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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D089819/05
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 D089819/05 .

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EUROPEAN
COMMISSION

Brussels, XXX
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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/EEC[1], 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) 2020/1498[2]. An application for the renewal of its approval had been submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[3] 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 Council[4]. 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 conclusion on the peer review of the pesticide risk assessment of the active substance

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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).

thiophanate-methyl[5], which identified a number of concerns and data gaps. In particular, the Authority concluded that, given the clastogenic potential of thiophanate-methyl, toxicological reference values for consumer 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 396/2005[6], the Authority noted that the two substances share a common mode of action and have similar metabolic patterns.

(5) 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 and, in light of the outcome of the assessment under Article 12 of that Regulation, the risks that the current MRLs for these substances may pose to consumers.

(6) Since the two active substances were no longer approved for use in the Union and that all authorisations were withdrawn, the Authority invited Member States to identify and submit possible Good Agricultural Practices ('GAPs') in non-EU countries for which import tolerances were authorised. In the framework of that consultation, one Member State informed the Authority that import tolerances for those two substances in 'citrus fruits', mangoes, papayas and okra/lady's fingers were currently in place. Those import tolerances had already been assessed in the framework of the review of all MRLs for carbendazim and thiophanate-methyl in accordance with Article 12 of Regulation (EC) No 396/2005. The recommendations included in that review were not yet implemented, pending the further review under Article 43 of Regulation (EC) No 396/2005.

(7) In its reasoned opinion[7], the Authority concluded that there is evidence indicating that carbendazim and thiophanate-methyl are not clastogenic but aneugenic. It proposed toxicological reference values for both substances. Based on that conclusion, the Authority also performed a combined risk assessment for the two active substances, and identified unacceptable risks concerning the current MRLs, set based on import tolerances, for thiophanate-methyl in grapefruits, oranges, lemons, mandarins, mangoes, and papayas and for carbendazim in oranges, grapefruits, mandarins, lemons, mangoes, and papayas. The Authority, however, noted that the approach followed for the combined exposure assessment leads to an overestimation of the exposure in lemons and mandarins, where residues resulting from the use of carbendazim and thiophanate-methyl have been combined while co-occurrence of these residues is not expected in practice for these crops. Therefore, the Authority concluded that only the MRLs for carbendazim in grapefruits, oranges, papayas and

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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.

mangoes, and for thiophanate-methyl in grapefruits, oranges, mandarins, papayas and mangoes are of concern. These MRLs should therefore be set at the relevant product specific limit of determination ('LOD').

(8) For the other MRLs established based on import tolerances for carbendazim in lemons, limes, mandarins, and okra/lady's fingers and for thiophanate-methyl in lemons, limes and okra/lady's fingers, the Authority concluded that there is no risk for consumers, provided that residues of both substances do not co-occur. The MRLs should therefore be maintained at the existing level or, in the case of carbendazim in okra/lady's fingers and thiophanate-methyl in lemons and okra/lady's fingers, set at the lower level identified by the Authority, based on the GAPs from third countries that were assessed in the framework of the review of MRLs in accordance with Article 12 of Regulation (EC) No 396/2005 and in the framework of the assessment of these two active substances under Article 43 of Regulation (EC) No 396/2005.

(9) While the Authority had proposed toxicological reference values for carbendazim, it had also noted some deficiencies in the studies based on which those values were derived. Therefore, in compliance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to carry out a follow-up qualitative assessment of the data gaps that were identified for those studies in order to confirm the reliability of the derived toxicological reference values.

(10) In its statement on this assessment, the Authority concluded that the toxicological reference values derived in its previous reasoned opinion for carbendazim are protective to consumers[8].

(11) Carbendazim and thiophanate-methyl are no longer approved in the Union, and all authorisations of plant protection products containing those active substances have been revoked in the Union. Therefore, it is appropriate to lower all other MRLs that are set out in Annexes II and III of Regulation (EC) No 396/2005 to the LODs without seeking the opinion of the Authority in accordance with Article 17 of that Regulation.

(12) In addition, in its reasoned opinions under Articles 12 and 43 of Regulation (EC) No 396/2005, the Authority proposed to modify the residue definition 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 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. Therefore, no EU toxicological reference values are available and the safety of MRLs for this substance could not be assessed. The Authority concluded that further consideration from risk managers was required. In the absence of such evidence on the safety of the substance, for all products, a risk for consumers cannot be ruled out. As uses for benomyl are not authorised in the Union, and as no import tolerances or Codex maximum residue limits ('CXLs') exist for this substance, MRLs should be set in

[8] EFSA 2024. Statement on the assessment of quality of data available to EFSA to derive the toxicological reference values for carbendazim. XXXX

Annex V to Regulation (EC) No 396/2005 and the default MRL should apply, as provided for in Article 18(1), point (b), of Regulation (EC) No 396/2005.

(14) 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.

(15) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(16) 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. 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.

(17) 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.

(18) 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