REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 582/2012

of 2 July 2012

approving the active substance bifenthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(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) and Article 78(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(c) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ([2]) is to apply to active substances for which completeness has been established in accordance with Article 16 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ([3]), with respect to the procedure and the conditions for approval. Bifenthrin is an active substance for which completeness has been established in accordance with that Regulation.

(2) Commission Regulations (EC) No 451/2000 ([4]) and (EC) No 1490/2002 ([5]) lay down the detailed rules for the implementation of the second and third stages 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 included bifenthrin. By Commission Decision 2009/887/EC ([6]) it was decided not to include bifenthrin in Annex I to Directive 91/414/EEC.

(3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Regulation (EC) No 33/2008.

(4) The application was submitted to France, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2009/887/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) France evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 6 August 2010. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on bifenthrin to the Commission on 11 May 2011 ([7]). The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 1 June 2012 in the format of the Commission review report for bifenthrin.

(6) The additional report by the rapporteur Member State and the new conclusion by the Authority concentrate on the concerns that led to the non-inclusion. Those concerns were in particular the potential contamination of groundwater by a major soil degradation product (TFP acid), a possible underestimation of the risk to consumers, due to the limited number of residue data made available and the lack of investigation on the metabolism pattern of the two isomers constituting bifenthrin. As regards ecotoxicology, the risk for

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) OJ L 230, 19.8.1991, p. 1.
([3]) OJ L 15, 18.1.2008, p. 5.
([4]) OJ L 55, 29.2.2000, p. 25.
([5]) OJ L 224, 21.8.2002, p. 23.
([6]) OJ L 318, 4.12.2009, p. 41.

([7]) European Food Safety Authority; 'Conclusion on the peer review of the pesticide risk assessment of the active substance bifenthrin'. *EFSA Journal* 2011;9(5):2159. 0;8(11): [101 pp.] doi:10.2903/j.efsa.2011.2159. Available online: www.efsa.europa.eu/efsajournal.htm

mammals, aquatic organisms, earthworms, non-target arthropods, non-target plants and non-target soil macro-organisms had not been sufficiently addressed.

(7) The new information submitted by the applicant shows that the potential contamination of groundwater by bifenthrin and its metabolites, including TFP acid, is low. Adequate residue data and information as regards the metabolisation of the isomers have been submitted and confirm an acceptable risk for consumers. As regards ecotoxicology, the refined risk assessment for mammals, aquatic organisms, earthworms, non-target arthropods, non-target macro-organisms and non-target plants permitted to identify acceptable risk scenarios for the concerned species.

(8) Consequently, the additional information provided by the applicant permits to eliminate the specific concerns that led to the non-inclusion. No other open scientific questions have arisen.

(9) It has appeared from the various examinations made that plant protection products containing bifenthrin 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 as regards the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve bifenthrin in accordance with Regulation (EC) No 1107/2009.

(10) The acceptable risk scenarios as regards ecotoxicology notwithstanding, the risk assessment revealed that bifenthrin has a potential to show bioaccumulation effects. The approval period should therefore be seven years rather than the possible maximum of 10 years.

(11) 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, however, necessary to include certain conditions and restrictions.

(12) Without prejudice to the conclusion that bifenthrin should be approved, it is, in particular, appropriate to require further confirmatory information.

(13) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 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 [1] should be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance bifenthrin, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

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

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

Done at Brussels, 2 July 2012.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 153, 11.6.2011, p. 1.

ANNEX I

Common name, identification numbers	IUPAC name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Bifenthrin CAS No 82657-04-3 CIPAC No 415	2-methylbiphenyl-3-ylmethyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate or 2-methylbiphenyl-3-ylmethyl (1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate	≥ 930 g/kg Impurities: Toluene: not more than 5 g/kg	1 August 2012	31 July 2019	PART A Only uses as insecticide 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 bifenthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the persistency in the environment; (b) the risk for bioaccumulation and biomagnification; (c) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; (d) the risk to aquatic organisms, in particular fish and invertebrates, non-target arthropods and bees, ensuring that conditions of authorisation include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the residual toxicity for non-target arthropods and the potential for recolonisation; (2) the fate and behaviour of soil metabolite 4'-OH bifenthrin; (3) the degradation in soil of the isomers which constitute bifenthrin, 4'-OH bifenthrin and TFP acid. The applicant shall submit to the Commission, the Member States and the Authority the information set out in points 1, 2 and 3 by 31 July 2014. The applicant shall present to the Commission, the Member States and the Authority a monitoring programme to assess the potential for bioaccumulation and biomagnification in the aquatic and terrestrial environment by 31 July 2013. The results of that monitoring programme shall be submitted as a monitoring report to the rapporteur Member State, the Commission and the Authority by 31 July 2015.

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

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) 540/2011, the following entry is added:

No	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'23	Bifenthrin CAS No 82657-04-3 CIPAC No 415	2-methylbiphenyl-3-ylmethyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate or 2-methylbiphenyl-3-ylmethyl (1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate	≥ 930 g/kg Impurities: Toluene: not more than 5 g/kg	1 August 2012	31 July 2019	PART A Only uses as insecticide 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 bifenthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the persistency in the environment; (b) the risk for bioaccumulation and biomagnification; (c) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; (d) the risk to aquatic organisms, in particular fish and invertebrates, non-target arthropods and bees, ensuring that conditions of authorisation include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the residual toxicity for non-target arthropods and the potential for recolonisation; (2) the fate and behaviour of soil metabolite 4'-OH bifenthrin; (3) the degradation in soil of the isomers which constitute bifenthrin, 4'-OH bifenthrin and TFP acid.

No	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit to the Commission, the Member States and the Authority the information set out in points 1, 2 and 3 by 31 July 2014. The applicant shall present to the Commission, the Member States and the Authority a monitoring programme to assess the potential for bioaccumulation and biomagnification in the aquatic and terrestrial environment by 31 July 2013. The results of that monitoring programme shall be submitted as a monitoring report to the rapporteur Member State, the Commission and the Authority by 31 July 2015.'

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