

**COMMISSION DIRECTIVE 2003/5/EC**  
**of 10 January 2003**  
**amending Council Directive 91/414/EEC to include deltamethrin as 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 <sup>(1)</sup>, as last amended by Commission Directive 2002/81/EC <sup>(2)</sup>, 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 <sup>(3)</sup>, as last amended by Regulation (EC) No 2266/2000 <sup>(4)</sup>, establishes 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 State for the implementation of Regulation (EEC) No 3600/92 <sup>(5)</sup>, as last amended by Regulation (EC) No 2230/95 <sup>(6)</sup>, and includes deltamethrin.
- (2) For deltamethrin 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 Sweden was designated as rapporteur Member State. Sweden submitted the relevant assessment reports and recommendations to the Commission on 6 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 18 October 2002 in the format of the Commission review report for deltamethrin.
- (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 deltamethrin 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 deltamethrin in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

- (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, should be kept available or made available by the Member States for consultation by any interested parties.
- (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 prepare themselves to meet the new requirements which will result from the inclusion.
- (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 deltamethrin, and in particular, to review existing authorisations to ensure that the conditions regarding deltamethrin set out in Annex I to Directive 91/414/EEC are satisfied. A longer period should be provided for the submission and assessment of the complete dossier of each plant protection product in accordance with the uniform principles laid down in Directive 91/414/EEC.
- (9) It is therefore appropriate 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.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(2)</sup> OJ L 276, 12.10.2002, p. 28.

<sup>(3)</sup> OJ L 366, 15.12.1992, p. 10.

<sup>(4)</sup> OJ L 259, 13.10.2000, p. 27.

<sup>(5)</sup> OJ L 107, 28.4.1994, p. 8.

<sup>(6)</sup> OJ L 225, 22.9.1995, p. 1.

*Article 2*

Member States shall keep available the review report for deltamethrin, 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 30 April 2004 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 May 2004.

When Member States adopt this provision, 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 deltamethrin to ensure that the conditions relating to deltamethrin set out in Annex I to Directive 91/414/EEC are complied with. Where necessary and by 30 April 2004 at the latest, they shall amend or withdraw the authorisation.

2. Member States shall, for each authorised plant protection product containing deltamethrin 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 October 2003 at the latest, 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. Where necessary and by 31 October 2007 at the latest, they shall amend or withdraw the authorisation.

*Article 5*

This Directive shall enter into force on 1 November 2003.

*Article 6*

This Directive is addressed to the Member States.

Done at Brussels, 10 January 2003.

*For the Commission*

David BYRNE

*Member of the Commission*

## ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EC:

No	Common name, identification numbers	IUPAC name	Purity <sup>(1)</sup>	Entry into force	Expiration of inclusion	Specific provisions
'40	Deltamethrin CAS No 52918-63-5 CIPAC No 333	(S)- $\alpha$ -cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromo-vinyl)-2,2-dimethylcyclopropane carboxylate	980 g/kg	1 November 2003	31 October 2013	<p>Only uses as insecticide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on deltamethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 18 October 2002 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> <li>— must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures,</li> <li>— should observe the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels,</li> <li>— must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate.</li> </ul>

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