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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 aminopyralid, chlorantraniliprole, cyflufenamid, mepiquat, metalaxyl-M, propamocarb, pyriofenone and quinoxifen in or on certain products (Text with EEA relevance)

Delegations will find attached document D029073/02.

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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 aminopyralid, chlorantraniliprole, cyflufenamid, mepiquat, metalaxyl-M, propamocarb, pyriofenone and quinoxyfen in or on certain products

(Text with EEA relevance)

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

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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 aminopyralid, chlorantraniliprole, cyflufenamid, mepiquat, metalaxyl-M, propamocarb, pyriofenone and quinoxyfen 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) thereof,

Whereas:

- (1) Annex II and Part B of Annex III to Regulation (EC) No 396/2005 set the maximum residue levels (MRLs) for metalaxyl-M and quinoxyfen and Part A of Annex III to that Regulation sets the MRLs for aminopyralid, chlorantraniliprole, cyflufenamid, mepiquat, pencycuron and propamocarb. As regards pyriofenone, no specific MRLs were set nor was the substance included in Annex IV to that Regulation, so the default value of 0.01 mg/kg applies.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance chlorantraniliprole on beetroot, carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, salsify, swedes, turnips and other root and tuber vegetables (except sugar beet and radishes), an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (3) Such applications were also submitted as regards cyflufenamid for pome fruits (except apples and pears), gherkins and cucurbits with inedible peel (except melons); as regards mepiquat for oats, wheat and products of animal origin considering residue levels in feed items resulting from the uses of mepiquat on wheat, rye and barley; as regards metalaxyl-M for currants; as regards pencycuron for potatoes; as regards propamocarb for rocket and leek; and as regards pyriofenone for table and wine grapes, barley, oats, rye and wheat.

¹ OJ L 70, 16.3.2005, p. 1.

- (4) In accordance with paragraphs 2 and 4 of Article 6 of Regulation (EC) No 396/2005 an application was submitted for aminopyralid in products of animal origin considering residue levels in feed items resulting from the use of aminopyralid on grass pasture. The applicant claims that the authorised use of aminopyralid on grass pasture in the United States, Canada, Bolivia, Argentina and Brazil leads to residues exceeding the MRLs authorised under Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of products of animal origin.
- (5) Such applications were also submitted as regards chlorantraniliprole for oilseeds (except peanuts, soya beans and cotton seeds) and as regards quinoxifen for hops. In both cases the applicants claim that the authorised use of the substances on those crops in the United States leads to residues exceeding the MRLs authorised under Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of oilseeds.
- (6) In accordance with Article 8 of Regulation (EC) No 396/2005 those applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.
- (7) The European Food Safety Authority ("the Authority") assessed the applications and the evaluation reports, examining in particular the risks to the consumer and, where relevant, to animals and gave reasoned opinions on the proposed MRLs². It forwarded those opinions to the Commission and the Member States and made them available to the public.
- (8) The Authority concluded that, as regards the use of aminopyralid on grass pasture, no modification of the existing MRLs is required for milk, eggs, poultry and swine products. As regards the use of chlorantraniliprole on oilseeds and the use of pencycuron on potatoes, it concluded that the submitted data are not sufficient to set a

² EFSA scientific reports available online: <http://www.efsa.europa.eu>:
Reasoned opinion on the modification of the existing MRLs for aminopyralid in food commodities of animal origin. EFSA Journal 2013;11(6):3271 [35 pp.]. doi:10.2903/j.efsa.2013.3271.
Reasoned opinion on the modification of the existing MRLs for chlorantraniliprole in several root and tuber vegetables and oilseeds. EFSA Journal 2013;11(7):3296 [36 pp.]. doi:10.2903/j.efsa.2013.3296.
Reasoned opinion on the modification of the existing MRLs for cyflufenamid in pome fruits, cucurbits (inedible peel) and gherkins. EFSA Journal 2013;11(7):3336 doi:10.2903/j.efsa.2013.3336.
Reasoned opinion on the modification of the existing MRLs for mepiquat in oats, wheat and food commodities of animal origin. EFSA Journal 2013;11(6):3275 [40 pp.]. doi:10.2903/j.efsa.2013.3275.
Reasoned opinion on the modification of the existing MRLs for metalaxyl-M in currant (red, black and white). EFSA Journal 2013;11(7):3297 [25 pp.]. doi:10.2903/j.efsa.2013.3297.
Reasoned opinion on the modification of the existing MRL for pencycuron in potatoes. EFSA Journal 2012;10(12):3011 [21 pp.]. doi:10.2903/j.efsa.2012.3011.
Reasoned opinion on the modification of the existing MRLs for propamocarb in rocket and leek. EFSA Journal 2013;11(6):3255 [32 pp.]. doi:10.2903/j.efsa.2013.3255.
Reasoned opinion on the setting of new MRLs for pyriofenone in cereals, grapes and animal products. EFSA Journal 2013;11(7):3342 [23 pp.]. doi:10.2903/j.efsa.2013.3342.
Reasoned opinion on the modification of the existing MRL for quinoxifen in hops. EFSA Journal 2013;11(7):3343 [22 pp.]. doi:10.2903/j.efsa.2013.3343.

new MRL. As regards the use of propamocarb on leek, the Authority does not recommend setting the proposed MRL since a risk for consumers cannot be excluded. Moreover, the intended drench application is not supported by data. The existing MRLs should therefore remain unchanged.

- (9) As regards all other applications, the Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicants were acceptable as regards consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. It took into account the most recent information on the toxicological properties of the substances. Neither the lifetime exposure to those substances via consumption of all food products that may contain them, nor the short-term exposure due to high consumption of the relevant crops and products showed that there is a risk that the acceptable daily intake (ADI) or the acute reference dose (ARfD) is exceeded.
- (10) As regards, aminopyralid the Authority proposed the implementation of the Codex maximum residue limits (CXLs) for food of animal origin as an alternative to the modifications of the MRLs requested by the applicant since the CXLs are based on the same scientific considerations. Those CXLs are safe for consumers in the Union and should therefore be included in Regulation (EC) No 396/2005 as MRL.
- (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) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (13) 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

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

ANNEX

Annexes II and III to Regulation (EC) No 396/2005 are amended as follows:

- (1) In Annex II, the columns for metalaxyl-M and quinoxyfen are replaced by the following:

[For Official Journal: insert table Annex II existing].

- (2) Annex III is amended as follows:

- (a) In Part A, the columns for aminopyralid, chlorantraniliprole, cyflufenamid, mepiquat and propamocarb are replaced by the following:

[For Official Journal: insert table Annex IIIA existing].

- (b) In Part A, the following column for pyriofenone is added:

[For Official Journal: insert table Annex IIIA new].

- (c) In Part B, the columns for metalaxyl-M and quinoxyfen are replaced by the following:

[For Official Journal: insert table Annex IIIB existing].