Commission Implementing Regulation (EU) 2019/1085 of 25 June 2019 renewing the approval of the active substance 1-methylcyclopropene, 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, and amending the Annex to Commission Implementing Regulation (EU) 2015/408 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1085

of 25 June 2019

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(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 78(2) thereof,

Whereas:

(1) Commission Directive 2006/19/EC[(2)] included 1-methylcyclopropene 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 1-methylcyclopropene, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2019.

(4) An application for the renewal of the approval of 1-methylcyclopropene 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) 2019/1085. 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 April 2017.

(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 28 May 2018, the Authority communicated to the Commission its conclusion[(6)] on whether 1-methylcyclopropene 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 1-methylcyclopropene to the Standing Committee on Plants, Animals, Food and Feed on 12 and 13 December 2018.

(9) As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[(7)], the conclusion of the Authority indicates that it is highly unlikely that 1-methylcyclopropene is an endocrine disrupter via the estrogenic, androgenic, thyroidogenic and steroidogenic modalities. On the basis of the available data and current knowledge[(8)], the Authority concludes that 1-methylcyclopropene is unlikely to have endocrine disrupting properties. Thus, the Commission considers that 1-methylcyclopropene is not to be considered as having endocrine disrupting properties.

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing 1-methylcyclopropene that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(11) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 of that Regulation 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 maintain the restriction of use as plant growth regulator for post harvest storage in sealable warehouses only.

(12) Commission Implementing Regulation (EU) 2015/408[(9)] listed 1-methylcyclopropene as a candidate for substitution based on its Acceptable Daily Intake being significantly lower than that of the majority of the approved active substances within its respective group of substances or use categories.

(13) Based on the new toxicological data provided in the dossier for the renewal process, the Authority concluded on a significant increase of the Acceptable Daily Intake. As a consequence, the Commission considers that 1-methylcyclopropene does not fulfil the criteria listed in point 4 of Annex II to Regulation (EC) No 1107/2009 and therefore, 1-methylcyclopropene no longer fulfils the criteria to be considered a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Accordingly, 1-methylcyclopropene should be deleted from the Annex to Implementing Regulation (EU) 2015/408.

(14) It is therefore appropriate to renew the approval of 1-methylcyclopropene.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1085. 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*

(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) 2018/1262[(10)] extended the expiry date of 1-methylcyclopropene to 31 October 2019 in order to allow the renewal process to be completed before the expiry of the approval of that substance. Given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply from 1 August 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,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of active substance

The approval of the active substance 1-methylcyclopropene, 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

Amendment to Implementing Regulation (EU) 2015/408

The entry for 1-methylcyclopropene is deleted from the Annex to Implementing Regulation (EU) 2015/408.

Article 4

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 August 2019.

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) 2019/1085. 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, 25 June 2019.

For the Commission

The President

Jean-Claude JUNCKER