COMMISSION DIRECTIVE 2005/34/EC

of 17 May 2005

amending Council Directive 91/414/EEC to include etoxazole and tepraloxydim as active substances

(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], and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC, France received on 21 April 1998 an application from Sumitomo Chemical Agro Europe SA for the inclusion of the active substance etoxazole, formerly also called 'etoxazol', in Annex I to Directive 91/414/EEC. Commission Decision 1999/43/EC [2] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) Spain received an application under Article 6(2) of Directive 91/414/EEC on 11 September 1997 from BASF AG for the inclusion of the active substance tepraloxydim in Annex I to Directive 91/414/EEC. Commission Decision 98/512/EC [3] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For those active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The designated rapporteur Member States submitted draft assessment reports concerning the substances to the Commission on 8 October 2001 (etoxazole) and 21 January 2002 (tepraloxydim).

(4) The draft assessment reports have 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 3 December 2004 in the format of the Commission review reports for etoxazole and tepraloxydim.

(5) The review of etoxazole and tepraloxydim did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants or of the European Food Safety Authority.

(6) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) 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 etoxazole and tepraloxydim in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances may be granted in accordance with the provisions of that Directive.

(7) After inclusion of etoxazole and tepraloxydim in Annex I to Directive 91/414/EEC, Member States should be allowed a reasonable period to implement the provisions of Directive 91/414/EEC as regards plant protection products containing those substances and in particular to review existing provisional authorisations and, by the end of this period at the latest, to transform those authorisations into full authorisations, to amend them or to withdraw them in accordance with the provisions of Directive 91/414/EEC.

(8) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(9) 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.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Directive 2005/25/EC (OJ L 90, 8.4.2005, p. 1).
[2] OJ L 14, 19.1.1999, p. 30.
[3] OJ L 228, 15.8.1998, p. 35.

Article 2

1. Member States shall adopt and publish by 30 November 2005 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 December 2005.

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.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

1. Member States shall review the authorisation for each plant protection product containing etoxazole or tepraloxydim to ensure that the conditions relating to those active substances set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw authorisations in accordance with Directive 91/414/EEC by 30 November 2005 at the latest.

2. For each authorised plant protection product containing etoxazole or tepraloxydim 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 31 May 2005 at the latest, Member States shall 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 to that Directive. 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.

Following that determination Member States shall:

(a) in the case of a product containing etoxazole or tepraloxydim as the only active substance, where necessary, amend or withdraw the authorisation by 30 November 2006 at the latest; or

(b) in the case of a product containing etoxazole or tepraloxydim as one of several active substances, where necessary, amend or withdraw the authorisation by 30 November 2006 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 June 2005.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 17 May 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

In Annex I to Directive 91/414/EEC, the following rows are added at the end of the table:

No	Common name, identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
'100	Etoxazole CAS No: 153233-91-1 CIPAC No: 623	(RS)-5-*tert*-butyl-2-[2-(2,6-difluoro-phenyl)-4,5-dihydro-1,3-oxazol-4-yl] phenetole	≥ 948 g/kg	1 June 2005	31 May 2015	Only uses as acaricide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on etoxazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.
101	Tepraloxydim CAS No: 149979-41-9 CIPAC No: 608	(EZ)-(RS)-2-{1-[(2E)-3-chloroally-loxyimino]propyl}-3-hydroxy-5-perhydropyran-4-ylcyclohex-2-en-1-one	≥ 920 g/kg	1 June 2005	31 May 2015	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on tepraloxydim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2004 shall be taken into account. In this overall assessment, Member States should pay particular attention to the protection of terrestrial non-target arthropods. Risk mitigation measures should be applied where appropriate.

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