



2023/2657

23.11.2023

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/2657**

**of 6 November 2023**

**concerning the non-renewal of the approval of the active substance benthialdicarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending 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 <sup>(1)</sup>, and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2008/44/EC <sup>(2)</sup> included benthialdicarb 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 benthialdicarb, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 November 2024.
- (4) An application for the renewal of the approval of the active substance benthialdicarb was submitted to Poland, the rapporteur Member State, and France, the co-rapporteur Member State, 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 applicant 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 admissible 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 Authority and the Commission on 31 October 2017.

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

<sup>(2)</sup> Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthialdicarb, boscalid, carvone, fluoxastrobin, Paecilomyces lilacinus and prothioconazole as active substances (OJ L 94, 5.4.2008, p. 13).

<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), which continues to apply to the procedure for the renewal of the approval of this active substance pursuant to Article 17 of Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 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, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20).

- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicant 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 23 August 2021, the Authority communicated to the Commission its conclusion <sup>(6)</sup> ('the Authority's conclusion') on whether benthiavalicarb can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) In that conclusion, the Authority identified certain specific concerns. In particular, it was concluded that benthiavalicarb has a carcinogenic potential, which is consistent with the proposal of the European Chemical Agency to classify it as carcinogen category 1B <sup>(7)</sup>. The authority considered also that benthiavalicarb shows endocrine disrupting properties that may have adverse effects in humans, as set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009. According to the Authority, residues of benthiavalicarb are expected to be above the value set in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, and, therefore, such requirement is not fulfilled.
- (10) In its evaluation of whether benthiavalicarb is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods in accordance with Article 4(7) of Regulation (EC) No 1107/2009, the Authority concluded that, despite the fact that there may be an insufficient number of chemical alternatives available for some uses of benthiavalicarb and in some Member States, some non-chemical methods are also available, and that a combination of chemical and non-chemical methods may be possible to control the pests in some crops. In addition, the Commission considers that no serious danger to plant health has been identified. Therefore, the Commission considers that the conditions for the application of the derogation in Article 4(7) of Regulation (EC) No 1107/2009 are not fulfilled.
- (11) The Commission presented its draft renewal report regarding benthiavalicarb and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 24 May 2023 and on 11 July 2023, respectively.
- (12) The Commission invited the applicant to submit its comments on the conclusion of the Authority and on the draft renewal report. The applicant submitted its comments, which have been carefully examined.
- (13) Despite the comments put forward by the applicant, the concerns raised in the risk assessment of benthiavalicarb 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 containing benthiavalicarb- 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 benthiavalicarb.
- (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 benthiavalicarb.
- (17) For plant protection products containing benthiavalicarb, 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.

<sup>(6)</sup> Peer review of the pesticide risk assessment of the active substance benthiavalicarb (variant assessed benthiavalicarb-isopropyl) (*EFSA Journal* 2021;19(9):6833; <https://doi.org/10.2903/j.efsa.2021.6833>).

<sup>(7)</sup> European Chemicals Agency, Committee for Risk Assessment RAC, Opinion proposing harmonised classification and labelling at EU level of benthiavalicarb-isopropyl (ISO); isopropyl [(S)-1- {[ (R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl}-2-methylpropyl] carbamate EC Number: – CAS Number: 177406-68-7 CLH-O-0000007106-79-01/E, adopted on 18 March 2022 (<https://echa.europa.eu/documents/10162/c334cdfd-3fd8-adff-04a2-9f84dd871f6a>).

- (18) Commission Implementing Regulation (EU) 2023/918 <sup>(8)</sup> extends, until 15 November 2024, the approval of benthiavalicarb 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 can be taken ahead of the expiry date, this Regulation should apply earlier than that date.
- (19) This Regulation does not preclude the submission of a further application for the approval of benthiavalicarb pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (20) 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 approval of active substance**

The approval of the active substance benthiavalicarb 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 163, benthiavalicarb, is deleted.

*Article 3*

**Transitional measures**

Member States shall withdraw authorisations for plant protection products containing benthiavalicarb as an active substance by 13 June 2024.

*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 13 December 2024.

*Article 5*

**Entry into force**

This Regulation shall enter into force on twentieth day following that of its publication in the *Official Journal of the European Union*.

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<sup>(8)</sup> Commission Implementing Regulation (EU) 2023/918 of 4 May 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aclonifen, ametoctradin, beflubutamid, benthiavalicarb, boscalid, captan, clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, dimethomorph, ethephon, fenazaquin, fluopicolide, fluoxastrobin, flurochloridone, folpet, formetanate, *Helicoverpa armigera* nucleopolyhedrovirus, hymexazol, indolybutyric acid, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole, S-metolachlor, *Spodoptera littoralis* nucleopolyhedrovirus, *Trichoderma asperellum* strain T34 and *Trichoderma atroviride* strain I-1237 (OJ L 119, 5.5.2023, p. 160).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 November 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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