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Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyflumetofen, oxathiapiprolin and pyraclostrobin in or on certain products

Delegations will find attached document D091942/2.

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyflumetofen, oxathiapiprolin and pyraclostrobin in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyflumetofen, oxathiapiprolin and pyraclostrobin 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[1], and in particular Article 14(1), point (a), thereof,

Whereas:

(1) For the active substances cyflumetofen, oxathiapiprolin and pyraclostrobin, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

(2) As regards cyflumetofen, an application requesting a modification of the existing MRL for cyflumetofen in courgettes and gherkins was submitted pursuant to Article 6(1) of Regulation (EC) No 396/2005.

(3) For that application, a Member State made a request to use the fast-track procedure, provided for in the Technical Guidelines on the MRL setting procedure[2], to set an MRL based on residue trials on cucumbers.

(4) The European Food Safety Authority ('the Authority') has assessed residue trials on cucumbers in the framework of the review of the existing MRLs for cyflumetofen and given a reasoned opinion on the proposed MRL[3]. That opinion relies on the current scientific and technical knowledge on the subject. As it is appropriate to extrapolate from the residue trials on cucumbers to courgettes, gherkins and 'other cucurbits with

[1] OJ L 70, 16.3.2005, p. 1.

[2] Technical guidelines MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005 and Article 8 of Regulation (EC) No 1107/2009 (SANTE/2015/10595 Rev. 6.1).

[3] European Food Safety Authority. Reasoned opinion on the review of the existing maximum residue levels for cyflumetofen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(8):6812.

edible peel', as confirmed by the Technical Guidelines on extrapolation of MRLs[4], it is unnecessary to request the Authority to provide a reasoned opinion on those crops specifically.

(5) It is therefore appropriate to set the MRL for cyflumetofen in courgettes, gherkins and 'other cucurbits with edible peel' at 0,4 mg/kg on the basis of the residue trials performed on cucumbers.

(6) As regards oxathiapiprolin, an application requesting a modification of the existing MRL for radish leaves was submitted pursuant to Article 6(1) of Regulation (EC) No 396/2005.

(7) As regards pyraclostrobin, an application for import tolerances for that substance used in Brazil on papayas was submitted pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005. The applicant provided data showing that the uses of pyraclostrobin on that crop that are authorised in Brazil lead to residues exceeding the MRL set in Regulation (EC) No 396/2005 and that a higher MRL would be needed to avoid trade barriers when importing this crop.

(8) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, the applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.

(9) The Authority assessed the applications and the evaluation reports. It examined in particular the risks to consumers and, where relevant, to animals, and gave reasoned opinions on the proposed MRLs[5]. It forwarded its reasoned opinions to the applicants, the Commission and the Member States and made them available to the public.

(10) As regards oxathiapiprolin in radish leaves, the Authority concluded that further consideration by risk managers was required concerning how to implement the proposed MRL since radish leaves are included in Part B of Annex I to Regulation (EC) No 396/2005 and classified under the subgroup of kales, referred to in Part A of that Annex, but residues of oxathiapiprolin in radish leaves derive from the use of this substance on radishes. Since no use is currently reported in the Union for oxathiapiprolin in kales, in accordance with the decision taken by the Standing Committee on Plants, Animals, Food and Feed[6], it is appropriate to establish the new MRL of 1,5 mg/kg proposed by the Authority for oxathiapiprolin in radish leaves only.

(11) As regards pyraclostrobin in papayas, the Authority concluded that further consideration by risk managers was required concerning whether to establish the new MRL at the level of 0,6 mg/kg, as derived by the Authority based on the assessment of the residue trials on papayas submitted by Brazil, or at the MRL of 0,5 mg/kg, which

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4 Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (SANTE/2019/12752 – 10 May 2023).

5 Reasoned Opinion on the modification of the existing maximum residue level for oxathiapiprolin in kales/radish leaves. EFSA Journal 2022;20(1):7049,
Reasoned Opinion on the setting of import tolerance for pyraclostrobin in papayas. EFSA Journal 2023;21(6):8056.

6 Report of the Standing Committee on Plants, Animals, Food and Feed, Section Phytopharmaceuticals – Residues, April 2022. https://food.ec.europa.eu/system/files/2022-05/sc_phyto_20220411_ppl_sum.pdf.

is in force in the exporting country, Brazil. In accordance with the Technical Guidelines on the MRL setting procedure[7], an MRL established in the framework of an import tolerance application should not exceed the one approved in the exporting country. Therefore, it is appropriate to set the MRL at the level established in Brazil (0,5 mg/kg).

(12) For all the above-mentioned modifications to MRLs for cyflumetofen, oxathiapiprolin and pyraclostrobin requested by the applicants, the Authority concluded that all the data requirements had been 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. In so concluding, the Authority took into account the most recent data on the toxicological properties of the substances. Neither the long-term exposure to these substances via consumption of all food products that may contain them nor the short-term exposure due to high consumption of relevant products show a risk that the acceptable daily intake or the acute reference dose is exceeded.

(13) Based on the reasoned opinions of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, the proposed modifications to the MRLs fulfil the requirements of that article.

(14) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(15) 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

Annex II to Regulation (EC) No 396/2005 is 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

[7] Technical guidelines MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005 and Article 8 of Regulation (EC) No 1107/2009 (SANTE/2015/10595 Rev. 6.1).