Commission Directive 2006/64/CE of 18 July 2006 amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances (Text with EEA relevance)

COMMISSION DIRECTIVE 2006/64/CE

of 18 July 2006

amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac 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 Regulations (EC) No 451/2000[(2)] and (EC) No 703/2001[(3)] lay down the detailed rules for the implementation of the second stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish 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 clopyralid, cyprodinil, fosetyl and trinexapac.

(2) For those active substances the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 703/2001 for a range of uses proposed by the notifier. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 8(1) of Regulation (EC) No 451/2000. For clopyralid the rapporteur Member State was Finland and all relevant information was submitted on 2 December 2003. For cyprodinil and fosetyl the rapporteur Member State was France and all relevant information was submitted on 16 January 2004 and 20 October 2003 respectively. For trinexapac the rapporteur Member State was The Netherlands and all relevant information was submitted on 7 November 2003.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 14 December 2005 in the format of the EFSA Scientific Reports for clopyralid, cyprodinil, fosetyl and trinexapac[(4)]. These reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 4 April 2006 in the format of the Commission review reports for clopyralid, cyprodinil, fosetyl and trinexapac.

(4) It has appeared from the various examinations made that plant protection products containing clopyralid, cyprodinil, fosetyl and trinexapac 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 reports. 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.

(5) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points concerning clopyralid, cyprodinil and fosetyl. Article 6(1) of Directive 91/414/EC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore it is appropriate to require that clopyralid, cyprodinil and fosetyl should be subjected to further testing for confirmation of the risk assessment for some issues and that such studies should be presented by the notifiers.

(6) 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.

(7) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing clopyralid, cyprodinil, fosetyl and trinexapac to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations, in accordance with the provisions of Directive 91/414/EEC. By way of derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.

(8) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92[(5)] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I.

(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 October 2007 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 November 2007.

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 in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing clopyralid, cyprodinil, fosetyl and trinexapac as active substances by 31 October 2007.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to clopyralid, cyprodinil, fosetyl and trinexapac are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13 of that Directive.

2 By way of derogation from paragraph 1, for each authorised plant protection product containing clopyralid, cyprodinil, fosetyl and trinexapac 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 30 April 2007 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 and taking into account part B of the entry in Annex I to that Directive concerning clopyralid, cyprodinil, fosetyl and trinexapac respectively. 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 clopyralid, cyprodinil, fosetyl and trinexapac as the only active substance, where necessary, amend or withdraw the authorisation by 30 April 2011 at the latest;

or

b in the case of a product containing clopyralid, cyprodinil, fosetyl and trinexapac as one of several active substances, where necessary, amend or withdraw the authorisation by 30 April 2011 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 May 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 18 July 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

The following entry 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[a]	Entry into force	Expiration of inclusion	Specific provisions
'131	Clopyralid CAS No 1702-17-6 CIPAC No 455	3,6-dichloropyridine-2-carboxylic acid	≥ 950 g/kg	1 May 2007	30 April 2017	PART A Only uses as herbicide may be authorised. PART B In assessing applications to authorise plant protection products containing clopyralid for uses other than spring applications, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of

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

						Annex VI, the conclusions of the review report on clopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of non target plants and groundwater under vulnerable conditions. Conditions of authorisation should include risk mitigation

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

						measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate. The concerned Member States shall request the submission of further studies to confirm the results on animal metabolism. They shall ensure that the notifiers at whose request clopyralid has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
132	Cyprodinil CAS No 121522-61-2	(4-cyclopropyl-6-methyl-	≥ 980 g/kg	1 May 2007	30 April 2017	PART A Only uses as

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

	CIPAC No 511	pyrimidin-2-yl)-phenyl-amine				fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cyprodinil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the safety of operators and ensure

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

						that conditions of use prescribe the application of adequate personal protective equipment; — must pay particular attention to the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones. The concerned Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals

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

						and for possible presence of residues of metabolite CGA 304075 in food of animal origin. They shall ensure that the notifiers at whose request cyprodinil has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
133	Fosetyl CAS No 15845-66-6 CIPAC No 384	Ethyl hydrogen phosphonate[a]	≥ 960 g/kg (expressed as fosetyl-Al)	1 May 2007	30 April 2017	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fosetyl, and in

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

						particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones.

a Further details on identity and specification of active substance are provided in the review report.’

						The concerned Member States shall request the submission of further studies to confirm the risk assessment for non-target arthropods, in particular with regard to in-field recovery, and for herbivorous mammals. They shall ensure that the notifier at whose request fosetyl has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
134	Trinexapac CAS No 104273-73-6 CIPAC No 732	4-(cyclopropyl-α-hydroxymethylene)-3,5-dioxo-cyclohexanecarboxylic acid	≥ 940g/kg (expressed as trinexapac-ethyl)[a]	1 May 2007	30 April 2017	PART A Only uses as plant growth regulator may be authorised. PART B

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

						For the implementation of the uniform principles of Annex VI, the conclusions of the review report on trinexapac, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of birds and mammals. Conditions of authorisation should

a Further details on identity and specification of active substance are provided in the review report.’

						include risk mitigation measures, where appropriate.

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

(**1**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/45/EC (OJ L 130, 18.5.2006, p. 27).

(**2**) OJ L 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1 044/2003 (OJ L 151, 19.6.2003, p. 32).

(**3**) OJ L 98, 7.4.2001, p. 6.

(**4**) EFSA Scientific Report (2005) 50, 1-65, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance clopyralid (finalised: 14 December 2005).
EFSA Scientific Report (2005) 51, 1-78, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance cyprodinil (finalised: 14 December 2005).
EFSA Scientific Report (2005) 54, 1-79, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance fosethyl (finalised: 14 December 2005).
EFSA Scientific Report (2005) 57, 1-70, Conclusion regarding the peer review of the pesticide risk assessment of the active substance trinexapac (finalised: 14 December 2005).

(**5**) 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. 27).