EUROPEAN
COMMISSION

Brussels, XXX
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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[1], and in particular Article 20(1) and Article 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 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[5] 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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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, fluazinam, 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).

(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[6] 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 identfied a number of concerns. In particular it concuded that 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. Furthermore, the Authority concluded on 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 . Finally, 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 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 benfluralin.

(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 benfluralin.

(15) 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 [*Office of Publications, please insert date 12 months from the date of entry into force of this Regulation.*].

(16) Commission Implementing Regulation (EU) 2019/2094[7] extended until 28 February 2021 the period of approval of benfluralin in order to allow the renewal

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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 Commission implementing Regulation (EU) 2019/2094 of 29 November 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (OJ L 317, 9.12.2019, p. 102).

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 as soon as possible.

(17) 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.

(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 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 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