# Commission Implementing Regulation (EU) 2017/843 of 17 May 2017 approving the active substance Beauveria bassiana strain NPP111B005, 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) 2017/843

## of 17 May 2017

## approving the active substance *Beauveria bassiana* strain NPP111B005, 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 France received on 6 November 2012 an application from Arysta Lifescience S.A.S. for the approval of the active substance *Beauveria bassiana* strain NPP111B005. In accordance with Article 9(3) of that Regulation, France, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority (hereinafter 'the Authority') on 5 February 2013 of the admissibility of the application.

(2) On 7 October 2014 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.

(3) 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 3 July 2015.

(4) On 6 October 2015 the Authority communicated to the applicant, the Member States and the Commission its conclusion[(2)] on whether the active substance *Beauveria bassiana*

**Changes to legislation:** *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/843. 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*

strain NPP111B005 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.

(5) On 8 March 2016 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for *Beauveria bassiana* strain NPP111B005 and a draft Regulation providing that *Beauveria bassiana* strain NPP111B005 is approved.

(6) The applicant was given the possibility to submit comments on the review report.

(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. It is therefore appropriate to approve *Beauveria bassiana* strain NPP111B005.

(8) 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 and restrictions.

(9) 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.

(10) 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 NPP111B005, 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*.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/843. 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*

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

Done at Brussels, 17 May 2017.

*For the Commission*

*The President*

Jean-Claude JUNCKER

**Changes to legislation:** *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/843. 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 NPP111B005 Accession number in the CNCM (Collection Nationale de Culture de Microorganismes) — Institut Pasteur, Paris, France: I-2961. | Not applicable | Max. level of beauvericin 24 µg/L | 7 June 2017 | 7 June 2027 | 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 NPP111B005, 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 protection of operators and workers, taking into account that *Beauveria bassiana* strain NPP111B005 is to |

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

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/843. 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*

| | | | | | |
|---|---|---|---|---|---|
| | | | | | be considered, as any micro-organism, as a potential sensitizer, and paying special attention to exposure through inhalation,<br>— the maximum level of the metabolite beauvericin in the formulated product.<br>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.<br>Conditions of use shall include risk mitigation measures, where appropriate. |

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