



Fenthion
SANCO/485/00-final
3 July 2003

Review report for the active substance **fenthion**

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

in support of a decision concerning the non-inclusion of fenthion 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 fenthion, 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 1972/99⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Fenthion 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, Bayer AG (now Bayer CropScience) on 21 July 1993 and Industrias Afrasa under the mandate of Sundat (S) PTE. Ltd. on 27 July 1993, notified to the Commission of their wish to secure the inclusion of the active substance fenthion in Annex I to the Directive. Industrias Afrasa, however on 12 October 1994, under the mandate of Sundat (S) PTE. Ltd later withdrew its notification.

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 Greece as rapporteur Member State to carry out the assessment of fenthion 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

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 244, 16.09.1999, p.41.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

the 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 fenthion this deadline was 30 April 1995.

Only Bayer CropScience submitted a dossier to the rapporteur Member State. Information has furthermore been submitted by third parties including the European Environmental Bureau (EEB).

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Greece submitted on 4 April 1996 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 fenthion 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 fenthion from Bayer CropScience between 15 and 25 September 1996.

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 as well as to Bayer CropScience being the main data submitter, on 24 June 1996.

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 September to November 1996.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 19 January 1997 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 18 April 1997.

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 April to December 1997, and was finalised in the meeting of the Standing Committee on 3 July 2003.

These documents were also submitted to the Scientific Committee for Plants for separate consultation on the establishment of an ADI and an AOEL. In its opinion⁵, and based on the conclusions of the human and environmental risk assessment, the Scientific Committee on Plants is of the opinion that it is not possible to complete a full assessment in the absence of data to prove that even the limited intended use as bait application on citrus and olive is safe for human health and the environment. The SCP acknowledges that the development of an innovative technique of application, namely bait formulation including fenthion plus attractant on only a part of the crop, would be promising to achieve limited exposure of humans and the environment; however specific studies have to be made available on such a type of application before a conclusive evaluation can be made.

Additional information has been submitted by Bayer CropScience and has been evaluated. The additional information and its evaluation has been submitted to the Scientific Committee for Plants. In its opinion⁶ the Committee concludes that its concerns in relation to possible risks to birds raised in the Committee's previous opinion remain unresolved.

The present review report contains the conclusions of this 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.

⁵ Opinion of the scientific Committee on Plants of 2 October 1998. SCP/FENTHI/007-Final.

⁶ Opinion of the scientific Committee on Plants of 17 December 2002. SCP/FENTHION-BIS/002 Final

2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of Decision **2004/140/EC**⁷ concerning the non-inclusion of fenthion 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

- **concerns were identified with regard to**
 - **its possible impact on birds.**

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.

⁷ OJ L46, 17.2.2004, p. 32