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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 bixafen, cyprodinil, fenhexamid, fenpicoxamid, fenpyroximate, flutianil, isoxaflutole, mandipropamid, methoxyfenozide, and spinetoram in or on certain products

Delegations will find attached document D087772/02.

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EUROPEAN
COMMISSION

Brussels, **XXX**
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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 bixafen, cyprodinil, fenhexamid, fenpicoxamid, fenpyroximate, flutianil, isoxaflutole, mandipropamid, methoxyfenozide, and spinetoram in or on certain products

(Text with EEA relevance)

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

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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) On 13 December 2022, the Codex Alimentarius Commission adopted new Codex maximum residue limits (CXLs) for acetamiprid, bixafen, chlorothalonil, clofentezine, clothianidin, cyprodinil, difenoconazole, ethiprole, fenhexamid, fenpicoxamid, fenpyroximate, fluensulfone, fluopyram, flutianil, imazalil, isoprothiolane, isoxaflutole, mandipropamid, metconazole, methoprene, methoxyfenozide, prothioconazole, pydiflumetofen, pyrasulfotole, pyraziflumid, quinoxifen, spinetoram, spiropidion, tebuconazole, thiamethoxam, trifloxystrobin, and trinexapac-ethyl².
- (2) Maximum residue levels (MRLs) had been set for those substances in Annexes II, III and V to Regulation (EC) No 396/2005, except for ethiprole, fluensulfone and pydiflumetofen, for which no specific MRLs were set nor were those substances included in Annex IV to Regulation (EC) No 396/2005, so the default value of 0.01 mg/kg laid down in Article 18(1), point (b), of that Regulation applies.
- (3) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council³, 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 would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level

¹ OJ L 70, 16.3.2005, p. 1.

² https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-45%252FFinal%252520Report%252520CAC45%252FCompiled%2BREP22_CAC.pdf

Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Appendix III. Forty-fifth Session. Virtual, 21-25 November, 12-13 and 19 December 2022 and 6 February 2023.

³ 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).

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 food law while ensuring that the high level of protection adopted in the Union is not reduced.

- (4) The European Food Safety Authority ('the Authority') assessed the risks to consumers and produced a scientific report⁴. In cases where the Authority had identified a potential consumer health risk, the Union presented reservations^{5,6} to the Codex Committee on Pesticides Residues on the CXLs proposed. This was the case for the following pesticide/product combinations: acetamiprid (all products), chlorothalonil (all products), clofentezine (all products), clothianidin (all products), difenoconazole (all products), ethiprole (all products), fenpyroximate (lemons and lime, pummelo and grapefruits), fluensulfone (all products), imazalil (all products), isoprothiolane (all products), metconazole (all products), methoprene (all products), prothioconazole (all products), pydiflumetofen (all products), pyrasulfotole (all products), pyraziflumid (all products), quinoxifen (all products), spinetoram (tea, green, black), spiropidion (all products), tebuconazole (all products), thiamethoxam (all products), trifloxystrobin (all products), and trinexapac-ethyl (all products).
- (5) Those CXLs for which the Union did not present a reservation to the Codex Committee on Pesticides Residues since the Authority did not identify risks for consumers in the Union, can therefore be considered safe. This is the case for certain CXLs for bixafen, cyprodinil, fenhexamid, fenpicoxamid, fenpyroximate, flutianil, isoxaflutole, mandipropamid, methoxyfenozide and spinetoram. 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. Thus, no change should be made as regards the MRLs for fluopyram.
- (6) 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 appropriate modifications to the MRLs fulfil the requirements of that article.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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.

⁴ Scientific support for preparing an EU position for the 53rd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2022;20(9):7521.

⁵ European Union comments on Codex CX/PR 22/53/5:
https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-53%252FCRDs%252Fpr53_crd13revx.pdf.

⁶ Report of the 53rd session of the Codex Committee on Pesticide Residues REP22/PR53:
https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-53%252FREPORT%252FFINAL%252FBREPORT%252FREP22_PR53e.pdf.

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