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AGRILEG 47 PESTICIDE 5

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	25 March 2025
То:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D102376/03
Subject:	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 cyantraniliprole, cyflumetofen, deltamethrin, mefentrifluconazole, mepiquat and oxathiapiprolin in or on certain products

Delegations will find attached document D102376/03.

Encl.: D102376/03

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Brussels, XXX PLAN/2024/2410 Rev. 2 (POOL/E4/2024/2410/2410R2-EN.docx) D102376/03 [...](2025) XXX draft

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 cyantraniliprole, cyflumetofen, deltamethrin, mefentrifluconazole, mepiquat and oxathiapiprolin 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/EEC¹, and in particular Article 14(1), point (a), thereof,

Whereas:

- (1) For cyantraniliprole, cyflumetofen, deltamethrin, mefentrifluconazole and oxathiapiprolin, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For mepiquat, MRLs were set in Part A of Annex III to that Regulation.
- (2) On 2 December 2023, the Codex Alimentarius Commission adopted a new Codex maximum residue limit (CXL) for the active substance mefentrifluconazole in oats².
- (3) On 30 November 2024, the Codex Alimentarius Commission adopted new CXLs for the active substances cyantraniliprole, cyflumetofen, deltamethrin, mefentrifluconazole, mepiquat and oxathiapiprolin³.
- (4) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴, 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

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

Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Forty-sixth Session. FAO headquarters, Rome, Italy, 27 November - 2 December 2023. 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%25E2%2598%2585Final%252520Report%252FREP23 CACe.pdf.

Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Forty-seventh Session, CICG, Geneva, Switzerland, 25-30 November 2024. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-47%252FFINAL%2BREPORT%252FREP24 CACe.pdf

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)

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.

- (5) The European Food Safety Authority ('the Authority') assessed the risks that those CXLs may pose to consumers and published scientific reports^{5,6}.
- (6) The Union presented reservations^{7,8} to the Codex Committee on Pesticides Residues on the CXL proposed for cyflumetofen in coffee beans due to the lack of metabolism studies in a representative commodity for coffee beans.
- (7) The Union also presented reservations⁹ to the Codex Alimentarius Commission on the CXLs proposed for cyantraniliprole in soybeans in the group of 'dry beans (subgroup)' and in grapes due to inconsistencies in the re-treatment intervals reported in the residue trials.
- (8) The CXLs for which the Authority did not identify risks to consumers in the Union, and for which the Union 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 certain CXLs for cyantraniliprole, cyflumetofen, deltamethrin, mefentrifluconazole, mepiquat and oxathiapiprolin. Those CXLs should therefore be included in Regulation (EC) No 396/2005, 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 for the pesticide/product combinations concerned as these were set based on authorised uses.
- (9) Based on the scientific reports 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 modifications to the MRLs are acceptable.
- (10) Annexes II and III to Regulation (EC) No 396/2005 should therefore be amended accordingly.

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European Food Safety Authority. 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.

European Food Safety Authority. Scientific support for preparing an EU position in the 55th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal, 22(7), e8841. https://doi.org/10.2903/j.efsa.2024.8841.

Comments submitted by the European Union. Codex Committee on Pesticide Residues 55th Session. CRD10 Rev.1, June 2024: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/de/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-55%252FCRDs%252Fpr55_CRD10x%2BRev.1.pdf

Report of the 55th session of the Codex Committee on Pesticide Residues REP24/PR55: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-55%252FREPORT%252FFINAL%252FREP24_PR55e.pdf.

Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Forty-seventh Session, CICG, Geneva, Switzerland, 25-30 November 2024. CAC47/CRD15. https://www.fao.org/fao-who-codexalimentarius/sh-

(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 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