Commission Implementing Regulation (EU) 2019/139 of 29 January 2019 approving the active substance Beauveria bassiana strain IMI389521, 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/139

of 29 January 2019

approving the active substance *Beauveria bassiana* strain IMI389521, 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) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 the Netherlands received on 28 October 2014 an application from Exosect Limited for the approval of the active substance *Beauveria bassiana* strain IMI389521.

(2) In accordance with Article 9(3) of Regulation (EC) No 1107/2009, the Netherlands, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 2 June 2015 of the admissibility of the application.

(3) On 22 February 2016 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 2 February 2017.

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/139. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

(5) On 26 April 2017 the Authority communicated to the applicant, the Member States and the Commission its conclusion[2] on whether the active substance *Beauveria bassiana* strain IMI389521 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.

(6) On 24 October 2018 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the draft review report for *Beauveria bassiana* strain IMI389521 and a draft Regulation providing that *Beauveria bassiana* strain IMI389521 is approved.

(7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(8) It is therefore appropriate to approve *Beauveria bassiana* strain IMI389521.

(9) In accordance with Article 13(2) 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 include certain conditions. In particular, it is appropriate to include risk mitigation measures where appropriate.

(10) 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.

(11) 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 active substance

The active substance *Beauveria bassiana* strain IMI389521, 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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/139. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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*.

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

Done at Brussels, 29 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/139. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Beauveria bassiana strain IMI389521 Accession number in the CABI Genetic Resource Collection: IMI389521	Not applicable	Max. level of beauvericin: 0,09 mg/kg	19 February 2019	19 February 2029	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 *Beauveria bassiana* strain IMI389521, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the storage stability of the formulation(s) containing *B. bassiana* strain IMI389521 including the

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

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

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/139. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

					level of the metabolite beauvericin content after storage, — the content of the metabolite beauvericin produced under the application conditions, — the risk posed by beauvericin in infected insects present in the stored grain. Measures are required to ensure that such products do not enter the food and feed chain, taking

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

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