



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

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**Conference of the Parties to the  
Rotterdam Convention on the Prior  
Informed Consent Procedure for Certain  
Hazardous Chemicals and Pesticides in  
International Trade**

**Sixth meeting**

Geneva, 28 April–10 May 2013

Item 5 (c) of the provisional agenda\*

**Matters related to the implementation of the  
Convention: consideration of chemicals for  
inclusion in Annex III to the Convention**

**Rationales and recommendation of the Chemical Review  
Committee on the inclusion of azinphos-methyl in Annex III to  
the Rotterdam Convention**

**Note by the Secretariat**

To facilitate consideration by the Conference of the Parties of the inclusion of azinphos-methyl in Annex III to the Rotterdam Convention,<sup>1</sup> the annexes to the present note set out the rationales pertaining to the substance prepared by the Chemical Review Committee at its fifth and sixth meetings and the recommendation prepared by the Committee at its seventh meeting.

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\* UNEP/FAO/RC/COP.6/1.

1 See UNEP/FAO/RC/COP.6/7.

## Annex I

### **Rationale for the conclusion by the Chemical Review Committee at its fifth meeting that the notification of final regulatory action for azinphos-methyl (CAS No. 86-50-0) from Canada meets the information requirements of Annex I and the criteria of Annex II to the Rotterdam Convention<sup>2</sup>**

1. In reviewing the notification of final regulatory action by Canada to severely restrict the use of azinphos-methyl as a pesticide, together with the supporting documentation, the Chemical Review Committee concluded at its fifth session that the regulatory action had been taken to protect human health.
2. Azinphos-methyl was used in Canada as a broad spectrum organophosphate insecticide on a wide variety of feed, food and ornamental crops. It was used on the feed crops alfalfa, clover and rye. Registered food crop use included fruit such as apples, crab apples, pears, quinces, cherries, peaches, apricots and berries, and vegetables such as Brussels sprouts, cabbages, cauliflowers, tomatoes and potatoes. Use on ornamental crops included nursery plants, forest trees and shade trees.
3. The regulatory action of Canada was to phase out by the end of 2005 all uses of azinphos-methyl for which alternatives exist: alfalfa, clover, rye, quince, potatoes, tomatoes, rutabagas, turnips, cabbage, broccoli, Brussels sprouts, cauliflowers, cucumbers, strawberries, boysenberries, longan berries, walnuts, melons, pumpkins, blueberries, outdoor ornamentals, nursery plants, forest trees and shade trees. Other uses that are part of an established integrated pest management programme or for which there are no alternatives continue to be registered until the end of 2012: apples, crab apples, apricots, blackberries, cherries, cranberries, grapes, pears, peaches, plums, prunes and raspberries.
4. The risks of azinphos-methyl were assessed considering two key factors: dose levels with no effect on human health and the dose to which people may be exposed. Only uses where exposure is well below levels that cause no effects in animal testing were considered acceptable for continued registration. Azinphos-methyl was found to be extremely acutely toxic via the oral and dermal routes and moderately toxic by inhalation and a dermal sensitizer. Symptoms are consistent with that of a cholinesterase inhibitor. Occupational risk estimates associated with application, mixing and loading for registered label uses exceeded the level of concern for most exposure scenarios, even after consideration of maximum feasible engineering controls and personal protective equipment and clothing. The personal protective equipment, engineering controls and use pattern changes required to mitigate worker exposure during the phase-out period were described. These included among others: coveralls, chemical-resistant gloves, chemical-resistant footwear, and protective eyewear and headgear and, for exposure in enclosed areas, a respirator. In addition, mixers and loaders must have a fully closed mixing and loading system.
5. The risk evaluation performed by Canada included an assessment of the hazards to human health (high acute toxicity and dermal sensitization) and human exposure (primarily occupational exposure associated with mixing, loading and application), and therefore meets the criteria for a risk evaluation.
6. The Committee established that the final regulatory action had been taken on the basis of a risk evaluation and that the evaluation had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognized methods and that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures. Data were either generated from internationally recognized sources – such as the Pesticide Manual – or from the United States Environmental Protection Agency review for azinphos-methyl. The review process took into account existing use patterns in Canada and the United States of America and was documented in a series of re-evaluation notes, which were available to the Committee. Overall, the available documents showed that the final regulatory action had been based on a chemical-specific risk evaluation, involving prevailing conditions of exposure within Canada.
7. The Committee noted that, as the regulatory action in Canada was a severe restriction of the use of azinphos-methyl, there would be a reduced risk of occupational exposure to the toxic effects of

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2 UNEP/FAO/RC/CRC.5/16, annex III, section A.

azinphos-methyl for uses that are no longer authorized. There would be further elimination of other uses by the end of 2012, with additional risk mitigation measures being introduced in the interim period.

8. There was no indication of industrial uses of azinphos-methyl in Canada. The Committee also noted that the considerations underlying the final regulatory action (namely occupational risks) were not of limited applicability since concerns similar to those identified in Canada could occur in other countries, in particular developing countries. Based on information provided to the Committee, there was evidence of ongoing trade in azinphos-methyl.

9. The Committee noted that the final regulatory action in Canada was not based on concerns over intentional misuse of azinphos-methyl, but on concerns from registered label uses.

10. The Committee concluded that the notification of final regulatory action by Canada had met the information requirements of Annex I and the criteria set out in Annex II to the Convention.

## Annex II

### **Rationale for the recommendation by the Chemical Review Committee at its sixth meeting that azinphos-methyl (CAS No. 86-50-0) should become subject to the prior informed consent procedure and that an intersessional drafting group should be established to prepare a draft decision guidance document<sup>1</sup>**

1. A notification from Norway for azinphos-methyl has been determined to meet the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.
2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.6/6 and Add.1 and 2 and UNEP/FAO/RC/CRC.6/INF/2.

#### **1. Scope of the notified regulatory action**

3. The final regulatory action was taken for the category “pesticide” to protect the environment. The use prior to the ban was as an insecticide for pome fruit, stone fruit, garden blueberries, strawberries, cabbages and ornamentals. The decision was made to ban all uses of plant protection products containing azinphos-methyl.
4. Gusathion (a product containing azinphos-methyl) was allowed to be imported until 31 December 2003 and allowed to be distributed until 31 December 2004. All use of Gusathion was strictly prohibited after 31 December 2005.

#### **2. Criterion Annex II (a)**

*Confirm that the final regulatory action has been taken in order to protect human health or the environment*

5. The regulatory action was taken to protect the environment. It was based on a risk evaluation and took into account toxicology, environmental fate and behaviour, ecotoxicology, residues and availability of alternatives. The review concluded that azinphos-methyl was extremely toxic to most aquatic organisms tested. Even a 30-metre buffer zone to surface water was not sufficient to protect the aquatic environment. By repeated use of azinphos-methyl, it was possible that some populations of invertebrates were adversely affected for a longer period.

#### **3. Criteria Annex II (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;*

6. The scientific data on hazards and exposure used for the risk evaluation of azinphos-methyl have been generated according to scientifically recognized methods. Moreover, data reviews were performed and documented according to generally recognized scientific principles and procedures. Documents supporting this were made available in document UNEP/FAO/RC/CRC.6/6/Add.2.

*(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;*

7. Scientific data have been reviewed in the context of the conditions prevailing in Norway. The data reviews were performed and documented according to generally recognized scientific principles and procedures. Documents supporting this were made available in document UNEP/FAO/RC/CRC.6/6/Add.2.

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

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1 UNEP/FAO/RC/CRC.6/16, annex II, section A.

8. The regulatory action was based on a risk evaluation conducted by the Norwegian Agricultural Inspection Service and a review by the Council for Pesticides. The risk evaluation took into account toxicology, environmental fate and behaviour, ecotoxicology, residues and availability of alternatives.
9. Under the Agricultural and Environmental Monitoring Programme of Pesticides in Norway (JOVÅ), Norway's pesticide laboratory (Planteforsk Pesticidlaboratoriet) carried out a spectrum analysis for the catchments that represent agricultural areas in Norway from 1996 to 2002 on the presence of azinphos-methyl. The findings of the study exceeded the limit for environmental damage, which is 0.01 µg/L.
10. In ecotoxicological studies, the no observed effect concentrations (NOECs) for fish (rainbow trout) range from 0.18 to 0.39 µg/L, the NOEC for invertebrates (*Daphnia magna*) is established at 0.25 µg/L, and EC15 for *Chironomus riparius* is established at 0.3 µg/L.
11. Employing the calculation method used at the time of the evaluation (Ganzelmeier et al, 1995), a maximum predicted environmental concentration (PEC) in surface water, taking into account a 30-metre buffer zone, of 1.53 µg/L was calculated. This was based on the application rate for apple fruit moths. This value was then compared to the NOEC of 0.32 µg/L established from a microcosm study. The ratio of these two figures is 5, indicating that the expected concentration in surface water is 5 times higher than an acceptable concentration for the protection of aquatic species. This conclusion was also supported by actual concentrations in Norway, in that concentrations detected in the monitoring programme were twice as high as the acceptable concentration for the protection of aquatic species.

#### 4. Criteria Annex II (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;*
- (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;*
- (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;*
- (iv) *Whether there is evidence of ongoing international trade in the chemical.*

12. All uses of azinphos-methyl as a pesticide were banned in Norway as provided in UNEP/FAO/RC/CRC.6/6/Add.2. Hence the final regulatory action led to a reduction of the released quantities of azinphos-methyl used, meeting the criterion in paragraph (c) (i) of Annex II, and in consequence to an actual reduction of the risk to the aquatic environment, meeting the criterion in paragraph (c) (ii) of Annex II. The considerations which led to the regulatory action were generally expected to be applicable to other countries and regions and are related to the intended use of azinphos-methyl as a pesticide, meeting the criterion in paragraph (c) (iii) of Annex II.

13. There was evidence of ongoing international trade in the chemical as outlined in document UNEP/FAO/RC/CRC.6/INF/2, meeting the criterion in paragraph (c) (iv) of Annex II.

#### 5. Criterion Annex II (d)

*Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.*

14. There was no indication in the notification that concern about intentional misuse was the reason for the regulatory action. It is clearly stated that concern about environmental exposure such as contamination of surface water and exposure of aquatic organisms was the main reason for the final regulatory action.

#### 6. Conclusion

15. The Committee concluded that the notification of final regulatory action from Norway met the information requirements of Annex I and the criteria set out in Annex II to the Convention. The Committee also concluded that a decision guidance document should be drafted on the basis of the notifications from Norway and Canada, which at the Committee's fifth meeting were found to meet the requirements of Annex I and the criteria of Annex II (as set out in the rationale in document UNEP/FAO/RC/CRC.6/6/Add.1).

## Annex III

### **Recommendation by the Chemical Review Committee at its seventh meeting on the decision guidance document for azinphos-methyl<sup>1</sup>**

*The Chemical Review Committee,*

*Recalling* its decision, adopted by consensus at its sixth meeting in accordance with paragraph 6 of Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, to recommend to the Conference of the Parties that it should include azinphos-methyl (CAS No. 86-50-0) in Annex III to the Rotterdam Convention,

*Recalling also* paragraphs 1 and 2 of Article 7 of the Convention,

*Decides* to agree upon the draft text of the decision guidance document on azinphos-methyl and to forward it to the Conference of the Parties for its consideration.

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1 UNEP/FAO/RC/CRC.7/15, annex I.