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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2390

of 6 September 2024

renewing the approval of the active substance metrafenone 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 ([1]), and in particular Article 20(1) thereof,

Whereas:

(1) Commission Directive 2007/6/EC ([2]) included metrafenone 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 metrafenone, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 December 2024.

(4) An application for the renewal of the approval of the active substance metrafenone was submitted to Latvia, the rapporteur Member State, and Slovakia, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) and 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 draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 30 October 2018. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of metrafenone.

([1]) OJ L 309, 24.11.2009, p. 1. ELI: http://data.europa.eu/eli/reg/2009/1107/oj.
([2]) Commission Directive 2007/6/EC of 14 February 2007 amending Council Directive 91/414/EEC to include metrafenone, Bacillus subtilis, spinosad and thiamethoxam as active substances (OJ L 43, 15.2.2007, p. 13, ELI: http://data.europa.eu/eli/dir/2007/6/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).

(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 29 November 2019, the Authority requested additional information on the endocrine disrupting properties of metrafenone pursuant to Article 13(3a) of Implementing Regulation (EU) No 844/2012. The applicant submitted the requested information required in order to determine whether metrafenone fulfils the criteria for identifying the endocrine disrupting properties of an active substance set out in point 3.8.2 of Annex II to Regulation (EC) No 1107/2009.

(9) In June 2022, the rapporteur Member State made the updated draft renewal assessment report available to the Authority, the Member States and the Commission. In its updated draft renewal assessment report, the rapporteur Member State considered the additional information regarding the endocrine disrupting properties of metrafenone, and still proposes, in light of that information, to renew the approval of metrafenone.

(10) On 18 April 2023, the Authority communicated to the Commission its conclusion ([6]), indicating that, taking into account the approval criteria laid down in Annex II to Regulation (EC) No 1107/2009, plant protection products with metrafenone can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(11) The Commission presented a draft renewal report on the 13 October 2023 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 11 December 2023.

(12) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.

(13) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance metrafenone that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(14) It is therefore appropriate to renew the approval of metrafenone.

(15) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions. It is, in particular, appropriate to require further confirmatory information.

(16) Specifically, in order to increase the confidence in the conclusion that metrafenone does not have endocrine disrupting properties, the applicant should provide an updated assessment, in accordance with point 2.2(b) of Annex II to Regulation (EC) No 1107/2009, of the criteria laid down in point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 and in accordance with the guidance for the identification of endocrine disruptors ([7]), to confirm the absence of endocrine activity concerning the T-modality of non-target organisms other than mammals, including the information already submitted, an additional XETA study ([8]) and, where relevant, further information. Furthermore, to increase the confidence in the conclusion that the metabolites CL 1500834 and CL 3000402 do not have genotoxic properties, the applicant should provide an updated assessment of their genotoxicity.

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

([6]) Conclusion on the peer review of the pesticide risk assessment of the active substance metrafenone, EFSA Journal https://doi.org/10.2903/j.efsa.2023.8012. Available online: www.efsa.europa.eu.

([7]) Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311.135 pp.

([8]) E.g. OECD test guideline Nr. 248.

(18) Commission Implementing Regulation (EU) 2023/689 ([9]) extends the approval period of metrafenone to 15 December 2024 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 renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.

(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

Renewal of the approval of the active substance

The approval of the active substance metrafenone, as specified in Annex I to this Regulation, is renewed, subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

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

It shall apply from 1 November 2024.

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

Done at Brussels, 6 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

([9]) Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances Bacillus subtilis (Cohn 1872) strain QST 713, Bacillus thuringiensis subsp. Aizawai strains ABTS-1857 and GC-91, Bacillus thuringiensis subsp. Israeliensis (serotype H-14) strain AM65-52, Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, Beauveria bassiana strains ATCC 74040 and GHA, clodinafop, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, Trichoderma asperellum (formerly T. harzianum) strains ICC012, T25 and TV1, Trichoderma atroviride (formerly T. harzianum) strain T11, Trichoderma gamsii (formerly T. viride) strain ICC080, Trichoderma harzianum strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/689/oj).

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Metrafenone CAS No: 220899-03-6 CIPAC No: 752	3′-bromo-2,3,4,6′-tetramethoxy-2′,6-dimethylbenzophenone	≥ 980 g/kg The impurity dimethyl sulphate shall not exceed 0,01 g/kg in the technical material.	1 November 2024	31 October 2039	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on metrafenone, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers; — the consumer exposure assessment with regards to residues that may be present in food. Conditions of use shall include risk mitigation measures, where appropriate. 1) An updated assessment for point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 to confirm the absence of endocrine activity concerning the T-modality of non-target organisms other than mammals, including where relevant, further information. 2) An updated assessment of the genotoxicity of the metabolites CL 1500834 and CL 3000402. The applicant shall submit the information related to point 1 by 29 March 2026 and the information related to point 2 by 29 December 2024.

(1) Further details on the identity and specification of the active substance are provided in the renewal report.

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 137 on metrafenone is deleted;

(2) in Part B, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ([1])	Date of approval	Expiration of approval	Specific provisions
'171	Metrafenone CAS No: 220899-03-6 CIPAC No: 752	3′-brom-o-2,3,4,6′-tetrame-thoxy-2′,6-dime-thylbenzo-phenone	≥ 980 g/kg The impurity dimethyl sul-phate shall not exceed 0,01 g/kg in the tech-nical material.	1 November 2024	31 October 2039	For the implementation of the uniform principles as referred to in Arti-cle 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on metrafenone, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers; — the consumer exposure assessment with regards to residues that may be present in food. Conditions of use shall include risk mitigation measures, where appropriate. 1) An updated assessment for point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 to confirm the absence of endocrine activity concerning the T-modality of non-target organisms other than mammals, including where relevant, further information. 2) An updated assessment of the genotoxicity of the metabolites CL 1500834 and CL 3000402. The applicant shall submit the information related to point 1 by 29 March 2026 and the information related to point 2 by 29 December 2024.'

([1]) Further details on the identity and specification of the active substance are provided in the renewal report.