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#### COVER NOTE

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| From:            | European Commission   |
| date of receipt: | 13 October 2015   |
| To:              | Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union |

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| No. Cion doc.: | D041475/02  |
| Subject:       | COMMISSION REGULATION (EU) .../... of XXX amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards COS-OGA, cerevisane, calcium hydroxide, lecithins, Salix spp cortex, vinegar, fructose, Pepino mosaic virus strain CH2 isolate 1906, Verticillium albo-atrum isolate WCS850 and Bacillus amyloliquefaciens subsp. plantarum strain D747 |

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Delegations will find attached document D041475/02.

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Brussels, **XXX**  
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**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards COS-OGA, cerevisane, calcium hydroxide, lecithins, *Salix* spp cortex, vinegar, fructose, *Pepino mosaic virus* strain CH2 isolate 1906, *Verticillium albo-atrum* isolate WCS850 and *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747**

(Text with EEA relevance)

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

of **XXX**

amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards COS-OGA, cerevisane, calcium hydroxide, lecithins, *Salix spp cortex*, vinegar, fructose, *Pepino mosaic virus strain CH2 isolate 1906*, *Verticillium albo-atrum* isolate WCS850 and *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747

(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 COS-OGA, cerevisane, calcium hydroxide, lecithins, *Salix spp cortex*, vinegar, fructose, *Pepino mosaic virus strain CH2 isolate 1906*, *Verticillium albo-atrum* isolate WCS850 and *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747 no specific MRLs were set. As those substances were not included in Annex IV to Regulation (EC) No 396/2005, 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 European Food Safety Authority ('the Authority') concluded<sup>2</sup> that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (3) As regards cerevisane, the Authority concluded<sup>3</sup> that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (4) As regards *Pepino mosaic virus strain CH2 isolate 1906*, the Authority concluded<sup>4</sup> that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.

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

<sup>2</sup> 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.

<sup>3</sup> 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.

- (5) Calcium-hydroxide is approved as basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>5</sup>. In view of Commission Implementing Regulation (EU) 2015/762<sup>6</sup>, the Commission considers that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (6) The basic substance `lecithins` is approved in accordance with Regulation (EC) No 1107/2009. In view of Commission Implementing Regulation (EU) 2015/1116<sup>7</sup>, the Commission considers that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (7) *Salix* spp cortex is approved as basic substance in accordance with Regulation (EC) No 1107/2009. In view of Commission Implementing Regulation (EU) 2015/1107<sup>8</sup>, the Commission considers that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (8) Vinegar is approved as basic substance in accordance with Regulation (EC) No 1107/2009. In view of Commission Implementing Regulation (EU) 2015/1108<sup>9</sup>, the Commission considers that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (9) Fructose is approved as basic substance in accordance with Regulation (EC) No 1107/2009. In view of Commission Implementing Regulation (EU) 2015/1392<sup>10</sup>, the Commission considers that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (10) *Verticillium albo-atrum* isolate WCS850 was included in Annex I to Council Directive 91/414/EEC by Commission Directive 2008/113/EC<sup>11</sup> and is deemed to

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<sup>4</sup> European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Pepino mosaic virus* strain CH2 isolate 1906. EFSA Journal 2015;13(1):3977, 25 pp.

<sup>5</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>6</sup> Commission Implementing Regulation (EU) 2015/762 of 12 May 2015 approving the basic substance calcium hydroxide 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 120, 13.5.2015, p. 6).

<sup>7</sup> Commission Implementing Regulation (EU) 2015/1116 of 9 July 2015 approving the basic substance lecithins, 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 182, 10.7.2015, p. 26).

<sup>8</sup> Commission Implementing Regulation (EU) 2015/1107 of 8 July 2015 approving the basic substance *Salix* spp. cortex, 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 181, 9.7.2015, p. 72).

<sup>9</sup> Commission Implementing Regulation (EU) 2015/1108 of 8 July 2015 approving the basic substance vinegar 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 181, 9.7.2015, p. 75).

<sup>10</sup> Commission Implementing Regulation (EU) 2015/1392 of 13 August 2015 approving the basic substance fructose 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 215, 14.8.2015, p. 34).

<sup>11</sup> Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, 6.).

have been approved under Regulation (EC) No 1107/2009. Natural exposure to *Verticillium albo-atrum* isolate WCS850 is far higher than the exposure linked to the use of that substance as a plant protection product. The Authority concluded<sup>12</sup> that *Verticillium albo-atrum* isolate WCS850 is not known to be pathogenic to humans and does not produce any significant toxins or secondary metabolites during the manufacturing process. It is therefore appropriate to include that substance in Annex IV to Regulation (EC) No 396/2005.

- (11) Commission Implementing Regulation (EU) No 1316/2014<sup>13</sup> approved the active substance *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747. The Authority concluded<sup>14</sup> that as regards the dietary risk assessment for consumers some information was not available and further consideration by risk managers was required. The review report for that substance<sup>15</sup> stated that it is not pathogenic to humans and is not expected to produce toxins that are relevant for human health. It is therefore appropriate to include that substance in Annex IV to Regulation (EC) No 396/2005.
- (12) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (13) 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 to Regulation (EC) No 396/2005, the following entries are inserted in alphabetical order: ‘COS-OGA’, ‘cerevisane’, ‘calcium hydroxide’, ‘lecithins’, ‘*Salix* spp cortex’, ‘vinegar’, ‘fructose’, ‘*Pepino mosaic virus* strain CH2 isolate 1906’, ‘*Verticillium albo-atrum* isolate WCS850’ and ‘*Bacillus amyloliquefaciens* subsp. *plantarum* strain D747’.

#### *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*.

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<sup>12</sup> 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.]

<sup>13</sup> Commission Implementing Regulation (EU) No 1316/2014 of 11 December 2014 approving the active substance *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747, 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 and allowing Member States to extend provisional authorisations granted for that active substance (OJ L 355, 12.12.2014, p. 1).

<sup>14</sup> 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.

<sup>15</sup> Review report for the active substance *Bacillus amyloliquefaciens* ssp. *plantarum* strain D747 [finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 10 October 2014] SANCO/11391/2014 – rev. 1, 10 October 2014.

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*