COMMISSION IMPLEMENTING REGULATION (EU) 2018/1075

of 27 July 2018

renewing the approval of the active substance *Ampelomyces quisqualis* strain AQ10, 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 *Ampelomyces quisqualis* strain AQ10 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 *Ampelomyces quisqualis* strain AQ10, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2018.

(4) An application for the renewal of the approval of *Ampelomyces quisqualis* strain AQ10 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 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 the 25 November 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 the 20 November 2017 the Authority communicated to the Commission its conclusion ([6]) on whether *Ampelomyces quisqualis* strain AQ10 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 *Ampelomyces quisqualis* strain AQ10 to the Standing Committee on Plants, Animals, Food and Feed on 23 March 2018.

(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 *Ampelomyces quisqualis* strain AQ10 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2005/2/EC of 19 January 2005 amending Council Directive 91/414/EEC to include Ampelomyces quisqualis and Gliocladium catenulatum as active substances. (OJ L 20, 22.1.2005, p. 15).

([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).

([6]) EFSA Journal 2017;15(11):5078, 24 pp. doi:10.2903/j.efsa.2017.5078 Available online: www.efsa.europa.eu.

(11) The risk assessment for the renewal of the approval of *Ampelomyces quisqualis* strain AQ10 is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing *Ampelomyces quisqualis* strain AQ10 may be authorised. It is therefore appropriate not to maintain the restriction for use only as a fungicide.

(12) The Commission further considers that *Ampelomyces quisqualis* strain AQ10 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Ampelomyces quisqualis* strain AQ10 fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. *Ampelomyces quisqualis* strain AQ10 is a strain of a micro-organism which, taking into account the intended uses, is expected to pose a low risk to humans, animals and the environment. Furthermore, *Ampelomyces quisqualis* strain AQ10 is a strain of a micro-organism (fungus) which is not pathogenic to humans, nor related to any known human, animal or plant pathogen, and for which no multiple resistance to antimicrobials used in human or veterinary medicine is known.

(13) It is therefore appropriate to renew the approval of *Ampelomyces quisqualis* strain AQ10 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) No 841/2017 ([1]) extended the expiry date of the approval of *Ampelomyces quisqualis* strain AQ10 to 31 July 2018 in order to allow the renewal process to be completed before the expiry of the approval of that substance. Taking into account that the approval of the active substance expires on 31 July 2018, this Regulation should apply from 1 August 2018.

(17) 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 active substance

The approval of the active substance *Ampelomyces quisqualis* strain AQ10, as set out 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 day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 August 2018.

([1]) Commission Implementing Regulation (EU) 2017/841 of 17 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, Ampelomyces quisqualis strain: aq 10, benalaxyl, bentazone, bifenazate, bromoxynil, carfentrazone ethyl, chlorpropham, cyazofamid, desmedipham, diquat, DPX KE 459 (flupyrsulfuron-methyl), etoxazole, famoxadone, fenamidone, flumioxazine, foramsulfuron, Gliocladium catenulatum strain: j1446, imazamox, imazosulfuron, isoxaflutole, laminarin, metalaxyl-m, methoxyfenozide, milbemectin, oxasulfuron, pendimethalin, phenmedipham, pymetrozine, s-metolachlor, and trifloxystrobin (OJ L 125, 18.5.2017, p. 12).

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

Done at Brussels, 27 July 2018.

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
Ampelomyces quisqualis strain AQ10	Not applicable	Minimum content of viable spores: $3{,}0 \times 10^{12}$ CFU/kg	1 August 2018	1 August 2033	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 *Ampelomyces quisqualis* strain AQ10, 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 protection of operators and workers, taking into account that microorganisms are *per se* considered as potential sensitizers and ensuring that adequate personal protective equipment is included as a condition of use. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. Conditions of use shall include risk mitigation measures, where appropriate.

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

ANNEX II

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

(1) in Part A, the entry on *Ampelomyces quisqualis* strain AQ10 is deleted;

(2) in Part D, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'14	*Ampelomyces quisqualis* strain AQ10	Not applicable	Minimum content of viable spores: $3{,}0 \times 10^{12}$ CFU/kg	1 August 2018	1 August 2033	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 *Ampelomyces quisqualis* strain AQ10, 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 protection of operators and workers, taking into account that microorganisms are *per se* considered as potential sensitizers and ensuring that adequate personal protective equipment is included as a condition of use. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. Conditions of use shall include risk mitigation measures, where appropriate.'

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