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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	5 August 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.:	D070306/05
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 amisulbrom, flubendiamide, meptyldinocap, metaflumizone and propineb in or on certain products

Delegations will find attached document D070306/05.

Encl.: D070306/05



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[...](2021) **XXX** draft

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 amisulbrom, flubendiamide, meptyldinocap, metaflumizone and propineb in or on certain products

(Text with EEA relevance)

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

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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 amisulbrom, flubendiamide, meptyldinocap, metaflumizone and propineb 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)(a), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For amisulbrom, flubendiamide, meptyldinocap and metaflumizone, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For propineb, MRLs were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.
- (2) For amisulbrom the European Food Safety Authority ("the Authority"), submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005². It recommended keeping the existing MRLs. As there is no risk for consumers, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.
- (3) For flubendiamide the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005³. It identified a risk for consumers concerning the MRLs for head cabbages and lettuces. It is therefore appropriate to lower these MRLs in Annex II to Regulation (EC) No 396/2005 to the limit of determination (LOD). For other products, the Authority recommended raising or keeping the existing MRLs. Those MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.

¹ OJ L 070, 16.3.2005, p. 1.

² European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for amisulbrom according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(7):6170.

³ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for flubendiamide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(6):6150.

- (4) For meptyldinocap the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁴. It recommended lowering the MRLs for cucumbers and courgettes. For other products, it recommended raising or keeping the existing MRLs. The Authority concluded that concerning the MRLs for table grapes, wine grapes, strawberries, melons and watermelons some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, those MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (5) For metaflumizone the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁵. It identified a risk for consumers concerning the MRLs for broccoli and escaroles/broad-leaved endives. It is therefore appropriate to lower these MRLs in Annex II to Regulation (EC) No 396/2005 to the LOD. The Authority recommended lowering the MRLs for potatoes, head cabbages, cotton seeds and milk (cattle, sheep, goat, horse). For other products, it recommended raising or keeping the existing MRLs. The Authority concluded that concerning the MRLs for tomatoes, sweet peppers/bell peppers, gherkins, cauliflowers, Chinese cabbages/pe-tsai, lamb's lettuces/corn salads, lettuces, cresses and other sprouts and shoots, land cresses, Roman rocket/rucola, red mustards and baby leaf crops (including brassica species) some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, those MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (6) For propineb the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁶. It proposed to change the residue definition. As propineb is no longer approved in the EU and all authorisations for this substance have been revoked, MRLs for that active substance should be set in Annex V to Regulation (EC) No 396/2005 to the LOD.
- (7) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or Codex maximum residue limits (CXLs) exist, MRLs should be set at the specific LOD or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (8) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.

⁴ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for meptyldinocap (DE-126) according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(6):6157.

⁵ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for metaflumizone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(6):6123.

⁶ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for propineb according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(8):6233.

- (9) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (10) 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.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (12) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional period for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (13) 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 themselves to meet the new requirements which will result from the modification of the MRLs.
- (14) 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

As regards amisulbrom in and on all products, flubendiamide in and on all products except head cabbages and lettuces, meptyldinocap in and on all products, metaflumizone in and on all products except broccoli and escaroles (broad-leaved endives) and propineb in and on all products, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before [*Office of Publications: please insert date 6 months after entry into force of this Regulation*].

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 Publication: please insert date 6 months after entry into force*].

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