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**Technical work: review of notifications of final regulatory
action: paraquat and paraquat dichloride**

**Draft rationale for the conclusion by the Chemical Review
Committee that the notifications of final regulatory action
submitted by Burkina Faso, Cabo Verde, Chad, Mali, Mauritania,
Niger and Senegal and Togo in respect of paraquat in the pesticide
category meet the criteria of Annex II to the Rotterdam
Convention**

**Submission by the contact group on paraquat and paraquat dichloride,
chlorpyrifos-methyl, dichlorvos and profenofos**

The annex to the present note sets out the draft rationale on paraquat for the conclusion by the Chemical Review Committee on the notifications of final regulatory action submitted by Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal and Togo in respect of paraquat in the pesticide category. The draft rationale is presented as submitted by the contact group, without formal editing.

Annex

Draft rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal and Togo in respect of paraquat in the pesticide category meet the criteria of Annex II to the Rotterdam Convention

1. The notifications on paraquat from Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal and Togo have been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. These notifications underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notifications appeared to meet the requirements of the Convention.

2. The notifications and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.20/16, UNEP/FAO/RC/CRC.20/INF/29 and UNEP/FAO/RC/CRC.20/INF/31. Information on trade was made available in document UNEP/FAO/RC/CRC.20/INF/6.

I. Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal

A. Scope of the regulatory action notified by Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal

3. The regulatory action notified by member countries of the Sahelian Pesticides Committee, hereinafter referred to as “CILSS member countries”, namely Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal) relates to paraquat and paraquat dichloride (CAS Nos. 4685-14-7 and 1910-42-5, respectively) in the pesticide category. Although the decision refers to paraquat, all notifications of final regulatory action relate to paraquat dichloride since paraquat generally is marketed as paraquat dichloride (EPA, 1997; Health Canada, 2006, UNEP/FAO/RC/CRC.20/INF/29).

4. The regulatory action is notified as a ban. The proposal to ban paraquat was put forward at the Sahelian Pesticide Committee (CSP) session held from 22 to 26 November 2010 and submitted for signature to the Coordinating Ministers of CILSS member countries. The decision banning paraquat was signed by the Coordinating Minister of CILSS on 5 August 2011. A letter containing the decision to ban paraquat was sent to each holder of the provisional authorization for sale and to each applicant for a new approval (section 2.2 of CILSS notifications and UNEP/FAO/RC/CRC.20/INF/29).

5. The ban on the use of paraquat and paraquat dichloride as of 5 August 2011 was based on risk to human health and the environment (section 3 of the CILSS notifications and UNEP/FAO/RC/CRC.20/INF/29).

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

B. Annex II paragraph (a) criterion

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

7. Before the final regulatory action, paraquat was used as a herbicide in cotton crops and maize (section 2.3.1 of the CILSS notifications). Formulations authorized include Gramoxone Super, Gramoquat Super (paraquat chloride), Gramoxone, Calloxone, Benaxone, Gramoquat, etc (UNEP/FAO/RC/CRC.20/INF/29).

8. In the CILSS countries, GRAMOXONE SUPER (paraquat 200 g/l) was granted a provisional authorization for sale (VPA), valid for three years, issued in May 2000 and renewed in January 2004. The PARANET SUPER 200 SL (paraquat 200 g/l) and Gramuron (paraquat 100 g/l + diuron 300 g/l) had their application dossiers under review at the September 2004 and July 2005 sessions respectively (INSAH, 2010). Since 2006, paraquat-based formulations are no longer registered by the Sahelian Pesticide Committee (UNEP/FAO/RC/CRC.20/16 and UNEP/FAO/RC/CRC.20/INF/29).

9. The notifications state that the final regulatory action was based on a risk or hazard evaluation in order to protect human health and environment (Section 2.4 of the CILSS notification). Hazard and risk evaluations undertaken by other countries and international organizations were reviewed with regards to toxicological and ecotoxicological data, as well as the hazard classification of paraquat.

10. 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;*

11. With regard to human health, the main concerns are linked to the high acute toxicity and the risk of toxicity to users in Sahelian conditions, which are considered unacceptable. The WHO classifies paraquat as Class II (moderately toxic) (Footprint, 2010, WHO, 2008). Some formulations are classified as Class Ib (this is the case of GRAMOXONE PLUS which is classified T+: very toxic by inhalation). The minimal lethal dose of paraquat in humans is approximately 35 mg/kg bw. Poisoning treatment is symptomatic and there is no antidote to date (Mégarbane, 2003). Signs and symptoms appearing following dermal contact are: dry and cracked hands, loss or horizontal protuberance of nails, ulceration and abrasion (Mégarbane, 2003; Reigart and Robert, 1999). A phase of hepatic cytolysis and acute renal failure may appear on the 12th hour after Contamination (Mégarbane, 2003).

12. The evaluation was also based on the study in Burkina Faso (Toe, 2010), which includes information on pesticide use and environment conditions in general, such as low utilization rate of PPEs, the use of surface water as drinking water for human and animals. This pilot study showed that paraquat poisonings are numerous and significant in Burkina Faso. Paraquat-based formulations (GRAMOXONE, CALLOXONE, GRAMOQUAT SUPER, BENAXONE) alone were responsible for 59 cases, which represents 20% of poisoning cases. A total of 922 cases of poisoning were reported in 42 health centers. However, there is insufficient information to indicate if these are intentional or unintentional poisonings. The pesticide formulation responsible for the poisoning and the circumstance of its occurrence had been identified only in 22 cases. Five (5) out of these 22 cases occurred during pesticide application and GRAMOXONE accounted for two (2) cases. In the particular case of the use of paraquat-based formulations, the absence of an antidote specific to this product together with the lack of specialized training of physicians leads to an inadequate management of intoxication case (UNEP/FAO/RC/CRC.20/INF/29).

13. With regard to the environment concerns, the notifications provide very general statements without details on hazard and exposure. Paraquat is non-mobile (Koc = 106). Therefore, it does not present a risk of contamination of surface water by runoff. It is very persistent in soil (TD50 = 3000 days). Moreover, it presents low risk of groundwater contamination (GUS = - 6.95). In conclusion, the substance is classified as Aquatic Acute 1 (H400) (M-factor = 1000) and Aquatic Chronic 1 (H410) (M-factor = 100), as in accordance with EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008.

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

15. The CILSS risk evaluation and supporting documentation provides limited bridging information and comparison with the risk assessments performed by other Parties/organisations. However, in the pilot study, the occurrence of two poisoning cases during application, the background of inadequate PPE usage, the absence of an antidote for paraquat, and the lack of specialized training for handling poisoning cases in Burkina Faso support that the final regulation action was based on a risk evaluation under prevailing conditions. Therefore, the Committee concludes that the criterion in paragraph (b) (iii) of Annex II is met.

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

17. Since the final regulatory decision banned the use of all pesticides containing paraquat and paraquat dichloride (UNEP/FAO/RC/CRC.20/16), it can be expected that the regulatory action will lead to a significant reduction in the quantity of the chemical distributed and used in all CILSS member countries.

18. 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;

19. Since the final regulatory decision banned the use of all pesticides containing paraquat and paraquat dichloride (UNEP/FAO/RC/CRC.20/16), it can be expected that this will represent a significant reduction of the health and environmental risks.

20. 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;

21. The notifications states that paraquat could be used in other countries under similar conditions. In Africa, according to the Paraquat Information Centre on behalf of Syngenta Crop Protection AG (Paraquat Information Centre, 2010), GRAMOXONE was registered and sold as of May 2009 in 19 countries, including Cameroon, Ghana, and Nigeria, all neighbours of Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal (UNEP/FAO/RC/CRC.20/INF/29). Therefore, the relevance is not limited to the notified countries, nor do the notifications contain any indications that the applicability of the considerations that led to the final regulatory action has any limitations.

22. 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;

23. The CILSS notifications reported that 25 440 and 1875 L. of paraquat product had been imported between 2007 and 2010 (UNEP/FAO/RC/CRC.20/16, Burkina Faso). In response to the Secretariat's request to provide information on ongoing international trade of candidate chemicals that will be considered at the twentieth meeting of the Chemicals Review Committee, UNEP/FAO/RC/CRC.20/INF/6, the European Union confirmed ongoing international trade in paraquat and paraquat dichloride.

24. 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.

25. The final regulatory decision to ban of the use of paraquat and paraquat dichloride pesticides was based on risks to human health mainly and the environment. There is no indication that intentional misuse was a reason for banning paraquat and paraquat dichloride in Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal.

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

F. Conclusion

27. The Committee concludes that the notifications of final regulatory action by Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal meets the criteria set out in Annex II to the Convention.

II. Togo

A. Scope of the regulatory action notified by Togo

28. The regulatory action notified by Togo relates to paraquat (CAS Nos. 4685-14-7) in the pesticide category.
29. According to the notification, all products containing paraquat are banned due to their high toxicity potential to humans and the environment. They can only be used in agriculture after a special derogation obtained from the competent services of the Ministry of Agriculture. The same applies to their importation, marketing, distribution, use and sale in the country. The decision came into force on 1 January 2015 (UNEP/FAO/RC/CRC.20/16).
30. The Legal basis outlined in the notification:
- (a) Law No. 96-007/PR of July 3, 1996 relating to protection of plants in Togo
 - (b) Regulation No. 007/2007/CM/UEMOA of April 6, 2007 relating to protection of plants, animals and food in WAEMU.
 - (c) Regulation C/REG.21/11/10 of November 2010 harmonizing the structural framework and operational rules in terms of health safety food, plants and animals in the ECOWAS region.
 - (d) Decision No. 125/COOR/2011 of August 5, 2011 prohibiting formulations based on paraquat within CILSS (Togo is a new member of CILSS): In CILSS member states, formulations based on paraquat are no longer authorized by the Sahelian pesticide committee since 2006. Any use of paraquat in the nine former CILSS countries (Burkina Faso, Cape Verde, Gambia, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad) and the three new countries of CILSS (Benin, Ivory Coast and Togo) was banned by Decision No. 125/COOR/2011 signed by the Coordinating Minister of CILSS on August 5, 2011.
31. The notification was found to meet the information requirements of Annex I.

B. Annex II paragraph (a) criterion

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

32. Before the final regulatory action, paraquat dichloride (CAS 4685-14-7) was used in Togo as a non-selective broad-spectrum herbicide particularly for weed control before the planting crops, aquatic weeds, and weeds orchard herbs (section 2.3.1 of the Togo notification).
33. The notification states that the final regulatory action is based on a risk or hazard evaluation (section 2.4 of the Togo notification). The notification refers to the CILSS Decision No. 125/COOR/2011 of August 5, 2011. The date of entry into force of the final regulatory action is 1 January 2015 (section 2.2.3 of the Togo notification).
34. 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;*
35. The final regulatory action is taken in the category of pesticides and prohibits all uses and formulations of paraquat dichloride in plant protection products.

36. The notification states that the final regulatory action is based on a risk or hazard evaluation (section 2.4 of the Togo notification). The notification refers to the CILSS Decision No. 125/COOR/2011 of August 5, 2011. The date of entry into force of the final regulatory action is 1 January 2015 (section 2.2.3 of the Togo notification).
37. According to the notification and supporting documentation, paraquat dichloride is harmful because of its highly acute toxicity if swallowed, even at low dose. It is fatal by inhalation, toxic by dermal contact and by ingestion. It causes damage to organs when ingested through prolonged and repeated exposure, is fatal by inhalation and toxic by skin contact or ingestion. Paraquat dichloride has a high proven risk to cause serious effects on the organs following repeated exposure or from prolonged exposure. In addition, paraquat dichloride is found to be very toxic to aquatic organisms and causes harmful long-term effects. Paraquat-induced toxicity in rats was also demonstrated with degenerative lesions of the nervous system similar to those of Parkinson's disease. A study shows that paraquat, like other neurotoxicants such as lead or mercury, can even at low doses inhibit the development and functioning of the brain and spinal cord by blocking the division of stem cells of the central nervous system (Togo Notification and UNEP/FAO/RC/CRC.20/INF/31).
38. Based on the above, the Committee concludes that the criteria in paragraph (b) (i) and (ii) of Annex II are met.
39. The supporting documentation includes a Pilot study on pesticide poisoning in central Togo (2011) which lists one incident involving GRAMOQUAT (paraquat 276 g/l) where a farmer got in contact with the solution, and experienced itching and swelling of testicles three days later. In addition, the study demonstrated a low level of the use of PPE which resulted in numerous cases of poisoning.
40. Based on this, the Committee concludes that the criterion in paragraph (b) (iii) of Annex II is met.
41. Therefore, the Committee concludes that the criteria in paragraph (b) of Annex II as a whole is 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;*

42. Since the final regulatory decision banned the use of all pesticides containing paraquat dichloride, it can be expected that the regulatory action will lead to a significant reduction of the quantity of the chemical used.

43. 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;*

44. Since the final regulatory decision banned the use of paraquat dichloride, it can be expected to result into a significant reduction of the health and environmental risks.

45. 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;*

46. The notification refers to the CILSS decision as being relevant to other countries or regions where paraquat dichloride may be used under similar conditions. In addition, the notification does not contain any indication that the applicability of the considerations that led to the final regulatory action has any limitations.

47. 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;*

48. The notification from Togo does not include quantities of paraquat dichloride imported or exported. In response to the Secretariat's request to provide information on ongoing international trade in chemicals that will be considered at the twentieth meeting of the Chemicals Review Committee,

UNEP/FAO/RC/CRC.20/INF/6, the European Union confirmed ongoing international trade in paraquat and paraquat dichloride.

49. 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.

50. The final regulatory decision to ban of the use of paraquat dichloride pesticides was based on risks to human health and the environment. There is no indication that intentional misuse was a reason for banning paraquat and paraquat dichloride in Togo.

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

F. Conclusion

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

III. Conclusion

53. The Committee concludes that the notifications of final regulatory action from CILSS member countries (Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal) and Togo meet all the criteria set out in Annex II to the Convention.