# Commission Implementing Regulation (EU) 2020/1280 of 14 September 2020 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)

## COMMISSION IMPLEMENTING REGULATION (EU) 2020/1280

## of 14 September 2020

## 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)

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 2004/58/EC[(2)] included benalaxyl 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 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 844/2012[(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 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.

**Changes to legislation:** *Commission Implementing Regulation (EU) 2020/1280 is up to date with all changes known to be in force on or before 21 March 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(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 conclusion[(6)] 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 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) 2020/869[(7)] extended the approval period of benalaxyl to 31 July 2021 in order to allow the renewal process to be completed 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.

***Changes to legislation:** Commission Implementing Regulation (EU) 2020/1280 is up to date with all changes known to be in force on or before 21 March 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(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 5 April 2021.

*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 5 October 2021.

*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.