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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)

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

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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)(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 cypronidil 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 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.

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-701-44%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.

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) The European Union did not present reservations⁴⁵ to the Codex Committee on Pesticides Residues on the CXL proposed for cypronidil in soyabeans.
- (5) This CXL should therefore be included in Regulation (EC) No 396/2005 as MRLs.
- (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 under Council Directive 91/414/EEC⁶ or Regulation (EC) No 1107/2009⁷ of the European Parliament and of the Council. The Authority evaluated those substances in the framework of the peer review in 2021. Based on EFSA Conclusions for calcium carbonate⁸, carbon dioxide⁹ and potassium hydrogen carbonate¹⁰, it is appropriate to retain these substances in Annex IV to Regulation (EC) No 396/2005 permanently¹¹.
- (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:

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*.

⁴ 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.

⁵ 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.

⁶ 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).

⁷ 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.)

⁸ 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.

⁹ 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):660.

¹⁰ 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.

¹¹ 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; 10(01):7061.

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