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## COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	24 July 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D096624/02
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 azoxystrobin, famoxadone, flutriafol, mandipropamid and mefentrifluconazole in or on certain products

Delegations will find attached document D096624/02.

Encl.: D096624/02



EUROPEAN  
COMMISSION

Brussels, **XXX**  
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[...](2024) **XXX** draft

**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 azoxystrobin, famoxadone, flutriafol, mandipropamid and mefentrifluconazole 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 azoxystrobin, famoxadone, flutriafol, mandipropamid and mefentrifluconazole 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 azoxystrobin, famoxadone, flutriafol, mandipropamid, and mefentrifluconazole, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) On 2 December 2023, the Codex Alimentarius Commission adopted new Codex maximum residue limits (CXLs) for the active substances azoxystrobin, famoxadone, flutriafol, mandipropamid, and mefentrifluconazole<sup>2</sup>.
- (3) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>3</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.

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/2023-10-21>.

<sup>2</sup> Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Forty-sixth Session. FAO headquarters, Rome, Italy. 27 November to 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](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).

<sup>3</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>).

- (4) The European Food Safety Authority ('the Authority') assessed the risks that those CXLs pose to consumers and published a scientific report<sup>4</sup>. The Union presented reservations<sup>5,6,7</sup> to the Codex Committee on Pesticides Residues on the CXLs proposed for the following pesticide/product combinations, for which the Authority had identified a potential consumer health risk in its scientific report: famoxadone in 'bulb onions, subgroup of', 'cane berries, subgroup of', 'fruiting vegetables, cucurbits-cucumbers and summer squashes, subgroup of', 'peppers chili' and 'peppers sweet-including pimento or pimienta'; mandipropamid in 'bulb onions, subgroup of', 'eggplants, subgroup of', and 'ginseng, dried, including red ginseng'; for mefenftrifluconazole in 'mammalian edible offal', 'eggs', 'mammalian fats except milk fats', 'meat from mammals other than marine mammals', 'milks', 'pome fruits, group of', 'edible offal of poultry', 'poultry fats', and 'poultry meat'.
- (5) 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 certain CXLs for azoxystrobin, famoxadone, flutriafol, mandipropamid and mefenftrifluconazole. 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.
- (6) As regards mandipropamid in courgettes, during the review of all MRLs for that active substance in accordance with Article 12 of Regulation (EC) No 396/2005, the Authority identified some information on residue trials for courgettes as unavailable<sup>4</sup>. The available information was sufficient for the Authority to propose an MRL of 0,2 mg/kg that is safe for consumers and the data gap was indicated in Annex II of that Regulation specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRLs. As the new CXL of 0,2 mg/kg for mandipropamid in 'fruiting vegetables, cucurbits – cucumbers and summer squashes (subgroup)' with edible peel, which applies to cucumbers, gherkins, courgettes, and 'cucurbits with edible peel, others', was fully supported by data, and the Union did not present a reservation to the Codex Committee on Pesticides Residues on it, the data

<sup>4</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>5</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>6</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).

<sup>7</sup> Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Forty-sixth Session. FAO headquarters, Rome, Italy. 27 November to 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](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).

gap concerning residue trials for mandipropamid in courgettes can be considered sufficiently addressed.

- (7) In addition, as regards mandipropamid in radish leaves, an application requesting a modification of the existing MRL was submitted to the Member State concerned pursuant to Article 6(1) of Regulation (EC) No 396/2005.
- (8) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, that application was evaluated by the Member States concerned and the evaluation report was forwarded to the Commission. The Commission forwarded the application, the evaluation report, and the supporting dossier to the Authority.
- (9) The Authority assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave reasoned opinion on the proposed MRL<sup>8</sup>. It forwarded its reasoned opinion to the applicant, the Commission and the Member States and made it available to the public.
- (10) As regards mandipropamid in radish leaves, the Authority concluded that further consideration by risk managers was required on how to implement the proposed MRL. While radish leaves are included in Part B of Annex I to Regulation (EC) No 396/2005 and classified under the subgroup of kales, residues of mandipropamid in radish leaves derive from the use of that substance on radishes and not on kales. As a different MRL is set for mandipropamid in kales, based on uses of that substance on that crop, it is not appropriate to establish the new MRL of 50 mg/kg proposed by the Authority for mandipropamid in radish leaves to the whole subgroup of kales. Therefore, that MRL should apply to mandipropamid in radish leaves only.
- (11) Based on the scientific report and on the reasoned opinion 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.
- (12) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (13) 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.

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<sup>8</sup> EFSA 2023. Modification of the existing maximum residue level for mandipropamid in radish leaves. EFSA journal, 21 (12): e8421. <https://doi.org/10.2903/j.efsa.2023.8421>.

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*