Commission Implementing Regulation (EU) 2018/1060 of 26 July 2018 renewing the approval of the active substance trifloxystrobin 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) 2018/1060

of 26 July 2018

renewing the approval of the active substance trifloxystrobin 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 2003/68/EC[(2)] included trifloxystrobin 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 trifloxystrobin, 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 trifloxystrobin 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 29 September 2016.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1060. 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*

(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 19 September 2017 the Authority communicated to the Commission its conclusion[6] on whether trifloxystrobin 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 trifloxystrobin to the Standing Committee on Plants, Animals, Food and Feed on 23 March 2018.

(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 the active substance that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(11) It is therefore appropriate to renew the approval of trifloxystrobin.

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

(13) 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 and restrictions. It is, in particular, appropriate to require further confirmatory information.

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

(15) Taking into account that the current approval of trifloxystrobin expires on 31 July 2018, this Regulation should enter into force as soon as possible.

(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 active substance

The approval of the active substance trifloxystrobin 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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1060. 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*

Article 3

Entry into force and date of application

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 August 2018.

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

Done at Brussels, 26 July 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1060. 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**
Trifloxystrobin CAS No 141517-21-7 CIPAC No 617	methyl (E)-methoxyimino-{(E)-α-[1-(α,α,α-trifluoro-m-tolyl)ethylideneaminooxyl]-o-tolyl}acetate	≥ 975 g/kg AE 1344136 (max. 4 g/kg)	1 August 2018	31 July 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 trifloxystrobin, 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 groundwater when the substance is applied in regions with vulnerable soil and/

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

b Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

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					or climate conditions; — the protection of aquatic organisms, bees, and of fish-eating birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the relevance of metabolites that may occur in groundwater, taking into account any relevant classification for

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

b Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).