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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bupirimate, carfentrazone-ethyl, ethirimol, and pyriofenone in or on certain products

Delegations will find attached document D065879/05.

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[...] (2020) **XXX** draft

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

of **XXX**

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bupirimate, carfentrazone-ethyl, ethirimol, and pyriofenone in or on certain products

(Text with EEA relevance)

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

of **XXX**

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bupirimate, carfentrazone-ethyl, ethirimol, and pyriofenone 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) and Article 49(2) thereof,

Whereas:

- (1) For carfentrazone-ethyl maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For bupirimate, ethirimol and pyriofenone MRLs were set in Part A of Annex III to that Regulation.
- (2) For bupirimate 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 proposed two separate residue definitions, "bupirimate" and "ethirimol", in order to cover the presence of the metabolite ethirimol from the use of bupirimate in commodities of plant origin. It proposed to change the residue definitions for commodities of animal origin into "desethyl ethirimol". The Authority recommended lowering the MRLs of bupirimate for strawberries, blackberries, dewberries, currants (black, red and white), gooseberries (green, red and yellow), tomatoes, sweet peppers/bell peppers, and courgettes. For other products, it recommended raising or keeping the existing MRLs. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. The Authority further concluded that concerning the MRLs for table and wine grapes, aubergines/eggplants and products of animal origin some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products 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.
- (3) As regards ethirimol, which is the major degradation product of bupirimate, the Authority recommended lowering the MRLs of ethirimol for apples, pears, apricots,

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 bupirimate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019; 17(7): 5757.

peaches, blackberries, dewberries, tomatoes, sweet peppers/bell peppers, cucumbers, gherkins and courgettes. For other products, it recommended raising or keeping the existing MRLs. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. The Authority further concluded that concerning the MRLs for table and wine grapes, aubergines/eggplants and products of animal origin some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products 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.

- (4) For carfentrazone-ethyl the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005³. The Authority proposed to change the residue definition. The Authority confirmed the proposal to change the residue definition in its peer review⁴. It recommended raising or keeping the existing MRLs. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.
- (5) For pyriofenone the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁵. It recommended raising or keeping the existing MRLs. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. The Authority further concluded that concerning the MRLs for swine (muscle, fat tissue, liver, kidney), bovine (muscle, fat tissue, liver, kidney), sheep (muscle, fat tissue, liver, kidney), goat (muscle, fat tissue, liver, kidney), equine (muscle, fat tissue, liver, kidney) and milk (cattle, sheep, goat, horse) some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products 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) Existing Codex maximum residue limits (CXLs) were taken into account in the reasoned opinions of the Authority. CXLs which are safe for consumers in the Union, were considered for MRL setting.
- (7) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or CXLs exist, MRLs should be set at the specific limit of determination (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 LODs. As regards several substances,

³ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for carfentrazone-ethyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(11):2956.

⁴ European Food Safety Authority; Peer review of the pesticide risk assessment of the active substance carfentrazone-ethyl. EFSA Journal 2016;14(8):4569.

⁵ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for pyriofenone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(6):5711.

those laboratories concluded that for certain commodities technical development requires the setting of specific LODs.

- (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 arrangement 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 and III 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 produced in the Union or imported into the Union before [*Office of Publications please insert date of application 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