

Brussels, XXX
PLAN/2024/2763 v1
D105274/01
[...] (2025) XXX draft

COMMISSION REGULATION (EU) .../...

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbendazim and thiophanate-methyl in or on certain products

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbendazim and thiophanate-methyl in or on certain products

(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 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC¹, and in particular Article 14(1), point (a), thereof,

Whereas:

- (1) For the active substances carbendazim and thiophanate-methyl, maximum residue levels ('MRLs') were set in Annex II and in Part B of Annex III to Regulation (EC) No 396/2005.
- (2) On 30 November 2014, the approval of the active substance carbendazim expired and no application for its renewal was submitted.
- (3) On 15 October 2020, the approval of the active substance thiophanate-methyl was not renewed by Commission Implementing Regulation (EU) 2020/1498². An application for the renewal of its approval had been submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012³ within the set time period and assessed in accordance with the procedure described by Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁴. However, the applicant decided to withdraw the application.

¹ OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/oj>.

² 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 (OJ L 342, 16.10.2020, p. 5, ELI: http://data.europa.eu/eli/reg_impl/2020/1498/oj).

³ 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, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj).

⁴ 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 (OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>).

- (4) Following the expiry of grace periods granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 for the use of plant protection products containing thiophanate-methyl, the Commission requested the European Food Safety Authority (“the Authority”) to provide a reasoned opinion under Article 43 of Regulation (EC) No 396/2005, assessing the toxicological properties of carbendazim and thiophanate-methyl and the risks that the current MRLs for these substances may pose to consumers, in light of the outcome of the review of all existing MRLs for carbendazim and thiophanate-methyl in accordance with Article 12 of Regulation (EC) No 396/2005⁵,
- (5) In its reasoned opinion⁶, the Authority proposed toxicological reference values for carbendazim and thiophanate-methyl. The toxicological reference values were confirmed by the Authority in two subsequent reasoned opinions^{7,8} and take into account the toxicological properties of the substances, with carbendazim classified according to Regulation (EC) No 1272/2008 as mutagenic, category 1B and toxic for reproduction, category 1B, and thiophanate-methyl meeting the endocrine disrupting criteria for the thyroid (T)-modality. Based on the toxicological reference values, the Authority performed a risk assessment for carbendazim and thiophanate-methyl, and identified unacceptable risks concerning the current MRLs, set based on import tolerances, for carbendazim in oranges, grapefruits, mangoes, and papayas, and for thiophanate-methyl in oranges, grapefruits, mandarins, mangoes, and papayas. These MRLs should therefore be set at the relevant product specific limit of determination (‘LOD’).
- (6) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.
- (7) Annex II to Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States, third countries and food business operators to prepare to meet the new requirements resulting from the amendments.
- (9) 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

In Annex II to Regulation (EC) No 396/2005, the MRLs for carbendazim in grapefruits (product code 0110010), in oranges (product code 0110020), in mangoes (product code 0163030) and in papayas (product code 0163040), and the MRLs for thiophanate-methyl in

⁵ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for thiophanate-methyl and carbendazim according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(12):3919.

⁶ European Food Safety Authority; Reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl. EFSA Journal 2021;19(8):6773.

⁷ European Food Safety Authority; Statement on the assessment of quality of data available to EFSA to derive the health-based guidance values for carbendazim. EFSA Journal. 2024;22:e8756.

⁸ European Food Safety Authority; Updated reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl. EFSA Journal. 2024;22:e8569.

grapefruits (product code 0110010), in oranges (product code 0110020), in mandarins (product code 0110050), in mangoes (product code 0163030) and in papayas (product code 0163040), are set at the level of 0.01* mg/kg.

Article 2

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 ... [*Office of Publications, please insert date 3 months after date of entry into force of this Regulation*].

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN