

Brussels, XXX
SANTE/10444/2019
[...] (2019) XXX draft

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 chlormequat in cultivated fungi

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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 chlormequat in cultivated fungi

(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)(a) and Article 16(1)(a) thereof,

Whereas:

- (1) For chlormequat, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.
- (2) The MRLs for chlormequat were recently reviewed by Commission Regulation (EU) 2017/693² in accordance with Article 12(1) of Regulation (EC) No 396/2005. In that framework, the European Food Safety Authority ('the Authority') proposed five different MRLs for cultivated fungi to be considered by the risk managers³, which were based on the approaches recommended by the Food and Agriculture Organization of the United Nations respectively for the setting of MRLs in spices and of extraneous MRLs⁴.
- (3) Mushroom growers submitted recent monitoring data specifically on oyster mushrooms showing that residues occur in those products at higher levels than the current temporary MRL set at 0.9 mg/kg for cultivated fungi. Some Member States submitted additional monitoring data from official controls performed specifically on oyster mushrooms, which confirmed the findings mentioned above. Such residues result from a cross-contamination of cultivated fungi with straw lawfully treated with chlormequat.
- (4) Germany submitted an application for modification of the existing MRL in accordance with Article 6(3) of Regulation (EC) No 396/2005.

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Regulation (EU) 2017/693 of 7 April 2017 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bitertanol, chlormequat and tebufenpyrad in or on certain products (OJ L 101, 13.4.2017, p. 1).

³ European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for chlormequat according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2016;14(3):4422.

⁴ FAO, 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

- (5) In accordance with Article 8 of Regulation (EC) No 396/2005, that application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.
- (6) The European Food Safety Authority assessed the application and the evaluation report, examining in particular the risks to the consumer and, where relevant, to animals and gave a scientific statement on the proposed MRLs⁵. The Authority forwarded that statement to the applicant, the Commission and the Member States and made it available to the public.
- (7) The Authority concluded in its scientific statement the modifications to the MRL requested by Germany was acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. The Authority took into account the most recent information on the toxicological properties of the substance. Neither the lifetime exposure to this substance via consumption of all food products that may contain it, nor the short-term exposure due to high consumption of the relevant products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.
- (8) As there is no risk to consumers, the MRL for oyster mushrooms should be set at the level corresponding to the 95th percentile of all the sample results while maintaining the existing MRL for other cultivated fungi. This MRL will be reviewed; the review will take into account the information available within 13 April 2021.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) 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
Jean-Claude JUNCKER

⁵ EFSA scientific reports available online: <http://www.efsa.europa.eu>: Statement on the setting of a temporary maximum residue level for chlormequat in cultivated fungi. EFSA Journal 2019;17(5):XXXX.