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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 acrinathrin, metalaxyl and thiabendazole in or on certain products

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Delegations will find attached document D049626/02.

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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 acrinathrin, metalaxyl and thiabendazole 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 acrinathrin, metalaxyl and thiabendazole 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/EEC<sup>1</sup>, and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

- (1) For acrinathrin, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For metalaxyl and thiabendazole MRLs were set in Annex II and Part B of Annex III to that Regulation.
- (2) For acrinathrin, the European Food Safety Authority, hereinafter "the Authority", submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>2</sup>. It proposed to change the residue definition. It identified concerning the MRLs for bananas, melons, peppers, watermelons, peaches and apricots a risk for consumers. It is therefore appropriate to lower these MRLs. For other products, it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for lamb's lettuce, escarole, cress, rocket, red mustard, soya beans and all animal origin products, 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 regardless of the data gaps identified the critical good agriculture practice was not compliant with the approval restrictions for acrinathrin for pome fruits, apricots, cherries, peaches, plums, strawberries, bananas, garlic, onions,

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

<sup>2</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for acrinathrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(7):4203.

tomatoes, peppers, aubergines, okra (lady's fingers), cucurbits with edible peel, gherkins, courgettes, melons, pumpkins, watermelons, lettuce, beans (fresh, with pods) and soya beans and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination.

- (3) For metalaxyl, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>3</sup>. It proposed to change the residue definition and recommended lowering the MRLs for head cabbage, Chinese cabbage, kohlrabi, spinach, beet leaves (chard), beans (fresh, with and without pods), peas (fresh, with and without pods), asparagus, leek, beans (dry), peas (dry), lupins (dry), linseed, poppy seed, rape seed, mustard seed, gold of pleasure seed, maize, swine meat and fat, bovine meat and fat, sheep meat and fat, goat meat and fat, poultry meat and fat, milk and birds eggs. It concluded that concerning the MRLs for grapefruits, oranges, lemons, limes, mandarins, apples, pears, table grapes, wine grapes, strawberries, onions, peppers, soya beans, swine liver and kidney, bovine liver and kidney, sheep liver and kidney and poultry liver 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 quinces, medlars, loquat, avocados, gherkins, cotton seed, barley, buckwheat, millet, oats, rice, rye, sorghum, wheat, spices from seeds and sugar beet (root), 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. The MRLs for spices from fruits should be set as temporary MRLs. These MRLs will be reviewed; the review will take into account the information available within four years from the publication of this Regulation.
- (4) For thiabendazole, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>4</sup>. It identified concerning the MRLs for mangoes and cultivated fungi a risk for consumers. It is therefore appropriate to lower these MRLs. The Authority proposed to change the residue definition for milk and other animal origin products. It recommended lowering the MRLs for apples, pears, potatoes, witloof/Belgian endives, swine muscle and fat and poultry muscle and fat. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for grapefruits, oranges, lemons, limes, mandarins, quinces, medlars, loquat, kumquats, avocados, bananas, papayas, potatoes, witloof/Belgian endives and all animal origin products 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.

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<sup>3</sup> European Food Safety Authority; Reasoned opinion on combined review of the existing maximum residue levels (MRLs) for the active substances metalaxyl and metalaxyl-M. EFSA Journal 2015;13(4):4076.

<sup>4</sup> European Food Safety Authority; Reasoned opinion on the revision of the review of the existing maximum residue levels (MRLs) for thiabendazole. EFSA Journal 2016;14(6):4516.

- (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 have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained. Because a risk to consumers cannot be excluded at the current MRLs, the value of 0.01 mg/kg for acrinathrin in and on bananas, melons, peppers, watermelons, peaches and apricots and the value of 0.01 mg/kg for thiabendazole in and on mangoes and cultivated fungi should apply to all products from the date of application of this Regulation.
- (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 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 Publication please insert date 6 months after entry into force of this Regulation*]:

- (1) as regards the active substance metalaxyl in and on all products;

- (2) as regards the active substance acrinathrin in and all products except bananas, melons, peppers, watermelons, peaches and apricots;
- (3) as regards the active substance thiabendazole in and on all products except mangoes and cultivated fungi.

### *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*