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Subject: COMMISSION REGULATION (EU) .../... of XXX amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products

Delegations will find attached document D055526/02.

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EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/12049/2017
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D055526/02
[...] (2018) **XXX** draft

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

of **XXX**

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products

(Text with EEA relevance)

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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) and Article 18(4) thereof,

Whereas:

- (1) For cyantraniliprole, cymoxanil, deltamethrin, fenamidone, folpet, mandestrobin, mepiquat, metazachlor, propamocarb, pyrimethanil, sulfoxaflor and trifloxystrobin, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For difenoconazole, flubendiamide, fluopicolide and fosetyl, MRLs were set in Part A of Annex III to that Regulation. For propargite, MRLs were set in Annex V to that Regulation.
- (2) On 11 July 2015, Codex Alimentarius Commission adopted Codex maximum residue limits (CXLs) for fenamidone².
- (3) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council³, where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation 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

¹ OJ L 70, 16.3.2005, p. 1.

² [ftp://ftp.fao.org/codex/reports/reports_2015/REP15_PRe.pdf](http://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 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).

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 Union. 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 on the CXLs proposed for the following pesticide/product combinations: fenamidone (flowerhead brassicas; fruiting vegetables other than cucurbits).
- (5) CXLs for fenamidone, 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 Union⁴.
- (6) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance cymoxanil on beans without pods, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (7) As regards deltamethrin, such an application was submitted for kale. As regards difenoconazole, such an application was submitted for "other flowering brassica", Brussels sprouts, escaroles, rocket, "spinaches and similar leaves", witloof and rhubarb. As regards fluopicolide, such an application was submitted for chards. As regards folpet, such an application was submitted for apples and pears. As regards fosetyl, such an application was submitted for pome fruits, peaches and potatoes. As regards mandestrobin, such an application was submitted for apricots, cherries, peaches and plums. As regards metazachlor, such an application was submitted for Chinese cabbage. As regards propamocarb, such an application was submitted for chards. As regards pyrimethanil, such an application was submitted for cucurbits with edible peel. As regards sulfoxaflor, such an application was submitted for grape leaves and globe artichokes. As regards trifloxystrobin, such an application was submitted for "other small fruits and berries", "lettuces and salad plants", purslanes, beans without pods, peas and pulses.
- (8) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 applications were submitted for flubendiamide used in the United States on apricots, peaches, plums and soyabeans, for disodium phosphonate used in the United States on tree nuts (except coconuts) and for propargite used in Brazil on oranges and India on tea. The applicants claim that the authorised uses of those substances on such crops in the respective exporting countries 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.
- (9) In accordance with Article 53 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁵, on 8 August 2017 the United Kingdom informed the

⁴ Scientific support for preparing an EU position for the 46th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2014;12(7):3737 [182 pp.].

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

Commission that it has authorised the placing on the market of a plant protection product containing the active substance cyantraniliprole to be used on blackberries and raspberries, due to an unexpected outbreak of *Drosophila suzukii*. On 13 September 2017, in accordance with Article 53 the United Kingdom informed the Commission of an authorisation of a plant protection product containing the active substance cyantraniliprole for the use on leeks due to an unexpected outbreak of *Thrips tabaci*, *Frankliniella occidentalis*, *Delia antiqua* and *Phytomyza gymnostoma*. Such authorisations appeared a necessary measure, because the outbreak of those pests constituted a danger that could not be contained by any other reasonable means. The United Kingdom has notified the authorisations to the other Member States, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 18(4) of Regulation (EC) No 396/2005 and submitted applications with a view to setting temporary MRLs for those crops.

- (10) In accordance with Article 53 of Regulation (EC) No 1107/2009, on 19 September 2017 Greece informed the Commission that it has authorised the placing on the market of a plant protection product containing the active substance mepiquat to be used on cotton as a plant growth regulator. Such authorisation appeared a necessary measure to avoid losses in yield. Greece has notified the authorisation to the other Member States, the Commission and the Authority in accordance with Article 18(4) of Regulation (EC) No 396/2005 and submitted an application with a view to setting a temporary MRL for cotton seeds.
- (11) 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.
- (12) 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 MRLs⁶. The Authority forwarded those opinions to the

⁶ EFSA scientific reports available online: <http://www.efsa.europa.eu>:

Reasoned opinion on the setting of maximum residue levels for cyantraniliprole in raspberries and blackberries. EFSA Journal 2017;15(11):5061 [24 pp.].

Reasoned opinion on the setting of maximum residue levels for cyantraniliprole in leeks. EFSA Journal 2018;16(1):5124 [24 pp.].

Reasoned opinion on the modification of the existing maximum residue level for cymoxanil in beans without pods. EFSA Journal 2017;15(11):5066 [19 pp.].

Reasoned opinion on the modification of the existing maximum residue level for deltamethrin in kale. EFSA Journal 2018;16(1):4683 [28 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for difenoconazole in various crops. EFSA Journal 2018;16(1):5143 [28 pp.].

Reasoned opinion on the setting of import tolerances for flubendiamide in apricots, peaches, nectarines, plums and soya beans. EFSA Journal 2018;16(1):5128 [31 pp.].

Reasoned opinion on the modification of the existing maximum residue level for fluopicolide in chards. EFSA Journal 2018;16(1):5135 [21 pp.].

Reasoned opinion on the Modification of the existing maximum residue levels for folpet in apples and pears. EFSA Journal 2017;15(10):5041 [21 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for fosetyl-Al in tree nuts, pome fruit, peach and potato. EFSA Journal 2018;16(2):5161 [36 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for mandestrobin in apricots, cherries, peaches/nectarines and plums. EFSA Journal 2018;16(1):5148 [22 pp.].

Reasoned opinion on the setting of maximum residue levels for mepiquat chloride in cotton. EFSA Journal 2018;16(2):5162 [25 pp.].

Reasoned opinion on the modification of the existing maximum residue level for metazachlor in

applicants, the Commission and the Member States and made them available to the public.

- (13) The Authority concluded in its reasoned opinion that, as regards the use of deltamethrin on kale, the risk assessment is affected by non-standard uncertainties. However, considering the low contribution of kale to the overall dietary exposure, it is appropriate to set the MRL at 0,15 mg/kg.
- (14) As regards trifloxystrobin, the applicant submitted the missing information on analytical methods for products of animal origin and made the reference standard for CGA321113 commercially available.
- (15) As regards the use of flubendiamide on soyabeans, the current MRL is set at 0,25 mg/kg in the exporting country. Considering that the highest residue measured in supervised field trials is slightly above that value, it is appropriate to set the MRL at a rounded value of 0,3 mg/kg.
- (16) As regards the use of cyantraniliprole on blackberries, raspberries and leeks, MRLs should be set as temporary valid until 30 June 2021.
- (17) As regards the use of mepiquat on cotton, the MRL should be set for cotton seeds as temporary valid until 30 June 2021.
- (18) 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. The Authority 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.
- (19) 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.
- (20) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (21) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

Chinese cabbage. EFSA Journal 2018;16(1):5127 [20 pp.].

Reasoned opinion on the modification of the existing maximum residue level for propamocarb in chards/beet leaves. EFSA Journal 2017;15(11):5055 [22 pp.].

Reasoned opinion on the setting of import tolerances for propargite in citrus fruits and tea. EFSA Journal 2018;16(2):5193 [25 pp.].

Reasoned opinion on the modification of the existing maximum residue level for pyrimethanil in cucurbits with edible peel. EFSA Journal 2018;16(2):5145 [20 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for sulfoxaflor in grape leaves and similar species, and globe artichokes. EFSA Journal 2017;15(11):5070 [23 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for trifloxystrobin in various crops. EFSA Journal 2018;16(1):5154 [33 pp.].

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III and V 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*