

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/1498****of 15 October 2020****concerning the non-renewal of approval of the active substance thiophanate-methyl, 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 <sup>(1)</sup>, and in particular Articles 20(1) and 78(2) thereof,

Whereas:

- (1) Commission Directive 2005/53/EC <sup>(2)</sup> included thiophanate-methyl as an active substance in Annex I to Directive 91/414/EEC <sup>(3)</sup>.
- (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 <sup>(4)</sup>.
- (3) The approval of the active substance thiophanate-methyl, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2020.
- (4) An application for the renewal of the approval of thiophanate-methyl was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> 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 1 November 2016.
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Commission Directive 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ L 241, 17.9.2005, p. 51).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

<sup>(5)</sup> 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).

- (8) On 17 January 2018, the Authority communicated to the Commission its conclusion <sup>(9)</sup> on whether thiophanate-methyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The conclusion identified a number of concerns and data gaps.
- (9) On 24 October 2018, the Commission presented the draft renewal report for thiophanate-methyl to the Standing Committee on Plants, Animal, Food and Feed, which discussed it during several meetings.
- (10) By letter of 10 July 2020, the applicant informed the Commission of its decision to withdraw the application for the renewal of approval of thiophanate-methyl.
- (11) The approval of thiophanate-methyl therefore should not be renewed.
- (12) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (13) Member States should be given sufficient time to withdraw authorisations for plant protection products containing thiophanate-methyl.
- (14) For plant protection products containing thiophanate-methyl, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 12 months from the date of entry into force of this Regulation.
- (15) This Regulation does not prevent the submission of a further application for the active substance thiophanate-methyl pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (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*

**Non-renewal of approval of active substance**

The approval of the active substance thiophanate-methyl is not renewed.

*Article 2*

**Amendment to Implementing Regulation (EU) No 540/2011**

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 105, on thiophanate-methyl, is deleted.

*Article 3*

**Transitional measures**

Member States shall withdraw authorisations for plant protection products containing thiophanate-methyl as active substance by 19 April 2021 at the latest.

*Article 4*

**Grace period**

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 19 October 2021 at the latest.

<sup>(9)</sup> EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance thiophanate-methyl EFSA Journal 2018;16(1):5133. <https://www.efsa.europa.eu/en/efsajournal/pub/5133>

*Article 5***Entry into force**

This Regulation shall enter into force on the third 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, 15 October 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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