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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 chlormequat in cultivated fungi

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Delegations will find attached document D061927/02.

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Brussels, **XXX**  
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[...] (2019) **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 chlormequat in cultivated fungi**

(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 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/EEC<sup>1</sup>, and in particular Article 14(1)(a) and Article 16(1)(a) thereof,

Whereas:

- (1) For chlormequat, maximum residue levels (MRLs) are set in Annex II to Regulation (EC) No 396/2005.
- (2) The MRLs for chlormequat were recently modified by Commission Regulation (EU) 2017/693<sup>2</sup> in accordance with Article 12(1) of Regulation (EC) No 396/2005. In that framework, a temporary MRL for cultivated fungi was set at 0.9 mg/kg due to monitoring data showing that residues occurred on untreated cultivated fungi at a level higher than the limit of determination where such residues may result from cross-contamination of cultivated fungi with straw lawfully treated with chlormequat.
- (3) Mushroom growers submitted to the Commission recent monitoring data specifically on oyster mushrooms showing that residues occur in those products at higher levels than the current temporary MRL set for cultivated fungi. Those residues result from a cross-contamination of cultivated fungi with straw lawfully treated with chlormequat. Several Member States submitted additional monitoring data from official controls performed specifically on oyster mushrooms, which confirmed those findings.
- (4) Germany compiled and evaluated an application for modification of the existing MRL in accordance with Article 6(3) of Regulation (EC) No 396/2005 and forwarded the evaluation report to the Commission.

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

<sup>2</sup> 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).

- (5) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals and gave a scientific statement on the proposed MRL<sup>3</sup>. It forwarded that statement to the applicant, the Commission and the Member States and made it available to the public.
- (6) The Authority concluded in its scientific statement that the modification 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.
- (7) In light of the Authority's conclusions on 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. That MRL will be reviewed; the review will take into account the information available within 13 April 2021.
- (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 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*  
*Jean-Claude JUNCKER*

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<sup>3</sup> EFSA scientific reports available online: <http://www.efsa.europa.eu>: Statement on the dietary risk assessment for the proposed temporary maximum residue level for chlormequat in oyster mushrooms. EFSA Journal 2019;17(5):5707.