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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 COS-OGA, cerevisane, calcium hydroxide, *Pythium oligandrum* M1, *Verticillium albo-atrum* strain WCS850 and *Bacillus amyloliquefaciens* ssp. *plantarum* D747 in or on certain products

(Text with EEA relevance)

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(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) thereof,

Whereas:

- (1) For COS-OGA, cerevisane, calcium hydroxide, *Pythium oligandrum* M1, *Verticillium albo-atrum* strain WCS850 and *Bacillus amyloliquefaciens* ssp. *plantarum* D747, 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) As regards COS-OGA, the Authority concluded² that its inclusion in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (3) As regards cerevisane, the Authority concluded³ that its inclusion in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (4) Calcium-hydroxide is approved as basic substance in accordance with Regulation No 1107/2009⁴. In view of Implementing Regulation (EU) No 762/2015⁵, the Commission considers that the inclusion of such substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (5) *Pythium oligandrum* M1 is approved under Directive 91/414/EEC⁶. Natural exposure to *Pythium oligandrum* M1 is expected to be higher than the one linked to the use of

¹ OJ L 70, 16.3.2005, p. 1.

² EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance COS-OGA. EFSA Journal 2014;12(10):3868, 39 pp.

³ EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance cerevisane (cell walls of *Saccharomyces cerevisiae* strain LAS117). EFSA Journal 2014;12(6):3583, 39 pp.

⁴ 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).

⁵ OJ L 120, 13.5.2015, p. 6

⁶ OJ L 70, 16.3.2005, p. 1.

that substance as a plant protection product. In view of this, it is considered appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.

- (6) *Verticillium albo-atrum* strain WCS850 is approved under Directive 91/414/EEC⁷. Natural exposure to *Verticillium albo-atrum* strain WCS850 is far higher than the one linked to the use of that substance as a plant protection product. The Authority⁸ concluded that *Verticillium albo-atrum* strain WCS850 is not known to be pathogenic to humans and does not produce any significant toxins/secondary metabolites during the manufacturing process. In view of this, it is considered appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.
- (7) As regards *Bacillus amyloliquefaciens* ssp. *plantarum* D747⁹, the European Food Safety Authority ('the Authority') could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was necessary. Such further consideration was reflected in the corresponding review report¹⁰ which concluded that this substance is not pathogenic to humans and is not expected to produce toxins that are relevant for human health. In view of those considerations, the Commission considers that the inclusion of this substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (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

Annex IV 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.

⁷ OJ L 70, 16.3.2005, p. 1.

⁸ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Verticillium albo-atrum* (strain WCS850). EFSA Journal 2013;11(1):3059. [22 pp.]

⁹ EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747. EFSA Journal 2014;12(4):3624, 29 pp.

¹⁰ Review report for the active substance *Bacillus amyloliquefaciens* ssp. *plantarum* D747. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 10 October 2014 in view of the approval of *Bacillus amyloliquefaciens* ssp. *plantarum* D747 as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/11391/2014 – rev. 1, 10 October 2014.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER