Commission Directive 2007/52/EC of 16 August 2007 amending Council Directive 91/414/EEC to include ethoprophos, pirimiphos-methyl and fipronil as active substances (Text with EEA relevance)

COMMISSION DIRECTIVE 2007/52/EC

of 16 August 2007

amending Council Directive 91/414/EEC to include ethoprophos, pirimiphos-methyl and fipronil 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 ethoprophos, pirimiphos-methyl and fipronil.

(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 ethoprophos and pirimiphos-methyl the rapporteur Member State was the United Kingdom and all relevant information was submitted on 19 January 2004 and 4 November 2003 respectively. For fipronil, the rapporteur Member State was France and all relevant information was submitted on 10 February 2004.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 3 March 2006 for ethoprophos, on 10 August 2005 for pirimiphos-methyl, on 3 March 2006 for fipronil, in the format of the EFSA Scientific Reports[(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 16 March 2007 in the format of the Commission review reports for ethoprophos, pirimiphos-methyl and fipronil.

(4) It has appeared from the various examinations made that plant protection products containing ethoprophos, pirimiphos-methyl and fipronil 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 ethoprophos, pirimiphos-methyl and fipronil. 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 ethoprophos, pirimiphos-methyl and fipronil 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 ethoprophos, pirimiphos-methyl and fipronil 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 March 2008 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 April 2008.

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 ethoprophos, pirimiphos-methyl and fipronil as active substances by 31 March 2008.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to ethoprophos, pirimiphos-methyl and fipronil 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 ethoprophos, pirimiphos-methyl and fipronil 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 September 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 ethoprophos, pirimiphos-methyl and fipronil 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 ethoprophos, pirimiphos-methyl or fipronil as the only active substance, where necessary, amend or withdraw the authorisation by 30 September 2011 at the latest; or

b in the case of a product containing ethoprophos, pirimiphos-methyl or fipronil as one of several active substances, where necessary, amend or withdraw the authorisation by 30 September 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 October 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 16 August 2007.

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/EEC:

No	Common name, identification Nos	IUPAC Name	Purity[a]	Entry into force	Expiration of inclusion	Specific provisions
‘161	ethoprophos CAS No: 13194-48-4 CIPAC No: 218	*O*-ethyl *S,S*-dipropyl phosphorodithioate	> 940 g/kg	1 October 2007	30 September 2017	PART A Only uses as nematicide and insecticide in soil application can be authorised. Authorisations should be limited to professional users. PART B In assessing applications to authorise plant protection products containing ethoprophos for uses other than potatoes not cultivated for human or animal consumption, Member States shall

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

						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 Annex VI, the conclusions of the review report on ethoprophos, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on

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

						16 March 2007 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the residues and evaluate the dietary exposure of consumers in view of future revisions of Maximum Residue Levels, — the operator safety. Authorised conditions of use must prescribe the application of adequate personal and respiratory protective equipment and other risk

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

						— mitigation measures such as the use of closed transfer system for the distribution of the product, the protection of birds, mammals, aquatic organisms, surface and groundwater under vulnerable conditions. Conditions of authorisation should include risk mitigation measures, such as buffer zones and the achievement of complete incorporation of granules in the soil.

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 short and long term risk assessment for birds and for earthworms eating mammals. They shall ensure that the notifiers at whose request ethoprophos has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
162	pirimiphos-methyl CAS No: 29232-93-7 CIPAC No: 239	*O*-2-diethylamino-6-methylpyrimidin-4-yl *O,O*-dimethylphosphorothioate	> 880 g/kg	1 October 2007	30 September 2017	PART A	Only uses as insecticide for post-harvest storage can be authorised.

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

						PART B	In assessing applications to authorise plant protection products containing pirimiphos-methyl for uses other than applications with automated systems in empty cereals storehouses, 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

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

						is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pirimiphos-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 March 2007 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operators safety. Authorised conditions of use must prescribe the application

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

						— of adequate personal protective equipment including respiratory protective equipment and risk mitigation measures to reduce the exposure, — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels. The Member States concerned shall request the submission of further studies to confirm the operator exposure assessment. They shall ensure that the notifiers at whose request pirimiphos-methyl has been

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

							included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
163	Fipronil CAS No: 120068-37-3 CIPAC No: 581	(±)-5-amino-1-(2,6-dichloro-α,α,α-trifluoro-para-tolyl)-4-trifluoromethylsulfinylpyrazole-3-carbonitrile	≥ 950 g/kg	1 October 2007	30 September 2017	PART A	Only uses as insecticide for use as seed treatment may be authorised. The seed coating shall only be performed in professional seed treatment facilities. These facilities must apply the best available techniques in order to ensure that the

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

							release of dust clouds during storage, transport and application can be excluded.
						PART B	For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fipronil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health

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

						on 16 March 2007 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the packaging of the marketed products to avoid the generation of photo-degradation products of concern, — the potential for groundwater contamination, especially from metabolites which are more persistent than the parent compound,

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

						when the active substance is applied in regions with vulnerable soil and/ or climatic conditions, — the protection of granivorous birds and mammals, aquatic organisms, non-target arthropods and honey bees, — the use of adequate equipment ensuring a high degree of incorporation in soil and a minimisation of spillage during application. Conditions of

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

						authorisation should include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of further studies to confirm the risk assessment for granivorous birds and mammals, and honey bees, especially bee brood. They shall ensure that the notifier at whose request fipronil has been included in this Annex provide such studies to the Commission within one year from the entry into force of this Directive.’

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 2007/31/EC (OJ L 140, 1.6.2007, p. 44).

(**2**) OJ L 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p. 32).

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

(**4**) EFSA Scientific Report (2006) 66, 1-72, Conclusion regarding the peer review of the pesticide risk assessment of the active substance ethoprophos (finalised: 3 March 2006). EFSA Scientific Report (2005) 44, 1-53, Conclusion regarding the peer review of the pesticide risk assessment of the active substance pirimiphos-methyl (finalised: 10 August 2005). EFSA Scientific Report (2006) 65, 1-110, Conclusion regarding the peer review of the pesticide risk assessment of the active substance fipronil (finalised: 3 March 2006 version of 12 April 2006).

(**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).