eye pain, ringing in the ears, abdominal pain, nausea, vomiting and lockjaw. In 15 cases, the treatment was unknown, whereas treatment was administered in 26 cases, and in an additional 11 cases hospitalization was required. A detailed report of the survey undertaken in three regions of Burkina Faso on intoxications due to agricultural pesticides is available.2

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

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

Criterion Annex IV, part 3 (a)

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

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

12. The Pilot Study on Agricultural Pesticide Poisoning in Burkino Faso clearly describes the common and recognized pesticide application practices in the field in Burkina Faso. Gramoxone Super is reported to be used in the field on cotton, rice and maize once at the beginning of the season and is applied by means of backpack sprayers at rates of 2 to 3 L/ha. The average duration of the operator's exposure during agricultural use as found in the Pilot study was 3½ hours/hectare on an average area of 2 hectares/farm, for a total of 7 hours of exposure during an average of 1½ to 2 days of treatment.

13. The common practices regarding use of PPE (personal protective equipment) in Burkina Faso were as follows: Only 20 per cent of pesticide distributors also sell protective equipment (dust masks,

[1] Excerpt from the Report of the Chemical Review Committee on the work of its seventh meeting (UNEP/FAO/RC/CRC.7/15).

boots and gloves in particular) to the farmers; limited use of PPE by farmers: dust masks (39 per cent), boots (29 per cent), suits (5 per cent). Around 13 per cent use both dust masks and boots, whereas around 1 per cent use gloves, boots, suits, dust masks and glasses at the same time. The combination of chemical cartridge respirator, gloves, boots, suit and glasses was used in 0.3 per cent of cases.

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

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

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

Criterion Annex IV, part 3 (b)

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

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

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

Criterion Annex IV, part 3 (c)

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

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

20. Evidence is provided by Burkina Faso and other parties that the majority of farmers in many developing countries do not use PPE (see also paragraphs 10–12), are illiterate and are unaware of the risks posed by pesticides. Reports are available about defective sprayers: more than half of the sprayers in use in Cameroon, for example, are damaged. In Brazil 80 per cent of sprayers are reported to have deficiencies, while in Costa Rica the figure stands at 58 per cent. Frequently leaking sprayers are also reported from China. A survey in Cameroon revealed that 85 per cent of the farmers there do not use PPE, and in particular 80 per cent of operators wear no boots. In Zimbabwe, the use of PPE was reported to be low, partly because the benefits of such equipment did not seem overwhelming and use of the

equipment was associated with discomfort, high cost and maintenance. In Nicaragua, field workers usually get no appropriate instructions (UNEP/FAO/RC/CRC.7/11/Add.3).

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

Criterion Annex IV, part 3 (d)

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

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

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

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

Criterion Annex IV, part 3 (e)

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

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

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

27. The Committee concluded at its seventh session that the proposal from Burkina Faso to list Gramoxone Super (paraquat dichloride formulated as emulsifiable concentrate of 276 g active ingredient/L, corresponding to paraquat ion at 200 g/L) in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of part 1 of Annex IV and all criteria set out in part 3 of Annex IV to the Convention, considering the information collected by the Secretariat in accordance with part 2 of Annex IV.

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

2. Rationale for the conclusion by the Chemical Review Committee that the proposal submitted by Chad for listing fenthion 640 ULV in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation meets the criteria of part 3 of Annex IV to the Convention[2]

Scope of the proposal

29. The proposal submitted by Chad referred to the formulation Fenthion 640 ULV (concentration of 640 g/L fenthion). This is an ultra low volume (ULV) formulation.

30. The proposal and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.9/4 and Add. 1 and 2.

31. Fenthion 640 ULV was used as an avicide against granivorous birds (Quelea quelea) in the context of bird control to reduce damage to grain crops. The product was used with a motorized backpack sprayer at a dose of 1.8 to 3 L/ha in 2009, 2011 and 2012.

32. The formulation is registered; the permitted uses are for avian control. Use is only permitted to be carried out by the Directorate of Plant Protection and Conditioning (DPVC).

33. After a first intervention in 2009 by governmental order, which was carried out by seven teams, the Ministry of Agriculture and Irrigation through the Directorate of Plant Protection and Conditioning (DPVC) organized in 2011 and 2012 a mission composed of four teams, three of which were charged with survey and control and the fourth with supplies and monitoring.

34. One incident is reported in detail. In the course of the avian control mission a 60 year old technician who had a long history of hypertension (the technician had hypertension but did not signal it to the DPVC when he departed on the control campaign) was intoxicated in a nest situated 200 km from N'Djamena (Bokoro) on 17 June 2011. The technician took part in both the filling of the sprayer and application of the pesticide. He was wearing protective clothing during the whole operation, including a hat, glasses, mask, a cotton overall, gloves and boots covered by trousers. The effects were observed one hour after application. The intoxicated person showed the following symptoms: vomiting, abundant salivation and titubation. He was immediately brought to Bokoro hospital, then moved to the emergency department of N'Djamena hospital, where he received further care. On the advice of the doctor, he was discharged the same day for home care. Unfortunately, despite the care at home, he relapsed on the fourth day and passed away.

35. In document UNEP/FAO/RC/CRC.9/4/Add.1 a second case of lethal intoxication of an operator following handling/land treatment with Fenthion 640 ULV is mentioned as occurring in 2009. In addition, one operator had gone into a coma for one week under the same circumstances. However, these cases were not included in the pesticide incident report form that was included in the proposal.

36. The documentation required according to part 1 of Annex IV to the Convention was submitted by Chad in its proposal and published in PIC Circular XXXVI, of December 2012.

37. The information collected by the Secretariat according to part 2 of Annex IV to the Convention was submitted by Parties and observers and was made available to the Committee in document UNEP/FAO/RC/CRC.9/4/Add.2.

Annex IV, part 3, paragraph (a) criterion

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

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

38. In Chad, Fenthion 640 ULV is reported to have been used in the field near grain crops and it was applied by means of motorized backpack sprayers against bird roosts at rates of 1.8 to 3 L/ha. The product label gives, among other information, an indication of high toxicity by inhalation and prolonged ingestion.

[2] Excerpt from the Report of the Chemical Review Committee on the work of its ninth meeting (UNEP/FAO/RC/CRC.9/11).

39. The use of Fenthion 640 ULV was by governmental order of the Ministry of Agriculture and Irrigation through the Directorate of Plant Protection and Conditioning (DPVC), which had organized bird control teams in 2009, 2011 and 2012.

40. An incident was reported of lethal intoxication of a 60 year old technician who had been involved in mixing and loading and had sprayed the product onto bird nests during the night by the use of a backpack sprayer. He was wearing protective clothing during the whole operation: a protective kit comprising a hat, glasses, mask, a cotton overall, gloves and boots covered by trousers.

41. Although there was uncertainty regarding the causal link between the death of the operator and the use of Fenthion 640 ULV taking into account his precondition of hypertension, the operator's symptoms can be clearly linked to intoxication resulting from that use. Further it is noted that the adverse effects from organophosphates poisoning generally can be acute, intermediate or delayed.

42. The Committee concluded that the evidence indicating that the use of Fenthion 640 ULV in accordance with common and recognized practices within Chad resulted in the reported incident was reliable.

43. The Committee concluded that this criterion was met.

Annex IV, part 3, paragraph (b) criterion

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

44. Documentation was available to the Committee (UNEP/FAO/RC/CRC.9/4/Add.2) indicating that the above listed conditions for Chad are similar to the conditions prevailing in other African States. It is reported from Gambia that in the 1980s the product was used for bird control (UNEP/FAO/RC/CRC.9/4/Add.2). The product is used for control of granivorous birds in Niger and has been used for that purpose for more than 20 years in Mauritania (UNEP/FAO/RC/CRC.9/4/Add.2). In a master's thesis from Mauritania, cases of poisoning caused by avicide treatments of fenthion are reported (UNEP/FAO/RC/CRC.9/4/Add.2).

45. Various formulations of fenthion are in use as an insecticide in several countries (e.g., Australia, Madagascar, Morocco and New Zealand).

46. A case of poisoning with a different fenthion formulation is reported from Norway in the context of a suicide attempt (UNEP/FAO/RC/CRC.9/4/Add.2). Poisoning incidents from the use of fenthion in mosquito control are reported by the Food and Agriculture Organization of the United Nations (UNEP/FAO/RC/CRC.9/4/Add.2).

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

Annex IV, part 3, paragraph (c) criterion

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

48. In Chad, the application of Fenthion 640 ULV is restricted to technicians specialized in bird control (Plant Protection Service teams equipped with motorized backpack sprayers or aerial application by specialized companies).

49. Information on general handling or applicator restrictions for the use of products containing fenthion have been provided by several parties, namely, the European Union, Australia and Norway. The information provided by parties shows that personal protective equipment is required in order to protect operators from adverse effects when applying plant protection products containing fenthion.

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

Annex IV, part 3, paragraph (d) criterion

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

51. In Chad, Fenthion 640 ULV is reported to have been used in the field near grain crops. It was applied to bird roosts in 2009, 2011 and 2012 by means of motorized backpack sprayers. The following quantities were used: in 2009 112 litres was used to treat 45 dormitories (59 ha) for ten days for one hour per day by six land teams at a dose of 1.8 L/ha; in 2011 105.5 litres was used to treat 16 dormitories

(54.7 ha) for 30 days for one hour per day by six land teams at a dose of 1.9 L/ha; in 2012 275 litres was used to treat 25 dormitories (53 ha) for 30 days for one hour per day by 3 land teams at a dose of 3 L/ha.

52. In 2011, the mission lasted 45 days for the teams in charge of survey and control and 15 days for the team in charge of supply and monitoring, from 6 June to 21 July 2011.

53. The information from Chad demonstrates that fenthion 640 ULV was used at a commonly used dose and on a small area only. However, the observed effects were quite important since serious health problems were reported.

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

Annex IV, part 3, paragraph (e) criterion

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

55. Intentional misuse was not reported as a reason for the proposal.

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

Conclusion

57. The Committee concluded at its ninth session that the proposal from Chad to list Fenthion 640 ULV (640 g/L fenthion) in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of Annex IV part 1 and the criteria set out in part 3 of Annex IV to the Convention, considering the information collected by the Secretariat according to part 2 of Annex IV.

58. The Committee therefore recommends that fenthion (ultra low volume (ULV) formulations at or above 640 g active ingredient/L) (CAS No. 55-38-9) be included in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation.

3. Review of the proposal for the inclusion of dimethoate emulsifiable concentrate 400 g/L as a severely hazardous pesticide formulation in Annex III[3]

59. The Committee had before it a proposal and supporting documentation for the inclusion of Dimethoate emulsifiable concentrate 400g/L as a severely hazardous pesticide formulation in Annex III submitted by Georgia (UNEP/FAO/RC/CRC.11/8), along with additional information submitted by other parties and international organizations, which had been compiled by the Secretariat in documents UNEP/FAO/RC/CRC.11/INF/16 and Add.1.

60. Mr. Fillmann, the co-coordinator of the intersessional task group that had undertaken a preliminary assessment of the proposal and its supporting documentation, reported on the work of the intersessional task group.

61. He said that the proposal from Georgia related to a pesticide retailer who had repeatedly been exposed to dimethoate between 1998 and 2010 while repacking the pesticide from large drums into half-litre containers. The retailer had reportedly been in contact with other pesticides in his profession. After suffering from headaches, in 2010 he had been diagnosed as having a cancerous growth in his throat and his voice box had been removed. The task group concluded that the proposal included adequate documentation as required in part 1 of Annex IV. The task group noted that the Secretariat had collected relevant information relating to the formulation, as outlined in part 2 of Annex IV, and had provided it to the intersessional task group and the Committee.

62. He indicated that, given the retailer's repeated and chronic exposure to various pesticides and the potential for additive or synergistic effects, the task group had found the causality of the cancer to be uncertain and was therefore unable to confirm that criterion (a) of part 3 of Annex IV to the Convention had been satisfied. Similarly, although it seemed plausible that related incidents reported in Georgia might be relevant to other States and regions, there was no documentation of that being so, nor of cases specifically caused by repacking containers; thus the requirements of criterion (b) of part 3 were also not satisfied. The task group deemed criterion (c) of part 3 to have been satisfied, as the information available suggested that the personal protective equipment required for handling products containing

[3] Excerpt from the Report of the Chemical Review Committee on the work of its eleventh meeting (UNEP/FAO/RC/CRC.11/9).

dimethoate had not been widely used in Georgia. It was noted that, although the worker had been provided with a facemask, he had not worn it because it was uncomfortable and inadequate. With regard to criterion (d) of part 3, the quantity of the formulation used in Georgia was not known and therefore it was not possible to judge whether that criterion was satisfied. The task group had concluded that the Chemical Review Committee should discuss whether criteria (a), (b) and (d) in Annex IV were satisfied.

63. In the ensuing discussion, all members who spoke concurred that there was insufficient evidence to conclude that criteria (a), (b) and (d) had been satisfied. There was also agreement, save on the part of one member, that criteria (c) and (e) had been met. As to criterion (e), the one member said that it had not been satisfied, suggesting that the individual in question might have diluted or mixed dimethoate with another substance and that his repacking and other handling of dimethoate was not a "use" covered by the Convention. Another member countered that the elements constituting intentional misuse were specified in the Committee's handbook and that according to those elements criterion (e) had clearly been met.

64. Following the discussion it was agreed that as criteria (a), (b) and (d) of Annex IV had not been met no further action would be taken in respect of the proposal.

4. Rationale for the conclusion by the Chemical Review Committee that the proposal submitted by Colombia for listing carbofuran suspension concentrate (SC) 330 g/L in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation meets the criteria of part 3 of Annex IV to the Convention[4]

Scope of the proposal

65. The proposal submitted by Colombia referred to carbofuran suspension concentrate (SC) 330 g/L.

66. The proposal and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.12/8, UNEP/FAO/RC/CRC.12/8/Add.1 and UNEP/FAO/RC/CRC.12/INF/9.

67. In Colombia, carbofuran suspension concentrate (SC) 330g/L is reported to have been used in the field in a wide range of crops and against a wide range of pests (mainly banana and coffee, but also plantain, bean, tomato, lulo, yucca, etc.). Carbofuran is an insecticide of the carbamates family with a broad spectrum of action. It is a suspension concentrate with systemic action when applied to the soil and absorbed by the roots, and it also acts by contact and ingestion when applied to foliage. It is effective against a wide range of sucking and chewing insects, with prolonged effect.

68. Recommended doses in Colombia range from 1 to 3.5 litres per hectare, depending on the pest, status and number of individuals per square metre. Applications are directed to the soil at planting, thus pervading the seeds. In addition, ffoliar applications are used in the case of adult plants.

69. As a broad-spectrum insecticide with good agronomic efficiency, it is used by farmers in a wide range of crops, and in some cases in uses not authorized by the Colombian Agricultural Institute. For cultural reasons, small farmers do not take the necessary measures to prevent incidents with such substances, are unaware of the content of the labels (where the needed precautions to handle the product are noted), grace and re-entry periods and do not perform optimal spraying equipment maintenance, which leads to poisoning events.

70. A targeted assessment of pesticide formulations containing carbofuran was carried out in Colombia based on notifications of pesticide poisoning submitted through the national monitoring system. As a result, carbofuran -based pesticides were found to be involved in more cases of occupational poisonings than other pesticides in the period 2011–2013. In particular, 699 cases of acute pesticide poisoning by occupational exposure were reported to Sivigila (National System for Public Health Surveillance) in 2011 (inhalation and dermal), where the active ingredients mainly involved were carbofuran (408 cases), glyphosate (69) and methomyl (36); most of the cases came from the departments of Valle (53 cases), Meta (47 cases), Huila (44 cases) and Quindio (40 cases).

71. Given this background, an evaluation of poisoning by occupational exposure to pesticide formulations with the active ingredient carbofuran has taken place in the departments of Meta, Valle, Norte de Santander, Tolima, Antioquia, Quindio, Huila, Caldas, Risaralda and Cundinamarca in Colombia, during the epidemiological period 1 January–2 November 2013, through the use of the

[4] Excerpt from the Report of the Chemical Review Committee on the work of its twelfth meeting (UNEP/FAO/RC/CRC.12/9).

Rotterdam Convention severely hazardous pesticide formulation human health incident report form in 2014. It was found that 95 per cent of human poisonings by carbofuran involved pesticide liquid formulations containing carbofuran at a concentration of 330 g/L.

72. The study, using a convenience sample, was conducted in Colombia with 100 people who had previously suffered intoxication by commercial formulations of carbofuran active ingredient. Subjects of the analysis were those that agreed to fill out the questionnaire; taking into account the type of sampling it is not necessary to define the representativeness of the data.

73. According to the information provided by the Colombian Technical Department of Agricultural Inputs Safety of the Colombian Agricultural Institute (ICA), which is the national authority responsible for the registration and control of chemical pesticides for agricultural use in Colombia, products with the active ingredient carbofuran, at the moment of initiating the proposal to list the formulations in Annex III to the Convention, were registered for import, export, distribution and marketing of this molecule. By means of ICA resolution 002915, of 26 August 2006, a process for the re-evaluation of agricultural chemical pesticides was carried out in accordance with Decision 684 of 2008 of the Andean Community Commission.

74. The carbofuran molecule was in the first group of substances called for re-evaluation, and after the process it did not achieve the environmental technical decision required for registering a product. ICA therefore began the process for removing the active ingredient carbofuran from the sales register.

75. At present, carbofuran is not registered for trade in Colombia, but there is a possibility that a company could launch the registration process again in compliance with the provisions of the Andean Regulation (Norma Andina), which could result in the granting of a national registration for the marketing and use of the molecule.

Annex IV, part 3, paragraph (a) criterion

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

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

76. In Colombia, carbofuran suspension concentrate ((SC) 330 g/L) is reported to have been used in the field on a wide range of crops and against a wide range of pests (mainly banana and coffee, but also plantain, bean, tomato, lulo, yucca, etc.). The retrospective questionnaire study identified that the main risk factor associated with occupational poisoning by carbofuran was the non-use of required personal protective equipment in all working processes (mixing, loading and application) in the handling of the pesticide.

77. The use of carbofuran suspension concentrate (SC) 330 g/L in Colombia had been authorized by order of the Colombian Technical Department of Agricultural Inputs Safety of the Colombian Agricultural Institute (ICA). Its use therefore clearly represents a “recognized practice”.

78. All reported symptoms in 95 per cent of the reported carbofuran poisoning incidents can clearly be linked to intoxication with these formulations as the symptoms occurred within a very short time after their use.

79. It is therefore considered that the evidence indicates that the use of carbofuran suspension concentrate (SC) 330 g/L, in accordance with the common and recognized practices within Colombia, resulted in the reported incidents and is reliable.

80. Therefore, the Committee concluded that this criterion was met.

Annex IV, part 3, paragraph (b) criterion

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

81. Documentation was available to the Committee (UNEP/FAO/RC/CRC.12/8/Add.1) indicating that the above-listed conditions for Colombia are similar to the conditions prevailing in other Latin American States.

82. It is reported from Colombia that in the period from 1 January to 2 November 2013, 100 poisoning incidents due to occupational exposure to pesticide formulations containing the active ingredient carbofuran occurred in the departments of Meta, Valle, Norte de Santander, Tolima, Antioquia, Quindio, Huila, Caldas, Risaralda and Cundinamarca in Colombia

(UNEP/FAO/RC/CRC.12/8). The subsequent questionnaire identified that 95 per cent of people had been poisoned by pesticide liquid formulations containing carbofuran at a concentration of 330 g/L.

83. Some countries in which carbofuran formulations are used have climatic conditions similar to those of Colombia and apply the formulations with the same technology to the same crops as did Colombia.

84. Pesticide formulations containing carbofuran are used in Brazil in agriculture as an insecticide, termiticide, acaricide or nematicide for soil application on cotton, peanuts, rice, bananas, potatoes, coffee, sugar cane, carrots, beans, tobacco, corn, cabbage, tomatoes and wheat and for the treatment of cotton seeds, rice, beans, corn and wheat. In Brazil, the suspension concentrates of 310g/L (one product) and 350g/L (three products) are registered, among others. An extensive review of the toxicological aspects of carbofuran was undertaken for the re-evaluation process, pursuant to which a ban on the active ingredient is proposed (UNEP/FAO/RC/CRC.12/8/Add.1). Other countries also report the use of pesticide formulations containing carbofuran (e.g., Honduras, Malaysia, Russian Federation).

85. In the European Union, Canada and Norway final regulatory actions to ban the use of carbofuran were adopted to protect human health and the environment.

86. Therefore, the incidents reported from Colombia are considered relevant to other States and regions.

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

Annex IV, part 3, paragraph (c) criterion

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

88. Safe handling of pesticides requires the proper use of appropriate personal protective equipment by operators. The study carried out in Colombia shows that farmers do not follow that basic requirement for a number of reasons, including the climatic conditions and a lack of financial resources. In addition, many farmers were not able to read label instructions. Due to those reasons, farmers were exposed to high quantities of these formulations, which resulted in the reported poisoning incidents.

89. General handling or applicator restrictions for the use of products containing carbofuran have been provided by different Parties, namely, Brazil, Canada, the European Union and Germany. They include, for example, requirements for the application of the pesticide formulation by entities registered and accredited by the national competent authorities and the use of appropriate equipment, e.g., specific land machines and personal protective equipment.

90. No specific handling or applicator restrictions have been introduced in Colombia for the application of carbofuran suspension concentrate (SC) 330 g/L in the country.

91. Therefore this criterion is considered to be met.

Annex IV, part 3, paragraph (d) criterion

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

92. In Colombia, carbofuran suspension concentrate (SC) 330 g/L is reported to have been used in the field on a broad range of crops and against a wide range of pests and in some cases for uses not authorized by the Colombian Agricultural Institute. Recommended doses range from 1 to 3.5 L/ha, depending on the pest, status and number of individuals per square metre. Applications are directed to the soil at planting, thus pervading the seeds. In addition, foliar application takes place on adult plants.

93. The evaluation of occupational poisoning due to exposure to carbofuran-based pesticide formulations was carried out in the departments of Meta, Valle, Norte de Santander, Tolima, Antioquia, Quindio, Huila, Caldas, Risaralda and Cundinamarca in Colombia, during the epidemiological period 1 January–2 November 2013. It was found by the retrospective study performed in 2014 that 95 per cent of people had been poisoned by pesticide liquid formulations containing carbofuran at a concentration of 330 g/L (100 operators/farmers).

94. The study also shows that small farmers are unaware of the content of hazard labels, of safety precautions and of grace and re-entry periods. Farmers do not take the necessary measures to prevent incidents with such substances and do not perform the prescribed optimal spraying equipment maintenance, which resulted in the reported poisoning incidents.

95. Based on the information provided, it can be concluded that farmers used the formulation containing carbofuran according to normal and common use patterns, in particular within the commonly applied range of dosage. In relation to the small quantity of the formulation used, the occupational poisoning incidents as a consequence of handling and treatment appear significant.

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

Annex IV, part 3, paragraph (e) criterion

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

97. Intentional misuse was not reported as a reason for the proposal.

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

Conclusion

99. The Committee concluded at its twelfth session that the proposal from Colombia to list carbofuran suspension concentrate (SC) 330 g/L in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of Annex IV part 1 and the criteria set out in Annex IV part 3 of the Convention. Information according to the criteria of Annex IV part 2 has been collected by the Secretariat.

100. The Committee therefore recommends that carbofuran (suspension concentrate (SC) at or above 330 g active ingredient/L) be included in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation.

5. Review of proposal for the inclusion of severely hazardous pesticide formulation lambda-cyhalothrin emulsifiable concentrate 50 g/L in Annex III[5]

Proposal from Georgia

101. The proposal, which was for the pesticide formulation Karate 5 EC (emulsifiable concentrate) containing 50 g/L of lambda-cyhalothrin, was based on a 2016 survey of pesticide practices in Georgia. The survey had found the pesticides most widely used against the main target pests were those with the active ingredient lambda-cyhalothrin, which were commonly used on crops such as potato, tomato, orchard fruits, as well as for an unregistered use against ecto-parasites on cattle. The survey had collected details of eight incident reports, three of which related to the unregistered use of Karate 5 EC. The reported symptoms, which included headache, skin irritation, eye irritation and coughing, could clearly be linked to intoxication with Karate 5 EC as the symptoms occurred within a very short time of its use. The task group had therefore considered that the evidence indicating that the use of Karate 5 EC in accordance with common and recognized practices within Georgia had resulted in the reported incidents was reliable, and that the criterion in paragraph (a) of part 3 of Annex IV to the Convention had been met.

102. The proposal indicated that the use of lambda-cyhalothrin in a large variety of formulations was widespread around the world. The same or similar formulations were used under similar prevailing conditions in neighbouring countries to Georgia, and appeared to be applied to similar crops using similar methods. The additional information collected in accordance with part 2 of Annex IV indicated that lambda-cyhalothrin formulations were used in Germany and Switzerland and were widely available in Africa, North America and South America. The task group had therefore considered the incidents reported by Georgia relevant to other States and regions, and the criterion in paragraph (b) of part 3 to have been met.

103. With regard to the criterion in paragraph (c), the reported incidents had occurred under the prevailing conditions of use in Georgia, which included a lack of availability of personal protective equipment and limited label instructions. The survey in Georgia had indicated that farmers did not use the appropriate personal protective equipment, in part because such equipment was not readily available. In addition, the translated label did not have application or safety instructions, information on crops or application rates or precautions regarding safe use. Hungary and Canada had both provided general

[5] Excerpt from the Report of the Chemical Review Committee on the work of its thirteenth meeting (UNEP/FAO/RC/CRC.13/19).

handling or applicator restrictions for the use of products containing the active ingredient lambda-cyhalothrin, but no specific handling or applicator restrictions had been introduced in Georgia for the application of Karate 5 EC, and any such restrictions would not be expected to be widely applied as the necessary infrastructure was lacking. Based on the above, the task group had concluded that the proposal met the criterion in paragraph (c) of part 3 of Annex IV.

104. With respect to the criterion in paragraph (d), the drafter indicated that the task group had had difficulty determining how to assess the significance of the reported effects in relation to the quantity of the formulation used, and had left its conclusion bracketed for further consideration by the Committee. He noted nevertheless that the registered use was widespread, and that four of the reported incidents related to applying pesticide to crops at a standard rate of 0.4-0.5 litres, or 20 to 25 grams, per hectare using backpack sprayers, brooms and brushes, while three related to the unregistered application of Karate 5 EC to cattle with sponges to control ecto-parasites, at a rate of 0.25 grams per litre, or 0.05 litres in 10 litres of water to wash five to six cows.

105. Intoxication from intentional misuse was not reported as a reason for the proposal, and the task group had therefore concluded that the criterion in paragraph (e) of part 3 of Annex IV had been met. Although the proposal to include lambda-cyhalothrin emulsifiable concentrate 50 g/L in Annex III was based in part on incidents resulting from the unregistered use to control parasites in cattle, the task group had considered those incidents relevant because the chemical was still being used as a pesticide.

Discussion of the proposal

106. Following the presentation, Ms. Luleva responded to a number of questions and comments from members. Addressing queries on the availability and pertinence of exposure data, Ms. Luleva recalled that Article 6 of the Convention only required a developing country or a country with an economy in transition to report on incidents involving a particular pesticide formulation; in her opinion, information on exposure, while very important for assessing the significance of adverse effects, would never be available in those countries as reporting systems had not been established. In response to a question regarding the need for more precise dates for the reported incidents, she said that exact dates were difficult to determine in a retrospective study, and that it was doubtful they were needed to assess the information provided against the criteria. Finally, addressing a comment regarding the total impact of the pesticide, she noted that significance was assessed not in relation to the total quantity imported but rather in relation to the quantity of the formulation used in the individual cases.

107. There was substantial discussion on the criteria in paragraph (d) of part 3, and on how to assess the significance of the reported effects in relation to the quantity of the formulation used. Several members referred to the definition of "severely hazardous pesticide formulation" in paragraph (d) of Article 2 of the Convention. One member asserted that based on an internationally recognized poisoning severity coding system, none of the reported incidents had resulted in severe effects, indicating that the chemical in question should not be considered as a severely hazardous pesticide formulation in accordance with the definition under the Convention. Reacting to that assertion, one member, supported by another, questioned whether the Committee had the mandate to interpret the severity of effects and, even if it had, which of the many internationally recognized systems it should use to do so and whether there was suitable expertise to undertake such a task within the Committee. It would be important, she said, to clarify the procedure to be used before entering into further discussion on the content of the proposal. Responding to the various comments, Mr. Holland noted that the definition of "severely hazardous pesticide formulation" made reference to "severe", but that this was not directly referred to in the criteria in Annex IV themselves. Subsequently, the task group had considered it necessary to downgrade the severity of the adverse effects reported by the proposing Party, although some had been upgraded in the light of information submitted by an observer at the meeting.

108. In response to a number of questions posed by members on how to assess the criteria, a representative of the Secretariat drew attention to paragraph 6 of Article 6 of the Convention. She explained that, in accordance with paragraph 5 of that Article, when reviewing a proposal regarding a severely hazardous pesticide formulation, the Committee was to review the information in the related proposal, which was listed in part 1 of Annex IV, and the additional information collected under part 2 of Annex IV, and, in accordance with the criteria set out in part 3, make a recommendation to the Conference of the Parties. Part 3 did not specify whether the information to be used by the Committee in reviewing the proposals was to be sourced from information collected under part 1 or part 2. Furthermore, it was noted that some of the information, such as the criterion in paragraph (b) for instance, would only be provided in the context of part 2 information.

109. Subsequently, one member said that she still felt unable to assess whether the criterion in paragraph (d) had been met. A number of other members echoed her comment and proposed that the

Committee consider postponing the discussion. One member, supported by a number of others, suggested that it would be very helpful for the Secretariat to undertake intersessional work on how to interpret paragraph (d).

Next steps

110. The Committee concluded that it was not in a position to determine whether the proposal from Georgia to include lambda-cyhalothrin emulsifiable concentrate 50 g/L as a severely hazardous pesticide formulation in Annex III to the Convention met all the criteria in part 3 of Annex IV, and agreed to take up the issue at a future meeting only if new information was submitted to the Committee for consideration. The Committee also asked the Secretariat, as a first step, to collect past experience cases to support its future work on severely hazardous pesticide formulations, and to provide that information to the Committee at its fourteenth meeting.

6. Review of proposal for the inclusion of severely hazardous pesticide formulation Lambda-cyhalothrin capsule suspension 50 g/L in Annex III[6]

Proposal from Georgia

111. The proposal, which was for the pesticide formulation Karate Zeon 5 CS (capsule suspension) containing 50 g/L of lambda-cyhalothrin, was based on a 2016 survey of pesticide practices in Georgia. The survey had collected the details of only one incident report covering three to five incidents related to the application of the formulation with a brush dipped into a bucket of pesticide, a method commonly used by women for kitchen gardens. The reported symptoms, which included eye irritation, fever, headache, dizziness, weakness and skin irritation, could be clearly be linked to intoxication with Karate Zeon 5 CS as the symptoms occurred within a very short time after its use. The task group had therefore considered that the evidence indicating that the use of Karate Zeon 5 CS in accordance with common and recognized practices within Georgia had resulted in the incident report was reliable, and that the criterion in paragraph (a) of part 3 of Annex IV to the Convention had been met.

112. The proposal indicated that the use of lambda-cyhalothrin in a large variety of formulations was widespread around the world. The same or similar formulations were used under similar prevailing conditions in neighbouring countries to Georgia, and appeared to be applied to similar crops using similar methods. The additional information collected in accordance with part 2 of Annex IV indicated that lambda-cyhalothrin formulations were used in Germany and Switzerland and were widely available in Africa, North America and South America. The task group had therefore considered the incidents reported by Georgia relevant to other States and regions, and the criterion in paragraph (b) of part 3 to have been met.

113. With regard to the criterion in paragraph (c), the reported incidents had occurred under the prevailing conditions of use in Georgia, which included a lack of availability of personal protective equipment and limited label instructions. The woman in question had not been wearing personal protective equipment when the incidents had occurred. In addition, the translated label did not have application instructions, although it did indicate Hazard Class II and a number of precautions regarding safe use. Hungary and Canada had both provided general handling or applicator restrictions for the use of products containing the active ingredient lambda-cyhalothrin, but no specific handling or applicator restrictions had been introduced in Georgia for the application of Karate 5 EC, and any such restrictions would not be expected to be widely applied as the necessary infrastructure was lacking. Based on the above, the task group had concluded that the proposal had met the criterion in part 3, paragraph (c).

114. With respect to the criterion in paragraph (d), the registered use was widespread, and although the dose for the reported incident was not known, the farmers usually applied the formulation to crops at a standard rate of 0.4- 0.5 litres, or 20 to 25 grams, per hectare as instructed by the shop advisors. Nevertheless, owing to the lack of details concerning the dose applied, the task group had determined that it was not possible to draw any conclusion on the significance of the reported effects from the use of Karate Zeon 5 CS in relation to the quantity of lambda cyhalothrin used, and had considered the criterion not met.

115. Intoxication from intentional misuse was not reported as a reason for the proposal, and the task group had therefore concluded that the criterion in paragraph (e) of part 3 of Annex IV had been met.

[6] Excerpt from the Report of the Chemical Review Committee on the work of its thirteenth meeting (UNEP/FAO/RC/CRC.13/19).

Discussion of the proposal

116. Following the presentation, a number of members indicated their support for the task group's conclusions, although one suggested that given the effects reported, the woman's repeated use of the formulation could be construed as intentional misuse. Another member expressed the view that the proposal failed to meet the criteria in paragraphs (a), (b), (c) and (d) of part 3 of Annex IV.

Next steps

117. The Committee concluded that the proposal from Georgia to include lambda-cyhalothrin capsule suspension 50 g/L as a severely hazardous pesticide formulation in Annex III did not meet the criteria of part 3 of Annex IV to the Convention, and that, as the proposal did not meet the criteria, no further action on the pesticide formulation would be taken at present.