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**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**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 fluxapyroxad,  
lambda-cyhalothrin, metalaxyl, and nicotine in or on certain products**

(Text with EEA relevance)

# COMMISSION REGULATION (EU) .../...

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**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 fluxapyroxad, lambda-cyhalothrin, metalaxyl, and nicotine 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 14(1), point (a), thereof,

Whereas:

- (1) For the active substances lambda-cyhalothrin and metalaxyl, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For the active substance nicotine, MRLs were set in Part A of Annex III to that Regulation. For the active substance fluxapyroxad, MRLs were set in both Annex II and Part A of Annex III to that Regulation.
- (2) As regards fluxapyroxad, an application requesting a modification of the existing MRLs was submitted for kaki/Japanese persimmons and cultivated fungi, pursuant to Article 6(1) of Regulation (EC) No 396/2005.
- (3) As regards lambda-cyhalothrin in avocados, an application for an import tolerance pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005 was submitted for that substance based on a use of that substance in Mexico. The applicant provided evidence that the authorised uses of lambda-cyhalothrin on avocados in Mexico lead to residues exceeding the MRLs set in Regulation (EC) No 396/2005 and that higher MRLs are needed to avoid trade barriers when importing those crops. As regards lambda-cyhalothrin in poultry products (muscle, fat, liver, kidney, edible offal) and birds' eggs, temporary MRLs were set by Commission Regulation (EU) 2021/590<sup>2</sup>, at 0.01 mg/kg pending the submission and evaluation of confirmatory data on metabolites formed under sterilisation conditions. The Commission received information from the Union monitoring programme showing the presence of lambda-cyhalothrin in commodities from poultry and birds' eggs leading to higher residues

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/oj>.

<sup>2</sup> Commission Regulation (EU) 2021/590 of 12 April 2021 amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, boscalid, cow milk, etofenprox, ferric pyrophosphate, L-cysteine, lambda-cyhalothrin, maleic hydrazide, mefentrifluconazole, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr in or on certain products (OJ L 125, 13.4.2021, p. 15, ELI: <http://data.europa.eu/eli/reg/2021/590/oj>).

than the default MRL of 0.01 mg/kg laid down in Regulation (EC) No 396/2005 due to authorised uses of biocidal products.

- (4) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, those applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission. The Commission forwarded the applications, the evaluation reports, and the supporting dossiers to the European Food Safety Authority (the 'Authority'). In addition, as regards lambda-cyhalothrin in poultry products and birds' eggs, the Commission sent a mandate to the Authority to perform a targeted risk assessment for residues of lambda-cyhalothrin in poultry products and birds' eggs to cover residues originating from biocidal uses. The Commission derived the proposed temporary MRLs based on monitoring data and set those MRLs at the level of 0.03 mg/kg and 0.02 mg/kg, for poultry products and birds' eggs respectively, corresponding to the 95<sup>th</sup> percentile of all the sample results.
- (5) The Authority assessed the applications and the evaluation reports, examining in particular the risks to consumers and, where relevant, to animals, and gave reasoned opinions on the proposed MRLs<sup>3</sup>. It forwarded its reasoned opinions to the applicants, the Commission and the Member States and made them available to the public. In addition, as regards in particular lambda-cyhalothrin in poultry products and birds' eggs, the Authority performed a dietary risk assessment<sup>4</sup> based on the Commission's mandate considering the lambda-cyhalothrin exposure via residues in food commodities from poultry and birds' eggs.
- (6) As regards the MRLs for fluxapyroxad in kaki/Japanese persimmons and cultivated fungi, the Authority concluded that the data submitted in support of the request were sufficient to derive MRL proposals for the commodities under assessment and that the short-term and long-term intake of residues resulting from the use of fluxapyroxad, according to the reported agricultural practices and pending the submission of the confirmatory data requested under the MRL review, is unlikely to present a risk to consumer health.
- (7) As regards the MRLs for lambda-cyhalothrin in avocados, the Authority concluded that the data submitted in support of the request were found to be sufficient to derive MRL proposals for that commodity and observed that a general data gap on toxicological data for degradation products in standard hydrolysis studies representative for sterilisation conditions has been introduced in the Union legislation for all food commodities. As avocados are mostly consumed unprocessed, the Authority concluded that this data gap is of lower relevance for avocados than for other products. It is therefore appropriate to set the MRLs at the level of 0.15 mg/kg for lambda-cyhalothrin in avocados. As regards the MRLs for lambda-cyhalothrin in poultry products (muscle, fat, liver, kidney, edible offal) and birds' eggs, the Authority concluded that MRLs based on monitoring data at the proposed levels of 0.03 mg/kg and 0.02 mg/kg respectively, are unlikely to pose a risk to consumer health. The Authority noted that the consumer exposure assessment is affected by uncertainties

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<sup>3</sup> EFSA 2024. Modification of the existing maximum residue level for fluxapyroxad in kaki/Japanese persimmons and cultivated mushrooms. EFSA Journal, 22 (4), e8696. <https://doi.org/10.2903/j.efsa.2024.8696>.

EFSA 2023. Setting of an import tolerance for lambda-cyhalothrin in avocados. EFSA Journal, 21 (12), e8464. <https://doi.org/10.2903/j.efsa.2024.8842>.

<sup>4</sup> EFSA 2024. Targeted risk assessment of maximum residue levels for lambda-cyhalothrin in commodities from poultry and birds' eggs. EFSA Journal, 22 (6), e8816. <https://doi.org/10.2903/j.efsa.2024.8816>.

related to the data gap on formation of metabolites under sterilisation conditions identified in the MRL review pursuant to Article 12 of Regulation (EC) No 396/2005. Therefore, the proposed MRLs should remain temporary pending the submission of the relevant confirmatory data to address that data gap.

- (8) Based on the opinions of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is concluded that the proposed modifications to the MRLs are acceptable.
- (9) As regards metalaxyl, the Codex Alimentarius Commission adopted new Codex maximum residue limits ('CXLs') for this active substances<sup>5</sup> on 2 December 2023.
- (10) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>6</sup>, where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts thereof would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of the Union food law, or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Union. Moreover, in accordance with Article 13, point (e), of that Regulation, the Union is to promote consistency between international technical standards and Union food law while ensuring that the high level of protection adopted in the Union is not reduced.
- (11) The Authority<sup>7</sup> assessed the risks that those CXLs pose to consumers and published a scientific report<sup>7</sup>. The Union presented reservations,<sup>4,8,9</sup> to the Codex Committee on Pesticides Residues on the CXLs proposed for some pesticide/product combinations, for which the Authority had identified a potential consumer health risk in its scientific report.
- (12) The CXLs for which the Authority did not identify risks to consumers in the Union, and for which the Union therefore did not present a reservation to the Codex Committee on Pesticides Residues or the Codex Alimentarius Commission, can be considered safe. This is the case for the CXLs for metalaxyl in pineapples and dried ginseng. Those CXLs should therefore be included in Regulation (EC) No 396/2005,

<sup>5</sup> Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Forty-sixth Session. FAO headquarters, Rome, Italy. 27 November to 2 December 2023. [fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-46%252F%252F%252F2598%2585Final%252520Report%252FREP23\\_CACe.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-46%252F%252F%252F2598%2585Final%252520Report%252FREP23_CACe.pdf).

<sup>6</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

<sup>7</sup> EFSA 2023. Scientific support for preparing an EU position for the 54th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal, 21(8), 1–303. <https://doi.org/10.2903/j.efsa.2023.8111>.

<sup>8</sup> European Union comments on Codex CX/PR 23/54/5-Add.1: [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-54%252FWDs%252Fpr54\\_05\\_Add1x.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-54%252FWDs%252Fpr54_05_Add1x.pdf).

<sup>9</sup> Report of the 54th session of the Codex Committee on Pesticide Residues REP23/PR54: [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-54%252FREPORT%252FFINAL%252520REPORT%252520CORRIGENDUM%252FREP23\\_PR54e\\_CORR.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-54%252FREPORT%252FFINAL%252520REPORT%252520CORRIGENDUM%252FREP23_PR54e_CORR.pdf).

except where they relate to products which are not listed in Annex I to that Regulation or where they are at a lower level than the current MRLs.

- (13) Based on the scientific report of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, the Commission has concluded that the proposed modifications to the MRLs are acceptable.
- (14) As regards nicotine in coffee beans, the default MRL of 0.01 mg/kg applies according to Article 18(1), point (b), of Regulation (EC) No 396/2005, since no specific MRL is set out in the Annexes of that Regulation. Based on monitoring data deriving from the Union monitoring programme and after consulting the European Union Reference Laboratory, which recommended the use of the typical extrapolation MRL for difficult commodities (0.05 mg/kg), it is appropriate to set a temporary MRL at the level of 0.05 mg/kg for nicotine in coffee beans to take into account residues resulting from potential sources other than pesticide use.
- (15) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (16) 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 and III 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*