

CRC-18/4: Paraquat

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 paraquat submitted by Malaysia and Mozambique¹ 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 paraquat 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 paraquat;
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 paraquat 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 eighteenth meeting.

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

1. The notifications on paraquat from Malaysia and Mozambique have been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. These notifications underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notifications appeared to meet the requirements of the Convention.
2. The notifications and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.18/13, UNEP/FAO/RC/CRC.18/INF/28 and UNEP/FAO/RC/CRC.18/INF/29. Information on trade was made available in document UNEP/FAO/RC/CRC.18/INF/6/Rev.1.

I. Malaysia

A. Scope of the regulatory action notified by Malaysia

3. The notified regulatory action relates to paraquat (CAS No. 4685-14-7), paraquat dichloride (CAS No. 1910-42-5), paraquat bistribromide (CAS No. 27041-84-5) and paraquat bis (methyl sulfate) (CAS No. 2074-50-2), in the pesticide category.
4. The regulatory action is notified as a ban. Malaysia by this action prohibited all applications of paraquat as a pesticide product as well as its import and export. The ban was introduced by the official circular JP/KRP/207/12/656/2 Vol.6 (54) on 16 May 2014 and entered into force on 1 January 2020 (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.2 of the Malaysia notification and UNEP/FAO/RC/CRC.18/INF/28, annex, p. 16).

¹ See UNEP/FAO/RC/CRC.18/13.

5. The ban on paraquat was introduced due to the highly toxic nature of paraquat, which has caused many incidences of poisoning and deaths of consumers (UNEP/FAO/RC/CRC.18/INF/28, annex, p. 20).

6. The notification was found to comply with the information requirements of Annex I to the Convention.

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 registered as a herbicide for various crops, including oil palm, rubber, pineapple stump and hill paddy (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.3.1 of the Malaysia notification). The pesticide formulations registered in Malaysia were Gramoxone 100, capayam, CS paraquat 13, Farmcare Paraquat 13, CH Paraquat P130, PP Paraquat 13, Agr Para 13 and WA Paraquat 130 (UNEP/FAO/RC/CRC.18/13, annex, sect. 1.3 of the Malaysia notification). According to the official circular JP/KRP/207/12/656/2 Vol.6 (54) of 16 May 2014, the ban was due to its highly toxic nature, which has caused many incidences of poisoning, sometimes leading to the death of users (UNEP/FAO/RC/CRC.18/INF/28, annex, p. 20). Paraquat is highly toxic if swallowed. Following ingestion of small amounts of the liquid concentrate, pulmonary oedema, cardiac failure, renal failure, liver failure and convulsions caused by central nervous system involvement can occur. Death from multiple organ failure may follow within hours or days. Furthermore, long-term and delayed health effects may occur, including Parkinson's disease, lung effects and skin cancer. There is no effective antidote for paraquat poisoning. Effects on humans indicate that spillage of concentrated poisons on the eyes can cause serious irritating effects. Exposure to the skin in turn can cause irritating effects and if this exposure is for a long period of time or chronic, skin cancer can occur. One of the long-term effects of exposure to paraquat over a long period of time is problems with nails, where the nails will come off or pull out. This situation is common among workers who carry out paraquat spray work on farms, if users do not practice safe use and spraying. If spray mist is inhaled during use on the farm it can cause nasal bleeding (UNEP/FAO/RC/CRC.18/INF/28, p. 4). The regulatory action taken entered into force on 1 January 2020 (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.2.3 of the Malaysia notification).

8. 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 notification states that the final regulatory action was based on a risk evaluation to protect human health (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.1 of the Malaysia notification). The evaluation referenced the tasks allotted to the Pesticides Board to undertake the review of paraquat because of concerns over its potential risk to occupational health and safety and the environment. The scope of the review considered the assessment of risks for humans and the environment and socioeconomic impacts. (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.1 of the Malaysia notification). During the review period from 2002 to 2013, the Ministry of Agriculture and Agro-based Industry of Malaysia, through the Department of Agriculture and the Pesticides Board,

reviewed and scrutinized many research information documents and publications related to paraquat from within and outside the country (UNEP/FAO/RC/CRC.18/INF/28, annex, p. 3).

10. The following topics were covered by the paraquat registration review:

- (a) Facts about paraquat;
- (b) Status of paraquat registration in Malaysia;
- (c) International status;
- (d) Assessment of paraquat poisoning cases in Malaysia;
- (e) Evaluation of cases of poisoning and suicide caused by paraquat at the international level;
- (f) Status of paraquat under the Rotterdam Convention;
- (g) Evaluation of alternative pesticides to paraquat;
- (h) Verification of the effectiveness of paraquat and alternative pesticides and demonstration;
- (i) Impact assessment on the agriculture sector;
- (j) Evaluation of the study by CABI/Roundtable on Sustainable Palm Oil;
- (k) Evaluation of paraquat study by the Malaysian Palm Oil Board;
- (l) Evaluation of the opinions of all stakeholders on paraquat.

11. In the supporting documentation, international risk evaluations are presented, including the 2003 evaluation report on paraquat dichloride of the Food and Agriculture Organization of the United Nations; the review report for the active substance paraquat by the European Commission (SANCO/10382/2002), which includes that knapsack and handheld use should be limited to trained/certified personnel where appropriate training and certification schemes are in operation; the 1991 World Health Organization (WHO) and International Programme on Chemical Safety "Paraquat: health and safety guide", which included that a face shield should be worn even when handling and using a diluted formulation; and the fact sheet from the 1997 reregistration eligibility decision of the Environmental Protection Agency of the United States of America, which states that personal protective equipment (PPE) requirements include a chemical resistant apron, face shield and gloves variously for mixers, loaders and sprayers. (UNEP/FAO/RC/CRC.18/INF/28, annex, p. 171).

12. The Pesticides Board classified paraquat under class Ib instead of class II (under the WHO Recommended Classification of Pesticides by Hazard) after taking into consideration that under local conditions paraquat cannot be used safely due to hot and humid weather, making wearing full protective equipment not always practical. In addition, pesticide poisoning cases reported yearly indicate that paraquat is the number one pesticide associated with poisoning incidences either due to suicide, accidental or occupational poisoning (UNEP/FAO/RC/CRC.18/INF/28, annex, p. 4). Supporting documentation further shows information related to cases of poisoning caused by chemicals, including pesticides, in Malaysia. The information is based on information from the Ministry of Health of cases of poisoning referred to government clinics and hospitals only. This means that the number of actual cases of poisoning is far greater if cases referred to private clinics and hospitals and unreported cases are taken into account. The pesticide involved in the most poisoning cases is paraquat, making up 45 per cent of cases (1,082 cases of poisoning) and involving at least 272 deaths. Analysis of poisoning data shows that the cause of paraquat poisoning is suicide, accidental drinking and occupational poisoning (UNEP/FAO/RC/CRC.18/INF/28, annex, p. 6).

13. At the international level, a report by the company Syngenta for the German national pesticides authority included that poisoning due to exposure through the skin is quite frequently reported and is mostly due to not wearing appropriate protective clothing and unsafe working methods such as inhaling spray mist or using leaky spray equipment. Among the effects reported

was damage to nails and skin as a result of repeated exposure. The study also recommended that several measures be taken to prevent poisoning from occurring, such as specific preventive measures and training for users. Malaysia notes that these may need strict implementation and enforcement (UNEP/FAO/RC/CRC.18/INF/28, annex, p. 7).

14. The Malaysian Palm Oil Board, in collaboration with Universiti Sains Malaysia, Universiti Putra Malaysia and several other parties conducted a study on the implication of a paraquat ban in Malaysia. The secretariat of the Pesticides Board commented in the study that in “the operator exposure level study, the findings support the argument that the risk of paraquat exposure to consumers under local conditions is unacceptably high and it was recommended that the use of complete PPE (long sleeves, long pants, face masks, gloves, boots and hats) when handling paraquat products. However, the use of complete PPE is not always practical in hot and humid countries like Malaysia.” The secretariat of the Pesticides Board added that some users experienced signs of paraquat poisoning, especially when not using PPE. Low levels of paraquat were detected in urine and blood analysis studies in samples taken from several operators who frequently sprayed paraquat (UNEP/FAO/RC/CRC.18/INF/28, annex, p. 11).

15. Based on the outcome of the above report and wide consultation, the Pesticides Board concluded that the continued registration of paraquat in the country would contribute to the high number of incidences of pesticide poisoning, as paraquat has been constantly reported to be the number one pesticide associated with poisoning; paraquat cannot be applied and used safely without complete PPE to prevent exposure, which is not always feasible in a country like Malaysia with hot and humid conditions; paraquat is very highly hazardous to humans, is in WHO class Ib (highly hazardous) and has no antidote for treating cases of poisoning; paraquat has been identified by the Roundtable on Sustainable Palm Oil as one of the pesticides that cannot be used in oil palm cultivation as it is not compatible with sustainable palm oil cultivation and production. Final analysis shows that the risks of paraquat outweigh the benefits (UNEP/FAO/RC/CRC.18/INF/28, annex, p. 12).

16. According to the supporting documentation, Malaysia developed a risk evaluation in which they analysed international risk assessments and compared these with local conditions of use of paraquat and actual exposure. Specifically, Paraquat has been classified by the Pesticides Board under class Ib (highly hazardous) instead of class II, after taking into consideration that under local conditions paraquat cannot be used safely, due to hot and humid weather making wearing full PPE not always practical. This decision was supported by the analysis of the operator exposure level identified by the evaluation of paraquat conducted by the Malaysian Palm Oil Board. Furthermore, the Ministry of Health of Malaysia has confirmed actual exposure to the pesticide according to the cases of poisoning referred to government clinics and hospitals; poisoning data shows that the main cause of paraquat poisoning is suicide, followed by accidental drinking and occupational poisoning.

17. Summarizing the above, the final regulatory action was based on a health hazard evaluation of paraquat, the prevailing conditions of the use of pesticides in Malaysia (intended uses, application doses, methods, protective measures, agricultural practices, etc.), and a risk assessment with a particular focus on occupational risks.

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

19. 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;

20. The final regulatory action is a ban on all imports and uses of paraquat to reduce poisoning cases amongst the public, users and bystanders (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Malaysia notification). Malaysia reported that significant quantities of paraquat were exported and used in 2018 and 2019 (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.5.1 of the Malaysia notification).

21. The final regulatory action would be expected to lead to zero exposure as no quantity of paraquat could be used in the country. Therefore, a ban is considered as fulfilling the criterion in paragraph (c) (i).

22. 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;*

23. Since the final regulatory action bans the import and use of paraquat in Malaysia, it can be expected that this will reduce poisoning cases amongst the public, users and bystanders in Malaysia, which will represent a significant reduction of risk for human health.

24. 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;*

25. The final regulatory action to ban all imports and uses of paraquat was taken to reduce poisoning cases amongst the public, users and bystanders (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Malaysia notification). The same concerns are considered to be relevant for other regions as poisoning cases involving paraquat have been reported in various countries (UNEP/FAO/RC/CRC.18/INF/28, p. 7).

26. 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;*

27. In response to the Secretariat request to provide information on ongoing international trade in candidate chemicals for the seventeenth meeting of the Chemical Review Committee, CropLife International and the Pesticide Action Network confirmed ongoing international trade in paraquat. The European Union, in response to the same request, provided proof of ongoing international trade in paraquat, through the data on the number of export notifications sent by the European Union and a number of importing countries that received or are expected to receive imports from the European Union (UNEP/FAO/RC/CRC.18/INF/6/Rev.1). Additionally, the Pesticide Action Network submitted a link to an online database with information on export notifications of paraquat processed by the European Union (<https://echa.europa.eu/information-on-chemicals/pic/export-notifications>).

28. 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.*

29. The Pesticides Board was designated to undertake a review of paraquat because of concerns over its potential risk to occupational health and safety and to the environment. The scope of the review included an assessment of risk for human health and the environment and socioeconomic impacts (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.1 of the Malaysia notification). As additional information related to the chemical or the final regulatory action, Malaysia noted that paraquat is highly used for suicidal purposes according to the cases reported by the Ministry of Health. Although analysis of poisoning data shows that the main cause of paraquat poisoning is suicide, accidental drinking and occupational poisoning have also been reported

(UNEP/FAO/RC/CRC.18/INF/28, p. 7) and were taken into account by the Pesticides Board when adopting the decision to ban the use of paraquat.

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

F. Conclusion

31. The Committee concludes that the notification of final regulatory action submitted by Malaysia fulfils all the information requirements of Annex I and the criteria set out in Annex II to the Convention.

II. Mozambique

A. Scope of the regulatory action notified by Mozambique

32. The regulatory action notified by Mozambique relates to paraquat (CAS No. 4685-14-7) in the pesticide category. The regulatory action is notified as a ban. Mozambique, by this action, banned the further import and use of paraquat in its territory. The ban was introduced by decision Nr 001/DNSA/2014 of the National Directorate of Agrarian Services. The ban of all formulations for all uses and the cancellation of the products containing paraquat in the country was decided due to the toxic nature and hazardous properties of this active substance, which, combined with the local conditions of use, can damage human and animal health and cause potential damage to the environment. The decision was taken as the last step of the project for risk reduction of highly hazardous pesticides. After consultations with different actors (public sector, private sector, civil society and others), the cancellation of registrations and consequent non-approval for their use in Mozambique was approved.

33. 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;

34. Before the final regulatory action, paraquat was registered as a herbicide for various crops, including sugar cane, various vegetables and bananas (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.3.1 of the Mozambique notification). The pesticide formulations registered in Mozambique were Moz Paraquat 20 per cent soluble liquid (SL) (paraquat 200 g/l), Paracot 20 per cent SL (paraquat 200 g/l), Para-Cure 20 per cent SL (paraquat 200 g/l), Paraxone 20 per cent SL (paraquat 200 g/l), Gramozat 20 per cent SL (paraquat 200 g/l), Agroquat 200 SL (paraquat 200 g/l), Universal Skoffos 14.5 percent SL (Paraquat 145 g/l) and Volquato 20-SL (Paraquat 200 g/l) (UNEP/FAO/RC/CRC.18/13, annex, sect. 1.3 of the Mozambique notification and UNEP/FAO/RC/CRC.18/INF/29, annex, pp. 34–35).

35. According to the notification and supporting documentation, the final regulatory action was taken because of the toxic nature and hazardous properties of paraquat, which, combined with the local conditions of use, can damage human and animal health and cause potential damage to the environment (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.2.1 of the Mozambique notification).

36. The regulatory action entered into force on 31 December 2014 (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.2.3 of the Mozambique notification).

37. 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;*

38. The notification states that the final regulatory action was based on a risk evaluation to protect human health and the environment (UNEP/FAO/RC/CRC.18/13, annex, sects. 2.4.1 and 2.4.2 of the Mozambique notification). The risk evaluation is referenced to project EP/MOZ/101/UEP, entitled “Reducing risks of highly hazardous pesticides (HHPs) in Mozambique”, initiated by the Government of Mozambique with the objective of reducing the greatest risks associated with pesticide use in the country. The ultimate goal was to develop and implement a highly hazardous pesticides risk reduction action plan for the most dangerous pesticides and use situations (UNEP/FAO/RC/CRC.18/INF/29).

39. The first phase of the project reviewed all pesticides registered in Mozambique. As a result, a shortlist of HHPs and pesticides “coming close” to HHPs was established. All pesticide formulations registered in Mozambique, including paraquat formulations, were classified using the formulations’ oral and dermal LD₅₀ values, as provided in the registration dossier. LD₅₀ values for the formulations were available or could be estimated for all registered pesticide products except for three microbial pesticides and one citronella oil (i.e., more than 99 per cent of the total) (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification).

40. The notification states that according to the WHO classification, paraquat 200 g/l SL pesticide formulation was classified as class II but with a chronic toxicity alert and dermal hazard was identified as “close to” class Ib (Come and van der Valk, 2014)² (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification). Additionally, the WHO classification notes that paraquat “has serious delayed effects if absorbed. It is of relatively low hazard in normal use but may be fatal if the concentrated product is taken by mouth or spread on the skin” (WHO, 2010). Specifically, the occupational hazard of paraquat is demonstrated by the very low acceptable operator exposure level defined in the Pesticides Properties DataBase³ (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification). Consequently, the paraquat 200 g/l SL pesticide formulation was placed on the list as “coming close to a highly hazardous pesticide”, based on the following criteria. For liquid formulations: pesticide products with an acute oral LD₅₀ of less than 200 mg/kg or an acute dermal LD₅₀ of less than 400 mg/kg (note that these are the class Ib limits in the previous 2005 version of the WHO classification).

41. In the second phase of the project, field surveys with farmers were carried out to assess actual use and exposure to pesticides under local conditions in Mozambique (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification, UNEP/FAO/RC/CRC.18/INF/29, annex, p. 52). The survey results showed that 95 per cent of the farmers used pesticides, up to 14 times per growing season. The survey also showed that the use of pesticides, including HHPs and “coming close to highly hazardous pesticides” was likely to result in excessive exposure of farmers in Mozambique. Half of the farmers interviewed in the survey had not received any training in using agrochemicals, and those who had often lacked a good understanding

² A.M. Come and H. van der Valk, “Reducing risks of highly hazardous pesticides in Mozambique: step 1 – shortlisting highly hazardous pesticides”, consultancy report undertaken under project EP/MOZ/101/UEP (2014).

³ Available at <https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/505.htm>.

of the risks involved. Almost half of the farmers declared that they did not read pesticide labels, including instructions such as proper dosage and protective measures, the main reason being illiteracy. A third of the farmers were storing pesticides inside their houses. Approximately half of the farmers surveyed reported that they had noticed deposits of pesticides on their clothes, bare skin or eyes when using pesticides, and a range of acute poisoning symptoms were reported but not linked to a particular pesticide. Almost none of the farmers (93 per cent) owned or wore adequate PPE (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification). The notification concludes that enforcing risk mitigation measures depending solely on wearing the appropriate PPE under the local conditions of use would be difficult and unlikely to give results.

42. In the third step of the project, stakeholders were consulted to further discuss the use and risks of HHPs in Mozambique and fine-tune the shortlist based on the survey results and the expertise of the stakeholders (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification).

43. In the fourth step of the project, the risk of occupational exposure was assessed in further detail for a subset of the shortlisted pesticides. The subset included nine pesticides, including paraquat, in seven different cropping systems and using 13 application scenarios, each with and without PPE (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification). Exposure of operators was estimated and then compared to a toxicologically acceptable level.

44. The exposure assessment used the registered dose rates and other application parameters for each pesticide based on farming conditions in Mozambique, including application with backpack sprayers (used in vegetables, tobacco, cereals and several other crops), handheld rotary atomizers (used in cotton) and tractor-mounted sprayers. In addition, the exposure of pesticide applicators wearing full PPE realistically available in Mozambique was compared to the exposure of applicators wearing shorts and a T-shirt, as is often the case for smallholder farmers (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification).

45. The toxicologically acceptable level of exposure applied in this study was the acceptable operator exposure level, which is defined as the maximum amount of active substance to which the operator may be exposed without any adverse health effects (European Commission, 2006).⁴ The cropping systems that were evaluated are those for which the pesticides were registered. In some cases, crops were grouped when the exposure to the pesticide was likely to be similar, based on the height of the crop and the application method (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification).

46. The volume application rates used in the model were generally those recommended on the label of the registered pesticide in Mozambique. If a volume application rate was not indicated on the label, 200 litres of pesticide mixture per ha was used as a default for emulsifiable concentrate (EC) or soluble concentrate (SC) formulations applied with hydraulic nozzles or by air-assisted sprayers (high volume application). In the case of cotton applications, a scenario where 10 litres of mixture per ha was applied using rotary atomizers (low-volume application) was also evaluated. The dose rates used in the models were the highest rates recommended on the labels of the registered pesticide. In some cases where a wide range of dose rates was recommended, the lowest dose rate was also evaluated (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification).

47. The risk of occupational exposure to pesticides was assessed, in particular when spraying the products. The risk of worker exposure in situations other than the application of the pesticide (e.g., during harvesting) or by a bystander was not evaluated. For the occupational risk assessment, an estimate of operator exposure was made, which was then compared to a toxicologically acceptable level, where workers' exposure to pesticides was estimated using occupational exposure models that are often applied in the European Union: the so-called "German model" and the predictive operator exposure model of the United Kingdom of Great Britain and Northern Ireland

⁴ European Commission, "Draft guidance for the setting and application of acceptable operator exposure levels (AOELs)", SANCO 7531 – rev. 10 (Brussels, 2006).

(UK-POEM) (Hamey and others, 2008;⁵ European Food Safety Authority, 2010)⁶
(UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification).

48. The models are different in their exposure calculations and also include different exposure scenarios. Therefore, both models are often used in parallel in the EU when assessing occupational exposure. The models' exposure scenarios and application parameters were based on Mozambican pesticides application conditions (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification).

49. The risk for the pesticide operator has been expressed as a risk quotient, which is the ratio between the estimated exposure of the operator to the pesticide (in mg a.i./kg bw/day) and the acceptable operator exposure level (in mg a.i./kg bw/day). A risk quotient of more than 1 implies that the risk is not acceptable; a risk quotient of less than 1 implies an acceptable risk. Risk quotients are given for the scenario when no PPE is worn during both mixing and spraying (worst case situation) and for the scenario with full PPE during both mixing and spraying (best-practice situation). Crops were grouped together as crop structure, and the application scenarios were considered similar (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.4.2.1 of the Mozambique notification).

50. The occupational risk assessments that were conducted showed that acceptable operator exposure levels were greatly exceeded for all crops and all pesticide application scenarios, irrespective of the application rate or use of PPE. This indicates that the application of paraquat likely poses a high risk under Mozambican conditions. Given the large risk quotient, it is unlikely that locally feasible mitigation measures would reduce the risk of paraquat to acceptable levels.

51. Summarizing the above, the final regulatory action was based on a health hazard evaluation of paraquat, the prevailing conditions of use of pesticides in Mozambique (intended uses, application doses, methods, protective measures, agricultural practices, etc.) and a risk assessment with a particular focus on occupational risks.

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

53. 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;

54. The final regulatory action bans all imports and uses of paraquat in Mozambique. In addition, the quantities of paraquat imported to Mozambique before the ban (i.e., between 2003 and 2013) were significant (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.5.1 of the Mozambique notification).

55. Therefore, the final regulatory action would be expected to lead to zero exposure as no quantity of paraquat could be used in the country. Therefore, a ban is considered as meeting the criterion in paragraph (c) (i).

56. Hence, the Committee concludes that the criterion in paragraph (c) (i) is met.

⁵ P. Hamey and others, "Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents: final report", European Food and Safety Authority Nr EFSA/PPR/2007/01 (Brussels, 2008).

⁶ European Food and Safety Authority, "Scientific opinion on preparation of a guidance document on pesticide exposure assessment for workers, operators, bystanders and residents" (Parma, Italy, 2010).

(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;*

57. Since the final regulatory action bans the use of paraquat in Mozambique, it can be expected that the action will result in a significant reduction of risks for human health caused by the use of paraquat.

58. 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;*

59. The human health concerns related to the use of paraquat are likely to be encountered in other countries with similar conditions, including where farmers use pesticides without the necessary PPE. Consequently, as also stated in the notification (UNEP/FAO/RC/CRC.18/13, annex, sect. 2.5.2 of the Mozambique notification), countries with similar conditions could apply the same considerations and make a similar decision to protect human health.

60. 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;*

61. In response to the Secretariat request to provide information on ongoing international trade in candidate chemicals for the seventeenth meeting of the Chemical Review Committee, CropLife International and the Pesticide Action Network confirmed ongoing international trade in paraquat. The European Union, in response to the same request, provided proof of ongoing international trade in paraquat, through the data on the number of export notifications sent by the European Union and the number of importing countries that received or are expected to receive imports from the European Union (UNEP/FAO/RC/CRC.18/INF/6/Rev.1). Additionally, the Pesticide Action Network submitted a link to an online database with information on export notifications of paraquat processed by the European Union (<https://echa.europa.eu/information-on-chemicals/pic/export-notifications>).

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.*

62. There is no indication in the notification or supporting documentation that intentional misuse of paraquat prompted the regulatory action.

63. Based on the above point, the Committee concludes that the criterion in paragraph (d) of Annex II is met.

F. Conclusion

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

III. Conclusion

65. The Committee concludes that the notifications of final regulatory action submitted by Malaysia and Mozambique fulfil all the information requirements of Annex I and the criteria set out in Annex II to the Convention.