COMMISSION IMPLEMENTING REGULATION (EU) 2020/2105

of 15 December 2020

renewing the approval of the active substance etoxazole as a candidate for substitution 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) in conjunction with Article 24(1) thereof,

Whereas:

(1) Commission Directive 2005/34/EC ([2]) included etoxazole as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([4]).

(3) The approval of the active substance etoxazole, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2021.

(4) An application for the renewal of the approval of the active substance etoxazole was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) within the time period provided for in that Article.

(5) 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.

(6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 20 September 2016.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

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

([2]) Commission Directive 2005/34/EC of 17 May 2005 amending Council Directive 91/414/EEC to include etoxazole and tepraloxydim as active substances (OJ L 125, 18.5.2005, p. 5).

([3]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([4]) 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).

([5]) 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).

(8) On 12 September 2017, the Authority communicated to the Commission its conclusion ([6]) on whether etoxazole can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented a renewal report and the draft Regulation for etoxazole on 21 March 2018 and a revised version of the renewal report in March 2020 to the Standing Committee on Plants, Animals, Food and Feed.

(9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ([7]), the conclusion of the Authority indicates that, based on the scientific evidence, it is highly unlikely that etoxazole is an endocrine disrupter via the estrogenic, androgenic and thyroidogenic modalities. Furthermore, the available evidence indicates that etoxazole is unlikely to be an endocrine disruptor via the steroidogenic modality. Thus, the Commission concludes that etoxazole is not to be considered as having endocrine disrupting properties.

(10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments on both versions of the renewal report, which have been carefully examined.

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

(12) The Commission, however, considers that etoxazole is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Etoxazole is considered a bioaccumulative and toxic substance in accordance with points 3.7.2.2 and the first sub point of 3.7.2.3 of Annex II to Regulation (EC) No 1107/2009. Etoxazole therefore fulfils the condition set in the second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.

(13) It is therefore appropriate to renew the approval of etoxazole as a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009.

(14) The risk assessment for the renewal of the approval of the active substance etoxazole is based on representative uses as an acaricide. While it is not necessary, in the light of this risk assessment, to maintain the restriction to use only as an acaricide, it is, however, necessary to provide, 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, for certain conditions and restrictions. It is, in particular, appropriate to restrict the use of plant protection products containing etoxazole to use on ornamental plants in permanent greenhouses. The restriction to ornamentals aims to exclude any dietary exposure of consumers because the risk assessment for processed commodities could not be finalised and uncertainties are too high. As high risk was identified to aquatic organisms, non-target arthropods and soil mites, the restriction to greenhouses as defined in Article 3 of Regulation (EC) No 1107/2009 aims to avoid exposure to the environment and non-target organisms.

(15) In order to increase the confidence in the conclusion that etoxazole does not have endocrine disrupting properties, the applicant should provide an updated assessment, in accordance with point 2.2(b) of Annex II to Regulation (EC) No 1107/2009, of the criteria laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, and in accordance with the guidance for the identification of endocrine disruptors ([8]).

(16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

([6]) *EFSA Journal* 2017;15(10):4988. Available online: www.efsa.europa.eu

([7]) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

([8]) Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009; https://www.efsa.europa.eu/en/efsajournal/pub/5311.

(17) Implementing Regulation (EU) 2020/869 ([9]) extended the approval period of etoxazole to 31 July 2021 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation shall apply from 1 February 2021.

(18) 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 the active substance

The approval of the active substance etoxazole is renewed as set out in Annex I.

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 February 2021.

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

Done at Brussels, 15 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

([9]) Commission Implementing Regulation (EU) 2020/869 of 24 June 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and S-metolachlor (OJ L 201, 25.6.2020, p. 7).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
etoxazole CAS No 153233-91-1 CIPAC No 623	(RS)-5-tert-butyl-2-[2-(2,6-difluorophenyl)-4,5-dihydro1,3-oxazol-4-yl]phenetole	≥ 948 g/kg	1 February 2021	31 January 2028	Only uses on ornamental plants in permanent greenhouses shall be authorised. 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 etoxazole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — possible uptake of persistent soil metabolites in rotational crops; — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment. The applicant shall submit to the Commission, the Member States and the Authority by 5 January 2023 confirmatory information as regards points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009 including an updated assessment of the information already submitted and, where relevant, further information.

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

ANNEX II

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

(1) in Part A, entry 99 on etoxazole is deleted;

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

No	Common Name, Identification Numbers	IUPAC Name	Purity ([1])	Date of approval	Expiration of approval	Specific provisions
'13	etoxazole CAS No 153233-91-1 CIPAC No 623	(RS)-5-tert-butyl-2-[2-(2,6-difluorophenyl)-4,5-dihydro1,3-oxazol-4-yl]phenetole	≥ 948 g/kg	1 February 2021	31 January 2028	Only uses on ornamental plants in permanent greenhouses shall be authorised. 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 etoxazole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — possible uptake of persistent soil metabolites in rotational crops; — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment. The applicant shall submit to the Commission, the Member States and the Authority by 5 January 2023 confirmatory information as regards points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, including an updated assessment of the information already submitted and, where relevant, further information.'

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