



Brussels, **XXX**
SANTE/10238/2020
[...] (2020) **XXX** draft

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

of **XXX**

concerning the non-renewal of the approval of the active substance benalaxyl, 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 2004/58/EC² included benalaxyl 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 benalaxyl, 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 benalaxyl 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 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.

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Directive 2004/58/EC of 23 April 2004 amending Council Directive 91/414/EEC to include alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ixoxynil and phenmedipham as active substances (OJ L 120, 24.4.2004, p. 26).

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 12 October 2016.
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (8) On 19 December 2019, the Authority communicated to the Commission its conclusion⁶ on whether benalaxyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) In its conclusion, the Authority identified a number of concerns. In particular, the potential groundwater contamination by relevant metabolites could not be excluded. Furthermore, a long-term risk to birds and earthworm-eating birds from secondary poisoning from benalaxyl was identified as a critical area of concern. Concerns were also identified in relation to the long-term risk to non-target arthropods for all representative uses. Finally, following the request by the Authority for additional information to assess the endocrine disrupting potential of benalaxyl, the applicant confirmed that no additional studies would be performed or submitted. Consequently, it cannot be concluded that the substance has no endocrine disrupting properties.
- (10) The Commission invited the applicant to submit its 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 applicant to submit comments on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (11) However, despite the arguments put forward by the applicant, 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 benalaxyl 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 given sufficient time to withdraw authorisations for plant protection products containing benalaxyl.
- (15) For plant protection products containing benalaxyl, 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) 2020/XXX⁷ extended the approval period of benalaxyl to 31 July 2021 in order to allow the renewal process to be completed

⁶ EFSA (European Food Safety Authority). 2019. Conclusion on the peer review of the pesticide risk assessment of the active substance benalaxyl. EFSA Journal 2020;18(1):5985, 41 pp. doi:10.2903/j.efsa.2020.5985.

⁷ Commission Implementing Regulation (EU) .../... (OJ L XX, XX.X.2020, p. XX).

before the expiry of the approval period of that substance. However, given that a decision on the non-renewal of the approval is being 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 benalaxyl 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 benalaxyl 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 84, on benalaxyl, is deleted.

Article 3

Transitional measures

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

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 the date corresponding to 12 months from the date of entry into force*].

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

Ursula VON DER LEYEN