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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 captan, propiconazole and spiroxamine in or on certain products

Delegations will find attached document D042723/16.

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[...](2015) **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 captan, propiconazole and spiroxamine 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 captan, propiconazole and spiroxamine 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 captan, propiconazole and spiroxamine, maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.
- (2) For captan, the European Food Safety Authority, hereinafter "the Authority", submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof². It proposed to change the residue definition for plant commodities. It recommended raising or keeping the existing MRLs for certain products. It concluded that concerning the MRLs for apples, pears, quinces, medlar, loquat, apricots, cherries, peaches, plums, strawberries, blackberries, raspberries, blueberries, currants, gooseberries and tomatoes 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.

¹ OJ L 70, 16.3.2005, p. 1.

² EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for captan according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(4):3663, 55 pp.

- (3) The Authority concluded that concerning the MRLs for almonds, table grapes, wine grapes, potatoes, cucumbers, melons, scarole, leek, maize and sorghum no information was available and that further consideration by risk managers was required.
- (4) The MRLs for these products should be set at the specific limit of determination.
- (5) For propiconazole, the Authority, submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof³. It concluded that concerning the MRLs for grapefruit, lemons, limes, mandarins, apples, apricots, table and wine grapes, bananas, rape seed, barley grain, oats grain, rice grain, rye grain, wheat grain, sugar beet (root), swine muscle and fat, bovine muscle and fat, sheep muscle and fat, goat muscle and fat, poultry muscle and fat, cattle, sheep and goat milk and birds' 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 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. The Authority concluded that concerning the MRLs for almonds, cherries, plums, strawberries, currants (red, black and white), gooseberries, peppers, cucumbers, globe artichokes, peanuts and tea 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.
- (6) For spiroxamine, the Authority, submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof⁴. It proposed to change the residue definition and concluded that concerning the MRLs for table and wine grapes, banana, barley, oats, rye, wheat, poultry muscle, fat and liver and birds' 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 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. As it is appropriate to set the residue definition for animal origin commodities as 'spiroxamine carboxylic acid metabolite M06, expressed as spiroxamine (sum of isomers)', sufficient information is available for setting MRLs for swine muscle, fat, liver and kidney, bovine muscle, fat, liver and kidney, sheep muscle, fat, liver and kidney, goat muscle, fat, liver and kidney, cattle, sheep and goat milk. As the MRLs for barley and oats of 0.4 mg/kg are based on a good agricultural practice that is no longer supported, the MRLs for those commodities should be reduced to 0.05 mg/kg.

³ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for propiconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3975.

⁴ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for spiroxamine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(1):3992.

- (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 limit of determination 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.
- (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. Comments were received from several third countries on the new residue definition and MRL for captan in wine grapes. It is appropriate to temporarily maintain the existing residue definition and MRL in order to allow for the generation of residue data on wine grapes in line with the newly proposed residue definition. That MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (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 before [*Office of Publications please insert the 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