

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) 2022/383

of 4 March 2022

**renewing the approval of the low-risk active substance *Metarhizium brunneum* strain Ma 43 (formerly *Metarhizium anisopliae* var. *anisopliae* strain BIPESCO 5/F52) 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 <sup>(1)</sup>, and in particular Article 20(1) in conjunction with Article 22(1) thereof,

Whereas:

- (1) Commission Directive 2008/113/EC <sup>(2)</sup> included *Metarhizium brunneum* strain Ma 43 (formerly *Metarhizium anisopliae* var. *anisopliae* strain BIPESCO 5/F52) as an active substance in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (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 <sup>(4)</sup>.
- (3) The approval of the active substance *Metarhizium brunneum* strain Ma 43 (formerly *Metarhizium anisopliae* var. *anisopliae* strain BIPESCO 5/F52), as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2022.
- (4) An application for the renewal of the approval of the active substance *Metarhizium brunneum* strain BIPESCO 5/F52 was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> within the time period provided for in that Article.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

<sup>(5)</sup> 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).

- (5) The applicants submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. 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 European Food Safety Authority ('the Authority') and the Commission on 3 June 2019.
- (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 28 September 2020, the Authority communicated to the Commission its conclusion <sup>(6)</sup> on whether *Metarhizium brunneum* strain BIPESCO 5/F52 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented a renewal report and a draft of this Regulation regarding *Metarhizium brunneum* strain Ma 43 (formerly *Metarhizium anisopliae* var. *anisopliae* strain BIPESCO 5/F52) to the Standing Committee on Plants, Animals, Food and Feed on 21 October 2021 and 1 December 2021, respectively. In their application, the applicants referred to the active substance with the name of *Metarhizium brunneum* strain BIPESCO 5/F52. The Commission proposed to change the name of the active substance to *Metarhizium brunneum* strain Ma 43. Indeed, it was confirmed by the Authority that BIPESCO 5 and F52 are subcultures of the strain Ma 43 and that these subcultures are identical in terms of biological and genetic properties and do not differ from the original strain Ma 43.
- (9) The Commission invited the applicants to submit their comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicants submitted their comments, which have been carefully examined.
- (10) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Metarhizium brunneum* strain Ma 43 (formerly *Metarhizium anisopliae* var. *anisopliae* strain BIPESCO 5/F52) that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (11) The Commission further considers that *Metarhizium brunneum* strain Ma 43 (formerly *Metarhizium anisopliae* var. *anisopliae* strain BIPESCO 5/F52) is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. That active substance fulfils the conditions set in point 5.2.1 of Annex II to Regulation (EC) No 1107/2009 because, at strain level, it has not demonstrated multiple resistance to anti-microbials used in human or veterinary medicine.
- (12) It is therefore appropriate to renew the approval of *Metarhizium brunneum* strain Ma 43 (formerly *Metarhizium anisopliae* var. *anisopliae* strain BIPESCO 5/F52) as a low-risk active substance.
- (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.
- (14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) This Regulation should apply from the day following the date of expiry of the approval of *Metarhizium brunneum* strain Ma 43 (formerly *Metarhizium anisopliae* var. *anisopliae* strain BIPESCO 5/F52).
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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<sup>(6)</sup> EFSA Journal 2020;18(10):6274. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

HAS ADOPTED THIS REGULATION:

*Article 1*

**Renewal of the approval of the active substance**

The approval of the active substance *Metarhizium brunneum* strain Ma 43, as specified in Annex I, 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 May 2022.

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

Done at Brussels, 4 March 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
<i>Metarhizium brunneum</i> strain Ma 43	Not applicable	No relevant impurities	1 May 2022	30 April 2037	<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>Metarhizium brunneum</i> strain Ma 43, 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 the protection of operators and workers, taking into account that microorganisms are as such considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.</p>

<sup>(1)</sup> 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 200 on *Metarhizium anisopliae* var. *anisopliae* strain BIPESCO 5/F52 is deleted;  
 (2) in Part D, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
'36	<i>Metarhizium brunneum</i> strain Ma 43	Not applicable	No relevant impurities	1 May 2022	30 April 2037	<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>Metarhizium brunneum</i> strain Ma 43, 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 the protection of operators and workers, taking into account that microorganisms are as such considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.'</p>

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