

COMMISSION IMPLEMENTING REGULATION (EU) 2023/149**of 20 January 2023****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)**

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 Articles 20(1) and 78(2) thereof,

Whereas:

- (1) Commission Directive 2008/108/EC ⁽²⁾ included benfluralin 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 benfluralin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 28 February 2023.
- (4) An application for the renewal of the approval of the active substance benfluralin was submitted to Norway, the rapporteur Member State, and the Netherlands, the co-rapporteur Member State, 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 applicants submitted the supplementary dossiers required to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') 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 draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 28 August 2017. In its draft renewal assessment report Norway proposed to not renew the approval of benfluralin.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2008/108/EC of 26 November 2008 amending Council Directive 91/414/EEC to include flutolanil, benfluralin, fluazininam, fuberidazole and mepiquat as active substances (OJ L 317, 27.11.2008, p. 6).

⁽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). This Regulation was replaced by Regulation (EU) 2020/1740, however, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft 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 ⁽⁶⁾ on whether benfluralin 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 it identified a long-term risk to birds and mammals, including the risk from secondary poisoning of earthworm-eating birds and mammals, as a critical area of concern. Furthermore, the Authority identified the presence of a long-term risk to aquatic organisms from benfluralin, even when applying mitigation measures and a long-term risk to aquatic organisms caused by the metabolites 371R and 372R as a critical area of concern. Finally, it stated that the 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.
- (10) The Commission invited the applicants to submit their comments on the conclusion of the Authority. Furthermore, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, the Commission invited the applicants to submit comments on the renewal report. The applicants submitted its comments, which were carefully examined.
- (11) On 16 July 2021, the Commission sent a mandate to the Authority with a request to review the exposure and risk assessments as regards birds, mammals and aquatic organisms. The Authority sent to the Commission an updated conclusion on 25 August 2022 ⁽⁷⁾ which confirmed the concerns identified in previous conclusion. The Commission invited the applicants to submit comments on the revised renewal report. The applicants submitted their comments, which have been carefully examined.
- (12) Despite the arguments put forward by the applicants, the concerns regarding the active substance and one of the metabolites could not be eliminated.
- (13) 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.
- (14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) Member States should be given time to withdraw authorisations for plant protection products containing benfluralin.
- (16) 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 at the latest, expire on 12 May 2024.
- (17) Commission Implementing Regulation (EU) 2021/2068 ⁽⁸⁾ extended until 28 February 2023 the period of approval of benfluralin in order to allow the renewal process to be completed before the expiry of the approval period of that substance. Given that a decision on the non-renewal of the approval has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.

⁽⁶⁾ EFSA. 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.

⁽⁷⁾ EFSA. 2022. Conclusion on the peer review of the pesticide risk assessment of the active substance benfluralin. EFSA Journal 2022;20(9):7556, 36 pp. doi:10.2903/j.efsa.2022.7556.

⁽⁸⁾ Commission Implementing Regulation (EU) 2021/2068 of 25 November 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mecoprop-P, pepiquat, metiram, oxamyl and pyraclostrobin (OJ L 421, 26.11.2021, p. 27).

- (18) This Regulation does not prevent the submission of another application for the approval of benfluralin pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (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 12 August 2023.

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 12 May 2024.

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, 20 January 2023.

For the Commission
The President
Ursula VON DER LEYEN
