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COMMISSION IMPLEMENTING REGULATION (EU) 2025/833

of 5 May 2025

renewing the approval of the active substance lenacil in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulations (EU) No 540/2011 and (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) thereof,

Whereas:

(1) Commission Directive 2008/69/EC ([2]) included lenacil 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 lenacil, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 August 2025.

(4) An application for the renewal of the approval of the active substance lenacil was submitted to Belgium, the rapporteur Member State, and Austria, 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 dossier 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 2 January 2019. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of lenacil.

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

([2]) Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances (OJ L 172, 2.7.2008, p. 9, ELI: http://data.europa.eu/eli/dir/2008/69/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) In March 2020, the Authority requested additional information from the applicant on the endocrine disrupting properties of lenacil pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012 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. The applicant submitted the requested information to the Authority.

(9) In May 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 regarding the criteria to identify endocrine disrupting properties and proposed renewing the approval of lenacil.

(10) On 11 June 2024, the Authority communicated to the Commission its Conclusion ([7]) indicating that plant protection products containing lenacil can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009, including that lenacil has no endocrine disrupting properties.

(11) The Commission presented a renewal report and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 4 December 2024 and 12 March 2025, respectively.

(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 lenacil 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 lenacil.

(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.

In particular, it is necessary to pay attention to the possible need for additional rotational crop field trials and livestock exposure assessment until the required confirmatory information has been assessed by the rapporteur Member State and evaluated by the Authority.

Further confirmatory information is required on rotational crops field trials, including analysis for known and possible new metabolites.

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

([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 lenacil. *EFSA Journal* 2024; 22(7): e8860 https://doi.org/10.2903/j.efsa.2024.8860.

(17) Lenacil had been included in the list of candidates for substitution established in the Annex to Commission Implementing Regulation (EU) 2015/408 ([8]) as it was considered to be a persistent and toxic substance. An active substance shall be approved as a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009 where it meets two of the criteria to be considered a persistent, bioaccumulative and toxic (PBT) substance. The risk assessment for the renewal of the approval of lenacil showed that the substance does not meet the criteria to be considered bioaccumulative and toxic substance in accordance with points 3.7.2.2 and 3.7.2.3 of Annex II to Regulation (EC) No 1107/2009, respectively. As two of the three criteria are not met, lenacil should not be considered as a candidate for substitution. It is therefore appropriate to delete the entry for the active substance lenacil in the Annex to Implementing Regulation (EU) 2015/408.

(18) Commission Implementing Regulation (EU) 2023/2592 ([9]) extended the approval period of lenacil to 15 August 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 lenacil 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 lenacil, 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

Amendments to Implementing Regulation (EU) 2015/408

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

([8]) 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).

([9]) Commission Implementing Regulation (EU) 2023/2592 of 21 November 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, 2-phenylphenol (incl. its salts such as sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fluazifop P, lenacil, napropamide, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, spiroxamine, sulphur, tetraconazole and tri-allate (OJ L, 2023/2592, 22.11.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2592/oj).

Article 4

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 July 2025.

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

Done at Brussels, 5 May 2025.

For the Commission
The President
Ursula VON DER LEYEN

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Lenacil CAS No: 2164-08-01 CIPAC No: 163	3-cyclohexyl-6,7-dihydro-1H-cyclopenta[d] pyrimidine-2,4(3H,5H)-dione or 3-cyclohexyl-1,5,6,7-tetrahydrocyclopenta-pyrimidine-2,4(3H)-dione	975 g/kg	1 July 2025	30 June 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 lenacil, and in particular Appendices I and II thereto, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. In this overall assessment Member States shall pay particular attention to the possible need for additional rotational crop field trials and a livestock exposure assessment until the required confirmatory information has been assessed by the rapporteur Member State and evaluated by the Authority. By 25 March 2027, the applicant shall submit to the Commission, the Member States and the Authority confirmatory information on rotational crops field trials, including analysis for known and possible new metabolites. If new metabolites are found, the applicant is requested to perform toxicological studies assessing these metabolites. The applicant is requested to perform an appropriate livestock exposure assessment if necessary.

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

ANNEX II

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

(1) in Part A, entry 176 on lenacil 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
‘175	Lenacil CAS No: 2164-08-01 CIPAC No: 163	3-cyclohexyl-6,7-dihydro-1H-cyclopenta[d] pyrimidine-2,4(3H,5H)-dione or 3-cyclohexyl-1,5,6,7-tetrahydro-cyclopentapyrimidine-2,4(3H)-dione	975 g/kg	1 July 2025	30 June 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 lenacil, and in particular Appendices I and II thereto, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. In this overall assessment Member States shall pay particular attention to the possible need for additional rotational crop field trials and a livestock exposure assessment until the required confirmatory information has been assessed by the rapporteur Member State and evaluated by the Authority. By 25 March 2027, the applicant shall submit to the Commission, the Member States and the Authority confirmatory information on rotational crops field trials, including analysis for known and possible new metabolites. If new metabolites are found, the applicant is requested to perform toxicological studies assessing these metabolites. The applicant is requested to perform an appropriate livestock exposure assessment if necessary.’

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