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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 fenpyroximate, triadimenol and triadimefon in or on certain products
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Delegations will find attached document D48327/02.

Encl.: D48327/02



Brussels, **XXX**
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[...](2016) **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 fenpyroximate, triadimenol and triadimefon 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 fenpyroximate, triadimenol and triadimefon 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 17, Article 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For fenpyroximate maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For triadimenol and triadimefon MRLs were set in Annex II and Part B of Annex III to that Regulation.
- (2) For fenpyroximate the European Food Safety Authority, hereinafter "the Authority", submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005². It proposed changing the residue definition and concluded that concerning the MRLs for citrus fruits, apples, pears, quinces, medlars, loquats, apricots, cherries, peaches, plums, table grapes, wine grapes, strawberries, blackberries, dewberries, raspberries, blueberries, cranberries, currants (red, black and white), gooseberries, rose hips, mulberries, azaroles, elderberries, tomatoes, peppers, aubergines, cucumbers, gherkins, courgettes, beans (fresh, with pods), hops, bovine liver and kidney, sheep liver and kidney and goat liver and kidney 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. The Authority concluded that concerning the MRLs for tree nuts, kumquats, avocados, potatoes, celeriac, okra, melons, pumpkins and beans (fresh, without pods) no information was available and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination. Taking into account additional information on the good agricultural practices provided by the United States after publication of the reasoned opinion, the MRLs for citrus fruits, almonds, apples, pears, cherries and cranberries should be set in Annex II to Regulation (EC) No 396/2005 at the existing level. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for fenpyroximate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;14(1):4382.

- (3) For triadimenol the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005³. It proposed changing the residue definition and concluded that concerning the MRLs for apples, table grapes, wine grapes, strawberries, blueberries, currants, gooseberries, swedes, turnips, tomatoes, peppers, aubergines, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, globe artichokes, rape seed, barley grain, oats grain, rye grain, wheat grain, hops, sugar beet, swine muscle, fat, liver and kidney, bovine muscle, fat, liver and kidney, sheep muscle, fat, liver and kidney, goat muscle, fat, liver and kidney, poultry muscle, fat, liver and kidney, cattle, sheep, goat and horse milk and bird's eggs 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. The Authority concluded that concerning the MRLs for bananas, pineapples, okra, Brussels sprouts, leek, buckwheat grain, millet grain, sorghum grain and coffee beans no information was available and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination.
- (4) The non-inclusion of triadimefon in Annex I to Directive 91/414/EEC is provided for by Commission Decision (EC) No 2004/129⁴. All existing authorisations for plant protection products containing the active substance triadimefon have been revoked. In accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof, the MRLs set out for this active substance in Annex II and in Part B of Annex III to that Regulation should therefore be deleted.
- (5) 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 limit of determination or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (6) 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.
- (7) 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.
- (8) 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.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which

³ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for triadimenol according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2016;14(1):4377.

⁴ Commission Decision (EC) No 2004/129 of 30 January 2004 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ L 37, 10.2.2004, p. 37).

have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.

- (11) 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.
- (12) 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 the active substances fenpyroximate, triadimenol and triadimefon 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 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
Jean-Claude JUNCKER