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COMMISSION IMPLEMENTING REGULATION (EU) 2025/150

of 29 January 2025

renewing the approval of the active substance mepiquat chloride 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 2008/108/EC ([2]) included mepiquat chloride as an active substance in Annex I to Council Directive 91/414/EEC ([3]), under the name 'mepiquat'.

(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 that active substance, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 15 October 2025.

(4) An application for the renewal of the approval of the active substance mepiquat chloride was submitted to Finland, the rapporteur Member State, and Estonia, 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. This 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 19 December 2018. In its draft renewal assessment report, the rapporteur Member State could not propose to renew the approval of mepiquat chloride, since further information was needed to exclude the endocrine disrupting properties of that active substance.

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

([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, ELI: http://data.europa.eu/eli/dir/2008/108/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 20 April 2020, the Authority requested additional information from the applicant on the endocrine disrupting properties of mepiquat chloride pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012. The applicant submitted information to allow the Authority to conclude the assessment as regards whether the scientific criteria for the determination of endocrine disrupting properties set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as introduced by Commission Regulation (EU) 2018/605 ([6]) are met.

(9) In April 2023, the rapporteur Member State made an updated draft renewal assesment 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 submitted by the applicant regarding the criteria to identify endocrine disrupting properties and concluded that mepiquat chloride had no such properties with respect to human, mammalian species and other non-target organisms.

(10) On 4 July 2024, the Authority communicated to the Commission its conclusion ([7]), which indicated that mepiquat chloride can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(11) The Commission presented a renewal report and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 2 October 2024.

(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 mepiquat chloride 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 mepiquat chloride.

(15) Although the risk assessment for the renewal of the approval of the active substance mepiquat chloride is based on a limited number of representative uses, this does not restrict the uses for which plant protection products containing mepiquat chloride may be authorised. It is therefore appropriate not to maintain the restriction to use mepiquat chloride only as a plant growth regulator.

(16) 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, in particular with respect to the specification of the technical material and the protection of operators. It is no longer necessary to maintain the specific condition that Member States pay particular attention to the residues in food of plant and animal origin and evaluate the dietary exposure of consumers, as the provisional consumer risk assessment showed an acceptable risk even for critical consumer groups.

([6]) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33, ELI: http://data.europa.eu/eli/reg/2018/605/oj).

([7]) EFSA (European Food Safety Authority), 2024. Peer review of the pesticide risk assessment of the active substance mepiquat (evaluated variant mepiquat chloride). *EFSA Journal* 2024; 22(7): e8923 https://doi.org/10.2903/j.efsa.2024.8923.

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

(18) Commission Implementing Regulation (EU) 2024/324 ([8]) extended the approval period of mepiquat to 15 October 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 renewal of the approval of that active substance 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 mepiquat chloride, 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 March 2025.

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

Done at Brussels, 29 January 2025.

For the Commission
The President
Ursula VON DER LEYEN

([8]) Commission Implementing Regulation (EU) 2024/324 of 19 January 2024 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benzovindiflupyr, bromuconazole, buprofezin, cyflufenamid, fluazinam, fluopyram, flutolanil, lambda-cyhalothrin, mecoprop-P, mepiquat, metsulfuron-methyl, phosphane and pyraclostrobin (OJ L, 2024/324, 22.1.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/324/oj).

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Mepiquat chloride CAS No: 24307-26-4 CIPAC No: 440.302	1,1-dimethylpiperidinium chloride	≥ 990 g/kg (theoretical dry technical material, TC) 615-665 g/L (technical concentrate, TK) The impurity N-methylpiperidine shall not exceed 3 g/kg (on theoretical dry weight basis) or 2 g/L (in the technical concentrate, TK).	1 March 2025	29 February 2040	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 mepiquat chloride, 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 specification of the technical material as commercially manufactured; — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment. Conditions of use shall include risk mitigation measures, where appropriate.

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

ELI: http://data.europa.eu/eli/reg_impl/2025/150/oj

ANNEX II

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

(1) in Part A, entry 191 on mepiquat 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
‘173	Mepiquat chloride CAS No: 24307-26-4 CIPAC No: 440.302	1,1-dimethyl-piperidinium chloride	≥ 990 g/kg (theoretical dry technical material, TC) 615-665 g/L (technical concentrate, TK) The impurity N-methylpiperi-dine shall not exceed 3 g/kg (on theoretical dry weight basis) or 2 g/L (in the technical concentrate, TK).	1 March 2025	29 February 2040	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 mepiquat chloride, 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 specification of the technical material as commercially manufactured; — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment. Conditions of use shall include risk mitigation measures, where appropriate.

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