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#### COVER NOTE

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From:	European Commission
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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlorpyrifos-methyl, cyproconazole, difenoconazole, fluazinam, flutriafol, prohexadione and sodium chloride in or on certain products

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Delegations will find attached document D052943/02.

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Brussels, **XXX**  
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(POOL/E4/2017/11234/11234-EN.doc)  
D052943/02  
[...](2017) **XXX** draft

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

**of **XXX****

**amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlorpyrifos-methyl, cyproconazole, difenoconazole, fluazinam, flutriafol, prohexadione and sodium chloride in or on certain products**

(Text with EEA relevance)

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

of **XXX**

**amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlorpyrifos-methyl, cyproconazole, difenoconazole, fluazinam, flutriafol, prohexadione and sodium chloride 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 5(1) and Article 14(1)(a) thereof,

Whereas:

- (1) For fluazinam, flutriafol and prohexadione, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For chlorpyrifos-methyl, MRLs were set in Annex II and Part B of Annex III to that Regulation. For ametoctradin, cyproconazole and difenoconazole, MRLs were set in Part A of Annex III to that Regulation. For sodium chloride, no specific MRLs were set nor was that substance included in Annex IV to that Regulation, so the default value of 0.01 mg/kg laid down in Article 18(1)(b) thereof applies.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance ametoctradin on "herbs and edible flowers", an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (3) As regards chlorpyrifos-methyl, such an application was submitted for Japanese persimmons and pomegranates. As regards cyproconazole, such an application was submitted for borage seeds. As regards difenoconazole, such an application was submitted for apricots, strawberries, head brassica, "lettuces and salad plants", chards, "herbs and edible flowers", cardoons, celeries, leeks, rhubarbs, pulses, barley and "root and rhizome spices". As regards fluazinam, such an application was submitted for onions, shallots and garlic. As regards prohexadione, such an application was submitted for plums.
- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for flutriafol used on hops. The applicant claims that the authorised uses of that substance on such crop in the United States 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.

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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, 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 MRLs<sup>2</sup>. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.
- (7) As regards cyproconazole, the Authority assessed an application with a view of setting an MRL for rapeseed and gave a reasoned opinion on the proposed MRL<sup>3</sup>. In accordance with the existing Union guidelines on extrapolation of MRLs, it is appropriate to set the MRL for rapeseed also for borage seeds.
- (8) 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.
- (9) Sodium chloride is approved as basic substance by Commission Implementing Regulation (EU) 2017/1529<sup>4</sup>. The conditions of use of that substance are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer. It is therefore appropriate to include that substance in Annex IV to Regulation (EC) No 396/2005.
- (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.

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<sup>2</sup> EFSA scientific reports available online: <http://www.efsa.europa.eu>:  
Reasoned opinion on the modification of the existing maximum residue levels for ametoctradin in herbs and edible flowers. EFSA Journal 2017;15(6):4869 [21 pp.].  
Reasoned opinion on the modification of the existing maximum residue levels for chlorpyrifos-methyl in kaki/Japanese persimmon and granate apple/pomegranate. EFSA Journal 2017;15(5):4838 [24 pp.].  
Reasoned opinion on the modification of the existing maximum residue levels for difenoconazole in various crops. EFSA Journal 2017;15(7):4893 [33 pp.].  
Reasoned opinion on the modification of the existing maximum residue levels for fluazinam in onions, shallots and garlic. EFSA Journal 2017;15(7):4904 [22 pp.].  
Reasoned opinion on the setting of import tolerance for flutriafol in hops. EFSA Journal 2017;15(7):4875 [22 pp.].  
Reasoned opinion on the modification of the existing maximum residue level for prohexadione (considered variant prohexadione-calcium) in plums. EFSA Journal 2017;15(6):4837 [20 pp.].

<sup>3</sup> Reasoned opinion on the modification of the existing MRLs for cyproconazole in rapeseed. EFSA Journal 2011;9(5):2187 [30 pp.].

<sup>4</sup> Commission Implementing Regulation (EU) 2017/1529 of 7 September 2017 approving the basic substance sodium chloride in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 232, 8.9.2017, p. 1).

- (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, III and IV 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*