



Council of the  
European Union

Brussels, 5 December 2014  
(OR. en)

16595/14

AGRILEG 255

**COVER NOTE**

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From:	European Commission
date of receipt:	4 December 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

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No. Cion doc.:	D035768/02
Subject:	COMMISSION REGULATION (EU) No .../. 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 1,4-dimethylnaphthalene, benfuracarb, carbofuran, carbosulfan, ethephon, fenamidone, fenvalerate, fenhexamid, furathiocarb, imazapyr, malathion, picoxystrobin, spirotetramat, tepraloxymid and trifloxystrobin in or on certain products (Text with EEA relevance)

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Delegations will find attached document D035768/02.

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Encl.: D035768/02



Brussels, **XXX**  
SANCO/11658/2014 Rev. 1  
(POOL/E3/2014/11658/11658R1-  
EN.doc) D035768/02  
[...](2014) **XXX** draft

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

**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 1,4-dimethylnaphthalene, benfuracarb, carbofuran, carbosulfan, ethephon, fenamidone, fenvalerate, fenhexamid, furathiocarb, imazapyr, malathion, picoxystrobin, spirotetramat, tepraloxym and trifloxystrobin in or on certain products**

(Text with EEA relevance)

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

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 1,4-dimethylnaphthalene, benfuracarb, carbofuran, carbosulfan, ethephon, fenamidone, fenvalerate, fenhexamid, furathiocarb, imazapyr, malathion, picoxystrobin, spirotetramat, tepraloxydim 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/EEC<sup>1</sup>, and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

- (1) For ethephon, fenvalerate, picoxystrobin and tepraloxydim maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For carbofuran, carbosulfan, fenamidone, fenhexamid and trifloxystrobin MRLs were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For malathion and spirotetramat MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For benfuracarb and furathiocarb MRLs were set in Annex V to Regulation (EC) No 396/2005. As regards 1,4-dimethylnaphthalene and imazapyr, no specific MRLs were set in these Annexes, nor were the substances included in Annex IV to that Regulation, so the default value of 0.01 mg/kg applies.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance 1,4-dimethylnaphthalene on potatoes, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL.
- (3) As regards esfenvalerate, such an application was made for peppers, broccoli and lettuce. As regards ethephon, an application for modification of the existing MRLs was made for table olives. As regards fenhexamid, such an application was made for blueberries, cranberries, gooseberries and azarole. As regards malathion, such an application was made for citrus fruit, strawberries and lettuce. As regards picoxystrobin, such an application was made for sugar beet. As regards spirotetramat,

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

such an application was made for olives for oil production. As regards tepraloxym, such an application was made for Jerusalem artichokes and radishes. As regards trifloxystrobin, such an application was made for cane fruit.

- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for fenamidone used on root and tuber vegetables of code number 0213000, bulb vegetables, tomatoes, peppers, Chilli peppers, aubergines, broccoli, Chinese cabbage, lettuce and other salad plants, spinach and similar (leaves), herbs, cardoons, celery, fennel and rhubarb. 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.
- (5) As regards imazapyr, an application for modification of the existing MRLs was submitted on genetically modified soya bean, lentils, sunflower seed, rape seed, mustard seed. The applicant claims that the authorised uses of such substance on those crops in Argentina, Brazil and Canada lead 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 malathion, such an application was submitted on apple, pears and plums. The applicant claims that the authorised uses of that substance on those crops in Argentina, Chile and South Africa lead 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 MRLs<sup>2</sup>. It forwarded these opinions to the Commission and the Member States and made them available to the public.

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<sup>2</sup> EFSA scientific reports available online: <http://www.efsa.europa.eu>:

Reasoned opinion on the setting of a new MRL for 1,4-dimethylnaphthalene in potatoes. EFSA Journal 2014;12(6):3735 [24 pp.]. doi:10.2903/j.efsa.2014.3735.

Reasoned Opinion on the modification of the existing maximum residue levels for esfenvalerate in peppers, broccoli and lettuce. EFSA Journal 2014;12(5):3693 [27 pp.]. doi:10.2903/j.efsa.2014.3693.

Reasoned opinion on the modification of the existing MRLs for ethephon in table olive and table grape. EFSA Journal 2014;12(5):3698 [22 pp.]. doi:10.2903/j.efsa.2014.3698.

Reasoned opinion on the modification of the existing MRLs for fenamidone in various vegetables. EFSA Journal 2014;12(3):3627 [36 pp.]. doi:10.2903/j.efsa.2014.3627.

Reasoned opinion on the modification of the MRLs for fenhexamid in various berries. EFSA Journal 2014;12(7):3785 [18 pp.]. doi:10.2903/j.efsa.2014.3785.

Reasoned opinion on the setting of MRLs for imazapyr in genetically modified soya bean and other oilseeds and in lentils. EFSA Journal 2014;12(6):3743 [31 pp.]. doi:10.2903/j.efsa.2014.3743.

Reasoned Opinion on the modification of the existing MRLs for malathion in various crops. EFSA Journal 2014;12(2):3588 [56 pp.]. doi:10.2903/j.efsa.2014.3588.

- (8) The Authority concluded in its reasoned opinion that the submitted data were not sufficient to set new MRLs for the use of malathion on apples, pears, plums and strawberries. The existing MRLs should therefore remain unchanged.
- (9) The Commission has been informed by the European Spice Association that a significant number of lots of dried white mushrooms imported from China contain residue levels of carbofuran above 0,1 mg/kg. In accordance with Article 43 of Regulation (EC) No 396/2005, the Commission asked the Authority to evaluate that information for the purpose of setting an import tolerance on cultivated mushrooms. In parallel, the Commission asked the Authority to review all existing MRLs for the N-methyl-carbamate insecticides carbofuran, carbosulfan, benfuracarb and furathiocarb, including the MRLs set by the Codex Alimentarius Commission (CXLs) that were implemented by that Regulation.
- (10) In its reasoned opinion of 3 February 2014<sup>3</sup> the Authority recommended maintaining the MRL for carbofuran in fresh cultivated mushrooms at the current limit of determination (LOD) of 0,01 mg/kg, since higher values may result in an acute consumer intake concern. Moreover, the Authority recommended the deletion of the MRLs set for carbofuran and carbosulfan on mandarin, orange, sunflower, rape seed and spices, which correspond to CXLs. As regards carbofuran, in view of its low toxicological reference values, the Authority recommended setting MRLs below the current LOD for products that contribute significantly to consumer diets.
- (11) The Commission consulted the European Union reference laboratories which provided evidence that during the analytical process, carbosulfan, benfuracarb and furathiocarb are partially converted to carbofuran. It is therefore appropriate to set a common residue definition for the N-methyl carbamate compounds. In addition, the European Union reference laboratories confirmed that for certain products technical development permits the setting of lower LODs.
- (12) 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.
- (13) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.
- (14) Regulation (EC) No 396/2005 should therefore be amended accordingly.

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Reasoned opinion on the modification of the existing MRL for picoxystrobin in sugar beet. EFSA Journal 2014;12(5):3716 [26 pp.]. doi:10.2903/j.efsa.2014.3716.

Reasoned opinion on the modification of the existing MRLs for spirotetramat in olives for oil production. EFSA Journal 2014;12(6):3739 [25 pp.]. doi:10.2903/j.efsa.2014.3739.

Reasoned opinion on the modification of the existing MRLs for tepraloxydim in Jerusalem artichoke and radishes. EFSA Journal 2014;12(7):3788 [18 pp.]. doi:10.2903/j.efsa.2014.3788.

Reasoned opinion on the modification of the existing MRL for trifloxystrobin in cane fruit. EFSA Journal 2014;12(7):3751 [17 pp.]. doi:10.2903/j.efsa.2014.3751.

<sup>3</sup> Reasoned opinion on the review of the existing MRLs for carbofuran, carbosulfan, benfuracarb and furathiocarb and the setting of an import tolerance for carbofuran in cultivated mushrooms. EFSA Journal 2014;12(2):3559 [38 pp.]. doi:10.2903/j.efsa.2014.3559.

- (15) In order to allow normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been lawfully produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (16) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States and interested parties to prepare themselves to meet the new requirements which will result from the modification of the MRLs.
- (17) 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 V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

*Article 2*

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were lawfully produced before [*Office of Publications please insert date of application of this Regulation*].

*Article 3*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*Office of Publications: please insert date 6 months after entry into force*] as regards the MRLs for benfuracarb, carbofuran, carbosulfan and furathiocarb.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
[...]