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Subject:	COMMISSION REGULATION (EU) .../... 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, azoxystrobin, cyfluthrin, difluoroacetic acid, dimethomorph, fenpyrazamine, flonicamid, fluazinam, fludioxonil, flupyradifurone, flutriafol, fluxapyroxad, metconazole, proquinazid, prothioconazole, pyriproxyfen, spirodiclofen and trifloxystrobin in or on certain products

Delegations will find attached document D045663/02.

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COMMISSION REGULATION (EU) .../...

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, azoxystrobin, cyfluthrin, difluoroacetic acid, dimethomorph, fenpyrazamine, flonicamid, fluazinam, fludioxonil, flupyradifurone, flutriafol, fluxapyroxad, metconazole, proquinazid, prothioconazole, pyriproxyfen, spiroadiclofen and trifloxystrobin in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

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, azoxystrobin, cyfluthrin, difluoroacetic acid, dimethomorph, fenpyrazamine, flonicamid, fluazinam, fludioxonil, flupyradifurone, flutriafol, fluxapyroxad, metconazole, proquinazid, prothioconazole, pyriproxyfen, spiroadiclofen and trifloxystrobin 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 acetamiprid, azoxystrobin, dimethomorph, flonicamid, fludioxonil, flutriafol, metconazole, prothioconazole and trifloxystrobin, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For cyfluthrin, MRLs were set in Annex II and Part B of Annex III to that Regulation. For ametoctradin, difluoroacetic acid, fenpyrazamine, fluazinam, flupyradifurone, fluxapyroxad, proquinazid, pyriproxyfen and spiroadiclofen, MRLs were set in Part A of Annex III to that Regulation.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance acetamiprid on table olives, tomatoes, gherkins, beans (with pods), peas (with pods), pulses (dry), rapeseeds, olives for oil production and wheat, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

¹ OJ L 70, 16.3.2005, p. 1.

- (3) As regards ametoctradin, such an application was submitted for spring onions. As regards azoxystrobin, such an application was submitted for table and wine grapes. As regards cyfluthrin, such an application was submitted for barley, oat, rye and wheat following the use of beta-cyfluthrin on those products. As regards dimethomorph, such an application was submitted for flowering brassica and "spinach and similar leaves". As regards flonicamid, such an application was submitted for "herbs and edible flowers". As regards fludioxonil, such an application was submitted for "lettuce and salad plants", "spinach and similar leaves", "herbs and edible flowers" and peas (without pods). As regards difluoroacetic acid and flupyradifurone, such an application was submitted for strawberries, blackberries and raspberries following the use of flupyradifurone on those products. As regards proquinazid, such an application was submitted for apples and pears. As regards prothioconazole, such an application was submitted for sunflower seeds. As regards pyriproxyfen, such an application was submitted for bananas. As regards spirodiclofen, such an application was submitted for cranberries and gooseberries. As regards trifloxystrobin, such an application was submitted for celeriacs.
- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for dimethomorph used on papaya, fenpyrazamine on cane fruits and blueberries, fluazinam on blueberries, flutriafol on strawberries, fluxapyroxad on almonds, Brazil nuts, chestnuts, hazelnuts, macadamia, pecans, pine nut kernels, walnuts, cherries, grapes, strawberries, blueberries, mangoes, "other root and tuber vegetables" of code 0213000, cucurbits, broccoli, Chinese cabbages, mustard greens, cardoons, celeries, Florence fennel, rhubarbs, rice and sugar cane and metconazole on blueberries, potatoes, "tropical root and tuber vegetables", pulses and sunflower seeds. The applicants claim that the authorised uses of those substances on such crops in the United States, Canada and Brazil lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.
- (5) 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.

- (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 those opinions to the Commission and the Member States and made them available to the public.
- (7) The Authority concluded in its reasoned opinion that, as regards the use of fluxapyroxad in root and tuber vegetables other than radishes, the submitted data were not sufficient to set new MRLs. The existing MRLs should therefore be kept.

² EFSA scientific reports available online: <http://www.efsa.europa.eu>:
Reasoned opinion on the modification of the existing maximum residue levels for acetamiprid in various crops. EFSA Journal 2016;14(2):4385 [25 pp.].
Reasoned opinion on the modification of the existing maximum residue level for ametoctradin in spring onions. EFSA Journal 2016;14(4):4448 [19 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for azoxystrobin in grapes. EFSA Journal 2016;14(2):4415 [17 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for beta-cyfluthrin in various cereals. EFSA Journal 2016;14(3):4417 [23 pp.].
Reasoned opinion on the setting of import tolerance for dimethomorph in papaya. EFSA Journal 2016;14(4):4449 [19 pp.].
Reasoned opinion on the modification of the existing maximum residue levels (MRLs) for dimethomorph in various crops. EFSA Journal 2016;14(1):4381 [19 pp.].
Reasoned opinion on the setting import tolerances for fenpyrazamine in blueberries and cane fruits. EFSA Journal 2016;14(2):4384 [20 pp.].
Reasoned opinion on the modification of the existing maximum residue level for flonicamid in herbs and edible flowers. EFSA Journal 2016;14(4):4467 [19 pp.].
Reasoned opinion on the setting of import tolerance for fluazinam in blueberries. EFSA Journal 2016;14(4):4460 [20 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for fludioxonil in various crops. EFSA Journal 2016;14(3):4445 [20 pp.].
Reasoned opinion on the setting of new maximum residue levels for flupyradifurone in strawberries, blackberries and raspberries. EFSA Journal 2016;14(3):4423 [19 pp.].
Reasoned opinion on the setting of import tolerance for flutriafol in strawberries. EFSA Journal 2016;14(3):4427 [20 pp.].
Reasoned opinion on the setting of import tolerances for fluxapyroxad in various crops. EFSA Journal 2016;14(3):4404 [28 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for metconazole in various crops. EFSA Journal 2016;14(4):4451 [23 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for proquinazid in apples, pears and animal commodities. EFSA Journal 2016;14(3):4428 [24 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for prothioconazole in sunflower seeds. EFSA Journal 2015;13(12):4371 [24 pp.].
Reasoned opinion on the modification of the existing maximum residue level for pyriproxyfen in bananas. EFSA Journal 2016;14(2):4387 [18 pp.].
Reasoned opinion on the modification of the existing maximum residue levels (MRLs) for spirodiclofen in berries. EFSA Journal 2016;14(4):4457 [17 pp.].
Reasoned opinion on the modification of the existing maximum residue level (MRL) for trifloxystrobin in celeriacs. EFSA Journal 2016;14(1):4383 [17 pp.].

- (8) As regards proquinazid, the Authority recommended increasing the existing MRLs for liver and kidney in sheep and goat in order to accommodate for the intended uses of that active substance on apples and pears. As no residues of proquinazid are found in ruminant products, it is appropriate to limit the enforcement residue definition to the relevant metabolite only (IN-MU210).
- (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 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 them, nor the short-term exposure due to high consumption of the relevant products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.
- (10) For flupyradifurone, the Authority submitted a conclusion on the peer review of the pesticide risk assessment of the active substance³. According to the relevant good agricultural practice, the MRL for difluoroacetic acid in lettuce needs to be set at 0.09 mg/kg to adequately address the use of flupyradifurone on that product.
- (11) Based on the reasoned opinions and the conclusion 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 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.

³ Conclusion on the peer review of the pesticide risk assessment of the active substance flupyradifurone. EFSA Journal 2015;13(2):4020 [101 pp.].

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