Commission Directive 2006/39/EC of 12 April 2006 amending Council Directive 91/414/EEC to include clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole as active substances (Text with EEA relevance)

COMMISSION DIRECTIVE 2006/39/EC

of 12 April 2006

amending Council Directive 91/414/EEC to include clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole 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 clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole.

(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 clodinafop the rapporteur Member State was The Netherlands and all relevant information was submitted on 7 November 2003. For pirimicarb the rapporteur Member State was United Kingdom and all relevant information was submitted on 4 November 2003. For rimsulfuron the rapporteur Member State was Germany and all relevant information was submitted on 6 August 2003. For tolclofos-methyl the rapporteur Member State was Sweden and all relevant information was submitted on 3 November 2003. For triticonazole the rapporteur Member State was Austria and all relevant information was submitted on 29 September 2003.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 14 March and 10 August 2005 in the format of the EFSA Scientific Reports for clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole[(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 27 January 2006 in the format of the Commission review reports for clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole.

(4) The review of pirimicarb revealed a number of open questions which were addressed by the Scientific Panel on Plant Health, Plant Protection Products and their residues (PPR) of the European Food Safety Authority (EFSA). The Scientific Panel was asked to give an opinion on the use of a 'time quotient approach' in the acute risk assessment for birds and on the assessment of the acute risk for birds which had been carried out. In its opinion to the first question the PPR Panel concluded that the 'time quotient approach' suggested by OECD is equivalent to the current European first tier acute avian risk assessment except that Annex VI of Directive 91/414/EEC stipulates a specific safety factor of 10. Therefore, a detailed scientific analysis would be required to assess whether the current safety factor takes appropriate account of all relevant issues. Since this would require substantial further work that is beyond the scope of the opinion, the PPR Panel suggests that a case by case approach should be used. As result, on the second question, the PPR Panel carried out a refined risk assessment and concluded that even at the upper limit of credible exposures birds feeding on insects in the field are unlikely to achieve a lethal dose of pirimicarb[(5)].

(5) The reviews of clodinafop, rimsulfuron, tolclofos-methyl and triticonazole did not reveal any open question to be addressed by the Scientific Panel on Plant Health, Plant Protection Products and their residues (PPR) of the European Food Safety Authority (EFSA).

(6) It has appeared from the various examinations made that plant protection products containing clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole 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.

(7) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points concerning pirimicarb and triticonazole. 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 pirimicarb and triticonazole 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.

(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) 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 clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl or triticonazole 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.

(10) 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[(6)] 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.

(11) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(12) 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 July 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 August 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 clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl or triticonazole as active substances by 31 July 2007.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole 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 clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl or triticonazole 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 January 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 clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole 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 clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl or triticonazole as the only active substance, where necessary, amend or withdraw the authorisation by 31 January 2011 at the latest; or

b in the case of a product containing clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl or triticonazole as one of several active substances, where necessary, amend or withdraw the authorisation by 31 January 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 February 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 12 April 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/EEC:

'No	**Common name, identification numbers**	**IUPAC name**	**Purity[a]**	**Entry into force**	**Expiration of inclusion**	**Specific provisions**
125	Clodinafop CAS No 114420-56-3 CIPAC No 683	(R)-2-[4-(5-chloro-3-fluoro- 2 pyridyloxy)-phenoxy]-propionic acid	≥ 950 g/kg (expressed as clodinafop-propargyl)	1 February 2007	31 January 2017	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on clodinafop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food

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

							Chain and Animal Health on 27 January 2006 shall be taken into account.
126	Pirimicarb CAS No 23103-98-2 CIPAC No 231	2-dimethylamino-5,6-dimethylpyrimidin-4-yl dimethylcarbamate	≥ 950 g/kg	1 February 2007	31 January 2017	PART A	Only uses as insecticide may be authorised.
						PART B	For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pirimicarb, and in particular Appendices I and II thereof, as finalised in the

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

						Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account. Member States must pay particular attention to the safety of operators and ensure that conditions of use prescribe the application of adequate personal protective equipment. Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk

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

						mitigation measures, where appropriate, such as buffer zones. The concerned Member States shall request the submission of further studies to confirm the long term risk assessment for birds and for potential groundwater contamination, in particular concerning metabolite R35140. They shall ensure that the notifiers at whose request pirimicarb has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
127	Rimsulfuron	1-(4-6 dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea	≥ 960 g/kg (expressed as	1 February 2007	31 January 2017	PART A Only uses

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

	CAS No 122931-48-0 (rimsulfuron) CIPAC No 716	yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl) urea	as rimsulfuron)				as herbicide may be authorised.
						PART B	For the implementation of the uniform principles of Annex VI, the conclusions of the review report on rimsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken

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

						into account. Member States must pay particular attention to the protection of non target plants and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate.
128	Tolclofos-methyl CAS No 57018-04-9 CIPAC No 479	O-2,6-dichloro-p-tolyl O,O-dimethyl phosphorothioate O-2,6-dichloro-4-methylphenyl O,O-dimethyl phosphorothioate	≥ 960 g/kg	1 February 2007	31 January 2017	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing tolclofos-methyl for uses other than pre-planting tuber

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

						(seed) treatment in potato and soil treatment in lettuce within greenhouses, 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 Annex VI, the conclusions of the review report on

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

						tolclofos-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account.
129	Triticonazole CAS No 131983-72-7 CIPAC No 652	(±)-(E)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol	≥ 950 g/kg	1 February 2007	31 January 2017	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing triticonazole for uses other than seed treatment, Member States shall pay particular attention to

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

						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 triticonazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into

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

						account. In this overall assessment Member States: — must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate, — must pay particular attention to the potential for groundwater contamination, in particular from the highly persistent active substance and its metabolite RPA 406341, in vulnerable zones, — must pay particular attention

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

						to the protection of granivorous birds (long term risk). Conditions of 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. They shall ensure that the notifier at whose request triticonazole has been included in this Annex provide such studies to the Commission within two years from the entry into force

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

						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 2006/19/EC (OJ L 44, 15.2.2006, p. 15).

(**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 (2005) 34, 1-78, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance clodinafop (finalised: 10 August 2005)'.
'EFSA Scientific Report (2005) 43, 1-76, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance pirimicarb (finalised: 10 August 2005)'.
'EFSA Scientific Report (2005) 45, 1-61, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance rimsulfuron (finalised: 10 August 2005)'.
'EFSA Scientific Report (2005) 28, 1-77, Conclusion regarding the peer review of the pesticide risk assessment of the active substance triticonazole (finalised: 14 March 2005)'.
'EFSA Scientific Report (2005) 28, 1-77, Conclusion regarding the peer review of the pesticide risk assessment of the active substance tolclofos-methyl (finalised: 14 March 2005)'.

(**5**) Opinion of the Scientific Panel on Plant Health, Plant protection products and their residues on a request from EFSA related to the evaluation of pirimicarb EFSA Journal (2005) 240, 1-21.

(**6**) 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).