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COVER NOTE

From:	European Commission
date of receipt:	9 April 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

No. Cion doc.:	D032091/02
Subject:	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 2-phenylphenol, chlormequat, cyflufenamid, cyfluthrin, dicamba, fluopicolide, flutriafol, fosetyl, indoxacarb, isoprothiolane, mandipropamid, metaldehyde, metconazole, phosmet, picloram, propyzamide, pyriproxyfen, saflufenacil, spinosad and trifloxystrobin in or on certain products (Text with EEA relevance)

Delegations will find attached document D032091/02.

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D032091/02
[...](2014) **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 2-phenylphenol, chlormequat, cyflufenamid, cyfluthrin, dicamba, fluopicolide, flutriafol, fosetyl, indoxacarb, isoprothiolane, mandipropamid, metaldehyde, metconazole, phosmet, picloram, propyzamide, pyriproxyfen, saflufenacil, spinosad and trifloxystrobin in or on certain products

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COMMISSION REGULATION (EU) No .../..

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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 2-phenylphenol, chlormequat, cyflufenamid, cyfluthrin, dicamba, fluopicolide, flutriafol, fosetyl, indoxacarb, isoprothiolane, mandipropamid, metaldehyde, metconazole, phosmet, picloram, propyzamide, pyriproxyfen, saflufenacil, spinosad 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 2-phenylphenol, indoxacarb and metconazole maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For chlormequat, cyfluthrin, propyzamide and trifloxystrobin MRLs were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For cyflufenamid, dicamba, fluopicolide, flutriafol, fosetyl, isoprothiolane, mandipropamid, metaldehyde, phosmet, picloram, pyriproxyfen and spinosad MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. As regards saflufenacil, no specific MRLs were set nor was the substance included in Annex IV to that Regulation, so the default value of 0.01 mg/kg laid down in Article 18(1)(b) of that Regulation applies.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance chlormequat on pears, cereals and products of animal origin, 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 cyflufenamid, such an application was made for strawberries and peppers. As regards cyfluthrin, such an application was made for artichokes. As regards dicamba, such an application was made for herbs and herbal infusions (leaves and flowers). As regards fluopicolide, such an application was made for hops. As regards fosetyl, such an application was made for kiwi, potatoes and spices. As regards

¹ OJ L 70, 16.3.2005, p. 1.

indoxacarb, such an application was made for beans (with pods) and mustard seed. As regards mandipropamid, such an application was made for tomatoes. As regards metaldehyde, such an application was made for beans (fresh and dry) and peas (fresh and dry). As regards metconazole, such an application was made for barley and oats. As regards phosmet, such an application was made for citrus fruit and pome fruit. As regards picloram, such an application was made for rape seed and mustard seed. As regards propyzamide, such an application was made for herbal infusions (leaves, flowers and roots). As regards spinosad, such an application was made for small fruit and berries of code number 0154000 and products of animal origin. As regards trifloxystrobin, such an application was made for horseradish, parsley root and purslane.

- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for saflufenacil on oranges, lemons, grapefruit, almond, pecan nuts, apples, pears, peaches, plums, cherries, grapes, banana, mango, potatoes, legume vegetables, sweet corn, maize, wheat, rice, barley, oat, rye, sorghum, millet, sugar cane, dry peas, dry beans, soya bean, sunflower seed, cotton seed and coffee beans. The applicant claims that the authorised use of that substance on such crops in Latin America, the United States and Canada leads to residues exceeding the MRLs in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.
- (5) Such applications were also submitted as regards fluopicolide on root and tuber vegetables and as regards flutriafol on pome fruits, cherries, peaches and plums. In both cases the applicants claim that the authorised use of those substances on such crops in the United States leads to residues exceeding the MRLs in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops. As regards pyriproxyfen, such an application was made for stone fruits and tea. The applicant claims that the authorised use of that substance on such crops in the United States and Japan leads to residues exceeding the MRLs in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.
- (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.

² EFSA scientific reports available online: <http://www.efsa.europa.eu>:
Reasoned opinion on the modification of the existing MRLs for chlormequat in pears, cereals and commodities of animal origin. EFSA Journal 2014;12(1):3544 [57 pp.]. doi:10.2903/j.efsa.2014.3544.
Reasoned opinion on the modification of the existing MRLs for cyflufenamid in strawberries and peppers. EFSA Journal 2014;12(1):3542 [26 pp.]. doi:10.2903/j.efsa.2014.3542.
Reasoned opinion on the modification of the existing MRL for cyfluthrin in artichokes. EFSA Journal 2013;11(10):3448 [26 pp.]. doi:10.2903/j.efsa.2013.3448.
Reasoned opinion on the modification of the existing MRLs for dicamba in herbs and herbal infusions (leaves and flowers). EFSA Journal 2013;11(11):3470 [25 pp.]. doi:10.2903/j.efsa.2013.3470.

- (8) The Authority concluded in its reasoned opinions that, as regards the use of fosetyl on potatoes, propyzamide on roots of herbal infusions, pyriproxyfen on apricots and trifloxystrobin on purslane, the submitted data were not sufficient to set a new MRL. The existing MRLs should therefore remain unchanged.
- (9) As regards the use of spinosad on small fruit and berries, the Authority concluded that the submitted data are sufficient to set a new MRL based on the indoor use.
- (10) As regards chlormequat in pears, a MRL was set until 31 July 2014 to accommodate for the carry-over of chlormequat residues due to formerly authorised uses on pear trees. Since monitoring data show that residues are still found at a level higher than the limit of determination (LOD), it is appropriate to extend the validity of the MRL until the entry into force of the Regulation reviewing the existing MRLs for chlormequat.
- (11) As regards fosetyl, the Authority based its reasoned opinion on the enforcement residue definitions proposed in the framework of the review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005. Since other substances, for which the MRLs are currently under review, have a shared metabolite with fosetyl, it is appropriate to keep the existing residue definition unchanged until the review of those substances has been carried out. Therefore, the Commission requested the Authority to recommend MRLs according to the current enforcement residue definition. The Authority recommended setting MRLs of 150 mg/kg for kiwi and 400 mg/kg for spices.
- (12) 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

Reasoned opinion on the modification of the existing MRLs for fluopicolide in hops and certain root and tuber vegetables. *EFSA Journal* 2013;11(11):3459 [39 pp.]. doi:10.2903/j.efsa.2013.3459.

Reasoned opinion on the modification of the existing MRLs for flutriafol in pome fruits, peaches, cherries and plums. *EFSA Journal* 2013;11(10):3446 [25 pp.]. doi:10.2903/j.efsa.2013.3446.

Reasoned opinion on the modification of the existing MRLs for fosetyl in potato, kiwi and certain spices. *EFSA Journal* 2012;10(12):3019 [43 pp.]. doi:10.2903/j.efsa.2012.3019.

Reasoned opinion on the modification of the existing MRLs for indoxacarb in beans (with pods) and mustard seed. *EFSA Journal* 2013;11(11):3458 [27 pp.]. doi:10.2903/j.efsa.2013.3458.

Reasoned opinion on the modification of the existing MRL for mandipropamid in tomato. *EFSA Journal* 2013;11(11):3466 doi:10.2903/j.efsa.2013.3466.

Reasoned opinion on the modification of the existing MRLs for metaldehyde in certain legume vegetables and pulses. *EFSA Journal* 2014;12(1):3537 [25 pp.]. doi:10.2903/j.efsa.2014.3537.

Reasoned opinion on the modification of the existing MRLs for metconazole in barley and oats. *EFSA Journal* 2013;11(4):3185 [38 pp.]. doi:10.2903/j.efsa.2013.3185.

Reasoned opinion on the modification of the existing MRLs for phosmet in citrus fruits, pome fruits and rape seed. *EFSA Journal* 2013;11(12):3510 [33 pp.]. doi:10.2903/j.efsa.2013.3510.

Reasoned opinion on the modification of the existing MRLs for picloram in rape seed and mustard seed. *EFSA Journal* 2013;11(10):3439 [27 pp.]. doi:10.2903/j.efsa.2013.3439.

Reasoned opinion on the modification of the existing MRLs for propyzamide in leaves, flowers and roots of herbal infusions. *EFSA Journal* 2013;11(9):3378 [28 pp.]. doi:10.2903/j.efsa.2013.3378.

Reasoned opinion on the setting of MRLs for saflufenacil in various crops, considering the risk related to the metabolite trifluoroacetic acid (TFA). *EFSA Journal* 2014;12(2):3585 [58 pp.]. doi:10.2903/j.efsa.2014.3585.

Reasoned opinion on the modification of the existing MRLs for spinosad in small fruit and berries and several commodities of animal origin. *EFSA Journal* 2013;11(11):3447 [38 pp.]. doi:10.2903/j.efsa.2013.3447.

Reasoned opinion on the modification of the existing MRLs for trifloxystrobin in horseradish, parsley root and purslane. *EFSA Journal* 2013;11(8):3349 [25 pp.]. doi:10.2903/j.efsa.2013.3349.

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 (ADI) or the acute reference dose (ARfD) is exceeded.

- (13) As regards 2-phenylphenol in citrus fruit, MRLs were set until 30 September 2014, pending the submission and evaluation of two additional residue trials on citrus fruit and valid storage stability studies. Those trials and data were submitted to Spain, rapporteur Member State for that substance, in March 2012. Spain evaluated those data and prepared an evaluation report, which was submitted to the Commission on 18 July 2012. In order to provide the necessary time for the Authority to evaluate that report and for the Commission to take its decision, it is appropriate to extend the validity of these MRLs until the entry into force of the Regulation reviewing the existing MRLs for 2-phenylphenol.
- (14) As regards isoprothiolane in rice, the applicant was requested to submit studies investigating the nature of isoprothiolane under baking/boiling conditions to the evaluating Member State, the Authority and the European Commission by 31 December 2013. Such data was submitted within the deadline and both the evaluating Member State and the Authority concluded there was no need to modify the existing MRL.
- (15) On 7 July 2012 the Codex Alimentarius Commission (CAC)³ adopted Codex maximum residue limits (CXLs) for saflufenacil on edible offal (mammalian) and rape seed. These CXLs are safe for consumers in the Union and should therefore be included in Regulation (EC) No 396/2005 as MRLs⁴.
- (16) 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.
- (17) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

³ Codex Committee on Pesticide Residues reports available on:
http://www.codexalimentarius.org/download/report/777/REP12_PRe.pdf

Joint FAO/WHO food standards programme Codex Alimentarius Commission. Appendix II and III. Thirty-Fifth Session. Rome, Italy, 2 - 7 July 2012.

⁴ Scientific support for preparing an EU position in the 44th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2012; 10(7):2859 [155 pp.]. doi:10.2903/j.efsa.2012.2859.

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
José Manuel BARROSO