DIRECTIVES

COMMISSION DIRECTIVE 2007/76/EC

of 20 December 2007

amending Council Directive 91/414/EEC to include fludioxonil, clomazone and prosulfocarb 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 1490/2002 [3] lay down the detailed rules for the implementation of the third 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 fludioxonil, clomazone and prosulfocarb.

(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 1490/2002 for a range of uses proposed by the notifiers. 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 10(1) of Regulation (EC) No 1490/2002. For fludioxonil and clomazone the rapporteur Member State was Denmark and all relevant information was submitted on 5 April 2005 and 16 March 2005 respectively. For prosulfocarb the rapporteur Member State was Sweden and all relevant information was submitted on 20 April 2005.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 27 July 2007 for fludioxonil, clomazone and prosulfocarb, 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 9 October 2007 in the format of the Commission review reports for fludioxonil, clomazone and prosulfocarb.

(4) It has appeared from the various examinations made that plant protection products containing fludioxonil, clomazone and prosulfocarb 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) 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.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/52/EC (OJ L 214, 17.8.2007, p. 3).
[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 224, 21.8.2002, p. 23. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19).
[4] EFSA Scientific Report (2007) 110, 1-85, Conclusion regarding the peer review of the pesticide risk assessment of the active substance fludioxonil (finalised 27 July 2007).
EFSA Scientific Report (2007) 109, 1-73, Conclusion regarding the peer review of the pesticide risk assessment of the active substance clomazone (finalised 27 July 2007), version of 3 August 2007.
EFSA Scientific Report (2007) 111, 1-81, Conclusion regarding the peer review of the pesticide risk assessment of the active substance prosulfocarb (finalised 27 July 2007).

(6) 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 fludioxonil, clomazone and prosulfocarb 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.

(7) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 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.

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

(9) 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 April 2009 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 May 2009.

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 fludioxonil, clomazone and prosulfocarb as active substances by 30 April 2009.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to fludioxonil, clomazone and prosulfocarb 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 fludioxonil, clomazone and prosulfocarb 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 October 2008 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 fludioxonil, clomazone and prosulfocarb 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 fludioxonil, clomazone or prosulfocarb as the only active substance, where necessary, amend or withdraw the authorisation by 31 October 2012 at the latest; or

(b) in the case of a product containing fludioxonil, clomazone or prosulfocarb as one of several active substances, where necessary, amend or withdraw the authorisation by 31 October 2012 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 November 2008.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 20 December 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/EC:

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'166	Prosulfocarb CAS No 52888-80-9 CIPAC No 539	S-benzyl dipropyl(thiocarbamat)	970 g/kg	1 November 2008	31 October 2018	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 prosulfocarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zone, — the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no spray buffer zone.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
167	Fludioxonil CAS No 131341-86-1 CIPAC No 522	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile	950 g/kg	1 November 2008	31 October 2018	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing fludioxonil for uses other than seed treatment, 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 and: — must pay particular attention to the potential for groundwater contamination, in particular from the soil photolysis metabolites CGA 339833 and CGA 192155, in vulnerable zones, — must pay particular attention to the protection of fish and aquatic invertebrates. Conditions of authorisation should include risk mitigation measures, where appropriate. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fludioxonil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account.
168	Clomazone CAS No 81777-89-1 CIPAC No 509	2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one	960 g/kg	1 November 2008	31 October 2018	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 clomazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones.’

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