Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances (Text with EEA relevance)

COMMISSION DIRECTIVE 2008/69/EC

of 1 July 2008

amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen 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 the active substances listed in the Annex to this Directive.

(2) By Regulation (EC) No 1095/2007 a new Article 11b was inserted into Regulation (EC) No 1490/2002 to allow active substances for which there are clear indications that it may be expected that they do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, to be included in Annex I to Directive 91/414/EEC without detailed scientific advice from the European Food Safety Authority (EFSA) having been sought.

(3) For the active substances listed in the Annex to this Directive the Commission examined in accordance with Article 11a of Regulation (EC) No 1490/2002 the effects on human, animal health, groundwater and the environment for a range of uses proposed by the notifiers, with the conclusion that those active substances satisfy the requirements of Article 11b of Regulation (EC) No 1490/2002.

(4) In accordance with Article 12(1) of Regulation (EC) No 1490/2002 the Commission has submitted draft review reports for the active substances listed in the Annex to this Directive to the Standing Committee on the Food Chain and Animal Health, for examination. Those 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. In accordance with Article 12a of Regulation (EC) No 1490/2002 the Commission is to request the EFSA to deliver its view on the draft review reports by 31 December 2010 at the latest.

(5) It has appeared from the various examinations made that plant protection products containing the active substances listed in the Annex to this Directive 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 have been examined and detailed in the Commission review report. It is therefore appropriate to include in Annex I to that Directive the active substances listed in the Annex to this Directive, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

(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 the active substances listed in the Annex 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 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[(4)] 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 that 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 the active substances listed in the Annex 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 the active substances listed in the Annex are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holders of the authorisations have, or have access to, dossiers 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 one of the active substances listed in the Annex 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 the active substances listed in the Annex. 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 one of the active substances listed in the Annex as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2013 at the latest; or

b in the case of a product containing one of the active substances listed in the Annex as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2013 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, 1 July 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/EEC:

No	Common name, identification numbers	IUPAC name	Purity[a]	Entry into force	Expiration of inclusion	Specific provisions
'177	Clofentezine CAS No 74115-24-5 CIPAC No 418	*3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine*	≥ 980 g/kg (TK material)	1 January 2009	31 December 2018	PART A Only uses as acaricide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on clofentezine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food

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

							Chain and Animal Health shall be taken into account.
178	Dicamba CAS No 1918-00-9 CIPAC No 85	*3,6-dichloro-2-methoxybenzoic acid*	≥ 850 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 dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the

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

							Food Chain and Animal Health shall be taken into account.
179	Difenoconazole CAS No 119446-68-3 CIPAC No 687	*1-[2-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether*	≥ 940 g/kg	1 January 2009	31 December 2018	PART A PART B	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on difenoconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on

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

						the Food Chain and Animal Health shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate.
180	Diflubenzuron CAS No 35367-38-5 CIPAC No 339	*1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl) urea*	≥ 950 g/kg impurity: max. 0,03 g/kg 4-chloroaniline	1 January 2009	31 December 2018	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI,

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

						the conclusions of the review report on diflubenzuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of aquatic organisms, — the protection of terrestrial organisms,

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

						— the protection of non-target arthropods including bees. Conditions of use shall include adequate risk mitigation measures, where appropriate.
181	Imazaquin CAS No 81335-37-7 CIPAC No 699	*2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]quinoline-3-carboxylic acid*	≥ 960 g/kg (racemic mixture)	1 January 2009	31 December 2018	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on imazaquin, and in particular Appendices I and

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

							II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.
182	Lenacil CAS No 2164-08-1 CIPAC No 163	*3-cyclohexyl-1,5,6,7-tetrahydrocyclopentapyrimidine-2,4(3H)-dione*	≥ 975 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 lenacil, and in particular Appendices I

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

							and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.
183	Oxadiazon CAS No 19666-30-9 CIPAC No 213	*5-tert-butyl-3-(2,4-dichloro-5-isopropoxyphenyl)-1,3,4-oxadiazol-2(3H)-one*	≥ 940 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 oxadiazon, and in particular Appendices

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

							I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.
184	Picloram CAS No 1918-02-1 CIPAC No 174	*4-amino-3,5,6-trichloropyridine-2-carboxylic 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 picloram, and in particular

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

							Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.
185	Pyriproxyfen CAS No 95737-68-1 CIPAC No 715	*4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether*	≥ 970 g/kg	1 January 2009	31 December 2018	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 pyriproxyfen, and in

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

						particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of non-target arthropods including bees. Conditions of use shall include adequate risk mitigation measures, where appropriate.

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

(**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**) 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).