

# SANTE/11743/2017 Rev. 0

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 abamectin, beer, fluopyram, fluxapyroxad, maleic hydrazide, mustard seeds powder and tefluthrin in or on certain products**

(Text with EEA relevance)

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

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 abamectin and maleic hydrazide, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For fluopyram, fluxapyroxad and tefluthrin, MRLs were set in Part A of Annex III to that Regulation. For beer and mustard seeds powder, 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 abamectin on bananas, 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 fluopyram, such an application was submitted for purslanes. As regards fluxapyroxad, such an application was submitted for "tropical root and tuber vegetables", "other root and tuber vegetables" of code 0213000, spring onions, "flowering brassica", Brussels sprouts, head cabbages, "lettuces and salad plants", "spinaches and similar leaves", witloofs, "herbs and edible flowers", globe artichokes, leeks, "herbal infusions from roots", "root and rhizome spices" and chicory roots. As regards tefluthrin, such an application was for submitted carrots.
- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for fluxapyroxad used on citrus fruits. The applicant claims that the authorised uses of that substance on such crops in Brazil 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) 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.

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

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

Reasoned opinion on the modification of the existing maximum residue level for abamectin in bananas. EFSA Journal 2017;15(10):4987 [24 pp.].

Reasoned opinion on the modification of the existing maximum residue level for fluopyram in purslanes. EFSA Journal 2017;15(9):4984 [22 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for fluxapyroxad in various crops. EFSA Journal 2017;15(9):4975 [30 pp.].

- (7) The Authority concluded in its reasoned opinions that, as regards the use of fluxapyroxad on citrus fruits, the submitted data were not sufficient to set a new MRL for the entire group. In accordance with the existing Union guidelines on extrapolation of MRLs, it is appropriate to set the MRL for oranges also for grapefruits. The existing MRLs for citrus fruits should therefore be kept at the existing values except for grapefruit for which the MRL should be increased to 0,3 mg/kg.
- (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) For maleic hydrazide, the Authority submitted a conclusion on the peer review of the pesticide risk assessment of the active substance<sup>3</sup>. In that framework, it recommended increasing the MRLs for potatoes, carrots, onions, garlic, shallots and milk.
- (10) Beer and mustard seeds powder are approved as basic substances by Commission Implementing Regulation (EU) 2017/xxxx<sup>4</sup> and Commission Implementing Regulation (EU) 2017/yyyy<sup>5</sup>, respectively. The conditions of use of those 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 to include those substances in Annex IV to Regulation (EC) No 396/2005.
- (11) Based on the reasoned opinions and the conclusion 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.
- (12) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (13) 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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Reasoned opinion on the modification of the existing maximum residue level for tefluthrin in carrots.  
EFSA Journal 2017;15(10):5016 [21 pp.].

<sup>3</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance maleic hydrazide.  
EFSA Journal 2016;14(6):4492 [22 pp.].

<sup>4</sup> Commission Implementing Regulation (EU) 2017/xxxx of X November 2017 approving the basic substance beer 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 xxx, x.11.2017, p. x).

<sup>5</sup> Commission Implementing Regulation (EU) 2017/yyyy of Y November 2017 approving the basic substance mustard seeds powder 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 yyy, y.11.2017, p. y).

*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,

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