

COMMISSION DIRECTIVE 2002/37/EC
of 3 May 2002
amending Council Directive 91/414/EEC to include ethofumesate as an active substance
(Text with EEA relevance)

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 2002/18/EC ⁽²⁾, and in particular Article 6(1) thereof,

Whereas:

(1) 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⁾, provides for the adoption of a list of active substances of plant protection products to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list is contained in 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⁾, and includes ethofumesate.

(2) For ethofumesate 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 notifiers. By Regulation (EC) No 933/94, as amended by Regulation (EC) No 491/95 ⁽⁷⁾, Sweden was designated as rapporteur Member State. Sweden submitted the relevant assessment reports and recommendations to the Commission on 2 October 1998 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) This assessment report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 26 February 2002 in the format of the Commission review report for ethofumesate.

(4) The review did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.

(5) It has appeared from the various examinations made that plant protection products containing ethofumesate may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include ethofumesate in Annex I to that Directive, in order to ensure that in all Member States authorisations of plant protection products containing ethofumesate can be granted in accordance with the provisions of Directive 91/414/EEC.

(6) The Commission review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in Directive 91/414/EEC. It is, therefore, appropriate to provide that the finalised review report, except for confidential information, is kept available or made available by the Member States for consultation by any interested parties. If the review report has to be updated to take account of technical and scientific developments, the conditions for the inclusion of the substance concerned in Annex I to Directive 91/414/EEC should also be amended in accordance with that Directive.

(7) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to take the requisite preparatory steps.

(8) After inclusion, Member States should be allowed a reasonable period within which to implement the provisions of Directive 91/414/EEC as regards plant protection products containing ethofumesate, and in particular, to review existing authorisations in accordance with the provisions of Directive 91/414/EEC to ensure that the conditions regarding ethofumesate set out in Annex I to Directive 91/414/EEC are satisfied. A longer period should be provided within which a complete dossier for each such plant protection product, satisfying the requirements of Annexes II and III to Directive 91/414/EEC should be submitted and that product re-evaluated in accordance with the uniform principles laid down in Directive 91/414/EEC.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 55, 26.2.2002, p. 29.

⁽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⁾ OJ L 49, 4.3.1995, p. 50.

- (9) It is therefore necessary to amend Directive 91/414/EEC accordingly.
- (10) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall keep available the review report for ethofumesate, except for confidential information within the meaning of Article 14 of Directive 91/414/EEC, for consultation by any interested parties or shall make it available to them on specific request.

Article 3

Member States shall adopt and publish by 31 August 2003 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 September 2003.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

1. Member States shall review the authorisation for each plant protection product containing ethofumesate to ensure that the conditions relating to ethofumesate set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw the authorisation in accordance with Directive 91/414/EEC before 1 September 2003.

2. Member States shall, for each authorised plant protection product containing ethofumesate as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 1 March 2003, re-evaluate the product in accordance with 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. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC. Where necessary and by 28 February 2007 at the latest, they shall amend or withdraw the authorisation for each such plant protection product.

Article 5

This Directive shall enter into force on 1 March 2003.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 3 May 2002.

For the Commission

David BYRNE

Member of the Commission

ANNEX

In Annex I the following row is added at the end of the table:

No	Common name, Identification numbers	IUPAC Name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
'29	Ethofumesate CAS No 26225-79-6 CICAP No 223	(±)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzo- furan-5-ylmethanesulfonate	960 g/kg	1 March 2003	28 February 2013	Only uses as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on ethofumesate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2002 shall be taken into account. In this overall assessment Member States may pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions and must apply risk mitigation measures, where appropriate.

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.'