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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, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products
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Delegations will find attached document D48316/03.

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Brussels, **XXX**
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[...](2016) **XXX** draft

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, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products

(Text with EEA relevance)

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

of **XXX**

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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) On 11 July 2015, the Codex Alimentarius Commission (CAC) adopted Codex maximum residue limits (CXLs) for mesotrione². On 1 July 2016, CAC adopted CXLs for abamectin, acetamiprid, acetochlor, chlorothalonil, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, flonicamid, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, lufenuron, profenofos, propiconazole, pyrimethanil, quinclorac, spirotetramat, tebuconazole, triazophos and trifloxystrobin³.
- (2) Maximum residue levels (MRLs) are set for those substances in Regulation (EC) No 396/2005.
- (3) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴, where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation

¹ OJ L 70, 16.3.2005, p. 1.

² ftp://ftp.fao.org/codex/reports/reports_2015/REP15_PRe.pdf
Joint FAO/WHO food standards programme Codex Alimentarius Commission. Appendices III and IV. Thirty-Eight Session. Geneva, Switzerland, 6-11 July 2015.

³ http://www.fao.org/fao-who-codexalimentarius/sh-proxy/ar/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMee%252FCX-718-48%252FReport%252FREP16_PRe.pdf
Joint FAO/WHO food standards programme Codex Alimentarius Commission. Appendix II. Thirty-Ninth Session. Rome, Italy, 27 June – 1 July 2016.

⁴ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community. Moreover, in accordance with point (e) of Article 13 of that Regulation, the Union is to promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Union is not reduced.

- (4) The Union presented a reservation to the Codex Committee on Pesticides Residues (CCPR) on the CXLs proposed for the following pesticide/product combinations: abamectin (all products); acetochlor (all products); chlorothalonil (all products); cyantraniliprole (milk); ethephon (barley; rye; wheat); flonicamid (all products); flutriafol (brassica vegetables; celery; cucurbits; peppers; pome fruit; products of animal origin); fluxapyroxad (celery; berries and other small fruits; brassica vegetables; brassica leafy vegetables; carrot; fruiting vegetables; cucurbits; garlic; onion; parsnip; shallot); lufenuron (all products); mesotrione (asparagus; bush berries; cane berries; cranberry; mammalian edible offal; eggs; mammalian meats; milks; okra; poultry edible offal; poultry meat; rhubarb; sugar cane); quinclorac (all products) and tebuconazole (sunflower seed).
- (5) CXLs for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin, which are not listed in recital 4, should therefore be included in Regulation (EC) No 396/2005 as MRLs except where they relate to products which are not set out in Annex I to that Regulation or where they are set at a lower level than the current MRLs. Those CXLs are safe for consumers in the Union⁵.
- (6) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance spirotetramat on kaki, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (7) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for flutriafol used on cucurbits with edible peel. The applicant claims that the authorised uses of that substance on such crops in the United States 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.
- (8) 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.
- (9) The European Food Safety Authority, hereinafter 'the Authority', assessed the applications and the evaluation reports, examining in particular the risks to the

⁵ Scientific support for preparing an EU position in the 47th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2015;13(7):4208 [178 pp.].
Scientific support for preparing an EU position in the 48th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2016;14(8):4571 [166 pp.].

consumer and, where relevant, to animals and gave reasoned opinions on the proposed MRLs⁶. It forwarded those opinions to the Commission and the Member States and made them available to the public.

- (10) As regards the uses covered by those 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 crops and products showed that there is a risk that the acceptable daily intake or the acute reference dose 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.
- (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.

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

⁶ EFSA scientific reports available online: <http://www.efsa.europa.eu>. Reasoned opinion on the setting of import tolerance for flutriafol in cucurbits with edible peel. EFSA Journal 2016;14(9):4577 [16 pp.]. Reasoned opinion on the modification of the existing maximum residue levels for spirotetramat in various crops. EFSA Journal 2016;14(3):4429 [34 pp.].