COMMISSION IMPLEMENTING REGULATION (EU) No 1100/2011

of 31 October 2011

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 13(2) thereof,

Whereas:

(1) The active substances dicamba, difenoconazole and imazaquin were included in Annex I to Council Directive 91/414/EEC ([2]) by Commission Directive 2008/69/EC ([3]) in accordance with the procedure provided for in Article 11b of Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 ([4]). Since the replacement of Directive 91/414/EEC by Regulation (EC) No 1107/2009, these substances are deemed to have been approved under that Regulation and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances ([5]).

(2) In accordance with Article 12a of Regulation (EC) No 1490/2002, the European Food Safety Authority, hereinafter 'the Authority', presented to the Commission the conclusions on the peer review for difenoconazole ([6]), dicamba ([7]) and imazaquin ([8]) on 17 December 2010. These conclusions were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and were finalised on 27 September 2011 in the format of the Commission review reports for difenoconazole, dicamba, and imazaquin.

(3) In accordance with Article 12(2) of Regulation (EC) No 1107/2009 the Commission invited the notifiers to submit their comments on the conclusions of the Authority. Furthermore, in accordance with Article 13(1) of that Regulation, the Commission invited the notifiers to submit comments on the draft review reports for dicamba, difenoconazole and imazaquin. The notifiers submitted their comments, which have been carefully examined.

(4) It is confirmed that the active substances dicamba, difenoconazole and imazaquin are to be deemed to have been approved under Regulation (EC) No 1107/2009.

(5) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to amend the conditions of approval of dicamba, difenoconazole and imazaquin. It is, in particular, appropriate to require further confirmatory information.

(6) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(7) A reasonable period of time should be allowed before the application of this Regulation in order to allow Member States, notifiers and holders of authorisations for plant protection products to meet the requirements resulting from amendment to the conditions of the approval.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) OJ L 230, 19.8.1991, p. 1.
([3]) OJ L 172, 2.7.2008, p. 9.
([4]) OJ L 224, 21.8.2002, p. 23.
([5]) OJ L 153, 11.6.2011, p. 1.
([6]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance difenoconazole. EFSA Journal 2011; 9(1):1967. [71 pp.]. doi:10.2903/j.efsa.2011.1967. Available online: www.efsa.europa.eu/efsajournal.htm
([7]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance dicamba. EFSA Journal 2011; 9(1):1965. [52 pp.] doi:10.2903/j.efsa.2011.1965. Available online: www.efsa.europa.eu/efsajournal.htm
([8]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance imazaquin. EFSA Journal 2011; 9(1):1968. [57 pp.]. doi:10.2903/j.efsa.2011.1968. Available online: www.efsa.europa.eu/efsajournal.htm

HAS ADOPTED THIS REGULATION:

Article 1

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 May 2012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 31 October 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) Number 172 on the active substance dicamba is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
'172	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 as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of non-target plants. Conditions of use shall include adequate risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) the identification and quantification of a group of soil transformation products formed in a soil incubation study; (b) the potential for long range transport through the atmosphere. The notifier shall submit this information to the Member States, the Commission and the Authority by 30 November 2013.'

(2) Number 173 on the active substance difenoconazole is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
'173	Difenoconazole CAS No 119446-68-3 CIPAC No 687	3-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	≥ 940g/kg Toluene maximum content: 5 g/kg	1 January 2009	31 December 2018	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on difenoconazole, and in particular Appendices I

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
						and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) further data on the specification of the technical material; (b) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops, processed commodities and products of animal origin; (c) the potential for endocrine disrupting effects on fish (fish full life cycle study) and the chronic risk to earthworms from the active substance and the metabolite CGA 205375 (*); (d) the possible impact of the variable isomer-ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and on the environment. The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by 31 May 2012, the information set out in points (b) and (c) by 30 November 2013 and the information set out in point (d) within 2 years from the adoption of specific guidance.'

(*) 1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-yl]-ethanol.

(3) Number 175 on the active substance imazaquin is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
'175	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 as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
						of the review report on imazaquin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account The notifier shall submit confirmatory information as regards: (a) further data on the specification of the technical material; (b) the possible impact of the variable isomer-ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and on the environment. The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by 31 May 2012 and the information set out in point (b) within 2 years from the adoption of specific guidance.'