



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/12796/2019
[...] (2019) **XXX** draft

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

of XXX

concerning the non-renewal of the approval of the active substance beta-cyfluthrin, 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)

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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/EEC¹, and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2003/31/EC² included beta-cyfluthrin as an active substance in Annex I to Council Directive 91/414/EEC³.
- (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 540/2011⁴.
- (3) The approval of the active substance beta-cyfluthrin as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2020.
- (4) An application for the renewal of the approval of the active substance beta-cyfluthrin was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012⁵ within the time period provided for in that Article.
- (5) The applicants 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.

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Directive 2003/31/EC of 11 April 2003 amending Council Directive 91/414/EEC to include 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide and pendimethalin as active substances (OJ L 101, 23.4.2003, p. 3).

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).

- (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 8 March 2017.
- (7) The Authority communicated the renewal assessment report to the applicants 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 9 August 2018, the Authority communicated to the Commission its conclusion⁶ on whether beta-cyfluthrin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Authority identified concerns. In particular, the Authority identified an unacceptable risk to workers loading and sowing the beet seeds treated with beta-cyfluthrin. In addition, for cases of potato and wheat field applications of beta-cyfluthrin the Authority identified high risk to residents, to non-target arthropods and to aquatic organisms. Furthermore, for the cases of use on tomatoes in greenhouses (permanent and non-permanent), the Authority identified unacceptable risk to operators and workers and, in case of use on tomatoes in non-permanent greenhouses, to non-target arthropods. In addition, the consumer assessment could not be finalised based on the available data.
- (10) The Commission invited the applicants to submit their comments on the conclusion of the Authority. Furthermore, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, the Commission invited the applicants to submit comments on the renewal report. The applicants submitted their comments, which have been carefully examined.
- (11) However, despite the arguments put forward by the applicants, the concerns regarding the active substance could not be eliminated.
- (12) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product 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 beta-cyfluthrin in accordance with Article 20(1)(b) of that Regulation.
- (13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (14) Member States should be provided with sufficient time to withdraw authorisations for plant protection products containing beta-cyfluthrin.
- (15) For plant protection products containing beta-cyfluthrin, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 12 months from the date of entry into force of this Regulation
- (16) Commission Implementing Regulation (EU) 2019/1589⁷ extended the approval period of beta-cyfluthrin to 31 October 2020 in order to allow the renewal process to be

⁶ EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance beta-cyfluthrin, EFSA Journal 2018;16(9):5405.

completed before the expiry of that approval period. However, given that a decision on the non-renewal of the approval is taken ahead of the expiry of that extended approval period, this Regulation should apply as soon as possible.

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

Non-renewal of the approval of the active substance

The approval of the active substance beta-cyfluthrin is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 48, on beta-cyfluthrin, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing beta-cyfluthrin as an active substance by [*Office of Publications please insert date corresponding to 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 expire by [*Office of Publications please insert date corresponding to 12 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*.

⁷ Commission Implementing Regulation (EU) 2019/1589 of 26 September 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, beta-cyfluthrin, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-P, fenprovidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanate-methyl, triflurosulfuron and tritosulfuron (OJ L 248, 27.9.2019, p. 24).

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN