

COMMISSION DIRECTIVE 2004/58/EC**of 23 April 2004****amending Council Directive 91/414/EEC to include alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham 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) 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 ⁽²⁾, establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham.

(2) For those active substances the effects on human health and the environment has 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 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 Commission Regulation (EEC) No 3600/92 ⁽³⁾, the following rapporteur Member States were designated, which in turn submitted the relevant assessment reports and recommendations to the Commission in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92. For alpha-cypermethrin the rapporteur Member State was Belgium, and all relevant information was submitted on 16 September 1999. For benalaxyl the rapporteur Member State was Portugal, and all relevant information was submitted on 27 April 2000. For bromoxynil the rapporteur Member State was France, and all relevant information was submitted on 16 March 2000. For desmedipham the rapporteur Member State was Finland, and all relevant information was submitted on 8 May 2000. For ioxynil the rapporteur Member State was France, and all relevant information was submitted on 16 March 2000. For phenmedipham the rapporteur Member State was Finland, and all relevant information was submitted on 5 January 2000.

(3) Those assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.

(4) The reviews of all active substances were finalised on 13 February 2004 in the format of the Commission review reports for alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham.

(5) The reviews of alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.

(6) It has appeared from the various examinations made that plant protection products containing alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham 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 these active substances in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances can be granted in accordance with the provisions of 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 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 alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil or phenmedipham, and in particular, to review existing authorisations to ensure that the conditions regarding those active substances set out in Annex I to Directive 91/414/EEC are satisfied. For efficiency reasons and considering the short deadlines it is appropriate that the rapporteur Member State coordinate such reviews between Member States. 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.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/60/EC (See page 39 of this Official Journal).

⁽²⁾ OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 10).

⁽³⁾ OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).

- (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.

Article 2

Member States shall adopt and publish by 31 August 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 September 2005.

When Member States adopt those provisions, they shall contain a reference to this Directive or 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 3

1. Member States shall review the authorisation for each plant protection product containing alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ixoxynil and phenmedipham 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 and by 31 August 2005 at the latest, they shall amend or withdraw the authorisation.

The respective rapporteur Member State shall organise the co-operation between Member States when carrying out such review.

2. For each authorised plant protection product containing alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ixoxynil and phenmedipham 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 28 February 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 alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ixoxynil or phenmedipham as the only active substance, where necessary, amend or withdraw the authorisation by 28 February 2009 at the latest; or
- (b) in the case of a product containing alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ixoxynil or phenmedipham as one of several active substances, where necessary, amend or withdraw the authorisation by 28 February 2009 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 March 2005.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 23 April 2004.

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 (1)	Entry into force	Expiration of inclusion	Specific provisions
84	alpha-cypermethrin CAS No 67375-30-8 CIPAC No	Racemate comprising (S)- α -cyano-3-phenoxybenzyl-(1R)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate and (R)- α -cyano-3-phenoxybenzyl-(1S)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (= cis-2 isomer pair of cypermethrin)	930 g/kg CIS-2	1 March 2005	28 February 2015	Only uses as insecticide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on alpha-cypermethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment: — Member States 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. — Member States must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures.
85	benalaxyl CAS No 71626-11-4 CIPAC No 416	Methyl N-phenylacetyl-N-2, 6-xylyl-DL-alaninate	960 g/kg	1 March 2005	28 February 2015	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on benalaxyl, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.
86	bromoxynil CAS No 1689-84-5 CIPAC No 87	3,5 dibromo – 4- hydroxybenzotrile	970 g/kg	1 March 2005	28 February 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 bromoxynil, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of birds and wild mammals, in particular if the substance is applied in winter, and of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

No	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
87	desmedipham CAS No 13684-56-5 CIPAC No 477	ethyl 3'-phenylcarbamoyloxy-carbanilate ethyl 3-phenylcarbamoyloxyphenylcarbamate	Min. 970 g/kg	1 March 2005	28 February 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 desmedipham, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms and earthworms. Risk mitigation measures should be applied if appropriate
88	ioxynil CAS No 13684-83-4 CIPAC No 86	4- hydroxy- 3,5- di-iodobenzonitrile	960 g/kg	1 March 2005	28 February 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 ioxynil, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of birds and wild mammals in particular if the substance is applied in winter and to aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.
89	phenmedipham CAS No 13684-63-4 CIPAC No 77	methyl 3-(3-methylcarbaniloxyloxy)carbanilate; 3-methoxycarbonylaminophenyl 3'-methylcarbanilate	Min. 970 g/kg	1 March 2005	28 February 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 phenmedipham, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

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