



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

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### Chemical Review Committee Seventh meeting

Rome, 28 March–1 April 2011

Item 4 (c) (i) of the provisional agenda\*

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

### Amitraz

#### Note by the Secretariat

#### Addendum

### Rationale for the Committee's conclusion that the European Community's notification met the requirements of the Convention

1. The documentation provided by the European Community<sup>1</sup> in support of its final regulatory action for amitraz was circulated for consideration at the Chemical Review Committee's sixth meeting in document UNEP/FAO/RC/CRC.6/5/Add.1.
2. The annex to the present note contains the rationale for the Committee's conclusion that the notification met the criteria set forth in Annexes I and II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. The rationale was originally made available in annex III to the report of the Committee's sixth meeting (UNEP/FAO/RC/CRC.6/16) and is reproduced in the annex to the present note without change.

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\* UNEP/FAO/RC/CRC.7/1.

1 As indicated by the Depositary of the Convention in a notification dated 31 March 2010 (reference: C.N.182.2010.TREATIES-2), which was in turn based on a communication from the Council of the European Union dated 8 March 2010, following the entry into force of the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, with effect from 1 December 2009 the European Union replaced the European Community (Article 1, third paragraph, of the Treaty of Lisbon) and took over all rights and obligations of the European Community. The former European Community has accordingly been replaced by the European Union in respect of all conventions or agreements for which the Secretary-General of the United Nations is the depositary and to which the European Community is a signatory or a contracting party.

## Annex

### **Rationale for the conclusion that the notification for amitraz (CAS No. 33089-61-1) submitted by the European Community meets the information requirements of Annex I and the criteria of Annex II to the Rotterdam Convention**

1. The notification from the European Community for amitraz 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 the supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.6/5 and Add.1 and UNEP/FAO/RC/CRC.6/INF/2.

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

3. The notified regulatory action relates to amitraz and its pesticidal use. Uses within the European Community included plant protection uses relating to apples, pears, stone fruits, strawberries, tomatoes, aubergines, peppers, hops, ornamentals, empty glasshouses, tree nurseries and public greens in Northern Europe and citrus fruits, apples, pears, stone fruits, bananas, grapes, strawberries, tomatoes, aubergines, peppers, cucurbits, cotton and ornamentals in Southern Europe, respectively. In addition the notification reports animal health uses: amitraz is used on mammalian domestic pets to control ticks, mites, lice and other animal pests.

4. The decision made was to ban all uses of amitraz in plant protection products, with the exception of certain essential uses in specific member States that were allowed to use amitraz until 30 June 2007. The notifier classified the prohibition of the use of plant protection products that contain amitraz as severe restriction.

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

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

5. The regulatory action was taken to protect human health and the environment. It was taken to protect consumers from the potential neurological effects of acute exposure to amitraz. Some environmental concerns were also identified with regard to non-target organisms, in particular birds and mammals eating treated insects.

#### **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 amitraz were generated according to scientifically recognized methods. Moreover, data reviews were performed and documented according to generally recognized scientific principles and procedures. The following supporting documents were made available: report of the Standing Committee on the Food Chain and Animal Health for the active substance amitraz, finalized at its meeting on 4 July 2003 (SANCO/10363/2003 – final of 6 June 2003) and other supporting documentation (Dossier, Monograph and Peer Review Report under the Peer Review Programme – ECCO, March 2000).

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

7. The scientific data were reviewed in the context of the conditions prevailing in the European Community (intended uses, recommended application rates, good agricultural practices). The data reviews were performed and documented according to generally recognized scientific principles and procedures. The following supporting documents were made available: report of the Standing Committee on the Food Chain and Animal Health for the active substance amitraz, finalized at its meeting on 4 July 2003 (SANCO/10363/200 – final of 6 June 2003) and other supporting

documentation (Dossier, Monograph and Peer Review Report under the Peer Review Programme – ECCO, March 2000).

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

8. The final regulatory action was based on a risk evaluation in the context of conditions prevailing within the European Community, taking into account the expected use patterns, i.e., the intended uses, the recommended application rates and good agricultural practices. The following supporting documents were made available: report of the Standing Committee on the Food Chain and Animal Health for the active substance amitraz, finalized at the Committee's meeting on 4 July 2003 (SANCO/10363/2003 – final of 6 June 2003) and other supporting documentation (Dossier, Monograph and Peer Review Report under the Peer Review Programme – ECCO, March 2000).

9. On the basis of this evaluation, concerns were identified with regard to the acceptability of possible neurological effects caused by acute exposure of consumers to the active substance. The final regulatory action was taken to protect consumers from the potential neurological effects of acute exposure to amitraz. Some environmental concerns were also identified with regards to non-target organisms, in particular birds and mammals eating treated insects.

#### 4. Criteria Annex II (c)

*Consider whether the final regulatory action provides a sufficiently broad basis to merit the 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*

10. Uses of amitraz within the European Community included plant protection uses relating to apples, pears, stone fruits, strawberries, tomatoes, aubergines, peppers, hops, ornamentals, empty glasshouses, tree nurseries and public greens in Northern Europe and citrus fruits, apples, pears, stone fruits, bananas, grapes, strawberries, tomatoes, aubergines, peppers, cucurbits, cotton and ornamentals in Southern Europe, respectively.

11. Amitraz is also used on mammalian domestic pets to control ticks, mites, lice and other animal pests. Since the decision made was to ban all uses of plant protection products containing amitraz, it was concluded that the regulatory action would lead to significant reduction in the quantity of the chemical used as well as the number of its use.

(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*

12. Since all uses of plant protection products containing amitraz were banned within the European Community, it can be expected that the exposure of consumers and of the environment will be significantly reduced. This reduction of exposure is expected to lead to a significant reduction of risk for human health and the environment.

(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*

13. The notification gave no indication of any geographical limitations or circumstances to the decision. Similar concerns could arise in other countries where the substance is used, particularly in developing countries.

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

14. Sufficient information on evidence of ongoing international trade in amitraz was made available in document UNEP/FAO/RC/CRC.6/INF/2.

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

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

15. There is no indication in the notification that concerns about intentional misuse prompted the regulatory action.

**6. Conclusion**

16. The Committee concluded that the notification from the European Community regarding amitraz met the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.

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