COMMISSION IMPLEMENTING REGULATION (EU) 2016/1426

of 25 August 2016

renewing the approval of the active substance ethofumesate 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 20(1) thereof,

Whereas:

(1) The approval of the active substance ethofumesate, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]), expires on 31 July 2017.

(2) An application for the renewal of the approval of ethofumesate was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([3]) within the time period provided for in that Article.

(3) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(4) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 28 January 2015.

(5) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(6) On 18 December 2015 the Authority communicated to the Commission its conclusion ([4]) on whether ethofumesate can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for ethofumesate to the Standing Committee on Plants, Animals, Food and Feed on 8 March 2016.

(7) The applicant was given the possibility to submit comments on the renewal report.

(8) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(9) It is therefore appropriate to renew the approval of ethofumesate.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) 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 (OJ L 153, 11.6.2011, p. 1).

([3]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

([4]) EFSA Journal 2016;14(1):4374, 141 pp. doi:10.2903/j.efsa.2016.4374.

(10) The risk assessment for the renewal of the approval of ethofumesate is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing ethofumesate may be authorised. It is therefore appropriate not to maintain the restriction to uses as a herbicide.

(11) In accordance with Article 14(1) 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. It is, in particular, appropriate to set maximum limits for two toxicologically relevant impurities in the active substance as manufactured.

(12) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(13) Commission Implementing Regulation (EU) 2016/950 [1] extended the expiry date of ethofumesate in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on renewal has been taken ahead of the extended expiry date, this Regulation should apply from 1 November 2016.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of active substance

The approval of the active substance ethofumesate, as specified in Annex I, is renewed 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*.

It shall apply from 1 November 2016.

[1] Commission Implementing Regulation (EU) 2016/950 of 15 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-DB, beta-cyfluthrin, carfentrazone ethyl, *Coniothyrium minitans* Strain CON/M/91-08 (DSM 9660), cyazofamid, deltamethrin, dimethenamid-P, ethofumesate, fenamidone, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mesotrione, oxasulfuron, pendimethalin, picoxystrobin, silthiofam and trifloxystrobin (OJ L 159, 16.6.2016, p. 3).

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

Done at Brussels, 25 August 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Ethofumesate CAS No 26225-79-6 CIPAC No 233	(RS)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate	≥ 970 g/kg The following impurities are of toxicological concern and must not exceed the following levels in the technical material: — EMS; ethyl methane sulfonate: maximum of 0,1 mg/kg — iBMS; iso-butyl methane sulfonate: maximum of 0,1 mg/kg	1 November 2016	31 October 2031	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on ethofumesate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.

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

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 29 on ethofumesate is deleted;

(2) in Part B, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'102	Ethofumesate CAS No 26225-79-6 CIPAC No 233	(RS)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate	≥ 970 g/kg The following impurities are of toxicological concern and must not exceed the following levels in the technical material: — EMS; ethyl methane sulfonate: maximum of 0,1 mg/kg — iBMS; iso-butyl methane sulfonate: maximum of 0,1 mg/kg	1 November 2016	31 October 2031	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on ethofumesate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.'

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