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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 amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products
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Delegations will find attached document D038149/02.

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Brussels, **XXX**
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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 amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin 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 amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin 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 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For amidosulfuron, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin, MRLs were set in Annex II and Part B of Annex III to that Regulation.
- (2) For amidosulfuron, 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 recommended lowering the MRL for linseed. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for barley, oats, rye and wheat grain 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) For fenhexamid, 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 recommended lowering the MRLs for almonds and

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for amidosulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(3):3614. [40 pp.].

³ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for fenhexamid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(1):3536. [42 pp.].

mulberries. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRL for kiwi some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRL for this product should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. This MRL 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 MRL for fennel no information was available and that further consideration by risk managers was required. The MRL for this product should be set at the specific limit of determination. As regards blueberries, cranberries, gooseberries and azarole, after submitting the opinion referred to in the first sentence, the Authority submitted a further opinion concerning the MRLs in accordance with Article 10 of Regulation (EC) No 396/2005⁴. It is appropriate to take this opinion into account.

- (4) For kresoxim-methyl, 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) thereof⁵. It proposed to change the residue definition and recommended lowering the MRLs for pecans, currants (red, black and white), gooseberries, peppers, sunflower seed, rye grain and wheat grain. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the 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 milk, sheep milk and goat milk 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 apricots, peaches and beet leaves (chard) 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.
- (5) For thiacloprid, 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) thereof⁶. It identified concerning the MRLs for blackberries, kale, lettuce and scarole a risk for consumers. It is therefore appropriate to lower these MRLs. The Authority recommended lowering the MRLs for celeriac, swedes, turnips, garlic, onions, shallots, kohlrabi, asparagus, barley grain, oats grain, rice grain, swine fat, bovine fat, sheep fat, goat fat, poultry muscle, poultry fat and poultry liver. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for courgettes, flowering brassica, scarole, land cress, rocket, leaves and sprouts of brassica, spinach, beet leaves (chard), beans (fresh, with pods), beans (dry), peas (dry), rape seed, mustard seed, maize grain, tea, herbal infusions

⁴ Reasoned opinion on modification of the MRLs for fenhexamid in various berries.. EFSA Journal 2014; 12(7):3785. [18 pp.].

⁵ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for kresoxim-methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(1):3549. [70 pp.]

⁶ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for thiacloprid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(3):3617. [111 pp.].

(dried, leaves), herbal infusions (dried, roots) and spices (seeds) 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 table grapes, wine grapes, sweet corn, witloof, beans (fresh without pods) and sunflower seed 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 trifloxystrobin, 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) thereof⁷. It recommended lowering the MRLs for table and wine grapes, papaya, garlic, onions, peanuts and sugar beet. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for currants (red, black and white), gooseberries, passion fruit, peppers, cucumbers, gherkins, leafy brassica, scarole (broad-leaf endive), herbs, beans (fresh, with pods), oats grain, 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 and liver, cattle milk, sheep milk 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 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 blackberries, raspberries, witloof, peas (fresh, with pods), olives for oil production and chicory roots 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. As regards cane fruit, after submitting the opinion referred to in the first sentence, the Authority submitted a further opinion concerning the MRLs in accordance with Article 10 of Regulation (EC) No 396/2005⁸. It is appropriate to take this opinion into account. Taking into account additional information on the good agricultural practice provided by Belgium and as there is no risk for consumers, the MRL for spring onions should be set in Annex II to Regulation (EC) No 396/2005 at the existing level. Taking into account additional information on the good agricultural practice provided by Austria and as there is no risk for consumers, the MRL for elderberries should be set in Annex II to Regulation (EC) No 396/2005 at the existing level.
- (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 or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.

⁷ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for trifloxystrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(2):3592. [81 pp.].

⁸ Reasoned opinion on the modification of the existing MRL for trifloxystrobin in cane fruit. EFSA Journal 2014; 12(7):3751. [17 pp.].

- (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 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. Because a risk to consumers cannot be excluded at the current MRLs, the values for thiacloprid of 1 mg/kg for blackberries, 0.4 mg/kg for kale, 1 mg/kg for lettuce and 0.15 mg/kg for scarole should apply to all products from the date of application of this Regulation.
- (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

As regards the active substances amidosulfuron, fenhexamid, kresoxim-methyl and trifloxystrobin 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 by [*Office of Publications please insert day before the date of application of this Regulation*].

As regards the active substance thiacloprid in and on all products except blackberries, kale, lettuce and scarole, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced by [*Office of Publications please insert day before the 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
Jean-Claude JUNCKER