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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 acetamiprid, ametoctradin, amisulbrom, bupirimate, clofentezine, ethephon, ethirimol, fluopicolide, imazapic, propamocarb, pyraclostrobin and tau-fluvalinate in or on certain products

Delegations will find attached document D036754/02.

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Brussels, **XXX**
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[...](2014) **XXX** draft

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

of **XXX**

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(Text with EEA relevance)

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(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) For acetamiprid, ethephon, propamocarb and pyraclostrobin maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For clofentezine MRLs were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For ametoctradin, amisulbrom, bupirimate, ethirimol, fluopicolide, imazapic and tau-fluvalinate MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance acetamiprid on bananas, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL.
- (3) As regards ametoctradin, such an application was made for hops. As regards amisulbrom, such an application was made for grapes. As regards bupirimate, such an application was made for apricots, peaches, strawberries, grapes, cane fruit, cucurbits, herbs and globe artichokes. As regards clofentezine, such an application was made for cherries, cucurbits with edible peel, tomatoes and aubergines. As regards ethephon, such an application was made for table grapes. As regards fluopicolide, such an application was made for Chinese cabbage. As regards propamocarb, such an application was made for spring onions and Chinese cabbage. As regards pyraclostrobin, such an application was made for swedes and turnips. As regards tau-fluvalinate, such an application was made for pome fruit, apricots and peaches.

¹ OJ L 70, 16.3.2005, p. 1.

- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for imazapic used on soya bean. The applicant claims that the authorised uses of that substance on such crop in Brazil lead to residues exceeding the MRL contained in Regulation (EC) No 396/2005 and that a higher MRL is necessary to avoid trade barriers for the importation of that crop.
- (5) In accordance with Article 8 of Regulation (EC) No 396/2005 these applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.
- (6) The European Food Safety Authority, hereinafter '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 these opinions to the Commission and the Member States and made them available to the public.
- (7) The Authority concluded in its reasoned opinions that, as regards the use of bupirimate on cucumbers, no modification of the existing MRL is required. As regards the use of bupirimate on herbs and globe artichokes and the use of clofentazine on cherries, tomatoes, aubergines and courgettes, the submitted data were not sufficient to set new MRLs. The existing MRLs should therefore remain unchanged.
- (8) As regards ethirimol, which is the major degradation product of bupirimate, the Authority recommends setting new MRLs for apricots, peaches, cane fruit and cucurbits with inedible peel to cover the uses of bupirimate on such crops.
- (9) As regards ethephon, the Authority recommends setting a new MRL on table grapes at the level of 1,5 mg/kg, which was derived by rounding up the value of 1 mg/kg calculated with the Organisation for Economic Co-operation and Development (OECD) MRL calculator. However, given the concerns raised by some Member

² EFSA scientific reports available online: <http://www.efsa.europa.eu>:
Reasoned opinion on the modification of the existing MRL for acetamiprid in bananas. EFSA Journal 2014;12(9):3824 [20 pp.]. doi:10.2903/j.efsa.2014.3824.
Reasoned opinion on the modification of the existing MRL for ametoctradin in hop. EFSA Journal 2014;12(10):3879 [17 pp.]. doi:10.2903/j.efsa.2014.3879.
Conclusion on the peer review of the pesticide risk assessment of the active substance amisulbrom. EFSA Journal 2014;12(4):3237 [75 pp.]. doi:10.2903/j.efsa.2014.3237.
Reasoned opinion on the modification of the existing MRLs for bupirimate in several crops. EFSA Journal 2014;12(7):3804 [35 pp.]. doi:10.2903/j.efsa.2014.3804.
Reasoned opinion on the modification of the existing MRLs for clofentazine in cherries, cucurbits with edible peel, tomatoes and aubergines. EFSA Journal 2014;12(10):3860 [22 pp.]. doi:10.2903/j.efsa.2014.3860.
Reasoned opinion on the modification of the existing MRLs for ethephon in table olive and table grape. EFSA Journal 2014;12(5):3698 [22 pp.]. doi:10.2903/j.efsa.2014.3698.
Reasoned opinion on the modification of the existing MRL for fluopicolide in Chinese cabbage. EFSA Journal 2014;12(9):3822 [20 pp.]. doi:10.2903/j.efsa.2014.3822.
Reasoned opinion on the setting of a new MRL for imazapic in genetically modified soya bean. EFSA Journal 2013;11(10):3426 [26 pp.]. doi:10.2903/j.efsa.2013.3426.
Reasoned opinion on the modification of the existing MRLs for propamocarb in spring onions and Chinese cabbage. EFSA Journal 2014;12(8):3811 [18 pp.]. doi:10.2903/j.efsa.2014.3811.
Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in swedes and turnips. EFSA Journal 2014;12(10):3872 [19 pp.]. doi:10.2903/j.efsa.2014.3872.
Reasoned opinion on the modification of the existing MRLs for tau-fluvalinate in various crops. EFSA Journal 2014;12(1):3548 [49 pp.]. doi:10.2903/j.efsa.2014.3548.

States, it is more appropriate to set the MRL at the unrounded level of 1 mg/kg. Such value adequately covers the intended uses on table grapes.

- (10) 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.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (12) 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

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
Jean-Claude JUNCKER