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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for calcium carbonate, carbon dioxide, cyprodinil and potassium hydrogen carbonate in or on certain products

Delegations will find attached document D080353/03.

Encl.: D080353/03



Brussels, **XXX**
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[...] (2022) **XXX** draft

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

of **XXX**

amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for calcium carbonate, carbon dioxide, cyprodinil and potassium hydrogen carbonate in or on certain products

(Text with EEA relevance)

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

of **XXX**

amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for calcium carbonate, carbon dioxide, cyprodinil and potassium hydrogen carbonate 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/EEC¹, and in particular Article 5(1) and Article 14(1), point (a), thereof,

Whereas:

- (1) For cyprodinil, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. Calcium carbonate, carbon dioxide and potassium hydrogen carbonate are included in Annex IV to Regulation (EC) No 396/2005.
- (2) On 14 December 2021, the Codex Alimentarius Commission adopted a new Codex maximum residue limit (CXL) for cyprodinil in soyabeans².
- (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 to fulfil 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 European Food Safety Authority ('the Authority') assessed the CXL proposed for cyprodinil in soyabeans and concluded it is safe for consumers in the Union⁴, and the

¹ OJ L 70, 16.3.2005, p. 1.

² Report of the 44th Session of the Codex Alimentarius Commission (REP21/CAC) 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.

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).

⁴ 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.

Union did not present reservations^{5,6} to the Codex Committee on Pesticides Residues on this proposed CXL.

- (5) It is therefore appropriate to include this CXL in Regulation (EC) No 396/2005 as a MRL.
- (6) Calcium carbonate, carbon dioxide and potassium hydrogen carbonate were temporarily included in Annex IV to Regulation (EC) No 396/2005 pending the finalisation of their evaluation either under Council Directive 91/414/EEC⁷ or under Regulation (EC) No 1107/2009⁸ of the European Parliament and of the Council, and pending their review according to Article 12 of Regulation (EU) No 396/2005. In the context of applications for renewal of the approval of these substances under Regulation (EC) No 1107/2009, the Authority issued conclusions on the peer review of the pesticide risk assessment of calcium carbonate⁹, carbon dioxide¹⁰ and potassium hydrogen carbonate¹¹. Based on the said conclusions of the Authority, no MRLs are required for calcium carbonate, carbon dioxide and potassium hydrogen carbonate. Therefore, it is appropriate for these substances to remain in Annex IV to Regulation (EC) No 396/2005¹².
- (7) Based on the scientific report and on the conclusions 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.
- (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:

⁵ 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.

⁶ 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.

⁷ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁸ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 Concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

⁹ EFSA (European Food Safety Authority), 2021. Conclusion on the peer review of the pesticide risk assessment of the active substance calcium carbonate. EFSA Journal 2021;19(4):6500.

¹⁰ EFSA (European Food Safety Authority), 2021. Conclusions on the peer review of the pesticide risk assessment of the active substance carbon dioxide. EFSA Journal 2021;19(6):6605.

¹¹ EFSA (European Food Safety Authority), 2021. Conclusion on the peer review of the pesticide risk assessment of the active substance potassium hydrogen carbonate. EFSA Journal 2021;19(5):6593.

¹² EFSA (European Food Safety Authority), 2022. Statement on pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2022; 20(01):7061.

Article 1

Annexes II and IV 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