

COMMISSION DIRECTIVE 2003/70/EC

of 17 July 2003

amending Council Directive 91/414/EEC to include mecoprop, mecoprop-P and propiconazole 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⁾, as last amended by Commission Directive 2003/68/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⁾, 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 mecoprop, mecoprop-P and propiconazole.
- (2) For those active substances 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 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 ⁽⁵⁾, as last amended by Regulation (EC) No 2230/95 ⁽⁶⁾, 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: mecoprop: Rapporteur Member State Denmark, all relevant information was submitted on 31 August 1999; mecoprop-P: Rapporteur Member State Denmark, all relevant information was submitted on 7 January 1999; propiconazole: Rapporteur Member State Finland, all relevant information was submitted on 30 November 1998.
- (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 15 April 2003 in the format of the Commission review reports for mecoprop, mecoprop-P and propiconazole.
- (5) The reviews of mecoprop, mecoprop-P and propiconazole 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 mecoprop, mecoprop-P or propiconazole 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) 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.
- (8) 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.
- (9) 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 mecoprop, mecoprop-P or propiconazole, 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. 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.
- (10) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 177, 16.7.2003, p. 12.

⁽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.

(11) 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 30 November 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 December 2004.

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 mecoprop, mecoprop-P or propiconazole 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 30 November 2004 at the latest, they shall amend or withdraw the authorisation.

2. Member States shall, for each authorised plant protection product containing mecoprop, mecoprop-P or propiconazole 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 2004 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 May 2008 at the latest, they shall amend or withdraw the authorisation.

Article 4

This Directive shall enter into force on 1 June 2004.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 17 July 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/EEC.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
56	Mecoprop CAS No 7085-19-0 CIPAC No 51	(RS)-2-(4-chloro-o-tolyloxy)-propionic acid	930 g/kg	1 June 2004	31 May 2014	<p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mecoprop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> — 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, — Member States should pay particular attention to the protection of non-target arthropods. Risk mitigation measures should be applied, where appropriate.
57	Mecoprop-P CAS No 16484-77-8 CIPAC No 475	(R)-2-(4-chloro-o-tolyloxy)-propionic acid	860 g/kg	1 June 2004	31 May 2014	<p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mecoprop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> — 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.

No	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
58	Propiconazole CAS No 60207-90-1 CIPAC No 408	(±)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole	920 g/kg	1 June 2004	31 May 2014	<p>Only uses as fungicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propiconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> — Member States should pay particular attention to the protection of non-target arthropods and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate, — Member States should pay particular attention to the protection of soil organisms for applications rates exceeding 625 g a.i./ha (e.g. uses in lawn). Conditions of authorisation should include risk mitigation measures (e.g. spotwise application scheme), where appropriate.

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