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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) No .../.. 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 benthialdicarb, cyazofamid, cyhalofop-butyl, forchlorfenuron, pymetrozine and silthiofam in or on certain products (Text with EEA relevance)

Delegations will find attached document D030448.

Encl.: D030448



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[...](2013) **XXX** draft

COMMISSION REGULATION (EU) No .../..

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 bentiavalicarb, cyazofamid, cyhalofop-butyl, forchlorfenuron, pymetrozine and silthiofam in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

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 benthialdicarb, cyazofamid, cyhalofop-butyl, forchlorfenuron, pymetrozine and silthiofam 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 cyazofamid, cyhalofop-butyl, pymetrozine and silthiofam, maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For benthialdicarb and forchlorfenuron MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) A technical adaptation should be made, replacing the name of the active substance 'florchlorfenuron' by 'forchlorfenuron'.
- (3) For benthialdicarb, 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 and recommended lowering the MRL for potatoes. For other products it recommended raising or keeping the existing MRLs. The Authority concluded that concerning the MRL for cucumbers 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

¹ 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 (OJ L 070, 16.3.2005 p. 1).

² European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for benthialdicarb according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012; 10(8):2872. [31 pp.].

Authority. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

- (4) For cyazofamid, 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, for certain products, raising or keeping the existing MRLs. The Authority concluded that concerning the MRLs for potatoes, tomatoes, cucurbits with edible peel and cucurbits with inedible peel some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, 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. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (5) For cyhalofop-butyl, 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. The Authority concluded that concerning the MRL for rice 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.
- (6) For forchlorfenuron, 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 recommended lowering the MRLs for table grapes, wine grapes and kiwi.
- (7) For pymetrozine, 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 MRL for scarole a risk for consumers. It is therefore appropriate to set this MRL at the level identified by the authority. The Authority proposed to change the residue definition and recommended lowering the MRLs for rape seed and cotton seed. For other products it recommended raising or keeping the existing MRLs. The Authority concluded that concerning the MRLs for citrus fruit, apples, pears, apricots, peaches, strawberries, blackberries, raspberries, blueberries, currants (red, black and white), gooseberries, potatoes, celeriac, radishes, tomatoes, peppers, aubergines, cucurbits with edible peel, cucurbits with inedible peel, sweet corn, flowering brassica, Brussels sprout, head cabbage,

³ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for cyazofamid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012; 10(12):3065. [38 pp.].

⁴ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for cyhalofop-butyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013; 11(2):3115. [25 pp.].

⁵ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for forchlorfenuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012; 10(8):2862. [26 pp.].

⁶ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for pymetrozine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012; 10(10):2919. [67 pp.], revised version of 10 January 2013.

leafy brassica, kohlrabi, lamb's lettuce, lettuce, cress, land cress, rocket, red mustard, leaves and sprouts of brassica spp, spinach, purslane, beet leaves, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil, bay leaves, tarragon, beans (fresh, with pods), peas (fresh, with pods), celery, fennel, globe artichokes, herbal infusions (dried, flowers), herbal infusions (dried, leaves), hops (dried), 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. Those 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 okra and beans (fresh, without pods) no information was available and that further consideration by risk managers was required. MRLs for okra and beans (fresh, without pods) should be set at the specific limit of determination or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.

- (8) For silthiofam, 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. The Authority concluded that concerning the MRLs for barley grain, rye 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. Those 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 of plant and animal origin for which no relevant authorisations or import tolerances were reported at Union level and no Codex MRL was available, the Authority concluded that further consideration by risk managers was required. Taking into account the current scientific and technical knowledge, MRLs for those products should be set at the specific limit of determination or at the default MRL as set out 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 LODs. As regards several substances, those laboratories concluded that for certain commodities technical development permits the setting of lower LODs.
- (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.

⁷ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for silthiofam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013; 11(1):3088. [25 pp.].

- (14) In order to allow normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been lawfully produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (15) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States and interested parties to prepare themselves to meet the new requirements which will result from the modification of the MRLs.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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 lawfully produced before [*Office of Publications please insert date of application of this Regulation*]

- (1) as regards the active substances benthiavalicarb, cyhalofop-butyl, cyazofamid, forchlorfenuron and silthiofam in and on all products,
- (2) as regards the active substance pymetrozine in and on all products except scarole (broad-leaf endive).

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
José Manuel BARROSO