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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 <i>Cydia pomonella</i> Granulovirus (CpGV), calcium carbide, potassium iodide, sodium hydrogen carbonate, rescalure and <i>Beauveria bassiana</i> strain ATCC 74040 and <i>Beauveria bassiana</i> strain GHA
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Delegations will find attached document D042746/16.

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Encl.: D042746/16



Brussels, **XXX**  
SANTE/11406/2015 Rev. 2  
(POOL/E3/2015/11406/11406R2-  
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[...](2015) **XXX** draft

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

**of **XXX****

**amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards *Cydia pomonella* Granulovirus (CpGV), calcium carbide, potassium iodide, sodium hydrogen carbonate, rescalure and *Beauveria bassiana* strain ATCC 74040 and *Beauveria bassiana* strain GHA**

(Text with EEA relevance)

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

## 1. of **XXX**

**amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards *Cydia pomonella* Granulovirus (CpGV), calcium carbide, potassium iodide, sodium hydrogen carbonate, rescalure and *Beauveria bassiana* strain ATCC 74040 and *Beauveria bassiana* strain GHA**

(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 *Cydia pomonella* Granulovirus (CpGV), calcium carbide, sodium hydrogen carbonate, rescalure, *Beauveria bassiana* strain ATCC 74040 and *Beauveria bassiana* strain GHA no specific MRLs were set. As those substances were not included in Annex IV to Regulation (EC) No 396/2005 either, the default value of 0.01 mg/kg laid down in Article 18(1)(b) of that Regulation applies. Potassium iodide is included in Annex IV to Regulation (EC) No 396/2005.
- (2) As regards *Cydia pomonella* Granulovirus (CpGV), the European Food Safety Authority ('the Authority') concluded<sup>2</sup> that these viruses are not pathogenic to humans and that they will not produce any toxins. Therefore, it is considered appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.
- (3) As regards calcium carbide, the Authority concluded<sup>3</sup> that this substance does not enter the human food chain. Therefore, it is considered appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.

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

<sup>2</sup> European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Cydia pomonella* granulovirus. EFSA Journal 2012;10(4):2655. [40 pp.] doi:10.2903/j.efsa.2012.2655.

<sup>3</sup> European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance calcium carbide. EFSA Journal 2011;9(10):2419. [48 pp.] doi:10.2903/j.efsa.2011.2419.

- (4) Potassium iodide is a mineral substance which may be used in the manufacture of food supplements in accordance with Directive 2002/46/EC<sup>4</sup>. In view of this, it is considered appropriate to remove the footnote requesting evaluation according to Article 12 of Regulation (EC) No 396/2005 for this substance.
- (5) Sodium hydrogen carbonate 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) 2015/2069<sup>6</sup>, the Commission considers that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (6) As regards rescalure, the Authority concluded<sup>7</sup> that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (7) As regards *Beauveria bassiana* strain ATCC 74040 and *Beauveria bassiana* strain GHA<sup>8</sup> 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 respective review reports<sup>9,10</sup> which concluded that the risk to humans through metabolites from these substances is negligible. In view of those conclusions, the Commission considers that the inclusion of those substances 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:

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<sup>4</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

<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) 2015/2069 of 17 November 2015 approving the basic substance sodium hydrogen carbonate 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 301, 18.11.2015, p. 42).

<sup>7</sup> European Food Safety Authority, 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance rescalure. EFSA Journal 2015;13(2):4031, 40 pp.

<sup>8</sup> European Food Safety Authority, 2013. Conclusion on the peer review of the pesticide risk assessment of the active substances *Beauveria bassiana* strains ATCC-74040 and GHA. EFSA Journal 2013;11(1):3031. 44 pp.

<sup>9</sup> Review report for the active substance *Beauveria bassiana* strain ATCC 74040 finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 11 July 2008 in view of the inclusion of *Beauveria bassiana* strain ATCC 74040 in Annex I of Directive 91/414/EEC. SANCO/1546/08 – rev. 5, 11 July 2014.

<sup>10</sup> Review report for the active substance *Beauveria bassiana* strain GHA finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 11 July 2008 in view of the inclusion of *Beauveria bassiana* strain GHA in Annex I of Directive 91/414/EEC. SANCO/1547/08 – rev. 5, 11 July 2014.

*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*.

1. This Regulation shall be binding in its entirety and directly applicable in all Member States.

1. Done at Brussels,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*