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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 1 naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluazifop-P, fuberidazole, mepiquat and tralkoxydim in or on certain products

Delegations will find attached document D044026/02.

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[...](2016) **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 1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluazifop-P, fuberidazole, mepiquat and tralkoxydim 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 1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluazifop-P, fuberidazole, mepiquat and tralkoxydim 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 1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluazifop-P, fuberidazole, mepiquat and tralkoxydim maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) For 1-naphthylacetamide and 1-naphthylacetic acid, 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 to change the residue definition and concluded that concerning the MRLs for apples, pears, tomatoes and aubergines 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.

¹ OJ L 070, 16.3.2005, p. 1.

² European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for 1-naphthylacetamide and 1-naphthylacetic acid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(8):4213.

The Authority concluded that concerning the MRLs for oranges, lemons, mandarins, cherries, peaches, plums, grapes, strawberries, raspberries, table olives, kiwi, potatoes, peppers, cucumbers, courgettes, melons, watermelons, spinach, beans (fresh, with pods), beans (fresh, without pods), peas (fresh, with pods), peas (fresh, without pods), asparagus, celery, globe artichoke, beans (dry), 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.

- (3) For chloridazon, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005³. It proposed to change the residue definition. It recommended lowering the MRL for sugar beet root. For other products it recommended keeping the existing MRL. It concluded that concerning the MRLs for lamb's lettuce, lettuce, scarole, cress, land cress, rocket, red mustard, purslane, asparagus, cardoons, celery, fennel, globe artichokes, leek, rhubarb, herbal infusions (dried, flowers), herbal infusions (dried, leaves), spices (bark), spices (buds) and spices (flower stigma) no information was available and that further consideration by risk managers was required. The authority indicated that a potential for accumulation of chloridazon residues in certain crops grown in rotation is expected and calculated MRLs for the products concerned which take into account that potential for accumulation after different plant back intervals and left it to risk managers to choose the required option. For the products concerned, for which the active substance is not to be used, residues inevitably result from soils where the active substance was previously used for other crops. As there is no risk for consumers, MRLs should be set for the products concerned in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. The authority concluded that concerning the MRLs for beetroot, horseradish, garlic, onions, shallots, leaves and sprouts of brassica, spinach, beet leaves (chard), herbs, 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 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.
- (4) For fluazifop-P, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁴. It proposed to change the residue definition. It recommended lowering the MRLs for grapefruit, oranges, lemons, limes, mandarins, almonds, brazil nuts, cashew nuts, chestnuts, hazelnuts, macadamia, pecans, pine nuts, pistachios, walnuts, apples, pears, quinces, apricots, cherries, peaches, plums, table and wine grapes, cane fruit, other small fruits and berries, figs, table olives, kumquats, kiwi, bananas, pineapples, yams, garlic,

³ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for chloridazon according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(9):4226.

⁴ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for fluazifop-P according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(9):4228.

- (5) shallots, cucumbers, gherkins, lettuce and other salad plants, spinach, purslane, beet leaves, witloof, herbs, asparagus, celery, fennel, dry peas, sunflower seed, rape seed, mustard seed, borage, gold of pleasure, olives for oil production, and chicory roots. For other products it recommended raising or keeping the existing MRLs. It identified concerning the MRLs for tomatoes, peppers, head cabbage and fresh beans without pods a risk for consumers. It is therefore appropriate to lower these MRLs. It concluded that concerning the MRLs for strawberries, carrots, herbal infusions (dried flowers, leaves and roots), hops, spices (seeds, fruits and berries and roots and rhizome), 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, 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 spring onions, leek and cotton 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 fuberidazole, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁵. It recommended lowering the MRLs for barley, oats, rye and wheat.
- (7) For mepiquat, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁶. It proposed to change the residue definition and recommended raising or keeping the existing MRLs for several products. It concluded that concerning the MRL for rape 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 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. 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 linseed 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.

⁵ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for fuberidazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(9):4220.

⁶ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for mepiquat according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(8):4214.

- (8) For tralkoxydim, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁷. It proposed to change the residue definition and concluded that concerning the MRLs for barley grain 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.
- (9) 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.
- (10) 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.
- (11) 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.
- (12) 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.
- (13) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (14) 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 MRL, the value for fluazifop-P of 0.01 mg/kg for peppers should apply to all products from the date of application of this Regulation.
- (15) 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.

⁷ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for tralkoxydim according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(9):4227.

(16) 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 1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fuberidazole, mepiquat and tralkoxydim 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*].

As regards the active substance fluazifop-P in and on all products except peppers, 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