

COMMISSION IMPLEMENTING REGULATION (EU) 2021/853**of 27 May 2021****renewing the approval of the active substance *Streptomyces* strain K61 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) thereof,

Whereas:

- (1) Commission Directive 2008/113/EC ⁽²⁾ included *Streptomyces* K61 (formerly '*S. griseoviridis*') as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) The concerned active substance is a bacterium, that was first named '*Streptomyces griseoviridis*'. Subsequently, for scientific reasons, that name was changed into *Streptomyces* K61. More recently, it was changed again into its current name *Streptomyces* strain K61.
- (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 *Streptomyces* strain K61, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2022.
- (5) An application for the renewal of the approval of the active substance *Streptomyces* strain K61 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 15 January 2019.
- (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.

⁽¹⁾ 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 microorganisms 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).

- (9) On 19 June 2020, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether *Streptomyces* strain K61 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented a renewal report on the 3 December 2020 and a draft Regulation regarding *Streptomyces* strain K61 to the Standing Committee on Plants, Animals, Food and Feed on 25 January 2021.
- (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 *Streptomyces* strain K61 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 *Streptomyces* strain K61.
- (12) The risk assessment for the renewal of the approval of the active substance *Streptomyces* strain K61 is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing *Streptomyces* strain K61 may be authorised. It is therefore appropriate not to maintain the restriction to use as a fungicide only.
- (13) 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.
- (14) Commission Implementing Regulation (EU) 2021/566 ⁽⁷⁾ extended the approval period of *Streptomyces* strain K61 to 30 April 2022 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.
- (15) 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 *Streptomyces* strain K61, 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.

⁽⁶⁾ EFSA Journal 2020;18(7):6182, 14 pp. doi:10.2903/j.efsa.2020.6182. Available online: www.efsa.europa.eu.

⁽⁷⁾ Commission Implementing Regulation (EU) 2021/566 of 30 March 2021 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, mepanipyrim, *Metarhizium anisopliae* (var. *anisopliae*) strain BIPESCO 5/F52, metconazole, metrafenone, 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*') strain T11, *Trichoderma gamsii* (formerly '*T. viride*') strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 118, 7.4.2021, p. 1).

*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 July 2021.

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

Done at Brussels, 27 May 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>Streptomyces</i> strain K61	Not applicable	No relevant impurities	1 July 2021	30 June 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>Streptomyces</i> strain K61 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 considered as potential sensitisers, 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 ⁽²⁾.</p>

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

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

- (1) in Part A, entry 203 on *Streptomyces* K61 (formerly *S. griseoviridis*) is deleted;
- (2) in Part B, the following entry is added:

‘145	<i>Streptomyces</i> strain K61	Not applicable	No relevant impurities	1 July 2021	30 June 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>Streptomyces</i> strain K61 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 considered as potential sensitisers, 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 (*).</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.