Official Journal
of the European Union

EN
L series

2024/1217

30.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1217

of 29 April 2024

concerning the non-renewal of the approval of the active substance mepanipyrim, 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) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2004/62/EC ([2]) included mepanipyrim 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 mepanipyrim, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 March 2025.

(4) An application for the renewal of the approval of the active substance mepanipyrim was submitted to Belgium, the rapporteur Member State, and Greece, 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 complete 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 3 May 2016. In its draft renewal assessment report the rapporteur Member State proposed to renew the approval of mepanipyrim.

(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.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2004/62/EC of 26 April 2004 amending Council Directive 91/414/EEC to include mepanipyrim as active substance (OJ L 125, 28.4.2004, p. 38).

([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).

(8) On 12 May 2017, the Authority communicated to the Commission its conclusion ([6]) on whether mepanipyrim can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Commission presented an initial draft renewal report for mepanipyrim to the Standing Committee on Plants, Animals, Food and Feed on 5 October 2017.

(10) In accordance with Article 14(1a), first subparagraph, of Implementing Regulation (EU) No 844/2012, the Commission requested the Authority to reassess the available information on endocrine disrupting properties of the active substance.

(11) On 14 July 2023, the Authority communicated to the Commission its updated conclusion ([7]) on whether mepanipyrim can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 including its finalised assessment of endocrine disrupting properties.

(12) The Authority identified certain specific concerns. In particular, it concluded that mepanipyrim is considered to meet the criteria for endocrine disruptors for humans and wild mammals as non-target organisms set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, due to its oestrogen, androgen and steroidogenesis (EAS)-modalities. Negligible exposure of humans to mepanipyrim cannot be demonstrated since residues above the default value of 0,01 mg/kg are expected to occur. Therefore, the requirements set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are not fulfilled. Additionally, a high long-term risk was identified for wild mammals exposed to mepanipyrim via dietary exposure, for all representative uses. Furthermore, several issues could not be finalised, including the consumer risk assessment.

(13) Article 4(7) of Regulation (EC) No 1107/2009 provides for the possibility of a restricted approval of substances identified as endocrine disruptors if it can be demonstrated that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods. As the applicant did not provide any information to demonstrate such necessity, this derogation cannot be considered.

(14) The Commission presented an updated draft renewal report for mepanipyrim to the Standing Committee on Plants, Animals, Food and Feed on 12 October 2023.

(15) 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.

(16) Despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.

(17) 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 mepanipyrim.

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

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

([6]) EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance mepanipyrim. *EFSA Journal* 2017;15(6):4852, 22 pp. doi: 10.2903/j.efsa.2017.4852.

([7]) EFSA (European Food Safety Authority), 2023. Updated conclusion on the peer review of the pesticide risk assessment of the active substance mepanipyrim. *EFSA Journal*, 21(8), 1–26. doi.org/10.2903/j.efsa.2023.8196.

(20) For plant protection products containing mepanipyrim, 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.

(21) Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 ([8]) extended the period of approval of mepanipyrim until 15 March 2025 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 is taken ahead of the expiry of that extended approval period, this Regulation should apply earlier than that date.

(22) This Regulation does not prevent the submission of a further application for the approval of mepanipyrim pursuant to Article 7 of Regulation (EC) No 1107/2009.

(23) 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 mepanipyrim 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 the entry on mepanipyrim is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing mepanipyrim as an active substance by 20 November 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 20 May 2025.

([8]) 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).

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*.

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

Done at Brussels, 29 April 2024.

For the Commission
The President
Ursula VON DER LEYEN