

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2314**of 25 November 2022****renewing the approval of the active substance *Pythium oligandrum* strain M1 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, and amending the Annex to 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 2008/113/EC ⁽²⁾ included *Pythium oligandrum* strain M1 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 *Pythium oligandrum* strain M1, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2023.
- (4) An application for the renewal of the approval of the active substance *Pythium oligandrum* strain M1 was submitted to the 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 in accordance with Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). The application was found to be complete 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 26 September 2018.
- (7) The Authority circulated the draft renewal assessment report to the applicant and to the Member States for comments, launched a public consultation on it and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, p. 6).

⁽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 8 October 2020, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether *Pythium oligandrum* strain M1 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report and a draft Regulation regarding *Pythium oligandrum* strain M1 to the Standing Committee on Plants, Animals, Food and Feed on 18 May 2022 and 15 July 2022, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third paragraph, of Implementing Regulation (EU) No 844/2012 ⁽⁷⁾, on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Pythium oligandrum* strain M1 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) It is therefore appropriate to renew the approval of *Pythium oligandrum* strain M1.
- (13) 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, it is, however, necessary to provide for certain conditions. It is, in particular, appropriate to require that Member States, when assessing applications for authorisations of products containing *Pythium oligandrum* strain M1, pay particular attention to the specification of the technical material and to the protection of operators and workers, and foresee risk mitigation measures such as personal and respiratory protective equipments to address the risks of sensitisation or physical effects on the respiratory system that may be caused by the micro-organism.
- (14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) Commission Implementing Regulation (EU) 2022/378 ⁽⁸⁾ extended the approval period of *Pythium oligandrum* strain M1 to 30 April 2023 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.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁶⁾ EFSA Journal 2020;18(11):6296, doi: 10.2903/j.efsa.2020.6296. Available online: www.efsa.europa.eu

⁽⁷⁾ This Regulation was replaced by Commission Implementing Regulation (EU) 2020/1740 (OJ L 392, 23.11.2020, p. 20), however, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

⁽⁸⁾ Commission Implementing Regulation (EU) 2022/378 of 4 March 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, *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, *Pseudomonas chlororaphis* strain MA342, pyrimethanil, *Pythium oligandrum* M1, 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 72, 7.3.2022, p. 2).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance *Pythium oligandrum* strain M1, 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 2023.

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

Done at Brussels, 25 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
<p><i>Pythium oligandrum</i> strain M1</p> <p>Culture collection No ATCC 38472</p>	Not applicable	No relevant impurities	1 March 2023	28 February 2038	<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 <i>Pythium oligandrum</i> strain M1, and in particular Appendices I and II thereof, 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 specification of the technical material as commercially manufactured, — the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitisers and that physical effects on the respiratory system due to the remnants of culture medium and co-formulants in the Microbial Pest Control Product (MPCP) cannot be excluded. <p>Conditions of use shall include risk mitigation measures, such as:</p> <ul style="list-style-type: none"> — adequate personal protective and respiratory protective equipment for operators using products containing <i>Pythium oligandrum</i> strain M1.

⁽¹⁾ Further details on the identity and the 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 202 on *Pythium oligandrum* strain M1 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
'155	<i>Pythium oligandrum</i> strain M1 Culture collection No ATCC 38472	Not applicable	No relevant impurities	1 March 2023	28 February 2038	<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 <i>Pythium oligandrum</i> strain M1, and in particular Appendices I and II thereof, 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 specification of the technical material as commercially manufactured, — the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitisers and that physical effects on the respiratory system due to the remnants of culture medium and co-formulants in the Microbial Pest Control Product (MPCP) cannot be excluded. <p>Conditions of use shall include risk mitigation measures, such as:</p> <ul style="list-style-type: none"> — adequate personal protective and respiratory protective equipment for operators using products containing <i>Pythium oligandrum</i> strain M1.

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