

CRC-13/1: Acetochlor

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 acetochlor submitted by the European Union and by Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal and Togo¹ 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 should list acetochlor 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 acetochlor;

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 acetochlor 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 thirteenth meeting.

Annex to decision CRC-13/1

Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by Burkina Faso, Cabo Verde, Chad, Gambia, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, Togo and the European Union in respect of acetochlor in the pesticide category meet the criteria of Annex II to the Rotterdam Convention

1. In reviewing the notifications of final regulatory action by Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal, Togo and the European Union to ban acetochlor as a pesticide, together with the supporting documentation provided by those parties, the Committee was able to confirm that the final regulatory action had been taken to protect human health and the environment. The notifications from those parties were found to meet the information requirements of Annex I to the Rotterdam Convention.

2. The notifications and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.13/2, UNEP/FAO/RC/CRC.13/3, UNEP/FAO/RC/CRC.13/INF/7 and UNEP/FAO/RC/CRC.13/INF/8. Information on ongoing international trade was provided by the European Union and CropLife International and made available in document UNEP/FAO/RC/CRC.13/INF/5.

I. Burkina Faso, Cabo Verde, Chad, Gambia, Guinea-Bissau, Mali, Mauritania, Niger, Senegal and Togo

(a) Scope of the notified regulatory action

3. The regulatory action notified by the member countries of the Permanent Inter-State Committee on Drought Control in the Sahel (CILSS), namely Burkina Faso, Cabo Verde, Chad, the

¹ See UNEP/FAO/RC/CRC.13/3.

Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal and Togo (hereinafter referred to as the CILSS countries), relates to the use of acetochlor as a pesticide. The final regulatory action, which entered into force on 20 March 2017, bans the use of all pesticide formulations containing acetochlor due to its potential risk to human health and the environment. The import, manufacture for domestic use, distribution and sale are also banned (UNEP/FAO/RC/CRC.13/3, annex, part B, sects. 2.1, 2.2.1 and 2.2.3).

4. The notification was found to comply with 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;

5. The Committee confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.13/3, annex, part B, sects. 2.4.1 and 2.4.2).

6. Acetochlor has been used as a pesticide in the CILSS countries. Acetochlor was used as a selective herbicide on maize (UNEP/FAO/RC/CRC.13/3, sect. 2.3.1). Several pesticide formulations containing acetochlor were authorized in the CILSS countries between 2010 and 2012. In 2014 a working session of the Sahelian Pesticides Committee was held. Based on the proposal forwarded during this working session, the Coordinating Minister decided to ban pesticide formulations containing acetochlor as from 20 March 2017. The Sahelian Pesticides Committee recommended halting the authorization of pesticide formulations containing acetochlor owing to the following:

- Risks of water resources contamination from several metabolites including t-norchloro-acetochlor.
- High risk to aquatic organisms and long-term risks to herbivorous birds and to human beings following prolonged exposure.

7. In addition, the following were taken into account (UNEP/FAO/RC/CRC.13/INF/8):

- Difficulties experienced by the local population in obtaining adequate personal protection equipment.
- The fragile ecology of CILSS countries, characterized by torrential rains on soils that are often poor in organic matter and thus highly subject to erosion and leaching.
- The absence of an environmental management system respecting buffer strips between treated fields and water courses, the use of surface water as drinking water for man and animals.
- The use of groundwater as the only reservoir of drinking water.
- The existence of alternatives to the use of acetochlor.

8. In 2014, on the recommendation of the Sahelian Pesticides Committee, acetochlor was banned by decision of the CILSS Coordinating Minister due to unacceptable risk to the health of populations and unacceptable risk to aquatic organisms and herbivorous birds in the environment, as well as the difficulty faced by users in the countries of the Sahel in using acetochlor without unacceptable risk. The ban or restrictions on the use of acetochlor in pesticide formulations in several other countries, such as the United States of America and the European Union, are also mentioned (UNEP/FAO/RC/CRC.13/INF/8).

9. In the notification and supporting documentation, risk to human health because of high risk of surface and groundwater contamination by acetochlor and its metabolites is reported.

10. In the United States, due to concerns over groundwater contamination, acetochlor cannot be used on coarse soils (for example sandy soil with less than 3 per cent of organic matter) where the depth of groundwater is less than 30 feet. Acetochlor cannot be applied with any irrigation system (irrigation by flooding included) nor can it be applied by aerial application. Acetochlor cannot be applied directly on water or in areas where surface water is present. Furthermore, acetochlor must not be mixed or filled less than 50 feet from surface water or wells, unless adequate confinement or disposal measures exist. Each of these measures is intended to prevent acetochlor from migrating to

groundwater and/or surface water resources (United States, Environmental Protection Agency (EPA), 2006).

11. The supporting documentation indicates that an environmental management system respecting buffer strips between treated fields and streams as a precaution is not possible in the Sahel.
12. Modelling values for organic carbon content are between 1.06 per cent to 1.36 per cent for soils within the perimeter (Direction culture/SN-SOSUCO, 2008). The mean organic carbon content in soils near the rivers is equal to 1.06 per cent (Ouedraogo et al, 2012). The fragile ecology of CILSS countries is sometimes characterized by torrential rainfall on soils which are often poor in organic matter and therefore subject to erosion and leaching.
13. The results of the modelling study by Ouedraogo et al (2012) indicated that acetochlor had a very high potential to contaminate surface water under actual usage conditions in Burkina Faso.
14. In a study measuring pesticide concentrations in two lakes in Burkina Faso, acetochlor concentrations of up to 53.1 µg/L were recorded (Soleri, 2013).
15. Contamination of groundwater and surface water in the CILSS countries results in the contamination of drinking water, since these are used as sources for drinking water. In countries like Burkina Faso, more than half of the farmers (67.5 per cent) have a water point in their fields or nearby. Most water points are less than 100 metres from the fields (Toe, 2010). Water pesticide contamination via different routes may result from the proximity of water points to the fields. Water from such water points was drunk by human beings in 50 per cent of cases, used for the preparation or the dilution of pesticides in 29.26 per cent and for animal drinking in 26.96 per cent (Toe, 2010), explaining the presence of acetochlor in some water courses in Burkina Faso (Soleri, 2013).
16. The CILSS countries concluded that using acetochlor as a pesticide under these conditions resulted in an unacceptable risk to human and animal health because of drinking water contamination.
17. In the notification and supporting documentation, risks to operators are also reported.
18. Reference is made to the European Food Safety Authority (EFSA) report (2011), which mentions that health risks for operators were accentuated because the estimated exposure to European Community formulations recorded higher values (between 1435 per cent and 5550 per cent) than the acceptable operator exposure level (AOEL), despite the use of trailed sprayer and the use of gloves during mixing, loading and application. Without personal protective equipment, values up to 35550 per cent of the AOEL are reported.
19. Contrary to the recommended use in the United States and European Union member States, the recommended use in Sahel countries was low-volume application (knapsack sprayer) of the formulation diluted with water at doses between 2.5 and 3.5 l/ha on cotton. Frequency of application was once a crop-year. Recommended personal protection devices were protective clothing, goggles and gloves.
20. In the CILSS countries, people experience difficulties in finding suitable personal protective equipment. Farmers don't use appropriate personal protective equipment (Gomgnimbou et al., 2010, Ouedraogo et al., 2009, Toe et al, 2010). The protective equipment sold to farmers consists essentially of masks, boots and gloves with masks being the most used (40 per cent of farmers use them, 39 per cent of which are dust masks and 1 per cent are cartridge filter masks), followed by boots (28.8 per cent), with the combination of the two being the least used (4.5 per cent). A total of 12.62 per cent of farmers wear both masks and boots, while only 0.93 per cent wear gloves, boots, overall, mask and glasses at the same time. Masks with filter cartridges are worn in combination with gloves, boots, coveralls and goggles in only 0.31 per cent of cases (Toe, 2010). People who do not use adequate personal protective equipment should not be allowed to carry out treatments which require the full protection of operators (as for acetochlor-based formulations).
21. In the notification and supporting documentation, the following risks to the environment are reported:

22. The modelling study by Ouedraogo et al (2012) predicts that acetochlor has a very high potential to contaminate surface water if used in sugar cane production in Burkina Faso at rates of 3.54 kg a.i/ha.
23. In a study measuring pesticide concentrations in two lakes in Burkina Faso, acetochlor concentrations of up to 53.1 µg/L were recorded (Soleri, 2013).
24. Contamination of groundwater and surface water in the CILSS countries can result in high short-term risk to birds drinking contaminated water following post-emergence treatment.
25. Further, a potential high risk to non-target terrestrial plants and long term-high risk to herbivorous birds were reported.
26. The notification describes the fact that the final regulatory action prohibits all use of acetochlor containing pesticide formulations after 20 March 2017 and is therefore expected to lead to a significant decrease in the quantity of the chemical used, resulting in a significant reduction of risk to human health and the environment.
27. The Committee confirms that the criterion in paragraph (a) 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;*

28. The notifications from the CILSS countries took into account scientific information from a variety of sources. In the annex to the decision to ban acetochlor, reference is made to several national reports, as well as reports from the United States EPA, EFSA and publications published in peer-reviewed journals.

29. The Committee concludes that in the supporting documentation provided by CILSS countries, data have been generated according to scientifically recognized methods and that data reviews have been performed and documented according to generally recognized scientific principles and procedures.

30. Consequently, the Committee confirms that the criteria in paragraph (b) (i) and (ii) are met.

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

31. The final regulatory action to ban acetochlor was based on a risk evaluation. The CILSS countries found that acetochlor posed risks to human health and the environment that caused great difficulties for users in the CILSS countries in using acetochlor without unacceptable risk. The risks to human health (by contamination of groundwater and surface water, which are both used as drinking water), operators (due to the absence of sufficient personal protection measures) and to the environment (due to the intrinsic properties of the substance, the risk of water contamination and the specific conditions in the Sahel) make it very difficult to use acetochlor safely.

32. The risk evaluation took into account the conditions within the notifying Parties, for example the conditions of application of the substance, the availability of personal protective equipment, and the regional environmental circumstances.

33. Consequently, the Committee confirms that the criterion in paragraph (b) (iii) is met.

34. The Committee confirms that the criteria in paragraph (b) 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;

35. The use of acetochlor is banned by the final regulatory action which bans all pesticide formulations containing acetochlor.

36. Since the regulatory action bans the use of acetochlor as a pesticide, it is expected that the regulatory action will lead to a significant reduction in the quantity of the chemical used.

37. Therefore 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;

38. Since the regulatory action to ban the use of pesticides containing acetochlor is expected to significantly reduce the quantity of the chemical used, it is also expected that the risks to the environment will be significantly reduced.

39. Therefore 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;

40. The notification states that the use of pesticides containing acetochlor may cause similar problems to health and the environment in other countries. The Committee concludes that similar problems are likely to be encountered in other countries.

41. 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;

42. The notification from the CILSS countries gives no information on the estimated quantity of acetochlor produced, imported, exported and used.

43. However, information gathered by the Secretariat shows that international trade in acetochlor is ongoing (UNEP/FAO/RC/CRC.13/INF/5).

44. 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.

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

46. Therefore the Committee confirms that the criterion in paragraph (d) is met.

(f) Conclusion

47. The Committee concludes that the notifications of final regulatory action by Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal and Togo meet the criteria set out in Annex II to the Convention.

II. European Union

(a) Scope of the notified regulatory action

48. The regulatory action notified by the European Union relates to the use of acetochlor as a pesticide. The marketing or the use of acetochlor is banned by the final regulatory action which states that it is prohibited to place on the market or use plant protection products containing acetochlor in the European Union. Acetochlor is not approved for placing on the market pursuant to Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market (which replaces Directive 91/414/EEC).

49. All authorizations for plant protection products containing acetochlor had to be withdrawn by the member States by 23 June 2012 and all uses of plant protection products containing acetochlor are prohibited as of 23 June 2013 at the latest.

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

(b) Annex II paragraph (a) criterion

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

51. The Committee confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.11/6, sect. 2.4.2 of the European Union notification).

52. Acetochlor was used as a herbicide on maize to control and reduce annual weeds through broadcast spraying (UNEP/FAO/RC/CRC.13/3, section 2.3.1).

53. A risk assessment was carried out on the basis of Directive 91/414/EEC (replaced by Regulation (EC) No 1107/2009). It was concluded that it was not demonstrated that it may be expected that plant protection products containing acetochlor satisfied in general the requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC (UNEP/FAO/RC/CRC.13/3, sect. 2.4.1).

54. According to the risk assessment related to human health the following concerns were identified (UNEP/FAO/RC/CRC.13/3, annex, part A, sect. 2.4.2.1):

- The potential human exposure is above 100 per cent of the acceptable daily intake (ADI) when predicted concentrations of the groundwater metabolites t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid and s-sulfonic acid that have been assessed as relevant metabolites are taken into account.
- There is a potential human exposure to metabolite t-norchloro acetochlor when surface water is abstracted for drinking water, which has been assessed as relevant from a toxicological hazard assessment perspective.
- A high potential for groundwater contamination has been identified over significant areas of the European Union by the metabolites t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid and s-sulfonic acid, which have been assessed as relevant metabolites.
- No valid method is available to quantify residues in food of plant origin.

55. Pursuant to the risk assessment related to the environment the following concerns were identified (UNEP/FAO/RC/CRC.13/3, annex, part B, sect. 2.4.2.2):

- Acetochlor is very toxic to all groups of aquatic organisms and there is a high risk to aquatic organisms.
- A high acute risk to birds from the uptake of contaminated drinking water was indicated for the post-emergence applications.
- There is a high risk to non-target terrestrial plants. The risk assessment suggests that an in-field no spray buffer zone of 5 metres is required to protect non-target plants in the off-field area.

- A high long-term risk for herbivorous birds has been identified.

56. The final regulatory action is expected to lead to a significant decrease in the quantity of the chemical used, resulting in significant reduction of risk to human health and the environment.

57. The Committee concludes that the criterion in paragraph (a) 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;*

58. Prior to the final regulatory action, a risk assessment was carried out on the basis of Directive 91/414/EEC (replaced by Regulation (EC) No 1107/2009), which provides for the European Commission to issue a work programme for the examination of existing active substances used in plant protection products with a view to their possible inclusion in Annex I to the Directive, and in accordance with the provisions of Regulation (EC) No 1095/2007 and Regulation (EC) No 2229/2004.

59. A member State was designated to undertake the risk assessment based on the information submitted by the applicant and to establish a draft assessment report, which was subject to peer review during which the European Food Safety Authority (EFSA) undertook consultations with experts from member States as well as with the applicant.

60. Based on the results of the risk assessment, the European Commission established a draft review report which was submitted to peer review by the Standing Committee on the Food Chain and Animal Health, which concluded that it was not demonstrated that it may be expected that plant protection products containing acetochlor satisfied in general the requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC, leading to the adoption of a decision on non-approval of acetochlor (Commission Implementing Regulation (EU) No 1372/2011 of 21 December 2011).

61. The evaluation was based on a review of scientific data taking into account the conditions prevailing in the European Union (intended uses, recommended application rates, good agricultural practices). Only data that had been generated according to scientifically recognized methods were validated and used for the evaluation. Moreover, data reviews were performed and documented according to generally recognized scientific principles and procedures (UNEP/FAO/RC/CRC.13/3, annex, part B, sect. 2.4.1).

62. Therefore the Committee established that the data reviewed for the risk evaluation were generated according to scientifically recognized methods and that the data reviews were performed according to generally recognized scientific principles and procedures.

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

63. The final regulatory action to ban acetochlor was based on a risk evaluation. The risk analysis considered the herbicide use on maize.

64. The decision to prohibit the use of acetochlor as a pesticide was based on a data package which consists of a wide range of information concerning identity, physical/chemical/technical properties and methods of analysis, mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology, including proposed conditions of use within the European Union, including the intended uses, the recommended application rates and good agricultural practices. All the information available in the data package has been taken into account in this risk evaluation, and

therefore in the decision by the European Union. The EFSA conclusion was reached on the basis of the evaluation of the representative use in the European Union.

65. Consequently, the Committee confirms that the criterion in paragraph b (iii) is met.

66. The Committee confirms that the paragraph (b) criteria 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;

67. The use of acetochlor is banned by the final regulatory action which entered into force on 23 June 2013. The final regulatory action bans the use of acetochlor as a pesticide by prohibiting the placement on the market or use of plant protection products containing acetochlor in the European Union. Acetochlor is not approved for placing on the market pursuant to Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market (which replaces Directive 91/414/EEC).

68. The final regulatory action is therefore expected to lead to a significant decrease in the quantity of the chemical used, resulting in a significant reduction in risk to human health and the environment.

69. Therefore the Committee confirms that the criterion in paragraph (c) (i) is met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

70. It is expected that since the regulatory action to ban the use of acetochlor significantly reduces the quantity of the chemical used, the risks to human health and the environment will also be significantly reduced.

71. Therefore the Committee confirms that the criterion in paragraph (c) (ii) is met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

72. The notification states that similar health and environmental problems are likely to be encountered in other countries where the substance is used, particularly in developing countries (UNEP/FAO/RC/CRC.13/3, annex, part B, sect. 2.5.2).

73. Therefore the Committee confirms that the criterion in paragraph (c) (iii) is met.

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

74. The notification from the European Union gives no information on the estimated quantity of acetochlor produced, imported, exported and used.

75. However, information gathered by the Secretariat shows that international trade in acetochlor is ongoing (UNEP/FAO/RC/CRC.13/INF/5).

76. Therefore the Committee confirms 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.

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

78. Therefore the Committee confirms that the criterion in paragraph (d) is met.

(f) Conclusion

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

Conclusion

80. The Committee concludes that the notifications of final regulatory action by Burkina Faso, Cabo Verde, Chad, the Gambia, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal, Togo and the European Union meet the criteria set out in Annex II to the Convention. The Committee also concludes that the final regulatory actions taken by these Parties provide a sufficient basis to merit including acetochlor in Annex III to the Rotterdam Convention in the pesticide category and that a decision guidance document should be drafted on the basis of the notifications.