COMMISSION DIRECTIVE 2000/67/EC

of 23 October 2000

including an active substance (esfenvalerate) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

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 2000/10/EC [2], and in particular Article 6(1) and the fourth subparagraph of Article 8(2) thereof,

Whereas:

(1) Commission Regulation (EEC) No 3600/92 [3], as last amended by Regulation (EC) No 2266/2000 [4], laid down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive'). Pursuant to that Regulation, Commission Regulation (EC) No 933/94 [5], as last amended by Regulation (EC) No 2230/95 [6], laid down the list of active substances of plant protection products to be assessed, with a view to their possible inclusion in Annex I to the Directive.

(2) In accordance with Article 5(1) of the Directive, an active substance should be included in Annex I if it may be expected that neither the use of, nor residues from, plant protection products containing that active substance will have any harmful effects on human or animal health or on groundwatr or any unacceptable influence on the environment.

(3) Such an active substance may be included in Annex I for a period not exceeding 10 years.

(4) For esfenvalerate the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifier. Portugal was designated as rapporteur Member State under Regulation (EC) No 933/94 laying down the active substance of plant protection products and designating the rapporteur Member State for the implementation of Regulation (EEC) No 3600/92. It submitted the relevant assessment report to the Commission on 11 October 1996, in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(5) The assessment report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. This review was finalised on 13 July 2000 in the format of the Commission review report for esfenvalerate.

(6) The dossier and the information from the review have also been submitted to the Scientific Committee for Plants for consultation. The Scientific Committee for Plants in its opinion [7] noted that Member States must apply appropriate risk mitigation measures to protect the aquatic environment and non-target arthropods.

(7) It has appeared from the assessments made that plant protection products containing the active substance concerned may be expected to satisfy in general the requirements laid down in Article 5(1)(a) and (b) of the Directive, in particular with regard to the uses which were examined. It is appropriate therefore to include the active substance concerned in Annex I, in order to ensure that in all Member States the granting, varying or withdrawing, as appropriate, of the authorisations of plant protection products containing esfenvalerate can be undertaken in accordance with the provisions of the Directive.

(8) Article 8(2) of the Directive provides that after inclusion of an active substance in its Annex I, Member States shall, within a prescribed period, grant, vary or withdraw, as appropriate, the authorisations of the plant protection products containing the active substance. In particular, Articles 4(1) and 13(1) of the Directive require that plant protection products are not authorised unless account is taken of the conditions associated with the inclusion of the active substance in Annex I and the uniform principles laid down in Annex VI on the basis of a dossier satisfying the data requirements laid down in its Article 13.

(9) Before inclusion, a reasonable deadline is necessary to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion. Moreover, after inclusion, a reasonable period is necessary for the Member States to implement the Directive and in particular to vary or withdraw, as appropriate, existing authorisations or grant new authorisations in accordance with the provisions of Directive 91/414/EEC. A longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product in accordance with the uniform principles laid down in Annex VI to the Directive. For plant protection products containing several active substances, the complete evaluation on the basis of the uniform principles can only be carried out when all the active substances concerned have been included in Annex I to the Directive.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 57, 2.3.2000, p. 28.
[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.
[7] Scientific Committee on Plants SCP/ESFEN/002 final. 6 April 2000.

(10) It is appropriate to provide that the finalised review report (except for confidential information in the meaning of Article 14 of the Directive) is kept available or made available by the Member States for consultation by any interested parties.

(11) The review report is required for the proper implementation by the Member States of several sections of the uniform principles laid down in Annex VI to the Directive, where these principles refer to the evaluation of the Annex II data which were submitted for the purpose of the inclusion of the active substance in Annex I to the Directive.

(12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Esfenvalerate is hereby designated as an active substance in Annex I to Directive 91/414/EEC, as set out in the Annex hereto.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, at the latest by 31 January 2002 and shall immediately inform the Commission thereof. In particular they shall, in accordance with the provisions of Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing esfenvalerate as an active substance within such period.

2. However, with regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the period laid down in the first paragraph is extended:

— for plant protection products containing esfenvalerate as the only active substance, to four years from the entry into force of this Directive,

— for plant protection products containing esfenvalerate together with another active substance which is in Annex I to Directive 91/414/EEC, to four years from the entry into force of such Directive as shall include the last of those substances in Annex I.

3. Member States shall keep available the review report (except for confidential information within the meaning of Article 14 of the Directive) for consultation by any interested parties or shall make it available to them on specific request.

4. When Member States adopt the provisions referred to in paragraph 1, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive shall enter into force on 1 August 2001.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 23 October 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Esfenvalerate

1. Identity:

   Common name: esfenvalerate

   IUPAC name: (S)-α-Cyano-3-phenoxybenzyl-(S)-2-(4-chlorophenyl)-3-methylbutyrate

2. Particular conditions to be fulfilled:

2.1. The active substance as manufactured shall have a minimum purity of 830 g/kg.

2.2. Only uses as insecticide may be authorised.

2.3. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on esfenvalerate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 13 July 2000 shall be taken into account. In this overall assessment Member States:

must pay particular attention to the potential impact on aquatic organisms and non-target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

3. Expiry date of the inclusion: 31 July 2011.