COMMISSION IMPLEMENTING REGULATION (EU) 2021/134
of 4 February 2021


(Text with EEA relevance)
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.

On 27 April 2020, the Authority communicated to the Commission its conclusion (*) 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.

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.

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.

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.

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.

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.

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 (†) 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.


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

<table>
<thead>
<tr>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity (¹)</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
<th>Specific provisions</th>
</tr>
</thead>
</table>
| **Akanthomyces muscarius strain Ve6 (formerly Lecanicillium muscarium strain Ve6)** (¹) | 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 Akanthomyces muscarius strain Ve6 (formerly Lecanicillium muscarium 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 (²).

(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.

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:

<table>
<thead>
<tr>
<th>No</th>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity (')</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
<th>Specific provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>'25</td>
<td>Akanthomyces muscarius strain Ve6 (formerly <em>Lecanicillium muscarium</em> strain Ve6) (')</td>
<td>Not applicable</td>
<td>No relevant impurities</td>
<td>1 March 2021</td>
<td>29 February 2036</td>
<td>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 Akanthomyces muscarius strain Ve6 (formerly <em>Lecanicillium muscarium</em> 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 sensitisers, 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 (').</td>
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(') Further details on the identity and the specification of the active substance are provided in the renewal report.

(') 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.