



## Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

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### Chemical Review Committee

#### Seventeenth meeting

Rome (online), 20–24 September 2021

Agenda item 4 (b) (vii)

**Technical work: review of notifications of  
final regulatory action: thiodicarb**

### **Draft rationale for the conclusion by the Chemical Review Committee on the notification of final regulatory action submitted by Mozambique in respect of thiodicarb in the pesticide category**

#### **Note by the Secretariat**

1. At its seventeenth meeting, the Chemical Review Committee considered the notifications of final regulatory action on thiodicarb submitted by Mozambique and the European Union set out in document UNEP/FAO/RC/CRC.17/9 along with supporting documentation set out in documents UNEP/FAO/RC/CRC.17/INF/20 and UNEP/FAO/RC/CRC.17/INF/21.
2. The Committee agreed that the notification from the European Union met all the criteria of Annex II to the Convention and adopted a rationale for its conclusion as set out in the annex to decision CRC-17/3.<sup>1</sup> With regard to the notification from Mozambique, the Committee was unable to reach consensus on whether it met the criteria of Annex II, specifically the criterion of paragraph (b) (iii) and agreed to continue its consideration at the eighteenth meeting.
3. The annex to the present note sets out a draft rationale for the conclusion by the Chemical Review Committee on the notification of final regulatory action submitted by Mozambique in respect of thiodicarb in the pesticide category which was under consideration by the contact group on thiodicarb established at the seventeenth meeting as the draft rationale stood when the contact group adjourned its work. The present note, including its annex, has not been formally edited.

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<sup>1</sup> UNEP/FAO/RC/CRC.17/10, annex I.

## Annex

### Draft rationale for the conclusion by the Chemical Review Committee on the notification of final regulatory action submitted by Mozambique in respect of thiodicarb in the pesticide category

#### (a) Scope of the regulatory action notified by Mozambique

1. The regulatory action notified by Mozambique relates to thiodicarb (CAS No. 59669-26-0) as a pesticide. Prior to the final regulatory action entering into force, thiodicarb was registered in Mozambique as an insecticide to be used on cotton (Section 2.3.1 of notification - UNEP/FAO/RC/CRC.17/9)
2. Thiodicarb was banned by the National Directorate of Agrarian Services from further import and use in Mozambique by the decision Nr 001/DNSA/2014. The regulatory action entered into force on 15 July 2014. The ban of all uses and the cancellation of the products containing thiodicarb in the country was decided due to the toxic nature and hazardous properties of this active substance which combined with the improper use in the country due to the local specific conditions of use can damage human and animal health.
3. The decision to ban the registration of thiodicarb was taken as the last step of the project for risk reduction of highly hazardous pesticides which identified highly hazardous pesticides and other pesticides that are registered in Mozambique. After consultations with different actors (public sector, private sector, civil society and others) cancellation of registrations and consequent ban and non-approval for their use in Mozambique was approved (Sections 2.2.1 and 2.2.3 of notification - UNEP/FAO/RC/CRC.17/9).
4. 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;*

5. The Committee confirms that the regulatory action was taken to reduce the risk from thiodicarb to human health (UNEP/FAO/RC/CRC.17/9, section 2.4.2.1 of the Mozambique notification).
6. The notification states that the ban of all uses and the cancellation of the products containing thiodicarb in Mozambique was decided based on the toxic nature and hazardous properties which combined with the improper use in the country due to the local specific conditions of use can damage human and animal health.
7. The notification refers to a consultancy report Shortlisting highly hazardous pesticides (Come A.M. and van der Valk H., 2014), which identified thiodicarb formulation as pesticide coming close to highly hazardous pesticides (HHPs) since its LD50(oral) < 200 mg/kg or acute dermal LD50 < 400 mg/kg (these criteria were established under the framework of the consultancy report for shortlisting acute toxic liquid formulation coming close to HHPs according to the FAO/WHO Joint Meeting on Pesticide Management (JMPM) criteria for HHPs based on the WHO International Classification of pesticides by hazard).
8. Results of a survey conducted amongst 325 subsistence farmers in Mozambique showed that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers. Therefore enforcing risk mitigation measures depending solely on wearing the appropriate Personal Protective Equipment (PPE) under the local conditions of use would be difficult and unlikely to give results.
9. Thiodicarb and the products containing this active ingredient were considered harmful for human health under the local conditions of use in Mozambique requiring risk mitigation measures. The decision to cancel the registration of thiodicarb was taken as the last step of the project for Risk Reduction of HHP. The expected effect of the final regulatory action was reducing the risk posed by the use of thiodicarb in Mozambique in the context of human health. (Sections 2.2.1 and 2.4.2.1 of notification - UNEP/FAO/RC/CRC.17/9)
10. The Committee therefore confirms that 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;*

11. The notification refers to a consultancy study that is based on international assessments and property data:

(a) Come A.M. & van der Valk H., 2014. Reducing Risks of Highly Hazardous Pesticides in Mozambique: Step 1 – Shortlisting highly hazardous pesticides, Consultancy report undertaken under the Project EP/MOZ/101/UEP.

(b) Come A.M.; Dona L.L.; Mancini F. & van der Valk H., 2014. Reducing Risks of Highly Hazardous Pesticides in Mozambique: Step 2 – Survey of pesticide use practices in selected cropping systems.

(c) FAO/ WHO (2008) Report of the 2nd Joint Meeting on Pesticide Management and the 4th Session of the FAO Panel of Experts on Pesticide Management. 6-8 October 2008, Geneva. Food and Agriculture Organization of the United Nations, Rome & World Health Organization, Geneva. [http://www.fao.org/fileadmin/templates/agphome/documents/Pests\\_Pesticides/Code/Report.pdf](http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Report.pdf) (p. 14–18).

(d) Lahr J., R. Kruijne & J. Groenwold, 2014. Hazards of pesticides imported into Mozambique, 2002-2011. Wageningen, Alterra Wageningen UR (University & Research centre).

12. The ultimate goal of the project was to develop and implement an "HHP Risk Reduction Action Plan" for the most dangerous pesticides and use situations, resulting over time in the implementation of a variety of risk reduction measures based on a review of use conditions (Sections 2.4 and 2.4.1 of notification - UNEP/FAO/RC/CRC.17/9).

13. The decision to cancel the registration of thiodicarb was taken as the last step of the project for Risk Reduction of Highly Hazardous Pesticides. The ban of all uses and the cancellation of the products containing thiodicarb in the country (Decision Nr 001/DNSA/2014) was decided due to the toxic nature and hazardous properties of this active substance which, combined with the improper use in the country due to the local specific conditions of use, can damage human and animal health (Sections 2.2.1 and 2.4.2.1 of notification - UNEP/FAO/RC/CRC.17/9).

The supporting documentation (UNEP/FAO/RC/CRC.17/INF/20) also includes the following documents referenced in the notification:

- (a) Pesticides Properties Database (PPDB):  
<https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/621.htm> (abstract).
- (b) EFSA Scientific Report (2005) 55, 1-76, Conclusion on the peer review of thiodicarb

14. The available consultancy reports, hazard assessment criteria by the FAO/WHO international panel and EFSA scientific report on thiodicarb are considered scientifically sound and generated according to scientifically recognized methods and reported according to generally recognized scientific principles and procedures.

15. The available reports developed under the Risk Reduction of Highly Hazardous Pesticides in Mozambique project and included in the supporting documentation provide detailed methodology that specifies that internationally recognized criteria established by the FAO/WHO JMPM for the identification of HHPs were used to identify HHPs in Mozambique, including thiodicarb (p.15 of UNEP/FAO/RC/CRC.17/INF/20). Also, the report on the survey of pesticide use practices in selected cropping systems indicates that survey design was informed by reviews of various existing pesticide use or exposure surveys conducted under the WHO and Rotterdam Convention, as well as general FAO guidance on development of this type of questionnaire. Interviewers were also trained on survey techniques (pp.57-58 of UNEP/FAO/RC/CRC.17/INF/20).

16. The data included in the notification and supporting documentation is considered to be scientifically sound and generated according to scientifically recognized methods and data reviews are considered to have been performed and documented according to generally recognized scientific principles and procedures.

17. The Committee therefore confirms that the criteria in paragraphs (b) (i) and (b) (ii) of Annex II are met.

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

18. The notification states that the final regulatory action was based on a risk or hazard evaluation involving prevailing conditions within the Party in order to protect human health (UNEP/FAO/RC/CRC.17/9, section 2.4 of the Mozambique notification). With the goal of reducing the greatest risks associated with pesticide use in Mozambique, the Reducing Risks of Highly Hazardous Pesticides in Mozambique project was initiated by the Government of Mozambique, with the technical support of FAO's Pesticides Management Unit, and funded by SAICM Quick Start Programme Trust Fund. Its ultimate goal was to develop and implement an "HHP Risk Reduction Action Plan" in Mozambique for the most dangerous pesticides and use situations, resulting over time in the implementation of a variety of risk reduction measures based on a review of use conditions. These could include the cancellation of specific registrations of HHPs, implementation of risk mitigation measures, appropriate use restrictions, development of alternative pest management strategies, promotion of good agricultural practices, and possible phase-out of specific pesticides (p.11 UNEP/FAO/RC/CRC.17/INF/20).

19. The project was separated into three steps, the first of which involved the review of all the pesticides registered in Mozambique and the establishment of a shortlist of HHPs. This shortlist was based on an assessment of the hazards of the pesticides, based on criteria established by the FAO/WHO Joint Meeting on Pesticide Management (JMPM) (FAO/WHO, 2008).

20. The thiodicarb formulations registered at the time in Mozambique is Larvin 37 5% SC (sections 1.3 and 2.3.1 of notification - UNEP/FAO/RC/CRC.17/9). This formulation was assessed against the following criterion FAO/WHO JMPM criterion: LD<sub>50</sub>(oral) < 200 mg/kg or acute dermal LD<sub>50</sub>< 400 mg/kg (these criteria were established under the framework of the consultancy report for shortlisting acute toxic liquid formulation coming close to HHPs according to the FAO/WHO Joint Meeting on Pesticide Management (JMPM) criteria for HHPs based on the WHO International Classification of pesticides by hazard) for identification as pesticide coming close to HHPs. The oral and dermal LD<sub>50</sub> value of the formulations, as provided in the registration dossier, were used as the basis for the classification. LD<sub>50</sub> values for the formulations were available or could be estimated. The thiodicarb formulation was identified as amongst the most dangerous pesticides registered in Mozambique, noting that is a WHO Class II formulation.

21. During the second step of the project, a use survey was carried out in selected regions and cropping systems in Mozambique. The main goal of the survey was to identify the conditions under which pesticides are being used in the country and their contribution to potential risks for human health and the environment.

The surveys (325 subsistence farmers interviewed) revealed that most of the farmers applied pesticides (95%), and that the conditions of use were likely to result in undue (excessive) exposure. Half of the farmers interviewed never received any training on pesticides use, and even the other half that did, often lacked understanding of the risks involved. Farmers were spraying vegetable crops at least 14 times per growing season. One out of three applications was involving one of the HHP containing formulation (Farmers using HHPs includes almost 30% of the interviewed farmers).

Also almost none of the farmers (93%) owned or wore adequate PPE having only one or no protective items at all. Only 2% of those applying HHPs wore adequate full body protection PPE. About half of the farmers had not received any training on the use of pesticides. The majority of pesticide applicators used manual sprayer (36%), followed by electric sprayer (with batteries); 33% and followed by inappropriate equipment such as watering can (13.5%) or other (unknown) means (12.5%). Approximately about half of the farmers surveyed reported that they noticed to receive pesticide on their clothes, bare skin or eyes when using pesticides. The main health symptoms associated with pesticide use by farmers noticing symptoms were headaches, skin rashes, burning eyes, vomiting, burning nose, blurred vision, dizziness and excessive sweating. Almost half of the farmers declared they did not read pesticide labels, including use instructions such as proper dosage and protective measures, the main reason being illiteracy. One out of four farmers poorly understood the hazard colour band on pesticide labels that indicates acute toxicity.

The survey results showed that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers in Mozambique. Therefore 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.

22. The third step of the project consisted of a stakeholder consultation to further discuss the use and risks of highly hazardous pesticides in Mozambique and fine-tune the shortlist based on the survey results and the expertise and experience of stakeholders.
23. Thiodicarb and the products containing this active ingredient were considered to pose unacceptable risk to human health under the local conditions of use in Mozambique requiring risk mitigation measures. Therefore the authorities decided to ban the active ingredient thiodicarb from future use in the country and to cancel the registration of all the products containing it (Sections 1.3 and 2.4.2.1 of notification - UNEP/FAO/RC/CRC.17/9, with a focus on thiodicarb specific information as included in the supporting documentation).
24. Although specific information related to actual or measured thiodicarb exposure in Mozambique was not included as part of the risk evaluation, the notification and supporting documentation provide an assessment of the prevailing conditions of use of pesticides in Mozambique. While no imports of thiodicarb formulations were recorded in the four years (2010-2013) prior to and including the period when the survey of users was carried out, registrations of this formulation remained in place and therefore future use could not be precluded (p.33 UNEP/FAO/RC/CRC.17/INF/20). The registered use for thiodicarb is formulation cotton. This cropping system was included in the survey of users conducted, and was one of the predominant crops in 5 of the regions of Mozambique surveyed. The notification and supporting documentation indicate that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers given the availability, knowledge and use of PPE amongst farmers and was evidenced by a high level of reporting of adverse health effects. The final regulatory action was taken as a result of Mozambique's national objective of reducing the greatest risks associated with pesticide use.
25. [Mozambique's goal to develop and implement an 'HHPs Risk Reduction Action Plan' could be considered as a national policy that HHPs not be registered based on the understanding that the prevailing conditions of use in Mozambique will result in unacceptable risks to agricultural workers. Thiodicarb and the thiodicarb formulation registered in Mozambique were identified as the formulation has an LD50 <200 mg/kg and the active ingredient has an LD50 = 50mg/Kg. The active ingredient is a WHO Class II based on an oral LD50 of 66mg/kg (section 3.2.2 of notification of Mozambique). The acute toxicity criteria used for shortlisting the most toxic pesticides registered in Mozambique are very close to category WHO Class 1b.
- Therefore, taking into consideration Mozambique's national objective of reducing risks of the most dangerous pesticides, the results of the survey of pesticide use practices in selected cropping systems in Mozambique, some of which are representative of potential thiodicarb use, which included the identification of inadequate availability and use of PPE and thiodicarb's high acute toxicity (LD50 = 50 mg/kg), it is concluded that the final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action.
26. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.
27. The Committee confirms that the criteria of paragraph (b) of Annex II 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;*
28. The final regulatory action canceled the registration of all pesticides containing thiodicarb and banned all their uses. Consequently, it is expected that the regulatory action will lead to a significant reduction of the quantity of the chemical used.
29. The Committee therefore 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;*
30. The final regulatory action cancelled the registration of all pesticides containing thiodicarb and banned all their uses. Consequently, it is expected that the regulatory action will lead to a significant reduction of risk to human health.
31. The Committee therefore 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;*

32. The notification states that countries with similar conditions as well as where the farmers use pesticides without protective equipment could make similar decision in order to protect human health.

33. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

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

34. The notification gives information on quantities of chemicals imported in the years 2003 and 2004. The Secretariat collected information on trade. The received information shows that there is evidence of ongoing trade.

35. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

36. The Committee confirms that the criteria of paragraph (c) of Annex II are 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.*

37. There is no indication in the notification that concerns for intentional misuse prompted the regulatory action.

38. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

**(f) Conclusion**

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

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