CRC-17/3: Thiodicarb

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 thiodicarb 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 thiodicarb 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-17/3

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

1. The notification on thiodicarb from the European Union has been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. The notification underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notification appeared to meet the requirements of the Convention.

2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.17/9 and UNEP/FAO/RC/CRC.17/INF/21. Information on trade was made available in document UNEP/FAO/RC/CRC.17/INF/5.

(a) Scope of the notified regulatory action

3. The regulatory action notified by the European Union relates to the use of thiodicarb (CAS No. 59669-26-0) as a pesticide. The marketing or the use of thiodicarb is banned by the final regulatory action which states that it is prohibited to place on the market or use plant protection products containing thiodicarb. Thiodicarb is no longer included in the list of authorized active ingredients in Annex I to Directive 91/414/EEC. From 31 May 2007 no authorization for plant protection products containing thiodicarb can be granted or renewed. The authorizations for plant protection products containing thiodicarb had to be withdrawn by 25 November 2007 (UNEP/FAO/RC/CRC.17/9, sect. 2.2.1 of the European Union notification).

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.17/9 sects. 2.4.1 and 2.4.2).

[1] See UNEP/FAO/RC/CRC.17/9.

6. Thiodicarb was used as an insecticide and molluscicide (foliar spraying in table and wine grapes and spreading baits to control slugs and snails in wheat, triticale, rye, barley and oats) (UNEP/FAO/RC/CRC.17/9, sects. 1.7.1 and 2.4.1 of the European Union notification).

7. A risk assessment was carried out on the basis of Directive 91/414/EEC. The evaluation was based on a review of scientific data generated for thiodicarb in the context of the conditions prevailing in the European Community (intended uses, recommended application rates, good agricultural practices).

8. The final regulatory action to ban thiodicarb was based on a risk evaluation. The risk analysis considered the use of thiodicarb as an insecticide and molluscicide (foliar spraying in table and wine grapes and spreading baits to control slugs and snails in cereals).

9. The following concerns and risks to human health were identified (UNEP/FAO/RC/CRC.17/9, sects. 2.4.1 and 2.4.2 of the European Union notification):

(a) An acute dietary risk for toddlers resulting from the consumption of treated table grapes and for adults resulting from the consumption of wine produced from treated wine grapes;

(b) Potential of groundwater contamination under vulnerable situations;

(c) Data gaps were identified concerning the use of thiodicarb as a molluscicide, in particular regarding operator exposure.

10. The following risks to the environment were identified (UNEP/FAO/RC/CRC.17/9, sects. 2.4.1 and 2.4.2 of the European Union notification):

(a) For use of the pellet formulation (Skipper), high acute and long-term risks were identified for birds and mammals from direct consumption of pellets and additionally an acute risk from consumption of methomyl-contaminated earthworms;

(b) With regard to the use of Skipper on soils vulnerable to drainage, there is a potential risk for exposure of surface water via drainage;

(c) Thiodicarb is toxic to honeybees and there is a long-term risk to earthworms from exposure to methomyl.

11. It was concluded that thiodicarb was not demonstrated to fulfil the safety requirements laid down in Article 5 (I) (a) and (b) of Directive 91/414/EEC. In particular, concerns were identified with regard to consumer exposure and the use as a molluscicide (UNEP/FAO/RC/CRC.17/9, sect. 2.3 of the European Union notification).

12. The Committee concludes that the Annex II, paragraph (a), criterion 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;

13. The notification states that the final regulatory action was based on a risk or hazard evaluation. In the notification, reference is made to the following documents:

(a) European Commission Directorate-General for Health and Food Safety, “Review report by the European Commission for the active substance thiodicarb”, SANCO/10013/2006 Rev.1(2007), and supporting background documents (dossier, monograph and the EFSA peer review report under the Peer Review Programme);

(b) EFSA, “Conclusion regarding the peer review of the pesticide risk assessment of the active substance thiodicarb”, EFSA Scientific Report 50, 1–65 (2005) (see UNEP/FAO/RC/CRC.17/9, sect. 2.4.1 of the European Union notification).

14. The review report has been developed and finalized in support of European Commission Decision 2007/366/EC concerning the non-inclusion of thiodicarb in Annex I to Directive 91/414/EEC.

15. 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. The report has been peer reviewed by the member States and EFSA. EFSA presented to the European Commission its conclusion on the risk assessment. The results were then reviewed by the member States and the Commission within the Standing Committee on the Food Chain and Animal Health (SCFCAH) and finalized on 14 July 2006.

16. 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 have 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.

17. It was concluded that thiodicarb was not demonstrated to fulfil the safety requirements laid down in Article 5 (I) (a) and (b) of Directive 91/414/EEC. In particular, concerns were identified with regard to consumer exposure and use as a molluscicide (UNEP/FAO/RC/CRC.17/9, sects. 2.3 and 2.4. of the European Union notification).

18. 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;

19. The final regulatory action to ban thiodicarb in the European Union was based on a risk evaluation involving the conditions within the European Union. The risk analysis considered insecticide use on table and wine grapes (foliar spraying) and molluscicide use to control slugs and snails in cereals.

20. The following risks to human health and the environment were identified:

(a) An acute dietary risk for toddlers resulting from the consumption of treated table grapes and for adults resulting from the consumption of wine produced from treated wine grapes;

(b) For use of the pellet formulation (Skipper), high acute and long-term risks were identified for birds and mammals from direct consumption of pellets and additionally an acute risk from consumption of methomyl-contaminated earthworms;

(c) With regard to the use of Skipper on soils vulnerable to drainage, there is a potential risk for exposure of surface water: there is a potential risk to aquatic organisms due to exposure to the contaminated surface water;

(d) Thiodicarb is toxic to honeybees and there is a long-term risk to earthworms from exposure to methomyl.

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

22. 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;

23. The final regulatory action states that it is prohibited to place on the market or use plant protection products containing thiodicarb.

24. The final regulatory action is thus expected to lead to a significant decrease in the quantity of the chemical used and the number of its uses.

25. 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;

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

27. 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;

28. 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.17/9, sect. 2.6 of the European Union notification).

29. 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;

30. The notification from the European Union gives no information on the estimated quantity of thiodicarb produced, imported, exported and used. The Secretariat collected information on trade. The information received shows that there is evidence of ongoing trade (UNEP/FAO/RC/CRC.17/INF/5).

31. 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.

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

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

(f) Conclusion

34. 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.