Commission Implementing Regulation (EU) 2019/151 of 30 January 2019 renewing the approval of the active substance Clonostachys rosea strain J1446 as a low-risk active substance 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) 2019/151

of 30 January 2019

renewing the approval of the active substance *Clonostachys rosea* strain J1446 as a low-risk active substance 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 22(1) in conjunction with Article 20(1) thereof,

Whereas:

(1) Commission Directive 2005/2/EC[(2)] included *Clonostachys rosea* strain J1446, under the old taxonomic name *Gliocladium catenulatum* strain J1446, as an active substance in Annex I to Council Directive 91/414/EEC[(3)].

(2) 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)].

(3) The approval of the active substance *Clonostachys rosea* strain J1446, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2019.

(4) An application for the renewal of the approval of *Clonostachys rosea* strain J1446 was submitted by Verdera Oy ('the applicant') in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[(5)] within the time period provided for in that Article.

(5) 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.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/151. 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*

(6) The rapporteur Member State prepared a 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 6 July 2016.

(7) The Authority communicated the 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.

(8) On 21 June 2017 the Authority communicated to the Commission its conclusion[(6)] on whether *Clonostachys rosea* strain J1446 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for *Clonostachys rosea* strain J1446 to the Standing Committee on Plants, Animals, Food and Feed on 11 December 2017.

(9) The applicant was given the possibility to submit comments on the renewal report.

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing *Clonostachys rosea* strain J1446 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 *Clonostachys rosea* strain J1446.

(11) The risk assessment for the renewal of the approval of *Clonostachys rosea* strain J1446 is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing *Clonostachys rosea* strain J1446 may be authorised. It is therefore appropriate not to maintain the restriction to use only as a fungicide.

(12) The Commission further considers that *Clonostachys rosea* strain J1446 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Clonostachys rosea* strain J1446 is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009.

(13) It is therefore appropriate to renew the approval of *Clonostachys rosea* strain J1446 as a low-risk substance.

(14) In accordance with Article 14(1) 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.

(15) 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 be amended accordingly.

(16) Commission Implementing Regulation (EU) 2018/917[(7)] extended the approval period of *Clonostachys rosea* strain J1446 to 31 July 2019 in order to allow the renewal process to be completed before the expiry date of the approval of that substance. However, given that a decision on renewal has been taken ahead of this extended expiry date, this Regulation shall apply from 1 April 2019.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of active substance

The approval of the active substance *Clonostachys rosea* strain J1446, 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 April 2019.

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

Done at Brussels, 30 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Clonostachys rosea strain J1446 Accession number in the culture collection of the German Collection of Microorganisms and Cell Cultures (DSMZ): DSM 9212	Not applicable	Not applicable Gliotoxin content: max. 50 µg/kg in the technical grade of the MCPA.	1 April 2019	31 March 2034	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 *Clonostachys rosea* strain J1446, 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 specification of technical material as commercially manufactured in plant protection products, including full characterisation

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

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					of potential metabolites of concern; — the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use; — the studies or information from the scientific literature recently made available in relation to antifungal susceptibility

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