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COMMISSION IMPLEMENTING REGULATION (EU) 2026/1976

of 8 September 2026

renewing the approval of the active substance pyraclostrobin 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 2004/30/EC ([2]) included pyraclostrobin 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 pyraclostrobin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 December 2026.

(4) An application for the renewal of the approval of the active substance pyraclostrobin was submitted to Germany, the rapporteur Member State, and Hungary, 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 19 February 2018. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of pyraclostrobin.

([1]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.
([2]) Commission Directive 2004/30/EC of 10 March 2004 amending Council Directive 91/414/EEC to include benzoic acid, flazasulfuron and pyraclostrobin as active substances (OJ L 77, 13.3.2004, p. 50, ELI: http://data.europa.eu/eli/dir/2004/30/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 pyraclostrobin pursuant to Article 13(3a) of Implementing Regulation (EU) No 844/2012. The applicant submitted the information required to determine whether pyraclostrobin fulfils the criteria for identifying the endocrine disrupting properties of a substance set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as introduced by Commission Regulation (EU) 2018/605 ([6]).

(9) On 8 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 evaluated the additional information on endocrine disrupting properties of pyraclostrobin and, in light of that information, maintained its proposition to renew the approval of pyraclostrobin.

(10) On 29 January 2025, the Authority communicated to the Commission its conclusion ([7]) indicating that, taking into account the approval criteria laid down in Annex II to Regulation (EC) No 1107/2009, plant protection products containing pyraclostrobin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority identified no critical area of concern.

(11) The Commission presented the draft renewal report and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 5 May 2026.

(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 pyraclostrobin that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

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

(15) It is therefore appropriate to renew the approval of pyraclostrobin. In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof, it is, however, necessary to provide for certain conditions.

(16) It is, in particular, appropriate to set maximum limits for dimethyl sulfate and toluene, which are toxicologically relevant impurities that might be present in the technical material as manufactured, to ensure that the active substance pyraclostrobin used in plant protection products does not lead to any harmful effects on human health.

([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]) 'Conclusion on the peer review of the pesticide risk assessment of the active substance pyraclostrobin', in *EFSA Journal* 2025, 23(3); e9257, https://doi.org/10.2903/j.efsa.2025.9257. Available online: www.efsa.europa.eu.

(17) Taking into account the outcome of the risk assessment it is necessary to require that Member States, when authorising plant protection products containing pyraclostrobin, pay particular attention to the assessment of co-formulants used in pyraclostrobin-containing plant protection products, the protection of aquatic organisms and the consumer risk assessment, including by imposing mitigation measures, where applicable.

(18) Moreover, it is appropriate to require confirmatory information to increase the confidence in the conclusion that there is no concern from possible exposure of consumers to metabolite 500M07 and to confirm the residue definition for risk assessment for commodities of plant or animal origin.

(19) Finally, given that new scientific and technical knowledge on the assessment of the potential effects of water treatment processes on residues of active substances or their metabolites in water, abstracted for the production of drinking water, has been developed during the evaluation process, which was not available at the time of the submission of the supplementary dossier for pyraclostrobin, notably a Guidance Document ([8]), the applicant should provide confirmatory information on the effects of water treatment processes on residues of pyraclostrobin or its metabolites potentially present in surface water, when surface water is abstracted for drinking water.

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

(21) Commission Implementing Regulation (EU) 2026/1826 ([9]) extended the expiry date of pyraclostrobin to 15 December 2026 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.

(22) 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 pyraclostrobin, as specified in Annex I to this Regulation, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendment 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.

([8]) ECHA and EFSA (European Chemicals Agency and European Food Safety Authority), Hofman-Caris, R., Dingemans, M., Reus, A., Shaikh, S. M., Muñoz Sierra, J., Karges, U., aus der Beek, T., Nogueiro, E., Lythgo, C., Parra Morte, J. M., Bastaki, M., Serafimova, R., Friel, A., Court Marques, D., Uphoff, A., Bielska, L., Putzu, C., Ruggeri, L., and Papadaki, P., 'Guidance document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water', in *EFSA Journal* 2023; 21(8),1-108, https://doi.org/10.2903/j.efsa.2023.8194.

([9]) Commission Implementing Regulation (EU) 2026/1826 of 28 July 2026 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aclonifen, amisulbrom, *Bacillus amyloliquefaciens* strain MBI 600, beflubutamid, clomazone, cyantraniliprole, cyprodinil, daminozide, dichlorprop-P, dimethachlor, fludioxonil, formetanate, fosetyl, isofetamid, metalaxyl, metazachlor, penconazole, phenmedipham, pirimicarb, pyraclostrobin and S-abscisic acid (OJ L, 2026/1826, 29.7.2026, ELI: http://data.europa.eu/eli/reg_impl/2026/1826/oj).

Article 3

Entry into force and date of application

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

It shall apply from 1 October 2026.

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

Done at Brussels, 8 September 2026.

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
Pyraclostrobin CAS No: 175013-18-0 CIPAC No: 657	methyl 2-({[1-(4-chlorophenyl)-1H-pyrazol-3- yl]oxy}methyl)-N-methoxycarbanilate	≥ 980 g/kg The following impurities shall not exceed the following levels in the technical material: — Dimethyl sulfate (DMS): 0,001 g/kg — Toluene: 8 g/kg	1 October 2026	30 September 2041	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 pyraclostrobin, 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 co-formulants present in pyraclostrobin-containing plant protection products, taking into account in particular the criteria for identification of unacceptable co-formulants as set out in Commission Implementing Regulation (EU) 2023/574 (2), — the exposure of aquatic organisms to relevant metabolites in water and sediment environmental compartments and the protection of aquatic organisms, — the consumer risk assessment, concerning the exposure to metabolites of pyraclostrobin, in particular 500M07 and 500M54 (for use on grapes), — the risk assessment to the aquatic environment for the metabolites BF 500–15 and 500M58. Conditions of use shall include risk mitigation measures, where applicable. The applicant shall submit confirmatory information as regards: (1) The toxicity profile of the metabolite 500M07 to confirm the residue definitions for risk assessment (commodities of plant and animal origin). (2) The effect of water treatment processes on the nature of residues of both the active substance and its identified metabolites potentially present in surface water, when surface water is abstracted for drinking water. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 and 2 by 12 September 2028.

(1) Further details on the identity and specification of the active substance are provided in the renewal report.
(2) Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L 75, 14.3.2023, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2023/574/oj).

ANNEX II

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

(1) in Part A, entry 81 on pyraclostrobin 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
‘182	Pyraclostrobin CAS No: 175013-18-0 CIPAC No: 657	methyl 2-({[1-(4-chlorophenyl)-1H-pyrazol-3- yl] oxy}methyl)-N-methoxycarbanilate	≥ 980 g/kg The following impurities shall not exceed the following levels in the technical material: — Dimethyl sulfate (DMS): 0,001 g/kg — Toluene: 8 g/kg	1 October 2026	30 September 2041	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 pyraclostrobin, 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 co-formulants present in pyraclostrobin-containing plant protection products, taking into account in particular the criteria for identification of unacceptable co-formulants as set out in n Implementing Regulation (EU) 2023/574, — the exposure of aquatic organisms to relevant metabolites in water and sediment environmental compartments and the protection of aquatic organisms, — the consumer risk assessment, concerning the exposure to metabolites of pyraclostrobin, in particular 500M07 and 500M54 (for use on grapes), — the risk assessment to the aquatic environment for the metabolites BF 500–15 and 500M58. Conditions of use shall include risk mitigation measures, where applicable. The applicant shall submit confirmatory information as regards: (1) The toxicity profile of the metabolite 500M07 to confirm the residue definitions for risk assessment (commodities of plant and animal origin). (2) The effect of water treatment processes on the nature of residues of both the active substance and its identified metabolites potentially present in surface water, when surface water is abstracted for drinking water. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 and 2 by 12 September 2028.’

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