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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 azoxystrobin, etofenprox, fenpropidin, flupyradifurone, hexythiazox, imazalil, spinosad and tebufenozide 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/EEC[1], and in particular Article 14(1), points (a) and (e), thereof,

Whereas:

(1) For azoxystrobin, etofenprox, fenpropidin, flupyradifurone, hexythiazox, imazalil, spinosad and tebufenozide, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

(2) On 12 July 2019, the Codex Alimentarius Commission adopted a new CXL for the active substance imazalil in bananas[2].

(3) On 13 November 2025, the Codex Alimentarius Commission adopted new CXLs for the active substances azoxystrobin, etofenprox, fenpropidin, flupyradifurone, hexythiazox, spinosad and tebufenozide in several food products [3].

(4) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[4], 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.

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

2 Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Forty-second Session. CICG, Geneva, Switzerland, 8-12 July 2019. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-42%252FReport%252FREP19_CACe_Final.pdf .

3 Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Forty-eighth Session, FAO headquarters Rome, Italy, 10-13 November 2025. LINK to summary report to add once available

4 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).

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) Regarding imazalil, the Union presented reservations[7] to the Codex Committee on Pesticides Residues on the CXL proposed for imazalil in bananas pending the outcome of the ongoing evaluation of toxicological properties of some metabolites of imazalil in the Union. In a subsequent Reasoned Opinion[8], the Authority concluded that the data gaps on the toxicology of these metabolites were satisfactorily addressed and that the CXL for imazalil in bananas is safe for consumers in the Union. The CXL for imazalil in bananas should therefore be included in Regulation (EC) No 396/2005.

(7) Regarding azoxystrobin, etofenprox, fenpropidin, flupyradifurone, hexythiazox, spinosad and tebufenozide, the Union presented reservations[9] to the Codex Committee on Pesticides Residues on the CXL proposed for etofenprox in eggs, the CXL proposed for fenpropidin in bananas, the CXLs proposed for flupyradifurone in edible offals, fat and muscle of avian, in edible offals and fat of mammalians (except milk fats), in muscle of mammals other than marine mammals, in milks and in eggs, and the CXL proposed for hexythiazox in cane berries.

(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 azoxystrobin, etofenprox, fenpropidin, flupyradifurone, hexythiazox, spinosad and tebufenozide. 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.

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5 European Food Safety Authority. Scientific support for preparing an EU position for the 51st Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal, 17(7), 5797. https://doi.org/10.2903/j.efsa.2019.5797.

6 European Food Safety Authority. Scientific support for preparing an EU position in the 56th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal. 2025;23:e9640. https://doi.org/10.2903/j.efsa.2025.9640.

7 Comments submitted by the European Union. Codex Committee on Pesticide Residues 51st Session. CRD04, April 2019. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-51%252FCRD%252Fpr51_CRD04x.pdf.

8 European Food Safety Authority. Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels in citrus fruits for imazalil. EFSA Journal. 2025;23:e9614. https://doi.org/10.2903/j.efsa.2025.9614.

9 Comments submitted by the European Union. Codex Committee on Pesticide Residues 56th Session. CRD18 Rev.1, September 2025. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-56%252FCRDs%252Fpr56_crd18x_Rev.1.pdf.

(10) Additionally, on 4 July 2009, the Codex Alimentarius Commission adopted a new Codex maximum residue limit (CXL) for the active substance azoxystrobin in critrus fruits[10]. Subsequently, the MRL for azoxystrobin in citrus fruits was set at the level of the CXL in Regulation (EC) No 396/2005 by Commission Regulation (EU) No 459/2010[11]. On 18 July 2014, the Codex Alimentarius Commission agreed on a revision to the Codex Classification of Food and Feed to include "kumquats" in the group of "citrus fruits"[12]. Therefore, the CXL for azoxystrobin in citrus fruits applies also to kumquats and the MRL for azoxystrobin in kumquats should be set at the level of the CXL in Regulation (EC) No 396/2005.

(11) Annex II to Regulation (EC) No 396/2005 should therefore be amended accordingly.

(12) 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

[10] Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Thirty-Second Session. FAO Headquarters, Rome, Italy, 29 June - 4 July 2009. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-32%252Fal32REPe.pdf.

[11] Commission Regulation (EU) No 459/2010 of 27 May 2010 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 certain pesticides in or on certain products. (OJ L 129, 28.5.2010, pp. 3–49, ELI: http://data.europa.eu/eli/reg/2010/459/oj).

[12] Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Thirty-seventh Session CICG, Geneva, Switzerland, 14-18 July 2014. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-37%252FREP14_CACe.pdf.