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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 ethofumesate, etoxazole, fenamidone, fluoxastrobin and flurtamone in or on certain products

Delegations will find attached document D044016/02.

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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 ethofumesate, etoxazole, fenamidone, fluoxastrobin and flurtamone 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 ethofumesate, etoxazole, fenamidone, fluoxastrobin and flurtamone 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 ethofumesate, etoxazole, fenamidone and flurtamone maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For fluoxastrobin, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) For ethofumesate, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005². It proposed to change the residue definition and concluded that concerning the MRLs for beetroot, spinach, witloof, parsley, sage, rosemary, thyme, basil, beans with pods, peas with pods, peas (dry), herbal infusions from flowers, herbal infusions from leaves, spices from roots, sugar beet root, chicory root, swine meat, fat, liver and kidney, bovine meat, fat, liver and kidney, sheep meat, fat, liver and kidney, goat meat, fat, liver and kidney, milk from cattle, from sheep and from goat, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for these products should be set at the specific limit of determination 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 (MRLs) for ethofumesate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(11):2959.

- (3) These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (4) 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 etoxazole, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005³. It recommended raising or keeping the existing MRLs for several products and lowering the MRLs for tree nuts, plums, tomatoes and aubergines. It concluded that concerning the MRLs for cotton seed some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRL for that product should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. That MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (6) For fenamidone, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁴. It recommended raising or keeping the existing MRLs for several products and lowering the MRLs for potatoes and witloof. It concluded that concerning the MRLs for strawberries, melons, lamb's lettuce, lettuce, scarole and rucola some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for these 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.
- (7) For fluoxastrobin, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁵. It proposed to change the residue definition. It recommended raising or keeping the existing MRLs for several products and lowering the MRLs for onions, rye and wheat. It concluded that concerning the MRLs for barley, oats and kidney and fat from bovine, from sheep and from goat some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for these 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 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for etoxazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(10):2931.

⁴ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fenamidone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(11):2960.

⁵ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fluoxastrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(12):3012.

- (8) The Authority concluded that concerning the MRLs for the other animal origin products, except kidney and fat from bovine, from sheep and from goat, 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.
- (9) For flurtamone, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁶. It recommended lowering the MRLs for peas, sunflower seed, barley, oats, rye and wheat.
- (10) 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.
- (11) The Commission consulted the European Union reference laboratories for residues of pesticides on analytical methods. Those laboratories concluded that for certain substance/commodity combinations technical development requires the setting of specific limits of determination and residue definitions should be updated to reflect technical progress and feasibility.
- (12) 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.
- (13) 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.
- (14) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (15) 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.
- (16) 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.

⁶ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for flurtamone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(12):3009.

(17) 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 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