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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

Amitraz
SANCO/10363/2003-final
6 June 2003

Review report for the active substance amitraz

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
4 July 2003

in support of a decision concerning the non-inclusion of amitraz in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of amitraz, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Amitraz is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, AgrEvo GmbH (now Bayer CropScience) on 27 July 1993, Chimac-Agriphar SA on 27 July 1993, SANC on 23 July 1993, Iberotam on 26 July 1993, AgriChem on 15 July 1993, Industrias Afrasas on 27 July 1993 and B. V. Luxan on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance amitraz in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94⁽³⁾, as last amended by Regulation (EC) No 2230/95⁽⁴⁾, designated Austria as rapporteur Member State to carry out the assessment of amitraz on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for amitraz this deadline was 31 October 1995.

Only Bayer CropScience submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Bayer CropScience was considered to be the main data submitter. CHIMAC-AGRIPHAR S.A. and Industrias Afrasas did not submit complete dossiers. Information has furthermore been submitted by third parties, including the European Environmental Bureau and the World Wide Fund for Nature.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Austria submitted on 6 January 1998 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of amitraz in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on amitraz from Bayer CropScience, on 5 November 1998.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 14 April 1998 as well as to Bayer CropScience being the main data submitter, on 23 April 1998.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from March to October 1999.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States on 17 March 2000 and the main data submitter on 21 March 2000 for comments and further clarification.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC concerning consultation in the light of a possible unfavourable decision for the active substance the Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 9 June 2000 and on 21 March 2003.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from October 2000 to July 2003, and was finalised in the meeting of the Standing Committee on 4 July 2003.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of Decision 2004/141/EC⁵ concerning the non-inclusion of amitraz in Annex I to Directive 91/414/EEC.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to all operators having notified for this active substance under Article 4(1) of this Regulation.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion of this evaluation, based on the information available and the proposed conditions of use, is that:

- **the information available is insufficient** to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC in particular with regard to the acute exposure of consumers.
- **concerns were identified with regard to**
 - The acceptability of acute exposure of consumers in view of the possible neurological effects of the active substance.

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC.

⁵ OJ L 46, 17.2.2004, p. 35