Excerpt of the report of CRC6 (UNEP/FAO/RC/CRC.6/16)

Annex II

A. Rationale for the recommendation that azinphos-methyl (CAS No. 86-50-0) should become subject to the prior informed consent procedure and an intersessional drafting group be established to prepare a draft decision guidance document

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.1and 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

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/CRC6/6/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).

B. Recommendation to the Conference of the Parties on the inclusion of azinphos-methyl in Annex III to the Rotterdam Convention

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,

Concluding that the notifications of the final regulatory actions relating to azinphos-methyl by Canada and Norway meet the criteria set forth in Annex II to the Convention,

Decides, in accordance with paragraph 6 of Article 5 of the Convention, to recommend to the Conference of the Parties that it should include azinphos-methyl (CAS No. 86-50-0) in Annex III to the Convention as a pesticide.