CRC-15/1: Amitrole

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 notification of final regulatory action for amitrole submitted by the European Union[1] meets 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. *Notes* that, as only a notification of final regulatory action from one prior informed consent region in respect of amitrole meets the criteria set out in Annex II to the Convention, it will take no further action on the chemical at present.

Annex to decision CRC-15/1

Rationale for the conclusion by the Chemical Review Committee that the notification of final regulatory action submitted by the European Union in respect of amitrole in the pesticide category meets the criteria of Annex II to the Rotterdam Convention

1. In reviewing the notification of final regulatory action by the European Union to ban amitrole as a pesticide, together with the supporting documentation provided by the European Union, the Committee was able to confirm that the final regulatory action had been taken to protect human health and the environment. The notification from the European Union was found to meet the information requirements of Annex I to the Rotterdam Convention.

2. The notification and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.15/4 and UNEP/FAO/RC/CRC.15/INF/8. Information on ongoing international trade was provided by CropLife International and made available in document UNEP/FAO/RC/CRC.15/INF/4.

I. European Union

(a) Scope of the notified regulatory action

3. The regulatory action notified by the European Union relates to the use of amitrole as a pesticide. The use of amitrole is banned by the final regulatory action which prohibits placing on the market or use of plant protection products containing amitrole. Amitrole is not included in the list of approved active substances under Regulation 1107/2009. The authorizations for plant protection products containing amitrole had to be withdrawn by 30 September 2016.

4. From 1 July 2016, no authorizations for plant protection products containing amitrole could be granted or renewed. Any grace period granted by the member States for the disposal, storage, placing on the market and use of existing stocks of plant protection products containing amitrole had to expire on 30 September 2017 at the latest (UNEP/FAO/RC/CRC.15/4, sect. 2.2.1, of the European Union notification).

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

[1] See UNEP/FAO/RC/CRC.15/4, annex, B.

(b) Annex II paragraph (a) criterion

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

6. The Committee confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.15/4, sects. 2.4.2.1, 2.4.2.2 of the European Union notification).

7. Amitrole was used as an herbicide on orchards (pome, citrus, stone and other fruits and tree nuts), grapes (table and wine), olives and non-crop uses.[2]

8. In the notification, the following reasons for the final regulatory action relevant to human health are reported: the hazard and risk assessments made on the basis of the information submitted by the applicant did not demonstrate that it may be expected that, under the proposed conditions of use, plant protection products containing amitrole are expected to satisfy in general the requirements laid down in Article 29 (1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EC)546/2011. In particular, according to the evaluation related to human health the following concerns were identified:

- Risks to operators, workers, bystanders and residents
- A high potential for groundwater exposure by the toxicologically relevant metabolite of amitrole (1,2,4-triazole) above the European Union parametric drinking water limit of 0.1 µg/L in situations represented by all 9 pertinent groundwater scenarios for crop uses

9. Amitrole is classified in accordance with Regulation (EC) No 1272/2008 as toxic for reproduction category 2, and it has toxic effects on endocrine organs (thyroid). Therefore, according to the European Union's interim criteria, amitrole was considered to have endocrine-disrupting properties (UNEP/FAO/RC/CRC.15/4, sects. 2.4.1, 2.4.2, of the European Union notification).

10. In addition, according to the evaluation relating to the environment, the following concerns were identified: risk to aquatic organisms for non-crop uses, high risk to soil non-target macroorganisms and microorganisms from the metabolite 1,2,4-triazole for all representative uses.

11. The Committee concludes that the final regulatory action was taken in order to protect human health and the environment and 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;

12. Prior to the final regulatory action, a risk assessment was carried out on the basis of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. The evaluation of the active substance amitrole, following the submission of an application to renew its approval for use in plant protection products, was made in the context of the work provided for in Articles 7 to 13 of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

[2] See UNEP/FAO/RC/CRC.15/INF/8, annex, European Food Safety Authority, "Conclusion on the peer review of the pesticide risk assessment of the active substance amitrole", p. 6.

13. For risk assessments according to Regulation (EC) No 1107/2009, scientific data on the technical active substance and at least one representative formulated product have to be submitted by the applicant. This data package consists of a wide range of information concerning identity, physical/chemical properties and methods of analysis, mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology. The data have to be generated according to scientifically recognized methods which are further specified in the regulation. The designated rapporteur member State, which in the case of amitrole was France and the co-rapporteur member State was Hungary, then evaluated this data package and performed a hazard and risk assessment based on the information submitted by the applicant. France then established an assessment report, which was subject to European Union peer review during which the European Food Safety Authority (EFSA) undertook consultations with experts from the member States as well as with the applicant.

14. Based on the results of the evaluation, the European Commission established a review report, which was finalized in the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee). The PAFF Committee concluded that no plant protection product containing the active substance amitrole is expected to satisfy in general the requirements laid down in Article 29 (1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EC) 546/2011. Therefore, amitrole should not be approved in accordance with Regulation (EC) No1107/2009.[3]

15. Therefore the Committee established that the data on which the Regulatory Act of 1 June 2016, the review report for the active substance amitrole, and the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance amitrole (26/08/2015) rely 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. Therefore the Committee concludes that criteria b (i) and b (ii) are met.

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

16. The final regulatory action to ban amitrole in the European Union was based on a risk evaluation involving the conditions within the European Union. The risk analysis considered the herbicide use on orchards (pome, citrus, stone and other fruits, and tree nuts), grapes (table and wine), olives and non-crop uses.

17. The decision to prohibit the use of amitrole 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.

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

19. 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;

20. The final regulatory action bans the use of amitrole as a pesticide in the European Union.

[3] See UNEP/FAO/RC/CRC.15/4, sect. 2.4.1; and UNEP/FAO/RC/CRC.15/INF/8, annex, European Food Safety Authority, “Conclusion on the peer review of the pesticide risk assessment of the active substance amitrole”, p. 8.

21. 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.

22. 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;

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

24. 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;

25. The notification states that similar human health and environmental problems are likely to be encountered in other regions where the substance is used, particularly in developing countries.

26. 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;

27. In response to the Secretariat request to provide information on ongoing international trade of candidate chemicals for the Chemical Review Committee at its fifteenth meeting, CropLife International confirmed ongoing international trade of amitrole (UNEP/FAO/RC/CRC.15/INF/4).

28. 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.

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

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

(f) Conclusion

31. 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.