DIRECTIVES

COMMISSION DIRECTIVE 2008/66/EC

of 30 June 2008

amending Council Directive 91/414/EEC to include bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine 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 bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine.

(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 bifenox the rapporteur Member State was Belgium and all relevant information was submitted on 4 July 2005. For diflufenican the rapporteur Member State was the United Kingdom and all relevant information was submitted on 1 August 2005. For fenoxaprop-P the rapporteur Member State was Austria and all relevant information was submitted on 2 May 2005. For fenpropidin and quinoclamine the rapporteur Member State was Sweden and all relevant information was submitted on 24 June 2005 and 15 June 2005 respectively.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 14 November 2007 for quinoclamine, on 29 November 2007 for bifenox and fenoxaprop-P and on 17 December 2007 for diflufenican and fenpropidin 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 14 March 2008 in the format of the Commission review reports for bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine.

(4) It has appeared from the various examinations made that plant protection products containing bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine 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

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2008/45/EC (OJ L 94, 5.4.2008, p. 21).
[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) 119, 1-84, Conclusion regarding the peer review of the pesticide risk assessment of the active substance bifenox (finalised 29 November 2007).*
EFSA Scientific Report (2007) 122, 1-84, Conclusion regarding the peer review of the pesticide risk assessment of the active substance diflufenican (finalised 17 December 2007).
EFSA Scientific Report (2007) 121, 1-76, Conclusion regarding the peer review of the pesticide risk assessment of the active substance fenoxaprop-P (finalised 29 November 2007).
EFSA Scientific Report (2007) 124, 1-84, Conclusion regarding the peer review of the pesticide risk assessment of the active substance fenpropidin (finalised 17 December, revision of 29 January 2008 with corrections of miscalculations in the aquatic risk assessment).
EFSA Scientific Report (2007) 117, 1-70, Conclusion regarding the peer review of the pesticide risk assessment of the active substance quinoclamine (finalised on 14 November 2007).

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. 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 bifenox should be subjected to further testing for confirmation of the risk assessment for consumers and the long-term risk to herbivorous mammals and that fenpropidin should be subjected to further testing for confirmation of the risk assessment for the long-term risk to herbivorous and insectivorous birds and 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 bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine 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 [1] 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 30 June 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 July 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 bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine as active substances by 30 June 2009.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine 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.

[1] OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 416/2008 (OJ L 125, 9.5.2008, p. 25).

2. By way of derogation from paragraph 1, for each authorised plant protection product containing bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine 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 December 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 bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine 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 bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2012 at the latest; or

(b) in the case of a product containing bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 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 January 2009.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 30 June 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/ECC:

No	Common name, identification numbers	IUPAC name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
'186	Bifenox CAS No 42576-02-3 CIPAC No 413	*Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate*	≥ 970 g/kg impurities: max. 3 g/kg 2,4-dichlorophenol max. 6 g/kg 2,4-dichloroanisole	1 January 2009	31 December 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 bifenox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 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 where, — the dietary exposure of consumers to bifenox residues in products of animal origin and in succeeding rotational crops. The Member States concerned shall request the submission of: — information on residues of bifenox and its metabolite hydroxy bifenox acid in food of animal origin and on residues of bifenox in rotational crops, — information to further address the long-term risk to herbivorous mammals arising from the use of bifenox. They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the entry into force of this Directive.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
187	Diflufenican CAS No 83164-33-4 CIPAC No 462	*2′,4′-difluoro-2-(α,α,α-trifluoro-m-tolyloxy) nicotinanilide*	≥ 970 g/kg	1 January 2009	31 December 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 diflufenican, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the protection of non-target plants. Risk mitigation measures such as an in-field no spray buffer zones shall be applied, where appropriate.
188	Fenoxaprop-P CAS No 113158-40-0 CIPAC No 484	*(R)-2[4-[(6-chloro-2-benzoxazolyl)oxy]-phenoxy]-propanoic acid*	≥ 920 g/kg	1 January 2009	31 December 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 fenoxaprop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 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, — the presence of the safener mefenpyr-diethyl in formulated products as regards operator, worker and bystander exposure, — the persistence of the substance and of some of its degradation products in colder zones and areas where anaerobic conditions may occur. Conditions of authorisation should include risk mitigation measures, where appropriate.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
189	Fenpropidin CAS No 67306-00-7 CIPAC No 520	*(R,S)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]-piperidine*	≥ 960 g/kg (racemate)	1 January 2009	31 December 2018	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 fenpropidin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker 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 Member States concerned shall request the submission of: — information to further address the long-term risk to herbivorous and insectivorous birds arising from the use of fenpropidin. They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the entry into force of this Directive.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
190	Quinoclamine CAS No 2797-51-5 CIPAC No 648	*2-amino-3-chloro-1,4-naphthoquinone*	≥ 965 g/kg impurity: dichlone (2,3-dichloro-1,4-naphthoquinone) max. 15 g/kg	1 January 2009	31 December 2018	PART A Only uses as herbicide may be authorised. PART B In assessing applications to authorise plant protection products containing quinoclamine for uses other than ornamentals or nursery plants, 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 quinoclamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator, worker and bystander safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms, — the protection of birds and small mammals. Conditions of use shall include adequate risk mitigation measures, where appropriate.

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