

Brussels, **XXX**  
SANTE/10884/2021 Rev. 1  
**[...]**(2021) **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 acrinathrin, fluvalinate, folpet, fosetyl, isofetamid, ‘*Pepino Mosaic Virus*, EU strain, mild isolate Abp1’, ‘*Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2’, spinetoram and spirotetramat in or on certain products**

(Text with EEA relevance)

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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/EEC<sup>1</sup>, and in particular Article 5(1) Article 14(1)(a) thereof,

Whereas:

- (1) For acrinathrin, fluvalinate, folpet, isofetamid, spinetoram and spirotetramat, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For fosetyl, MRLs were set in Part A of Annex III to that Regulation. For *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2, no specific MRLs were set in Regulation (EC) No 396/2005 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 acrinathrin on peaches and sweet peppers/bell peppers, 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 fluvalinate, such an application was submitted for tomatoes and watermelons. As regards folpet, such an application was submitted for barley, oat and rye. As regards fosetyl, such an application was submitted for lemons, limes, mandarins and 'herbal infusions from leaves and herbs', following the use of potassium phosphonates. As regards isofetamid, such an application was submitted for cane fruits. As regards spinetoram, such an application was submitted for purslanes. As regards spirotetramat, such an application was submitted for leeks, 'spring onions/green onions and Welsh onions' and 'honey and other apicultural products'.
- (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.

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

- (5) The European Food Safety Authority ('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) As regards spinetoram in purslanes, the Authority assessed an application with a view of setting an MRL for lettuces and gave a reasoned opinion on the proposed MRL<sup>3</sup>. In accordance with the existing Union guidelines on extrapolation of MRLs, it is appropriate to set the MRL for purslanes at 4 mg/kg based on the residue trials performed on lettuces.
- (7) 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 a risk of exceeding the acceptable daily intake or the acute reference dose.
- (8) In the context of the approval of the low-risk active substances *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2, MRL applications were included in the summary dossiers in accordance with Article 8(1)(g) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>4</sup>. Those applications were evaluated by the Member State concerned in accordance with Article 11(2) of that Regulation. The Authority assessed the applications and delivered a conclusion on the peer review of the pesticide risk assessment of those active substances<sup>5</sup>, where it recommended the inclusion of *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2 in Annex IV to Regulation (EC) No 396/2005.

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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 level for acrinathrin in peaches and sweet peppers. EFSA Journal 2021;19(7):6681.

Reasoned opinion on the modification of the existing maximum residue levels for tau-fluvalinate in tomatoes and watermelons. EFSA Journal 2021;19(6):6646.

Reasoned opinion on the modification of the existing maximum residue levels for folpet in barley, oat, rye and wheat. EFSA Journal 2021;19(5):6578.

Reasoned opinion on the modification of the existing MRLs for potassium phosphonates in lemons, limes and mandarins and in herbal infusions from leaves and herbs. EFSA Journal 2021;19(6):6673.

Reasoned opinion on the modification of the existing maximum residue levels for isofetamid in raspberries, blackberries and dewberries. EFSA Journal 2021;19(6):6677.

Reasoned opinion on the modification of the existing maximum residue levels for spirotetramat in leeks, spring onions and honey. EFSA Journal 2021;19(3):6517.

<sup>3</sup> Reasoned opinion on the review of the existing maximum residue levels for spinetoram according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5997.

<sup>4</sup> 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).

<sup>5</sup> Conclusion on the peer review of the pesticide risk assessment of the active substances *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2. EFSA Journal 2021;19(1):6388.

- (9) Based on the reasoned opinions and the conclusion of the Authority and taking into account the factors relevant to the matter under consideration, the respective modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (10) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (11) 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 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*  
*Ursula VON DER LEYEN*