



Brussels, **XXX**  
SANCO/11157/2014 rev. 2  
[...](2014) **XXX** draft

**COMMISSION REGULATION (EU) No .../..**

**of **XXX****

[...]

COMMISSION REGULATION (EU) No .../..

of **XXX**

**amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for lactic acid, *Lecanicillium muscarium* strain Ve6, chitosan hydrochloride and *Equisetum arvense* L. 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 5(1) thereof,

Whereas:

- (1) For lactic acid, *Lecanicillium muscarium* strain Ve6, chitosan hydrochloride and *Equisetum arvense* L., no specific MRLs were set nor were the 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.
- (2) Chitosan hydrochloride is approved as basic substance in accordance with Regulation No 1107/2009<sup>2</sup>. In view of Implementing Regulation (EU) No 563/2014<sup>3</sup>, the Commission considers that the inclusion of such substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (3) *Equisetum arvense* L. is approved as basic substance in accordance with Regulation No 1107/2009. In view of Implementing Regulation (EU) No 462/2014<sup>4</sup>, the

---

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

<sup>2</sup> 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).

<sup>3</sup> Commission Implementing Regulation (EU) No 563/2014 of 23 May 2014 approving the basic substance *chitosan hydrochloride*, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Implementing Regulation (EU) No 540/2011 (OJ L 156, 24.5.2014, p. 5).

<sup>4</sup> Commission Implementing Regulation (EU) No 462/2014 of 5 May 2014 approving the basic substance *Equisetum arvense* L., in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Implementing Regulation (EU) No 540/2011 (OJ L 134, 7.5.2014, p. 28).

Commission considers that the inclusion of such substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.

- (4) Lactic acid is approved as a food additive in accordance with Regulation No 1333/2008<sup>5</sup>. In view of Commission Regulation (EU) No 1129/2011<sup>6</sup>, the Commission considers that the inclusion of lactic acid in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (5) As regards *Lecanicillium muscarium* strain Ve6, the European Food Safety Authority ('the Authority') concluded<sup>7</sup> that its inclusion in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (6) Based on the conclusion of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the relevant requirements of Article 5(1) and Article 14(2) of Regulation (EC) No 396/2005.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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*

In Annex IV, the entries: 'lactic acid<sup>(2)</sup>', '*Lecanicillium muscarium* strain Ve6', 'chitosan hydrochloride', and '*Equisetum arvense* L.' are added, in alphabetical order.

#### *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*  
**José Manuel BARROSO**

---

<sup>5</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

<sup>6</sup> Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives. Text with EEA relevance (OJ L 295, 12.11.2011, p. 1).

<sup>7</sup> European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Lecanicillium muscarium* strain Ve6, notified as *Verticillium lecanii*. EFSA Journal 2010; 8(1):1446. [45 pp.]. doi:10.2903/j.efsa.2010.1446.