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Subject: 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, bifenazate, captan, fluazinam, fluopicolide, folpet, kresoxim-methyl, penthiopyrad, proquinazid, pyridate and tembotrione in or on certain products

Delegations will find attached Commission document D024727/02.

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[...](2012) **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, bifenazate, captan, fluazinam, fluopicolide, folpet, kresoxim-methyl, penthiopyrad, proquinazid, pyridate and tembotrione 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 aminopyralid, bifenazate, captan, fluazinam, fluopicolide, folpet, kresoxim-methyl, penthiopyrad, proquinazid, pyridate and tembotrione 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) For bifenazate, captan, dimethoate, folpet, iprodione, kresoxim-methyl, pymetrozine and pyridate maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For aminopyralid, fluazinam, fluopicolide, proquinazid and tembotrione MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For penthiopyrad, no specific MRLs were set in Annex II and III nor was the substance included in Annex IV to Regulation (EC) No 396/2005, 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 aminopyralid on rape seed, an application was made in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL.
- (3) As regards bifenazate, such an application was made for citrus fruit, pome fruit, stone fruit, table and wine grapes, hops, strawberries, tomatoes, peppers, aubergines and cucurbits (inedible peel). As regards captan, such an application was made for tomatoes. As regards dimethoate, such an application was made for table olives and olives for oil production. As regards fluazinam, such an application was made for apples. As regards fluopicolide, such an application was made for lettuce and other salad plants, spinach and similar (leaves) and fresh herbs. As regards folpet, such an application was made for blackberries, raspberries, currants and gooseberries. As

¹ OJ L 70, 16.3.2005, p. 1.

regards iprodione, such an application was made for celeriac. As regards kresoxim-methyl, such an application was made for barley, rye and wheat. As regards proquinazid, such an application was made for tomatoes, aubergines and cucurbits (edible peel). As regards pymetrozine, such an application was made for lamb's lettuce and beans (with pods). As regards pyridate, such an application was made for dill leaves. As regards tembotrione, such an application was made for kidney and liver of bovine and swine considering residue levels in feed items resulting from the use of tembotrione on maize.

- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was made for fluopicolide on carrots, radishes and sugar beet. The applicant claims that the authorised use of fluopicolide on such 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 these crops.
- (5) As regards penthiopyrad, an application was made in accordance with Article 6(1) and (4) of Regulation (EC) No 396/2005 with a view of setting MRLs for tree nuts (except coconuts and pine nuts), pome fruit, cherries, peaches, plums, strawberries, root and tuber vegetables, garlic, onions, shallots, spring onions, tomatoes, peppers, aubergines, cucurbits, sweet corn, flowering brassica, head cabbage, Chinese cabbage, lettuce and other salad plants including brassicacea, spinach and similar (leaves), chervil, parsley leaves, beans (with and without pods), peas (with and without pods), cardoons, celery, fennel, rhubarb, leek, dry pulses, peanuts, sunflower seed, rape seed, soya bean, cotton seed, barley, maize, oats, rye, sorghum, wheat, sugar beet and animal commodities, considering residue levels in feed items. The applicant claims that the authorised use of that substance on such products in the United States and Canada leads to residues exceeding the MRLs in Regulation (EC) No 396/2005 and that the requested MRLs are needed to accommodate intended uses in the European Union and authorised uses in the United States and Canada. To avoid trade barriers for the importation of these products higher MRLs are necessary.
- (6) 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.

- (7) 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.
- (8) The Authority concluded in its reasoned opinions that, as regards the use of dimethoate on table olives and olives for oil production, the risk assessment in the framework of the reasoned opinion should be considered as provisional and may underestimate the actual risk to consumers as the final evaluation is still to be provided. As regards the use of iprodione on celeriac, the Authority highlighted deficiencies regarding the studies on the plant metabolism. As regards the use of penthiopyrad on Chinese cabbage and scarole, the Authority does not recommend setting the proposed MRL since a risk to consumers cannot be excluded. Furthermore, residue trials on maize, oilseed rape, cotton, sunflower and soya have been performed with a genetically modified crop. The applicant has to confirm that the metabolism of penthiopyrad in genetically modified crop proceeds in the same way as in its conventional counterpart. As regards the use of pymetrozine on lamb's lettuce and beans (with pods), the Authority concluded that the submitted data are not sufficient to set a new MRL. 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 with regard to consumer safety on the basis of a consumer

² EFSA scientific reports available online: <http://www.efsa.europa.eu>:
 Reasoned opinion on the modification of the existing MRL for aminopyralid in rape seed. EFSA Journal 2012;10(9):2894 [28 pp.]. doi:10.2903/j.efsa.2012.2894.
 Reasoned opinion on the modification of the existing MRL(s) for bifenazate in citrus fruit, pome fruit, stone fruit, grapes, hops, strawberries, tomatoes, peppers, aubergines, melons and watermelons. EFSA Journal 2012;10(10):2920 [45 pp.]. doi:10.2903/j.efsa.2012.2920.
 Reasoned opinion of EFSA: Modification of the existing MRLs for captan in certain berries. EFSA Journal 2011;9(11):2452 [31 pp.]. doi:10.2903/j.efsa.2011.2452.
 Reasoned opinion on the modification of the existing MRLs for dimethoate in olives for oil production and table olives. EFSA Journal 2012;10(5):2709 [31 pp.]. doi:10.2903/j.efsa.2012.2709.
 Reasoned opinion on the modification of the existing MRL for fluazinam in apples. EFSA Journal 2012;10(5):2710 [27 pp.]. doi:10.2903/j.efsa.2012.2710.
 Reasoned opinion on the modification of the existing MRLs for fluopicolide in various vegetable crops. EFSA Journal 2012;10(9):2895 [43 pp.]. doi:10.2903/j.efsa.2012.2895.
 Reasoned opinion of EFSA: Modification of the existing MRLs for folpet in wine grapes, garlic and tomatoes. EFSA Journal 2011;9(9):2391 [40 pp.]. doi:10.2903/j.efsa.2011.2391.
 Reasoned opinion on the modification of the existing MRL for iprodione in celeriac. EFSA Journal 2012;10(10):2947 [29 pp.]. doi:10.2903/j.efsa.2012.2947.
 Conclusion on the peer review of the pesticide risk assessment of the active substance kresoxim-methyl. EFSA Journal 2010;8(11):1891 [88 pp.]. doi:10.2903/j.efsa.2010.1891.
 Reasoned opinion on the setting of new MRLs for penthiopyrad in various crops. EFSA Journal 2012;10(10):2948 [96 pp.]. doi:10.2903/j.efsa.2012.2948.
 Reasoned opinion on the modification of the existing MRLs for proquinazid in tomatoes, aubergines and cucurbits with edible peel. EFSA Journal 2012;10(9):2896 [27 pp.]. doi:10.2903/j.efsa.2012.2896.
 Reasoned opinion on the modification of the existing MRLs for pymetrozine in lamb's lettuce and beans (with pods). EFSA Journal 2012;10(10):2939 [20 pp.]. doi:10.2903/j.efsa.2012.2939.
 Reasoned opinion on the modification of the existing MRL for pyridate in celery leaves (dill leaves). EFSA Journal 2012;10(9):2892 [25 pp.]. doi:10.2903/j.efsa.2012.2892.
 Reasoned opinion on the setting of new MRLs for tembotrione in kidney and liver of bovine and swine. EFSA Journal 2012;10(10):2932 [39 pp.]. doi:10.2903/j.efsa.2012.2932.

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 these substances via consumption of all food products that may contain these substances, nor the short-term exposure due to extreme 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) 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 the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

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 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 bifenazate, captan, folpet, kresoxim-methyl and pyridate are replaced by the following:

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

- (2) Part A of Annex III is amended as follows:

- (a) The columns for aminopyralid, fluazinam, fluopicolide, proquinazid and tembotrione are replaced by the following:

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

- (b) The following column for penthiopyrad is added:

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

- (3) In Part B of Annex III, the columns for bifenazate, captan, kresoxim-methyl and pyridate are replaced by the following:

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