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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 acclonifen, acrinathrin, <i>Bacillus pumilus</i> QST 2808, ethirimol, penthiopyrad, picloram and <i>Pseudomonas sp.</i> strain DSMZ 13134 in or on certain products

Delegations will find attached document D070113/06.

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EUROPEAN
COMMISSION

Brussels, **XXX**
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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 aclonifen, acrinathrin, *Bacillus pumilus* QST 2808, ethirimol, penthiopyrad, picloram and *Pseudomonas sp.* strain DSMZ 13134 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 aclonifen, acrinathrin, *Bacillus pumilus* QST 2808, ethirimol, penthiopyrad, picloram and *Pseudomonas sp.* strain DSMZ 13134 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 5(1) and Article 14(1)(a) thereof,

Whereas:

- (1) For aclonifen, acrinathrin and ethirimol, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For penthiopyrad and picloram, MRLs were set in Part A of Annex III to that Regulation. For *Bacillus pumilus* QST 2808 and *Pseudomonas sp.* strain DSMZ 13134, 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 aclonifen on fennel seeds and caraway fruit, 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 acrinathrin, such an application was submitted for lettuces. As regards penthiopyrad, such an application was submitted for celeries and Florence fennels. As regards picloram, such an application was submitted for flowering brassica.
- (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 ('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

¹ OJ L 70, 16.3.2005, p. 1.

² EFSA scientific reports available online: <http://www.efsa.europa.eu>: Reasoned opinion on the modification of the existing maximum residue levels for aclonifen in fennel seed and caraway fruit. EFSA Journal 2020;18(7):6219.
Reasoned opinion on the modification of the existing maximum residue level for acrinathrin in lettuce. EFSA Journal 2020;18(7):6218.

those opinions to the applicants, the Commission and the Member States and made them available to the public.

- (6) As regards all 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.
- (7) For ethirimol, several MRLs were modified by Commission Regulation (EU) 2020/1566³. That Regulation lowered the MRL for ethirimol in cucumbers to 0.05 mg/kg due to a reporting error. Ethirimol is the main metabolite of bupirimate, which is currently used in plant protection products in several Member States. As a consequence, the lowering of the MRL for ethirimol may result in potential MRL exceedances following the lawful use of bupirimate. To avoid this, the Rapporteur Member State submitted on 25 August 2020 an amended evaluation report to the Authority, who has published a correction to the relevant reasoned opinion on 30 September 2020⁴, where it recommended setting the MRL for ethirimol in cucumbers at 0.2 mg/kg. In the interest of legal certainty, it is appropriate for the MRL for ethirimol in cucumbers, provided for by this Regulation, to apply from the same date as the date of application of Regulation (EU) 2020/1566.
- (8) For *Bacillus pumilus* QST 2808 and *Pseudomonas sp.* strain DSMZ 13134, the Authority submitted reasoned opinions⁵⁶ in accordance with Article 12(1) of Regulation (EC) No 396/2005. In those opinions, the Authority recommended the inclusion of the two substances in Annex IV to Regulation (EC) No 396/2005.
- (9) Based on the reasoned opinions 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:

Reasoned opinion on the modification of the existing maximum residue levels for penthiopyrad in Florence fennels and celeries. EFSA Journal 2020;18(9):6259.

Reasoned opinion on the modification of the existing MRL for picloram in flowering brassica. EFSA Journal 2020;18(10):6272.

³ Commission Regulation (EU) 2020/1566 of 27 October 2020 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 bupirimate, carfentrazone-ethyl, ethirimol, and pyriofenone in or on certain products (OJ L 358, 28.10.2020, p. 30).

⁴ Reasoned opinion on the Review of the existing maximum residue levels for bupirimate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(7):5757.

⁵ Reasoned opinion on the review of the existing maximum residue levels for *Bacillus pumilus* QST 2808 according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(5):6115.

⁶ Reasoned opinion on the review of the existing maximum residue levels for *Pseudomonas sp.* strain DSMZ 13134 according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(8):6234.

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*.

It shall apply from 17 May 2021 as regards the MRL for ethirimol in cucumbers.

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