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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products

Delegations will find attached document D038141/02.

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EUROPEAN
COMMISSION

Brussels, **XXX**
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D038141/02
[...](2015) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron 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 dimoxystrobin and metrafenone, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For azoxystrobin, fluroxypyr, methoxyfenozide, oxadiargyl and tribenuron maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.
- (2) For azoxystrobin, 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 recommended lowering the MRLs for almonds, brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts, macadamia, pecans, pine nuts, walnuts, asparagus, maize grains, coffee beans, herbal infusions (dried, roots), sugar beet (root) and chicory roots. For other products it recommended keeping or raising the existing MRLs. It concluded that concerning the MRLs for lamb's lettuce, scarole (broad-leaf endive), cress, rocket, rucola, red mustard, leaves and sprouts of Brassica spp, swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), poultry (muscle, fat, liver), milk (cattle, sheep, goat) 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

¹ OJ L 070, 16.3.2005, p. 1.

² European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for azoxystrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(12):3497. [97 pp.]

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) As regards azoxystrobin in barley, coffee beans, oats, potatoes and sorghum, the Codex Alimentarius Commission (CAC)³ adopted Codex MRLs (CXLs). As these CXLs are supported by an updated assessment of the Authority, it is appropriate to take them into account, with the exception of those CXLs which are not safe for consumers in the Union and for which the Union presented a reservation to the CAC⁴.
- (4) For dimoxystrobin, 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 wheat grain. For other products it recommended keeping the existing MRLs. It concluded that concerning the MRLs for bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney) and milk (cattle, sheep, 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 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.
- (5) For fluroxypyr, 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 proposed to change the residue definition. It concluded that concerning the MRLs for apples, garlic, onions, shallots, thyme, leek, barley grain, maize grain, oats grain, rye grain, sorghum grain, wheat grain, herbal infusions (flowers), sugar cane, swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney) and milk (cattle, sheep, 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 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 citrus fruits, table olives and olives for oil production no information was available and concerning the MRLs for pears, quinces, medlar, loquat and spring onions the information available was insufficient to derive a tentative MRL and further

³ Codex Committee on Pesticide Residues reports available on: http://www.codexalimentarius.org/download/report/917/REP14_PRe.pdf Joint FAO/WHO food standards programme Codex Alimentarius Commission. Appendices II and III. Thirty-Seventh Session. Geneva, Switzerland, 14-18 July 2014.

⁴ Scientific support for preparing a EU position for the 46th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2014;12(7):3737 [182 pp.]. doi:10.2903/j.efsa.2014.3737.

⁵ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for dimoxystrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(11):3464. [41 pp.]

⁶ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for fluroxypyr according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(12):3495. [49 pp.]

consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination.

- (6) For methoxyfenozide, 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 beans (dry) and peanuts. For other products it recommended keeping or raising the existing MRLs. It concluded that concerning the MRLs for aubergines, swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), poultry (muscle, fat, liver), milk (cattle, sheep, goat) 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 oranges, mandarins and maize grain no information was available and that further consideration by risk managers was required. The MRL for maize grain should be set at the specific limit of determination. As regards oranges and mandarins, CXLs were adopted after the Authority submitted its opinion⁸. The MRLs set out for those products in Regulation (EC) No 396/2005, as it stands, reflect those CXLs. The MRLs for oranges and mandarins should therefore not be modified.
- (7) For metrafenone, 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) thereof⁹. It proposed to change the residue definition and recommended lowering the MRLs for wheat grain and rye grain. For other products it recommended keeping or raising the existing MRLs. It concluded that concerning the MRLs for aubergines, some information was not available and that further consideration by risk managers was required. As regards aubergine, the Authority submitted an earlier opinion concerning this MRL¹⁰. It is now considered appropriate to take the proportionality approach used in that opinion into account. The Authority concluded that concerning the MRLs for bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney) and milk (cattle, sheep, 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.

⁷ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for methoxyfenozide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(1):3509. [68 pp.]

⁸ Commission Regulation (EU) No 491/2014 of 5 May 2014 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 ametoctradin, azoxystrobin, cycloxydim, cyfluthrin, dinotefuran, fenbuconazole, fenvalerate, fludioxonil, fluopyram, flutriafol, fluxapyroxad, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products (OJ L 146, 16.5.2014, p. 1).

⁹ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for metrafenone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(12):3498. [43 pp.]

¹⁰ European Food Safety Authority; Modification of the existing MRLs for metrafenone in various crops. EFSA Journal 2013;11(1):3075. [30 pp.]

- (8) Pursuant to Commission Regulation (EU) No 823/2012¹¹ the approval of oxadiargyl expired on 31 March 2014. All existing authorisations for plant protection products containing the active substance oxadiargyl have been revoked and grace periods end on 30 September 2015 at the latest. In accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1) thereof the MRLs set out for that active substance in Annexes II and III should therefore be deleted. This should not apply to those MRLs corresponding to CXLs based on uses in third countries provided that they are acceptable with regard to consumer safety. Nor should it apply in cases where MRLs have been specifically set as import tolerances.
- (9) For tribenuron, 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) thereof¹². It recommended keeping the existing MRLs.
- (10) 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.
- (11) 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.
- (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

¹¹ Commission Regulation (EU) No 823/2012 of 14 September 2012 derogating from Implementing Regulation (EU) No 540/2011 as regards the expiry dates of the approval of the active substances 2,4-DB, benzoic acid, beta-cyfluthrin, carfentrazone ethyl, Coniothyrium minitans Strain CON/M/91-08 (DSM 9660), cyazofamid, cyfluthrin, deltamethrin, dimethenamid-P, ethofumesate, ethoxysulfuron, fenamidone, flazasulfuron, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mecoprop, mecoprop-P, mesosulfuron, mesotrione, oxadiargyl, oxasulfuron, pendimethalin, picoxystrobin, propiconazole, propineb, propoxycarbazone, propyzamide, pyraclostrobin, silthiofam, trifloxystrobin, warfarin and zoxamide (OJ L 250, 15.9.2012, p. 13).

¹² European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for tribenuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(11):3457. [32 pp.]

operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs.

- (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 by [*Office of Publications please insert day before 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*]
However, point (1)(c) and point (3) of the Annex shall apply from 01 October 2015.

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