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**COMMISSION IMPLEMENTING REGULATION (EU) …/...**

**of XXX**

**concerning the non-renewal of approval of the active substance etoxazole, 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 Commission Implementing Regulation (EU) No 540/2011**

(Text with EEA relevance)

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(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) and Article 78(2) 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 2019.

(4) An application for the renewal of the approval of 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 Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

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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 amending 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).

(6) 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 ('the Authority') and the Commission on 20 September 2016.

(7) 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.

(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 Authority concluded that the consumer dietary risk assessment couldn't be finalised because of the outstanding data to conclude on the residue definition for risk assessment for processed commodities and the fate of persistent soil metabolites in rotational crops. The Authority also concluded that there is a high risk to aquatic invertebrates for all representative uses, a high risk for non-target arthropods for all representative uses evaluated and, in particular, a high risk for soil mites for representative uses in tomato, cucurbit, ornamentals, pome/stone fruit, grapes, strawberry and cotton. Furthermore, etoxazole is a bioaccumulative and toxic substance in accordance with point 3.7.2.2 and point 3.7.2.3 of Annex II to Regulation (EC) No 1107/2009.

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

(10) However, despite the arguments put forward by the applicant, the concerns related to the substance could not be eliminated.

(11) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product containing etoxazole, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance etoxazole in accordance with Article 20(1)(b) of that Regulation.

(12) Member States should be given sufficient time to withdraw authorisations for plant protection products containing etoxazole.

(13) For plant protection products containing etoxazole, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on *[Office of Publications please insert date 15 months from the date of entry into force]*.

(14) Commission Implementing Regulation (EU) XXX[7] extended the expiry date of etoxazole to 31 July 2019 in order to allow the renewal process to be completed before

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6 EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance etoxazole. EFSA Journal 2017;15(10):4988 [27 pp.]. doi: 10.2903/j.efsa.2017.4988.

7 Commission Implementing Regulation (EU) …/… of XXX amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, *Ampelomyces quisqualis* strain: AQ 10, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, carfentrazone ethyl, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diquat, ethephon, ethoprophos, etoxazole, famoxadone, fenamidone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, *Gliocladium catenulatum* strain: J1446, isoxaflutole, metalaxyl-m, methiocarb, methoxyfenozide, metribuzin,

the expiry of the approval of that substance. Given that a decision has been taken ahead of this extended expiry date, this Regulation should apply as soon as possible.

(15) This Regulation does not prevent the submission of a further application for the approval of etoxazole pursuant to Article 7 of Regulation (EC) No 1107/2009.

(16) 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*
*Non-renewal of approval of active substance*

The approval of the active substance etoxazole is not renewed.

*Article 2*
*Amendments to Implementing Regulation (EU) No 540/2011*

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 99, on etoxazole, is deleted.

*Article 3*
*Transitional measures*

Member States shall withdraw authorisations for plant protection products containing etoxazole as active substance by [*Office of Publications please insert date 6 months from the date of entry into force*] at the latest.

*Article 4*
*Grace Period*

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by *[Office of Publications please insert date 15 months from the date of entry into force]* at the latest.

*Article 5*
*Entry into force*

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,

*For the Commission*
*The President*
*Jean-Claude JUNCKER*

milbemectin, oxasulfuron, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, pymetrozine, s-metolachlor and trifloxystrobin (OJ L...., p. ).