Official Journal
of the European Union

EN
L series

2024/2806

4.11.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2806

of 31 October 2024

concerning the non-renewal of the approval of the active substance metribuzin, 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 and Commission Implementing Regulation (EU) 2015/408

(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 2007/25/EC ([2]) included metribuzin 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 metribuzin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 February 2025.

(4) An application for the renewal of the approval of the active substance metribuzin was submitted to Estonia, the rapporteur Member State, and Germany, 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 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.

([1]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.

([2]) Commission Directive 2007/25/EC of 23 April 2007 amending Council Directive 91/414/EEC to include dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as active substances (OJ L 106, 24.4.2007, p. 34, ELI: http://data.europa.eu/eli/dir/2007/25/oj).

([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, ELI: http://data.europa.eu/eli/dir/1991/414/oj).

([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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

([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, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj), 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, ELI: http://data.europa.eu/eli/reg_impl/2020/1740/oj).

(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 30 September 2019. In its draft renewal assessment report, the rapporteur Member State proposed to not renew the approval of metribuzin.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft 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 25 July 2023, the Authority communicated to the Commission its conclusion ([6]) on whether metribuzin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Authority identified concerns. In particular, it concluded that metribuzin meets the criteria to be identified as an endocrine disruptor for the thyroid (T)-modality for humans and that it has not been demonstrated that the exposure of humans to that active substance in a plant protection product, under realistic proposed conditions of use, is negligible. Furthermore, the Authority concluded that the bystander and resident exposure estimates exceed the established limit value for all representative uses evaluated, and that the available studies were not sufficient to exclude a high risk to bees.

(10) The Authority evaluated whether metribuzin is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods. This evaluation included only cases where metribuzin is used to control weeds for pre-emergence and post-emergence herbicide applications. The Authority concluded that an insufficient number of chemical alternatives were available at the time of assessment for all crops evaluated and therefore that in that regard the derogation is scientifically supported in all crops evaluated. The assessment of non-chemical alternatives for the presented uses concluded that a wide range of non-chemical methods are available, despite of the fact that these methods might not have the same efficacy as chemical methods or might have economic limitations. 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 a renewal report and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 22 May 2024 and on 10 July 2024, respectively.

(12) The Commission invited the applicant to submit its 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 applicant to submit comments on the renewal report. The applicant submitted its comments, which have been carefully examined.

(13) Despite the arguments put forward by the applicant, the concerns regarding the active substance metribuzin 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 metribuzin 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 metribuzin in accordance with Article 20(1), point (b), of that Regulation.

(15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

([6]) EFSA (European Food Safety Authority), 2023. Peer review of the pesticide risk assessment of the active substance metribuzin. EFSA Journal 2023;21(8):8140 https://doi.org/10.2903/j.efsa.2023.8140.
The conclusion was reissued with editorial corrections in the main body of the text and Appendix B on 13 May 2024 to reflect the results of an additional expert consultation. The corrections do not materially affect the contents or outcome of this scientific output.

(16) Commission Implementing Regulation (EU) 2015/408 ([7]) listed metribuzin as a candidate for substitution. In the light of the non-renewal of the approval of metribuzin that listing is no longer relevant. Accordingly, metribuzin should be removed from the Annex to Implementing Regulation (EU) 2015/408.

(17) Member States should be given sufficient time to withdraw authorisations for plant protection products containing metribuzin.

(18) For plant protection products containing metribuzin, 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.

(19) Commission Implementing Regulation (EU) 2023/918 ([8]) extended the approval period of metribuzin to 15 February 2025 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on the non-renewal of the approval is taken ahead of the expiry date of that extended approval period, this Regulation should apply earlier than that date.

(20) This Regulation does not prevent the submission of another application for the approval of metribuzin pursuant to Article 7 of Regulation (EC) No 1107/2009.

(21) 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 metribuzin 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 152, on metribuzin, is deleted.

Article 3

Amendment to Implementing Regulation (EU) 2015/408

The entry for metribuzin is deleted from the Annex to Implementing Regulation (EU) 2015/408.

([7]) Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (OJ L 67, 12.3.2015, p. 18, ELI: http://data.europa.eu/eli/reg_impl/2015/408/oj).

([8]) 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, indolylbutyric 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, ELI: http://data.europa.eu/eli/reg_impl/2023/918/oj).

Article 4

Transitional measures

Member States shall withdraw authorisations for plant protection products containing metribuzin as an active substance by 24 May 2025.

Article 5

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 24 November 2025.

Article 6

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, 31 October 2024

For the Commission
The President
Ursula VON DER LEYEN