



2025/881

8.5.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/881

of 7 May 2025

amending Implementing Regulations (EU) 2019/1085 and (EU) No 540/2011 as regards the conditions of approval of the active substance 1-methylcyclopropene

(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 13(2)(c) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2019/1085 ⁽²⁾ renewed the approval of the active substance 1-methylcyclopropene.
- (2) Following that renewal, the approval of the active substance 1-methylcyclopropene, as set out in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾, includes a restriction to uses as plant growth regulator in post-harvest storage in sealable warehouses only.
- (3) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, on 4 March 2019, AgroFresh Holding France SAS submitted an application to the designated rapporteur Member State, the Netherlands, seeking an amendment to the conditions of approval of 1-methylcyclopropene in order to remove the restriction to uses as plant growth regulator in post-harvest storage in sealable warehouses only and to allow pre-harvest in field uses via orchard spray fed by direct injection system. The application was found to be admissible by the rapporteur Member State.
- (4) The rapporteur Member State assessed the proposed new uses of the active substance 1-methylcyclopropene in relation to the potential effects on human and animal health and the environment in accordance with Article 4 of Regulation (EC) No 1107/2009 and prepared a revised renewal assessment report which was submitted to the European Food Safety Authority ('the Authority') and the Commission on 12 October 2021.
- (5) In accordance with Article 12(1) of Regulation (EC) No 1107/2009, the Authority circulated the revised renewal assessment report to the applicant and to the Member States for comments and made it available to the public. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, additional information was requested from the applicant. The rapporteur Member State evaluated the additional information and submitted the revised renewal assessment report to the Commission and to the Authority in October 2023.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

⁽²⁾ 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. (OJ L 171, 26.6.2019, p. 110, ELI: http://data.europa.eu/eli/reg_impl/2019/1085/oj).

⁽³⁾ 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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

- (6) On 19 July 2024, the Authority communicated to the Commission its conclusion ⁽⁴⁾ on whether the proposed new uses of the active substance 1-methylcyclopropene can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (7) The Commission presented to the Standing Committee on Plants, Animals, Food and Feed an addendum to the renewal report for 1-methylcyclopropene on 4 December 2024 and a draft of this Regulation on 12 March 2025, respectively.
- (8) The Commission invited the applicant to submit comments on the addendum to the renewal report. The applicant submitted comments, which have been carefully examined.
- (9) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance 1-methylcyclopropene that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied for the new uses. It is therefore appropriate to remove the restriction and to allow pre-harvest in field uses.
- (10) In addition, to increase the confidence in the decision, the applicant should submit to the Commission, the Member States and the Authority confirmatory information as regards the presence of methallyl alcohol in soil and aquatic compartments and, if it is formed in relevant amounts, information on its toxicological properties and potential risk to aquatic and soil organisms. Moreover, the applicant should submit information as regards the effect of water treatment processes on the nature of residues present in drinking water. That confirmatory information should be submitted within 2 years from the date of entry into force of this Regulation.
- (11) Implementing Regulations (EU) 2019/1085 and (EU) No 540/2011 should therefore be amended accordingly.
- (12) 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

Amendment to Implementing Regulation (EU) 2019/1085

Annex I to Implementing Regulation (EU) 2019/1085 is amended in accordance with the Annex to this Regulation.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

⁽⁴⁾ EFSA (European Food Safety Authority), Anastassiadou M, Arena M, Auteri D, Brancato A, Bura L, Carrasco Cabrera L, Chaideftou E, Chiusolo A, Crivellente F, De Lentdecker C, Egsmose M, Fait G, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Magrans O, Mangas I, Miron I, Molnar T, Padovani L, Parra Morte JM, Pedersen R, Reich H, Santos M, Sharp R, Stanek A, Sturma J, Szentes C, Terron A, Tiramani M, Vagenende B and Villamar-Bouza L, 2024. Conclusion on the peer review of the pesticide risk assessment of the active substance 1-methylcyclopropene. *EFSA Journal*. 2024;22:e8977. <https://doi.org/10.2903/j.efsa.2024.8977>.

*Article 3***Entry into force**

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

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

Done at Brussels, 7 May 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The column 'Specific provisions' of Annex I to Implementing Regulation (EU) 2019/1085 is replaced by the following:

'For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1-methylcyclopropene, 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 climatic conditions.

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 the presence of methallyl alcohol in soil and aquatic compartments and, if formed in relevant amounts, information on its toxicological properties and potential risk to aquatic and soil organisms and as regards the effect of water treatment processes on the nature of residues present in drinking water. The confirmatory information shall be submitted by 27 May 2027.'

The column 'Specific provisions' of row 136, 1-methylcyclopropene, in Part B of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

'For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1-methylcyclopropene, 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 climatic conditions.

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 the presence of methallyl alcohol in soil and aquatic compartments and, if formed in relevant amounts, information on its toxicological properties and potential risk to aquatic and soil organisms and as regards the effect of water treatment processes on the nature of residues present in drinking water. The confirmatory information shall be submitted by 27 May 2027.'
