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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 fenarimol, metaflumizone and teflubenzuron in or on certain products (Text with EEA relevance)

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Delegations will find attached document D030333/02.

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Encl.: D030333/02



Brussels, **XXX**  
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(POOL/E3/2013/11865/11865-EN.doc)  
D030333/02  
[...] (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 fenarimol, metaflumizone and teflubenzuron 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 fenarimol, metaflumizone and teflubenzuron 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/EEC<sup>1</sup>, and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

- (1) For fenarimol maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For metaflumizone and teflubenzuron 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 metaflumizone on cucurbits (edible peel), melons, watermelons, broccoli, cauliflower, Chinese cabbage, lettuce and other salad plants, herbs, beans (with pods), peas (with pods), globe artichokes and cotton seed, an application was made in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (3) As regards teflubenzuron, such an application was made for crops belonging to the Solanaceae group and cucurbits (edible peel).
- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for fenarimol on apples, cherries, peaches, grapes strawberries, bananas, tomatoes, cucumbers, melons, pumpkins and watermelons. The applicant claims that the authorised uses of fenarimol on such crops in several third countries lead to residues exceeding the MRLs in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of these crops.

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

- (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 MRLs<sup>2</sup>. 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 fenarimol on peaches, grapes, strawberries, bananas, tomatoes and watermelons and the use of metaflumizone on melons, watermelons, herbs and salad plants (except lettuce), the submitted data are not sufficient to set new MRLs. As regards the use of metaflumizone on scarole, the Authority does not recommend setting the proposed MRL since a risk for consumers cannot be excluded. The existing MRLs should therefore remain unchanged.
- (8) As regards the use of metaflumizone on broccoli and lettuce, the Authority recommends setting lower MRLs than the ones proposed by the applicant.
- (9) As regards the use of teflubenzuron on Solanaceae crops and cucurbits (edible peel), the Authority identified chronic consumer intake concerns. However, the main contributor to the total exposure is apple. The Authority recommends lowering the MRL set for apples when increasing the MRLs for the above crops. Since such MRL was set to accommodate an import tolerance request based on authorised uses in Brazil, the applicant has been contacted in order to avoid trade barriers. The applicant proposed a fall-back MRL of 0,5 mg/kg, which is sufficient to accommodate the uses authorised in Brazil. As a high level of consumer protection is maintained, it is appropriate to set that MRL to 0,5 mg/kg.
- (10) 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 with regard to 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.
- (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.

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<sup>2</sup> EFSA scientific reports available online: <http://www.efsa.europa.eu>:  
Reasoned opinion of EFSA on the modification of the existing MRLs for fenarimol in various crops. EFSA Journal 2011; 9(9):2350 [32 pp.]. doi:10.2903/j.efsa.2011.2350.  
Reasoned opinion on the modification of the existing MRLs for metaflumizone in various commodities. EFSA Journal 2013; 11(7):3316 [50 pp.]. doi:10.2903/j.efsa.2013.3316.  
Reasoned opinion on the modification of the existing MRLs for teflubenzuron in various fruiting vegetables. EFSA Journal 2012; 10(3):2633 [27 pp.]. doi:10.2903/j.efsa.2012.2633.

- (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 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, third countries and food business operators 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*].

*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 Publications: 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*