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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benomyl, carbendazim and thiophanate-methyl in or on certain products

Delegations will find attached document D105274/04.

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[...] (2026) **XXX** draft v6

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

of **XXX**

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

(Text with EEA relevance)

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

of **XXX**

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benomyl, 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), Article 18(1), point (b), and Article 49(2) 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) The approval of the active substance carbendazim expired on 30 November 2014 and no application for its renewal was submitted.
- (3) 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. Nevertheless, based on the assessment of that application, the European Food Safety Authority ('the Authority') published its

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>).

conclusion on the peer review of the pesticide risk assessment of the active substance thiophanate-methyl⁵, which identified a number of critical areas of concern and data gaps. In particular, the Authority concluded that, given the clastogenic potential of thiophanate-methyl, toxicological reference values for consumers and operator risk assessment could not be derived. Based on the dossier available on thiophanate-methyl, the Authority indicated that carbendazim might also have a clastogenic potential.

- (4) In its earlier reasoned opinion on the review of all existing MRLs for carbendazim and thiophanate-methyl in accordance with Article 12 of Regulation (EC) No 396/2005⁶, the Authority noted that the two substances share a common mode of action and have similar metabolic patterns. In view of the concerns about the potential clastogenicity of carbendazim and thiophanate-methyl raised in the conclusions of the peer review, the Commission requested 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. In its reasoned opinion⁷, the Authority concluded that there is evidence indicating that carbendazim and thiophanate-methyl are aneugenic and proposed toxicological reference values for both substances. The toxicological reference values were confirmed by the Authority in two subsequent reasoned opinions^{8,9} and took into account the toxicological properties of the substances.
- (5) Carbendazim is classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹⁰ as mutagenic, category 1B and toxic for reproduction, category 1B¹¹, and the Authority concluded that thiophanate-methyl meets the endocrine disrupting criteria for the thyroid (T)-modality¹².
- (6) In 2021¹³, the Union submitted public health concerns with regards to the active substances carbendazim and thiophanate-methyl to the Codex Committee on Pesticide

⁵ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance thiophanate-methyl. EFSA Journal 2018;16(1):5133.

⁶ 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.

⁷ 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.

⁸ 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.

⁹ 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.

¹⁰ 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. 1–1355, ELI: <http://data.europa.eu/eli/reg/2008/1272/2023-12-01>).

¹¹ <https://chem.echa.europa.eu/100.031.108/harmonised/369298>.

¹² European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance thiophanate-methyl. EFSA Journal 2018;16(1):5133.

¹³ Concern form submitted by the European Union in March 2021 on Benomyl (69), Carbendazim (72) and Thiophanate-methyl (77). CODEX COMMITTEE ON PESTICIDE RESIDUES. 52 Session. Agenda item 6. CX/PR 21/52/5-Add.1. 18-19. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-52%252FWDs-2021%252Fpr52_05_Add1e.pdf.

Residues. Consequently, carbendazim was scheduled for periodic review by the Joint FAO/WHO meeting on pesticides residues (JMPR) in 2023. On 14 November 2025¹⁴, the Codex Alimentarius Commission revoked all Codex maximum residue limits ('CXLs') for the sum of carbendazim, benomyl and thiophanate-methyl (expressed as carbendazim), as insufficient data had been submitted to allow a re-evaluation of the toxicological properties of carbendazim, including the toxicological reference values established in 1995 and 2005. Thus, CXLs no longer exist for carbendazim or for benomyl. For thiophanate-methyl separately, there is only one CXL, for almonds, but the Union expressed a reservation based on the incompatibility of the residue definition of thiophanate-methyl in almonds in the Union with the residue definition set by JMPR, and that CXL was never implemented in the Union¹⁵.

- (7) Carbendazim and thiophanate-methyl are no longer approved for use in the Union and all authorisations for plant protection products containing carbendazim or thiophanate-methyl have been revoked. MRLs based on import tolerances are currently in place for those two substances in citrus fruits, in mangoes, papayas, and in okra/lady's fingers. Those import tolerances had been assessed by the Authority in the framework of the review of all MRLs for carbendazim and thiophanate-methyl in accordance with Article 12 of Regulation (EC) No 396/2005¹⁶.
- (8) However, the Good Agricultural Practices ('GAPs') supporting those import tolerances for carbendazim and thiophanate-methyl on citrus fruits are no longer authorised¹⁷. Under Article 14(2), point (e), of Regulation (EC) No 396/2005, a MRL may be set based on a GAP implemented in a third country for the legal use of an active substance in that country. Since the GAPs previously submitted for setting those MRLs based on import tolerances are no longer authorised, there is no basis to maintain the MRLs based on import tolerances in citrus fruits. The MRLs for carbendazim and thiophanate-methyl in citrus fruits should therefore be lowered to the limit of determination ('LOD').
- (9) Additionally, in its 2024 risk assessment¹⁸, the Authority conducted a combined risk assessment for residues of carbendazim and thiophanate-methyl considering that these substances have similar metabolic patterns, share the same mode of action and may be used on the same crop. In this combined risk assessment, the Authority identified

¹⁴ Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Forty-eighth Session, FAO Headquarters, Rome, Italy, 10-14 November 2025. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-48%252FFINAL%252520REPORT%252FREP25_CACe.pdf.

¹⁵ Report of the 55th Session of the Codex Committee on Pesticide Residues, Chengdu, Sichuan Province, P.R. China, 3-8 June 2024. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/jp/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-55%252FREPORT%252FFINAL%252FREP24_PR55e.pdf.

¹⁶ 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.

¹⁷ South Africa Government Gazette no 49189, 25 August 2023. Fertilizer, farm feeds, agricultural remedies and stock remedies act (Act No. 36 of 1947), Regulations relating to Agricultural remedy https://www.gov.za/sites/default/files/gcis_document/202308/49189gon3812.pdf <https://www.agri-intel.com/>.

¹⁸ 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.

unacceptable risks concerning the current MRLs for carbendazim in grapefruits, oranges, mangoes and papayas, and for thiophanate-methyl in grapefruits, oranges, mandarins, mangoes and papayas. Since it cannot be excluded that both substances may be used on the same crop, the MRLs based on import tolerances for carbendazim in grapefruits, oranges, mangoes and papayas, and for thiophanate-methyl in grapefruits, oranges, mandarins, mangoes and papayas should therefore be lowered to the LOD.

- (10) With regards to okra/lady's fingers, the Authority could not conduct a combined exposure assessment as only a GAP for thiophanate-methyl had been submitted to the Union¹⁹. In this regard, uncertainty remains as to whether both substances may be applied on the same crop in practice, or whether they may be present together in a plant protection product used in a third country. GAPs for both plant protection products containing carbendazim and plant protection products containing thiophanate-methyl on okra/lady's fingers, as well as GAPs for plant protection products containing a mixture of both, are registered in some third countries²⁰. It is not possible to know how these plant protection products are applied in practice in third countries. Therefore, to ensure a high level of consumer protection, the Commission considers it appropriate to also lower the MRLs for both substances on okra/lady's fingers to the LOD.
- (11) In view of the above, all MRLs for carbendazim and thiophanate-methyl should be lowered to the relevant product-specific LODs and listed in Annex V to Regulation (EC) No 396/2005.
- (12) In addition, in its reasoned opinions, the Authority proposed to modify the residue definitions for carbendazim, which currently includes benomyl, and to set separate MRLs for both substances. It also proposed to change the residue definitions for enforcement purposes for carbendazim in all products of animal origin from 'carbendazim and thiophanate-methyl, expressed as carbendazim' to 'sum of carbendazim and 5-hydroxy-carbendazim, expressed as carbendazim' and for thiophanate-methyl in all products of animal origin from 'carbendazim and thiophanate-methyl, expressed as carbendazim' to 'thiophanate-methyl'. The Commission, therefore, considers it appropriate to establish these new residue definitions.
- (13) Benomyl is not approved as an active substance in plant protection products under Regulation (EC) No 1107/2009 and was never assessed in the Union. It is classified as mutagenic and reprotoxic, category B, under Regulation (EC) No 1272/2008²¹.
- (14) For benomyl, no EU toxicological reference values are available and the safety of MRLs for this substance could not be assessed. As uses for benomyl are not authorised in the Union, and as no import tolerances or CXLs exist for this substance, default MRL values should be listed in Annex V to Regulation (EC) No 396/2005, as provided for in Article 18(1), point (b), of that Regulation.
- (15) 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.

¹⁹ 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.

²⁰ <https://homologa.com/>.

²¹ <https://chem.echa.europa.eu/100.037.962/harmonised/293138>.

- (16) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (17) For all active substances covered by this Regulation, in order to allow for normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been placed on the market in the Union before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained. Based on the opinion of the Authority²², this applies to all products except for carbendazim in grapefruits, oranges, papayas and mangoes, and for thiophanate-methyl in grapefruits, oranges, mandarins, papayas and mangoes.
- (18) 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.
- (19) 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

Annexes II, III and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were placed on the market in the Union before ... [*Office of Publications: please insert date = 6 months after date of entry into force of this Regulation*], except for carbendazim in grapefruits, oranges, papayas and mangoes, and for thiophanate-methyl in grapefruits, oranges, mandarins, papayas and mangoes.

Article 3

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 = 6 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

²² 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.