



COMMISSION IMPLEMENTING REGULATION (EU) 2026/355

of 18 February 2026

renewing the approval of the active substance pyrimethanil 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 2006/74/EC ⁽²⁾ included pyrimethanil 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 pyrimethanil, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 June 2026.
- (4) An application for the renewal of the approval of the active substance pyrimethanil was submitted to Czech Republic, 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 applicants 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 31 August 2017. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of pyrimethanil.

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

⁽²⁾ Commission Directive 2006/74/EC of 21 August 2006 amending Council Directive 91/414/EEC to include dichlorprop-P, metconazole, pyrimethanil and triclopyr as active substances (OJ L 235, 30.8.2006, p. 17, ELI: <http://data.europa.eu/eli/dir/2006/74/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 applicants 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 16 December 2019, the Authority requested additional information from the applicants on the endocrine disrupting properties of pyrimethanil pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012. The applicants 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 September 2022, the rapporteur Member State made an updated draft renewal assessment report available to the Authority, the Member States and the Commission. In that report, the rapporteur Member State considered the additional information regarding the criteria to identify endocrine disrupting properties and proposed renewing the approval of pyrimethanil.
- (10) On 3 September 2024, 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 pyrimethanil 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 to the Standing Committee on Plants, Animals, Food and Feed on 1 October 2025 and a draft of this Regulation on 10 December 2025.
- (12) The Commission invited the applicants to submit their 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 applicants submitted their comments, which have been carefully examined and taken into due 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 pyrimethanil 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 pyrimethanil.
- (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 and restrictions.
- (16) It is, in particular, appropriate to set maximum limits for cyanamide, aniline, and acetylacetone, which are toxicologically relevant impurities that might be present in the technical material as manufactured, to ensure that the active substance pyrimethanil used in plant protection products does not lead to any harmful effects on human health.
- (17) Based on the findings of the risk assessment, it is also necessary to require Member States to pay particular attention to the protection of operators, bystanders, residents, aquatic organisms, bees and pollinators when carrying out assessments for the authorisation of plant protection products containing pyrimethanil. Member States shall impose, where appropriate, the use of personal protective equipment to reduce the exposure of operators, and other risk mitigation measures to reduce the exposure of bystanders, residents, aquatic organisms, bees and pollinators.

⁽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 pesticides peer review of the pesticide risk assessment of the active substance pyrimethanil (*EFSA Journal* 2024;22:e8998, available online: <https://doi.org/10.2903/j.efsa.2024.8998>).

- (18) Provisional residue definitions for the consumer risk assessment for certain commodities of plant or animal origin, as well as for certain processed commodities, have been established due to a data gap on the toxicity of metabolites of pyrimethanil that may be present in those commodities: metabolite M605F004 and its conjugates and metabolite M605F007. The applicants should provide further information on the toxicity of the metabolite M605F004, including its conjugates, and of the metabolite M605F007, so that definitive residue definitions can be set in relation to the commodities concerned.
- (19) In addition, in order to increase the confidence in the conclusion that the metabolite U2 is present in soil in an amount that does not trigger the need for its identification according to the data requirements for active substances⁽⁸⁾, and that, therefore, the subsequent soil, surface water, sediment and groundwater exposure and risk assessment for the metabolite U2 is not needed, the applicants should provide confirmatory information on the degradation of pyrimethanil in soils.
- (20) 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 pyrimethanil, notably a Guidance Document⁽⁹⁾, the applicants should provide confirmatory information on the effects of water treatment processes on residues of pyrimethanil or its metabolites that may occur in water abstracted for the production of drinking water.
- (21) It is therefore appropriate to renew the approval of pyrimethanil, subject to the conditions set out in the Annex to this Regulation. Implementing Regulation (EU) No 540/2011 should be amended accordingly.
- (22) Commission Implementing Regulation (EU) 2025/99⁽¹⁰⁾ extended the approval period of pyrimethanil to 30 June 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.
- (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

Renewal of the approval of the active substance

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

⁽⁸⁾ See point 7.1.1 of Part A of the Annex to Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with 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 93, 3.4.2013, p. 1, ELI: <http://data.europa.eu/eli/reg/2013/283/oj>).

⁽⁹⁾ 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' (EFSA Journal 2023;21(8),1-108, <https://doi.org/10.2903/j.efsa.2023.8194>).

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2025/99 of 21 January 2025 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), *Bacillus amyloliquefaciens* subsp. *plantarum* D747, benalaxyl-M, cyprodinil, dichlorprop-P, formetanate, fosetyl, halosulfuron-methyl, imazamox, milbemectin, phenmedipham, pirimicarb, *Pseudomonas* sp. strain DSMZ 13134, pyrimethanil, pyriofenone, pyroxsulam, spinosad, sulphur, *Trichoderma harzianum* Rifai strains T-22 and ITEM 908, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T-25 and TV-1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, triticonazole and ziram (OJ L, 2025/99, 22.1.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/99/oj).

*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 April 2026.

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

Done at Brussels, 18 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (%)	Date of approval	Expiration of approval	Specific provisions
Pyrimethanil CAS No: 53112-28-0 CIPAC No: 714	N-(4,6-dimethylpyrimidin-2-yl) aniline	≥ 975 g/kg The following impurities shall not exceed the following levels in the technical material: — cyanamide: 0,5 g/kg; — aniline: 4 g/kg; — acetylacetone: 0,1 g/kg.	1 May 2026	30 April 2041	<p>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 pyrimethanil, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of bystanders and residents, ensuring that drift reduction measures are applied, where necessary; — the protection of aquatic organisms, bees and other pollinators. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ol style="list-style-type: none"> (1) the toxicity of the metabolite M605F004, including its conjugates, and the metabolite M605F007, to confirm the relevant residue definitions for risk assessment; (2) the effect of water treatment processes on the residues of pyrimethanil or its metabolites present in water abstracted for the production of drinking water, in accordance with the EFSA and ECHA 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;

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
					<p>(3) the degradation of pyrimethanil in soil, including where relevant the identification and characterisation of metabolites. If the information indicates the relevance of the metabolite U2, soil, surface water, sediment and groundwater exposure and risk assessment for the metabolite U2 shall be provided.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1.2 and 3 by 11 March 2028.</p>

⁽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 135 on pyrimethanil is deleted;
- (2) in Part B, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity (%)	Date of approval	Expiration of approval	Specific provisions
179	Pyrimethanil CAS No: 53112-28-0 CIPAC No: 714	N-(4,6-dimethylpyrimidin-2-yl) aniline	≥ 975 g/kg The following impurities shall not exceed the following levels in the technical material: — cyanamide: 0,5 g/kg; — aniline: 4 g/kg; — acetylacetone: 0,1 g/kg.	1 May 2026	30 April 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 pyrimethanil, 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, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of bystanders and residents, ensuring that drift reduction measures are applied, where necessary; — the protection of aquatic organisms, bees and other pollinators. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the toxicity of the metabolite M605F004, including its conjugates, and the metabolite M605F007, to confirm the relevant residue definitions for risk assessment; (2) the effect of water treatment processes on the residues of pyrimethanil or its metabolites present in water abstracted for the production of drinking water, in accordance with the EFSA and ECHA 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;

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						<p>(3) the degradation of pyrimethanil in soil, including where relevant the identification and characterisation of metabolites. If the information indicates the relevance of the metabolite U2, soil, surface water, sediment and groundwater exposure and risk assessment for the metabolite U2 shall be provided.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1.2 and 3 by 11 March 2028.'</p>

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