COMMISSION IMPLEMENTING REGULATION (EU) 2019/1675

of 4 October 2019

renewing the approval of the active substance *Verticillium albo-atrum* strain WCS850 as a low-risk 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 20(1) in conjunction with Article 22(1) thereof,

Whereas:

(1) Commission Directive 2008/113/EC ([2]) included *Verticillium albo-atrum* (formerly *Verticillium dahlia*) strain WCS850 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 *Verticillium albo-atrum* strain WCS850, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 30 April 2020.

(4) An application for the renewal of the approval of *Verticillium albo-atrum* strain WCS850 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.

(6) 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 1 November 2017.

([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 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).

(7) 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.

(8) On 19 December 2018, the Authority communicated to the Commission its conclusion ([6]) on whether *Verticillium albo-atrum* strain WCS850 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented an initial draft renewal report for *Verticillium albo-atrum* strain WCS850 to the Standing Committee on Plants, Animals, Food and Feed on 22 March 2019.

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

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing *Verticillium albo-atrum* strain WCS850 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 *Verticillium albo-atrum* strain WCS850 is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing *Verticillium albo-atrum* strain WCS850 may be authorised. It is therefore appropriate not to maintain the restriction to use as a fungicide.

(12) The Commission considers that *Verticillium albo-atrum* strain WCS850 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Verticillium albo-atrum* strain WCS850 is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. *Verticillium albo-atrum* strain WCS850 is a micro-organism. Following the assessment by the rapporteur Member State and the Authority and taking into account the intended uses it is expected to pose a low-risk for humans, animals and the environment. In particular, the potential transfer or acquisition of resistance to antimicrobials in fungi such as *Verticillium albo-atrum* strain WCS850 is multifactorial and is not coded by a single gene, thus horizontal transfer of anti-microbial resistance genes between fungal species appears to be very rare and is not associated with specific mechanisms, as described for bacteria. Therefore, the Commission considers that multiple resistance to anti-microbials used in human and veterinary medicine is not demonstrated.

(13) It is therefore appropriate to renew the approval of *Verticillium albo-atrum* WCS850 as a low-risk active 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 provide for certain conditions.

(15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(16) Commission Implementing Regulation (EU) 2019/168 ([7]) extended the expiry date of *Verticillium albo-atrum* strain WCS850 to 30 April 2020 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should start to apply earlier than that date.

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

([6]) EFSA Journal 2019;17(1):5575. Available online: www.efsa.europa.eu

([7]) Commission Implementing Regulation (EU) 2019/168 of 31 January 2019 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, Bacillus thuringiensis subsp. israeliensis, Bacillus thuringiensis subsp. kurstaki, Beauveria bassiana, benfluralin, clodinafop, clopyralid, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, epoxiconazole, fenpyroximate, fluazinam, flutolanil, fosetyl, Lecanicillium muscarium, mepanipyrim, mepiquat, Metarhizium anisopliae var. Anisopliae, metconazole, metrafenone, Phlebiopsis gigantea, pirimicarb, Pseudomonas chlororaphis strain: MA 342, pyrimethanil, Pythium oligandrum, rimsulfuron, spinosad, Streptomyces K61, thiacloprid, tolclofos-methyl, Trichoderma asperellum, Trichoderma atroviride, Trichoderma gamsii, Trichoderma harzianum, triclopyr, trinexapac, triticonazole, Verticillium albo-atrum and ziram (OJ L 33, 5.2.2019, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance *Verticillium albo-atrum* strain WCS850 is renewed as set out in Annex I.

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 November 2019.

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

Done at Brussels, 4 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Verticillium albo-atrum strain WCS850 (culture collection No CBS 276.92)	Not applicable	Minimum concentration: $0,7 \times 10^7$ CFU/ml distilled water Maximum concentration: $1,5 \times 10^7$ CFU/ml distilled water No relevant impurities.	1 November 2019	31 October 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 *Verticillium albo-atrum* strain WCS850, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that *Verticillium albo-atrum* strain WCS850 is to be considered as a potential sensitiser. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products, contained in the Commission Working Document SANCO/12116/2012 (2)

(1) Further details on the identity and the specification of the active substance are provided in the renewal report (EU Pesticide database.
(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 Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 209 on *Verticillium albo-atrum* 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
'18	*Verticillium albo-atrum* strain WCS850 (culture collection No CBS 276.92)	Not applicable	Minimum concentration: $0,7 \times 10^7$ CFU/ml distilled water Maximum concentration: $1,5 \times 10^7$ CFU/ml distilled water No relevant impurity	1 November 2019	31 October 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 *Verticillium albo-atrum* strain WCS850, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that *Verticillium albo-atrum* strain WCS850 is to be considered as a potential sensitiser. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products, contained in the Commission Working Document SANCO/12116/2012 (2).'

(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

COMMISSION REGULATION (EU) 2019/1676

of 7 October 2019

correcting certain language versions of Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ([1]), and in particular Article 10(3) thereof,

Whereas:

(1) The Czech language version of Regulation (EC) No 1333/2008 contains errors in Annex II, Part A, Table 2 and in Annex II, Part E, food categories 02.1, 02.2.2, 04.2.5.1, 04.2.5.2, 04.2.5.3, 08.2, 08.3.1, 08.3.2, 08.3.3, 14.1.4, 15.1 and 15.2. Therefore, in the Czech language version, the conditions of use (restrictions/exceptions) of food additives in those provisions should be corrected in order to ensure legal clarity for food business operators and the smooth functioning of the internal market.

(2) The Latvian language version of Regulation (EC) No 1333/2008 contains an error in Annex II, Part E, food category 04.1.2. Therefore, in the Latvian language version, the conditions of use (restrictions/exceptions) of food additives in that provision should be corrected in order to ensure legal clarity for food business operators and the smooth functioning of the internal market.

(3) The Slovak language version of Regulation (EC) No 1333/2008 contains an error in Annex II, Part E, food category 07.1. Therefore, in the Slovak language version, the conditions of use (restrictions/exceptions) of food additives in that provision should be corrected in order to ensure legal clarity for food business operators and the smooth functioning of the internal market.

(4) The Czech, Latvian and Slovak language versions of Annex II to Regulation (EC) No 1333/2008 should therefore be corrected accordingly. The other language versions are not affected.

(5) 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

(does not concern the English language)

([1]) OJ L 354, 31.12.2008, p. 16.