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COMMISSION DECISION

of 11 February 2004

concerning the non-inclusion of fenthion in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance

(notified under document number C(2004) 313)

(Text with EEA relevance)

(2004/140/EC)

(OJ L 46, 17.2.2004, p. 32)

Amended by:

	Official Journal		
	No	page	date
► M1 Commission Regulation (EC) No 1335/2005 of 12 August 2005	L 211	6	13.8.2005



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(Text with EEA relevance)

(2004/140/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, as last amended by Commission Directive 2003/119/EC ⁽²⁾, and in particular the third and the fourth subparagraph of Article 8(2) thereof,

Having regard to Commission Regulation (EEC) No 3600/92 of 11 December 1992 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 concerning the placing of plant protection products on the market ⁽³⁾, as last amended by Regulation (EC) No 2266/2000 ⁽⁴⁾, and in particular Article 7(3A)(b) thereof,

Whereas:

- (1) Article 8(2) of Directive 91/414/EEC provided for the Commission to carry out a programme of work for the examination of the active substances used in plant protection products which were already on the market on 25 July 1993. Detailed rules for the carrying out of this programme were established in Regulation (EEC) No 3600/92.
- (2) Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member States for the implementation of Commission Regulation (EEC) No 3600/92 ⁽⁵⁾, as last amended by Regulation (EC) No 2230/95 ⁽⁶⁾, designated the active substances which should be assessed in the framework of Regulation (EEC) No 3600/92, designated a Member State to act as rapporteur in respect of the assessment of each substance and identified the producers of each active substance who submitted a notification in due time.
- (3) Fenthion is one of the 89 active substances designated in Regulation (EC) No 933/94.
- (4) In accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92, Greece, being the designated rapporteur Member State, submitted on 4 April 1996 to the Commission the report of its assessment of the information submitted by the notifiers in accordance with Article 6(1) of that Regulation.
- (5) On receipt of the report of the rapporteur Member State, the Commission undertook consultations with experts of the Member States as well as with the main notifier Bayer CropScience as provided for in Article 7(3) of Regulation (EEC) No 3600/92.
- (6) The Commission organised two tripartite meetings with the main data submitter and the rapporteur Member State for this active substance on 18 April 1997 and 11 February 2003.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 325, 12.12.2003, p. 41.

⁽³⁾ OJ L 366, 15.12.1992, p. 10.

⁽⁴⁾ OJ L 259, 13.10.2000, p. 27.

⁽⁵⁾ OJ L 107, 28.4.1994, p. 8.

⁽⁶⁾ OJ L 225, 22.9.1995, p. 1.

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- (7) The assessment report prepared by Greece has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. This review was finalised on 4 July 2003 in the format of the Commission review report for fenthion.
- (8) The dossier and the information from the review were also submitted to the Scientific Committee for Plants (SCP). The SCP was asked to comment on the establishment of an Acceptable Daily Intake and an Acceptable Operator Exposure Level. In its first opinion of 2 October 1998, and based on the conclusions of the human and environmental risk assessment, the SCP considered that it was 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 was safe for human health and the environment. The SCP particularly noted the very high acute risk for birds. In that opinion, the SCP acknowledged that the development of an innovative technique of application, namely bait formulation including fenthion plus attractant on only a part of the crop, might be promising to achieve limited exposure of humans and the environment; however it noted that specific studies would have to be made available on such a type of application before a conclusive evaluation could be made.

Additional information, in particular in relation to the bait application use, has subsequently been submitted by Bayer CropScience and has been evaluated. The additional information and its evaluation has been submitted to the SCP. In its opinion of 17 December 2002 the SCP concluded that the risk to birds from the proposed uses of fenthion remained uncertain. As a result, the concerns in relation to possible risks to birds raised in its previous opinion remained unresolved.

- (9) Assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing fenthion satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to its possible impact on birds.
- (10) Fenthion should therefore not be included in Annex I to Directive 91/414/EEC.
- (11) Measures should be taken to ensure that existing authorisations for plant protection products containing fenthion are withdrawn within a prescribed period and are not renewed and that no new authorisations for such products are granted.
- (12) In the light of the information submitted to the Commission it appears that, in the absence of efficient alternatives for certain limited uses in certain Member States, there is a need for further use of the active substance so as to enable the development of alternatives. It is therefore justified in the present circumstances to prescribe under strict conditions aimed at minimising risk a longer period for the withdrawal of existing authorisations for the limited uses considered as essential for which no efficient alternatives appear currently to be available for the control of harmful organisms.
- (13) Any period of grace for disposal, storage, placing on the market and use of existing stocks of plant protection products containing fenthion allowed by Member States, should be limited to a period no longer than 12 months to allow existing stocks to be used in no more than one further growing season.

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- (14) This Decision does not prejudice any action the Commission may undertake at a later stage for this active substance within the framework of Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances ⁽¹⁾, as last amended by Regulation (EC) No 807/2003 ⁽²⁾.
- (15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Fenthion shall not be included as active substance in Annex I to Directive 91/414/EEC.

Article 2

Member States shall ensure that:

1. Authorisations for plant protection products containing fenthion are withdrawn by 11 August 2004;
2. from 17 February 2004 no authorisations for plant protection products containing fenthion are granted or renewed under the derogation provided for in Article 8(2) of Directive 91/414/EEC;
3. In relation to the uses listed in column B of the Annex, a Member State specified in column A may maintain in force authorisations for plant protection products containing fenthion until 30 June 2007 provided that it:
 - (a) ensures that such plant protection products remaining on the market are relabelled in order to match the restricted use conditions;
 - (b) imposes all appropriate risk mitigation measures to reduce any possible risks in order to ensure the protection of human and animal health and the environment; and
 - (c) ensures that alternative products or methods for such uses are being seriously sought, in particular, by means of action plans.

The Member State concerned shall inform the Commission on 31 December 2004 at the latest on the application of this paragraph and in particular on the actions taken pursuant to points (a) to (c) and provide on a yearly basis estimates of the amounts of fenthion used for essential uses pursuant to this Article.

Article 3

Any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC, shall be as short as possible and:

- (a) for the uses for which the authorisation is to be withdrawn on 11 August 2004, shall expire not later than 11 August 2005;
- (b) for the uses for which the authorisation is to be withdrawn by 30 June 2007, shall expire not later than 31 December 2007.

Article 4

This Decision is addressed to the Member States.

⁽¹⁾ OJ L 33, 8.2.1979, p. 36.

⁽²⁾ OJ L 122, 16.5.2003, p. 36.

▼B*ANNEX***List of authorisations referred to in Article 2(3)**

Column A	Column B
Member State	Use
Spain	Bait application in citrus and peaches
Greece	Bait application in olives
Italy	Bait application in olives
Portugal	Bait application in citrus and olives
▼M1 Cyprus	Bait application in citrus and olives