Commission Implementing Regulation (EU) 2020/1003 of 9 July 2020 renewing the approval of the active substances Phlebiopsis gigantea strains VRA 1835, VRA 1984 and FOC PG 410.3 as low-risk substances 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) 2020/1003

of 9 July 2020

renewing the approval of the active substances *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 as low-risk substances 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 *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 as active substances 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 substances *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 30 April 2021.

(4) An application for the renewal of the approval of the active substances *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 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.

(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) 2020/1003. 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 28 September 2018.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

(8) On 18 September 2019, the Authority communicated to the Commission its conclusion[6] on whether *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented an initial renewal report and the draft Regulation regarding *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 to the Standing Committee on Plants, Animals, Food and Feed in March 2020.

(9) 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.

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substances *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 or FOC PG 410.3 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(11) The risk assessment for the renewal of the approval of the active substances *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 or FOC PG 410.3 may be authorised. It is therefore appropriate not to maintain the restriction to use as a fungicide only.

(12) The Commission further considers that *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 are low-risk active substances pursuant to Article 22 of Regulation (EC) No 1107/2009. *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 are not substances of concern and fulfil the conditions set in Annex II point 5 to Regulation (EC) No 1107/2009. Following the assessment by the Rapporteur Member State and the Authority, and taking into account the intended uses, *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 are microorganisms for which it is expected a low-risk for humans, animals and the environment. No critical areas of concern were identified, and *Phlebiopsis gigantea* is not known to be related to any human or animal pathogen. *Phlebiopsis gigantea* has been used as a biocontrol agent for over a decade without leading to any adverse effect on humans since the previous peer review, and based on the intended use (i.e. direct application onto stump surface of coniferous trees) the potential exposure for humans and effects on the naturally occurring soil-concentration are considered negligible. For these reasons only

general mitigation measures are foreseen for workers, and overall the approval criteria and qualification as low-risk are met for these active substances.

(13) It is therefore appropriate to renew the approval of *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 as low-risk substances.

(14) 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) Commission Implementing Regulation (EU) 2020/421[7] extended the approval period of *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3 to 30 April 2021 in order to allow the renewal process to be completed before the expiry of the approval period of those active substances. Given that a decision on renewal is being taken ahead of the expiry of that extended approval period, this Regulation should apply from 1 September 2020.

(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 substances *Phlebiopsis gigantea* strains VRA 1835, VRA 1984 and FOC PG 410.3, 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 September 2020.

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

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2020/1003. 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*

Done at Brussels, 9 July 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2020/1003. 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**
Phlebiopsis gigantea strain VRA 1835	Not applicable	No relevant impurities	1 September 2020	31 August 2035	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 *Phlebiopsis gigantea* strain VRA 1835, 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. Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down

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

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