

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/501

of 25 March 2022

approving the active substance *Beauveria bassiana* strain 203 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 13(2) thereof,

Whereas:

- (1) GlenBiotech submitted to the rapporteur Member State, the Netherlands, on 10 March 2017 an application pursuant to Article 7(1) of Regulation (EC) No 1107/2009 for the approval of the active substance *Beauveria bassiana* strain 203.
- (2) In accordance with Article 9(3) of Regulation (EC) No 1107/2009, the rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') of the admissibility of the application on 20 July 2017.
- (3) For that active substance, the effects on human and animal health and the environment have been assessed, pursuant to Article 11(2) and (3) of Regulation (EC) No 1107/2009, for the use proposed by the applicant. On 5 June 2019, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, concluding that the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (4) In accordance with Article 12(1) of Regulation (EC) No 1107/2009 the Authority circulated the draft assessment report received from the rapporteur Member State to the applicant and the other Member States and organised a public consultation on it.
- (5) In accordance with Article 12(3) of Regulation (EC) No 1107/2009, the Authority requested the applicant to submit additional information to the Member States, the Commission and the Authority. The rapporteur Member State assessed the additional information and submitted its assessment to the Authority in the form of an updated draft assessment report in July 2020.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

- (6) On 6 October 2020, the Authority communicated to the applicant, the Member States and the Commission its conclusion ⁽²⁾ on whether the active substance *Beauveria bassiana* strain 203 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.
- (7) On 22 October 2021, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed a review report and the draft of this Regulation providing that *Beauveria bassiana* strain 203 is approved.
- (8) The applicant was given the possibility to submit comments on the review report.
- (9) The Commission considers that, based on the draft assessment report from the rapporteur Member State, the conclusions from the Authority and the comments from the applicant, with respect to the representative use of at least one plant protection product containing *Beauveria bassiana* 203 which was examined and is detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to approve *Beauveria bassiana* strain 203.
- (10) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 (b), (c) and (e) thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions, these are, the maximum content of the metabolite of concern beauvericin in plant protection products, as well as the restriction of use to ornamental palm trees.
- (11) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾ should be amended accordingly.
- (12) 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

Approval of the active substance

The active substance *Beauveria bassiana* strain 203, as specified in Annex I, is approved 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

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

⁽²⁾ Conclusion on the Peer review of the pesticide risk assessment of the active substance *Beauveria bassiana* strain 203. EFSA Journal 2020;18(11):6295. Doi: 10.2903/j.efsa.2020.6295.

⁽³⁾ 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).

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

Done at Brussels, 25 March 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>Beauveria bassiana</i> strain 203</p> <p>Accession number at Centraal Bureau voor Schimmelcultures (Fungal Biodiversity Centre, Institute of the Royal Netherlands Academy of Arts and Sciences, Utrecht, Netherlands): CBS 121097</p>	Not applicable	Max. level of beauvericin: 80 µg/kg in the formulated product.	19 April 2022	18 April 2032	<p>Only uses on ornamental palm trees shall be authorised.</p> <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 review report on <i>Beauveria bassiana</i> strain 203, 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> <p>a) the maximum level of the metabolite beauvericin in the plant protection product;</p> <p>b) the protection of operators and workers, taking into account that the species <i>Beauveria bassiana</i>, irrespective of the strain, is a potential human allergen by both skin and inhalatory exposure, and therefore ensuring that adequate personal protective equipment is included as a condition of use.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

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

⁽²⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

'151	<p><i>Beauveria bassiana</i> strain 203</p> <p>Accession number at Centraal Bureau voor Schimmelcultures (Fungal Biodiversity Centre, Institute of the Royal Netherlands Academy of Arts and Sciences, Utrecht, Netherlands): CBS 121097</p>	Not applicable	<p>Max. level of beauvericin: 80 µg/kg in the formulated product.</p>	19 April 2022	18 April 2032	<p>Only uses on ornamental palm trees shall be authorised.</p> <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 review report on <i>Beauveria bassiana</i> strain 203, 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> <ol style="list-style-type: none"> a) the maximum level of the metabolite beauvericin in the plant protection product; b) the protection of operators and workers, taking into account that the species <i>Beauveria bassiana</i>, irrespective of the strain, is a potential human allergen by both skin and inhalatory exposure, and therefore ensuring that adequate personal protective equipment is included as a condition of use. <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (*).</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>
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(*) https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.