



Council of the  
European Union

Brussels, 17 July 2017  
(OR. en)

11350/17

AGRILEG 136

#### COVER NOTE

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From:	European Commission
date of receipt:	14 July 2017
To:	General Secretariat of the Council

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No. Cion doc.:	D051407/02
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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 <i>Bacillus amyloliquefaciens</i> strain FZB24, <i>Bacillus amyloliquefaciens</i> strain MBI 600, clayed charcoal, dichlorprop-P, ethephon, etridiazole, flonicamid, fluazifop-P, hydrogen peroxide, metaldehyde, penconazole, spinetoram, tau-fluvalinate and <i>Urtica</i> spp. in or on certain products
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Delegations will find attached document D051407/02.

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Encl.: D051407/02



Brussels, **XXX**  
SANTE/10656/2017  
(POOL/E4/2017/10656/10656-EN.doc)  
D051407/02  
[...](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 *Bacillus amyloliquefaciens* strain FZB24, *Bacillus amyloliquefaciens* strain MBI 600, clayed charcoal, dichlorprop-P, ethephon, etridiazole, flonicamid, fluazifop-P, hydrogen peroxide, metaldehyde, penconazole, spinetoram, tau-fluvalinate and *Urtica* spp. 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 *Bacillus amyloliquefaciens* strain FZB24, *Bacillus amyloliquefaciens* strain MBI 600, clayed charcoal, dichlorprop-P, ethephon, etridiazole, flonicamid, fluazifop-P, hydrogen peroxide, metaldehyde, penconazole, spinetoram, tau-fluvalinate and *Urtica* spp. 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 dichlorprop-P, ethephon, flonicamid, fluazifop-P and metaldehyde, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For penconazole, MRLs were set in Annex II and Part B of Annex III to that Regulation. For etridiazole, spinetoram and tau-fluvalinate, MRLs were set in Part A of Annex III to that Regulation. For *Bacillus amyloliquefaciens* strain FZB24, *Bacillus amyloliquefaciens* strain MBI 600, clayed charcoal, hydrogen peroxide and *Urtica* spp., no specific MRLs were set nor were those substances 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 dichlorprop-P on citrus fruits, 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 ethephon, such an application was submitted for Japanese persimmons. As regards etridiazole, such an application was submitted for cucurbits with edible peel. As regards flonicamid, such an application was submitted for apricots, head cabbage, beans and peas (with pods) and sugar beet roots. As regards fluazifop-P, such an application was submitted for carrots and courgettes. As regards metaldehyde, such an application was submitted for leeks. As regards penconazole, such an application was submitted for grapes. As regards spinetoram, such an application was submitted for cherries, cane fruit, "other small fruits and berries", "lettuces and salad plants", "spinaches and similar leaves", "herbs and edible flowers", leeks and herbal infusions

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

from leaves and herbs. As regards tau-fluvalinate, such an application was submitted for citrus fruits.

- (4) 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.
- (5) 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.
- (6) The Authority concluded in its reasoned opinion on spinetoram that, as regards its use on scarole, a risk to the consumer could not be excluded. The existing MRL should therefore be kept.
- (7) As regards flonicamid, the Authority recommended increasing the existing MRLs for several products of animal origin in order to accommodate for the intended uses of that active substance on sugar beet.
- (8) As regards etridiazole, the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. The Standing Committee on Plants, Animals, Food and Feed noted at its meeting on 29 May 2015 that the substance concerned does not produce relevant metabolites of significant toxicity or at levels leading to an exposure higher than negligible<sup>3</sup>. It is therefore appropriate to set the MRL for cucurbits with edible peel in Regulation (EC) No 396/2005 at the level of 0.4 mg/kg, which reflects the Good Agricultural Practice.
- (9) 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

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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 dichlorprop-P in citrus fruits. EFSA Journal 2017;15(4):4834 [24 pp.].  
Reasoned opinion on the modification of the existing maximum residue level for ethephon in kaki/Japanese persimmons. EFSA Journal 2017;15(3):4747 [17 pp.].  
Reasoned opinion on the modification of the existing maximum residue levels for etridiazole in various crops. EFSA Journal 2017;15(3):4736 [19 pp.].  
Reasoned opinion on modification of existing maximum residue levels for flonicamid in various commodities. EFSA Journal 2017;15(3):4748 [20 pp.].  
Reasoned opinion on the modification of the existing maximum residue levels for fluazifop-P in carrots, tomatoes and courgettes. EFSA Journal 2017;15(5):4831 [32 pp.].  
Reasoned opinion on the modification of the existing maximum residue level for metaldehyde in leek. EFSA Journal 2017;15(3):4740 [15 pp.].  
Reasoned opinion on the modification of the existing maximum residue level for penconazole in grapes. EFSA Journal 2017;15(4):4768 [15 pp.].  
Reasoned opinion on the modification of the existing maximum residue levels for spinetoram in various crops. EFSA Journal 2017;15(5):4867 [34 pp.].  
Reasoned opinion on the modification of the existing MRLs for tau-fluvalinate in various crops. EFSA Journal 2014;12(1):3548 [49 pp.].

<sup>3</sup> Review report for the active substance etridiazole (SANCO/13145/2010 Final).

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.

- (10) For *Bacillus amyloliquefaciens* strain FZB24 and *Bacillus amyloliquefaciens* strain MBI 600, the Authority submitted conclusions on the peer review of the pesticide risk assessment of those active substances<sup>4</sup>. For all of these substances, the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. Such further consideration was reflected in the respective review reports<sup>5</sup> which concluded that the risk to humans through metabolites from these substances is negligible. In view of those conclusions, the Commission considers that the inclusion of those substances in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (11) Clayed charcoal, hydrogen peroxide and *Urtica* spp. are approved as basic substances by Commission Implementing Regulation (EU) 2017/428<sup>6</sup>, Commission Implementing Regulation (EU) 2017/409<sup>7</sup> and Commission Implementing Regulation (EU) 2017/419<sup>8</sup>, respectively. The conditions of use of those active substances 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 that those substances are included in Annex IV to Regulation (EC) No 396/2005.
- (12) Based on the reasoned opinions and the conclusions 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) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (14) 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:

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<sup>4</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance *Bacillus amyloliquefaciens* strain FZB24. EFSA Journal 2016;14(6):4494 [18 pp].

Conclusion on the peer review of the pesticide risk assessment of the active substance *Bacillus amyloliquefaciens* strain MBI 600. EFSA Journal 2016;14(1):4359 [37 pp].

<sup>5</sup> Review report for the active substance *Bacillus amyloliquefaciens* strain FZB24 (SANTE/12037/2016 Rev. 1).

Review report for the active substance *Bacillus amyloliquefaciens* strain MBI 600 (SANTE/10008/2016 Rev. 2).

<sup>6</sup> Commission Implementing Regulation (EU) 2017/428 of 10 March 2017 approving the basic substance clayed charcoal 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 66, 11.3.2017, p. 1).

<sup>7</sup> Commission Implementing Regulation (EU) 2017/409 of 8 March 2017 approving the basic substance hydrogen peroxide 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 63, 9.3.2017, p. 95).

<sup>8</sup> Commission Implementing Regulation (EU) 2017/419 of 9 March 2017 approving the basic substance *Urtica* spp. 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 64, 10.3.2017, p. 4).

*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*