



Brussels, **XXX**  
SANTE/10234/2020  
[...] (2020) **XXX** draft

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

**of XXX**

**concerning the non-renewal of the approval of the active substance benfluralin, 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/EEC<sup>1</sup>, and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2008/108/EC<sup>2</sup> included benfluralin as an active substance in Annex I to Council Directive 91/414/EEC<sup>3</sup>.
- (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<sup>4</sup>.
- (3) The approval of the active substance benfluralin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 28 February 2021.
- (4) An application for the renewal of the approval of the active substance benfluralin was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012<sup>5</sup> 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.

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<sup>1</sup> OJ L 309, 24.11.2009, p. 1.

<sup>2</sup> OJ L 317, 27.11.2008, p. 6.

<sup>3</sup> 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).

<sup>4</sup> 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).

<sup>5</sup> 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 28 August 2017.
- (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 27 September 2019, the Authority communicated to the Commission its conclusion<sup>6</sup> on whether benfluralin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Authority identified a number of concerns. In particular a long-term risk to birds and mammals including the risk from secondary poisoning of earthworm-eating birds and mammals was identified as a critical area of concern.
- (10) Furthermore, a long-term risk to aquatic organisms from benfluralin even when applying mitigation measures and the long-term risk to aquatic organisms from metabolites 371R and 372R could not be excluded.
- (11) Finally, a genotoxic potential of an impurity cannot be excluded since the technical specification, including the level of that impurity, was not supported by the toxicological assessment.
- (12) 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.
- (13) However, despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.
- (14) 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 benfluralin in accordance with Article 20(1)(b) of that Regulation.
- (15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (16) Member States should be given sufficient time to withdraw authorisations for plant protection products containing benfluralin.
- (17) For plant protection products containing benfluralin, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 18 months from the date of entry into force of this Regulation.
- (18) This Regulation does not prevent the submission of a further application for the approval of benfluralin pursuant to Article 7 of Regulation (EC) No 1107/2009.

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<sup>6</sup> EFSA (European Food Safety Authority). 2019. Conclusion on the peer review of the pesticide risk assessment of the active substance benfluralin. EFSA Journal 2019;17(10):5842, 34 pp. doi:10.2903/j.efsa.2019.5842.

(19) 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 benfluralin 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 188 on benfluralin, is deleted.

*Article 3*

***Transitional measures***

Member States shall withdraw authorisations for plant protection products containing benfluralin as an active substance by ... [*Office of Publications please insert date 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 date 18 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*