



Council of the  
European Union

Brussels, 24 May 2022  
(OR. fr)

9474/22

AGRILEG 79  
PESTICIDE 13

#### COVER NOTE

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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	16 May 2022
To:	General Secretariat of the Council

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No. Cion doc.:	D079006/03
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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 benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-Al, isofetamid, metaflumizone, pyraclostrobin, spirotetramat, thiabendazole and tolclofos-methyl in or on certain products
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Delegations will find attached document D079006/03.

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Encl.: D079006/03



Brussels, **XXX**  
SANTE/10016/2022  
(POOL/E4/2022/10016/10016-EN.docx)  
D079006/03  
[...](2022) **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 benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-Al, isofetamid, metaflumizone, pyraclostrobin, spirotetramat, thiabendazole and tolclofos-methyl in or on certain products**

(Text with EEA relevance)

# 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 benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-Al, isofetamid, metaflumizone, pyraclostrobin, spirotetramat, thiabendazole and tolclofos-methyl 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)(a) thereof,

Whereas:

- (1) On 14 December 2021, the Codex Alimentarius Commission adopted new Codex maximum residue limits (CXLs) for acetochlor, afidopyropen, benzovindiflupyr, bifenthrin, boscalid, buprofezin, carbendazim, chlorantraniliprole, cyclaniliprole, cypermethrins (including alpha- and zeta- cypermethrin), dicamba, fenazaquin, flonicamid, fluazifop-P, fluensulfone, flupyradifurone, fluxapyroxad, fosetyl-Al, glyphosate, isofetamid, kresoxim-methyl, mandestrobin, mesotrione, metaflumizone, metconazole, methoprene, pendimethalin, penthiopyrad, picoxystrobin, propiconazole, pydiflumetofen, pyraclostrobin, pyriofenone, pyriproxyfen, spirotetramat, tebuconazole, thiabendazole, tolclofos-methyl and tolfenpyrad<sup>2</sup>.
- (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 afidopyropen, fluensulfone, pydiflumetofen and tolfenpyrad, 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)(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 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

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

<sup>2</sup> [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-44%252FFINAL%252520REPORT%252FRep21\\_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-701-44%252FFINAL%252520REPORT%252FRep21_CACe.pdf).  
Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Appendix III. Forty-fourth Session. Virtual, 8-15, 17-18 November and 14 December 2021.

<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).

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 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 Union presented reservations<sup>45</sup> to the Codex Committee on Pesticides Residues on the CXLs proposed for the following pesticide/product combinations: acetochlor (all products), afidopyropen (all products), bifenthrin (all products), boscalid (pome fruits subgroup), buprofezin (all products), carbendazim (all products), cyclaniliprole (all products), cypermethrin (including alpha and zeta-cypermethrin) (all products), dicamba (all products), flonicamid (all products), fluazifop-P (elderberries, strawberry), fluensulfone (all products), fosetyl-AI (coffee beans), glyphosate (all products), mandestrobin (rape seed), metaflumizone (grape), metconazole (all products), methoprene (all products), penthiopyrad (all products), picoxystrobin (all products), propiconazole (all products), pydiflumetofen (all products), tebuconazole (all products), tolclofos-methyl (potatoes) and tolfenpyrad (all products).
- (5) In addition, the European Food Safety Authority ('the Authority') identified a potential acute intake concern for thiabendazole in sweet potatoes<sup>6</sup>. Therefore, the CXL concerned will not be included in Regulation (EC) No 396/2005 as MRL.
- (6) The CXLs for which the Union did not present a reservation to the Codex Committee on Pesticides Residues and for which the Authority did not identify a potential acute intake concern, which concern certain CXLs for benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-AI, isofetamid, metaflumizone, pyraclostrobin, spirotetramat, thiabendazole and tolclofos-methyl, are safe for consumers in the Union<sup>7</sup>. These CXLs should therefore be included in Regulation (EC) No 396/2005 as MRLs, except where they relate to products which are not referred to 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 chlorantraniliprole, kresoxim-methyl, mesotrione, pendimethalin, pyriofenone, pyriproxifen and tebuconazole.
- (7) Based on the scientific report of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (8) Regulation (EC) No 396/2005 should therefore be amended accordingly.

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<sup>4</sup> European Union comments on Codex CX/PR 21/52/5(REV):

[https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-52%252FCRDs%252Fpr52\\_CRD22x.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-52%252FCRDs%252Fpr52_CRD22x.pdf).

<sup>5</sup> Report of the 52nd session of the Codex Committee on Pesticide Residues REP21/PR: [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-52%252FREPORT%252FFINAL%252FBREPORT%252FREP21\\_PR52e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-52%252FREPORT%252FFINAL%252FBREPORT%252FREP21_PR52e.pdf).

<sup>6</sup> Scientific support for preparing an EU position for the 52nd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2021;19(8):6766.

<sup>7</sup> Scientific support for preparing an EU position for the 52nd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2021;19(8):6766.

(9) 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*