

COMMISSION IMPLEMENTING REGULATION (EU) 2021/134**of 4 February 2021****renewing the approval of the low-risk active substance *Akanthomyces muscarius* strain Ve6 (formerly *Lecanicillium muscarium* strain Ve6) 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) in conjunction with Article 22(1) thereof,

Whereas:

- (1) The concerned active substance is a fungus that was first named *Verticillium lecanii*. Subsequently, for scientific reasons, that name was changed into *Lecanicillium muscarium* strain Ve6. More recently, it was changed again into its current name *Akanthomyces muscarius* strain Ve6.
- (2) Commission Directive 2008/113/EC ⁽²⁾ included *Lecanicillium muscarium* (formerly *Verticillium lecanii*) Strain: Ve6 as active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (3) 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⁾.
- (4) The approval of the active substance *Akanthomyces muscarius* strain Ve6 (formerly *Lecanicillium muscarium* strain Ve6), as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2021.
- (5) An application for the renewal of the approval of the active substance *Akanthomyces muscarius* strain Ve6 was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ within the time period provided for in that Article.
- (6) The applicant 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.
- (7) 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 30 January 2018.

⁽¹⁾ 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 (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) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (9) On 27 April 2020, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether *Akanthomyces muscarius* strain Ve6 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented to the Standing Committee on Plants, Animals, Food and Feed the renewal report regarding *Akanthomyces muscarius* strain Ve6 on 22 October 2020 and the draft Regulation regarding that substance on 4 December 2020.
- (10) The Commission invited the applicant to submit its 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 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 *Akanthomyces muscarius* strain Ve6 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of *Akanthomyces muscarius* strain Ve6.
- (12) The risk assessment for the renewal of the approval of the active substance *Akanthomyces muscarius* strain Ve6 is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing *Akanthomyces muscarius* strain Ve6 may be authorised. It is therefore appropriate not to maintain the restriction to use that substance as an insecticide only.
- (13) The Commission further considers that *Akanthomyces muscarius* strain Ve6 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Akanthomyces muscarius* strain Ve6 is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Taking into account the assessment by the Rapporteur Member State and the Authority, and the intended uses, *Akanthomyces muscarius* strain Ve6 is a microorganism which is expected to have a low risk for humans, animals and the environment. No critical areas of concern were identified, and *Akanthomyces muscarius* is not known to be related to any human or animal pathogen. *Akanthomyces muscarius* strain Ve6 has been used in plant protection for over a decade without leading to any adverse effect on humans and based on the intended use (which is high technology (permanent) greenhouses and walk-in tunnels) the potential exposure for humans, non-target organisms and the environment is considered negligible. For these reasons, only general mitigation measures should be taken for operators and workers.
- (14) It is therefore appropriate to renew the approval of *Akanthomyces muscarius* strain Ve6 as a low-risk substance. In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) The approval period of *Akanthomyces muscarius* strain Ve6 (formerly *Lecanicillium muscarium* strain Ve6) was last extended to 30 April 2021 by Commission Implementing Regulation (EU) 2020/421 ⁽⁷⁾ in order to allow the renewal process to be completed before the expiry of that period. However, given that a decision on renewal is being taken ahead of the expiry of that extended approval period, this Regulation should start to apply earlier than that date.

⁽⁶⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance *Akanthomyces muscarius* strain Ve6, formerly *Lecanicillium muscarium* strain Ve6. *EFSA Journal* 2020;18(6):6121. doi: 10.2903/j.efsa.2020.6121. Available online: www.efsa.europa.eu

⁽⁷⁾ Commission Implementing Regulation (EU) 2020/421 of 18 March 2020 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, clopyralid, *Cydia pomonella* Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, *Lecanicillium muscarium* (formerly '*Verticillium lecanii*') strain Ve6, mepanipyrim, *Metarhizium anisopliae* (var. *anisopliae*) strain BIPESCO 5/F52, metconazole, metrafenone, *Phlebiopsis gigantea* strains FOC PG 410.3, VRA 1835 and VRA 1984, pirimicarb, *Pseudomonas chlororaphis* strain MA342, pyrimethanil, *Pythium oligandrum* M1, rimsulfuron, spinosad, *Streptomyces* K61 (formerly '*S. griseoviridis*'), *Trichoderma asperellum* (formerly '*T. harzianum*') strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly '*T. harzianum*') strains IMI 206040 and T11, *Trichoderma gamsii* (formerly '*T. viride*') strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 84, 20.3.2020, p. 7).

- (16) 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

Renewal of the approval of the active substance

The approval of the active substance *Akanthomyces muscarius* strain Ve6 (formerly *Lecanicillium muscarium* strain Ve6), 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 March 2021.

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

Done at Brussels, 4 February 2021.

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
<i>Akanthomyces muscarius</i> strain Ve6 (formerly <i>Lecanicillium muscarium</i> strain Ve6) ⁽²⁾	Not applicable	No relevant impurities	1 March 2021	29 February 2036	<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>Akanthomyces muscarius</i> strain Ve6 (formerly <i>Lecanicillium muscarium</i> strain Ve6) and in particular Appendices I and II thereto, shall be taken into account.</p> <p>Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, and shall ensure that adequate personal protective equipment is included as a condition of use.</p> <p>Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination ⁽³⁾.</p>

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

⁽²⁾ The concerned active substance was initially approved as *Verticillium lecanii*, but later, for scientific reasons, its name was changed to *Lecanicillium muscarium* strain Ve6, which was later changed again to the name under which the approval was renewed, *Akanthomyces muscarius* strain Ve6.

⁽³⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf

ANNEX II

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, the entry 199 on *Lecanicillium muscarium* (formerly *Verticillium lecanii*) STRAIN: Ve 6 is deleted;
- (2) in Part D, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'25	<i>Akanthomyces muscarius</i> strain Ve6 (formerly <i>Lecanicillium muscarium</i> strain Ve6) ⁽²⁾	Not applicable	No relevant impurities	1 March 2021	29 February 2036	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>Akanthomyces muscarius</i> strain Ve6 (formerly <i>Lecanicillium muscarium</i> strain Ve6) and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, and shall ensure that adequate personal protective equipment is included as a condition of use. Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination ⁽³⁾ .

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

⁽²⁾ The concerned active substance was initially approved as *Verticillium lecanii*, but later, for scientific reasons, its name was changed to *Lecanicillium muscarium* strain Ve6, which was later changed again to the name under which the approval was renewed, *Akanthomyces muscarius* strain Ve6.

⁽³⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app_proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf