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

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(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:

(**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).