



Council of the
European Union

Brussels, 1 April 2015
(OR. en)

7699/15

AGRILEG 72

COVER NOTE

From:	European Commission
date of receipt:	31 March 2015
To:	General Secretariat of the Council
No. Cion doc.:	D036787/03
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 maximum residue levels for <i>Trichoderma polysporum</i> strain IMI 206039, <i>Trichoderma asperellum</i> (formerly <i>T. harzianum</i>) strains ICC012, T25 and TV1, <i>Trichoderma atroviride</i> (formerly <i>T. harzianum</i>) strains IMI 206040 and T11, <i>Trichoderma harzianum</i> strains T-22 and ITEM 908, <i>Trichoderma gamsii</i> (formerly <i>T. viride</i>) strain ICC080, <i>Trichoderma asperellum</i> (strain T34), <i>Trichoderma atroviride</i> strain I-1237, geraniol, thymol, sucrose, ferric sulphate (Iron (III) sulphate), ferrous sulphate (Iron (II) sulphate) and folic acid in or on certain products

Delegations will find attached document D036787/03.

Encl.: D036787/03



Brussels, **XXX**
SANCO/11632/2014 Rev. 1
(POOL/E3/2014/11632/11632R1-EN
ANNEX.doc) D036787/03
[...] (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 maximum residue levels for *Trichoderma polysporum* strain IMI 206039, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strains IMI 206040 and T11, *Trichoderma harzianum* strains T-22 and ITEM 908, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma asperellum* (strain T34), *Trichoderma atroviride* strain I-1237, geraniol, thymol, sucrose, ferric sulphate (Iron (III) sulphate), ferrous sulphate (Iron (II) sulphate) and folic acid in or on certain products

(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 maximum residue levels for *Trichoderma polysporum* strain IMI 206039, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strains IMI 206040 and T11, *Trichoderma harzianum* strains T-22 and ITEM 908, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma asperellum* (strain T34), *Trichoderma atroviride* strain I-1237, geraniol, thymol, sucrose, ferric sulphate (Iron (III) sulphate), ferrous sulphate (Iron (II) sulphate) and folic acid 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/EEC¹, and in particular Article 5(1) thereof,

Whereas:

- (1) For *Trichoderma polysporum* strain IMI 206039, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strains IMI 206040 and T11, *Trichoderma harzianum* strains T-22 and ITEM 908, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma asperellum* (strain T34), *Trichoderma atroviride* strain I-1237, sucrose, geraniol and thymol, 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. Ferric sulphate (Iron (III) sulphate), ferrous sulphate (Iron (II) sulphate) and folic acid are included in Annex IV to Regulation (EC) No 396/2005.
- (2) As regards *Trichoderma polysporum* strain IMI 206039², *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1³, *Trichoderma atroviride*

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma polysporum* strain IMI 206039. EFSA Journal 2013;11(1):3035. [38 pp.] doi:10.2903/j.efsa.2013.3035.

³ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma asperellum* strains ICC012, T25 and TV1. EFSA Journal 2013;11(1):3036. [61 pp.] doi:10.2903/j.efsa.2013.3036.

(formerly *T. harzianum*) strains IMI 206040 and T11⁴, *Trichoderma harzianum* strains T-22 and ITEM 908⁵, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080⁶, *Trichoderma asperellum* (strain T34)⁷ and *Trichoderma atroviride* strain I-1237⁸ 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 reports^{9,10,11,12,13,14,15,16,17} which concluded that these substances are not pathogenic to humans and are not expected to produce toxins that are relevant for human health. In view of those conclusions, the Commission considers that the inclusion of such substances in Annex IV to Regulation (EC) No 396/2005 is appropriate.

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- ⁴ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strains IMI-206040 and T11. EFSA Journal 2013;11(1):3056. [69 pp.] doi:10.2903/j.efsa.2013.3056.
- ⁵ European Food Safety Authority, 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma harzianum* Rifai strains T-22 and ITEM-908. EFSA Journal 2013;11(10):3055. [47 pp.], doi:10.2903/j.efsa.2013.3055.
- ⁶ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma gamsii* ICC080. EFSA Journal 2013;11(1):3062. [29 pp.] doi:10.2903/j.efsa.2013.3062.
- ⁷ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma asperellum* strain T34. EFSA Journal 2012;10(5):2666. [37 pp.] doi:10.2903/j.efsa.2012.2666.
- ⁸ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance [*Trichoderma atroviride* strain I-1237.]. EFSA Journal 2012;10(10):2706. [33 pp.] doi:10.2903/j.efsa.2012.2706.
- ⁹ Review report for the active substance *Trichoderma polysporum* IMI 206039. 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 *Trichoderma polysporum* IMI 206039 in Annex I of Directive 91/414/EEC. SANCO/1867/08 – rev. 6, 11 July 2014.
- ¹⁰ Review report for the active substance *Trichoderma asperellum* (formerly *T. harzianum*) ICC012. 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 *Trichoderma asperellum* (formerly *T. harzianum*) ICC012 in Annex I of Directive 91/414/EEC. SANCO/1842/08 – rev. 5, 11 July 2014.
- ¹¹ Review report for the active substances *Trichoderma gamsii* ICC080 (formerly *Trichoderma viride* strain ICC080), *Trichoderma asperellum* T25* (formerly identified as *Trichoderma viride* strain T-25) and *Trichoderma asperellum* TV1 (formerly identified as *Trichoderma viride* strain TV1). 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 *Trichoderma gamsii* ICC080 (formerly *Trichoderma viride* strain ICC080), *Trichoderma asperellum* T25* (formerly identified as *Trichoderma viride* strain T-25) and *Trichoderma asperellum* TV1 (formerly identified as *Trichoderma viride* strain TV1) in Annex I of Directive 91/414/EEC. SANCO/1868/08 – rev. 6, 11 July 2014.
- ¹² Review report for the active substance *Trichoderma atroviride* IMI 206040 (formerly *T. harzianum* IMI 206040). 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 *Trichoderma atroviride* IMI 206040 (formerly *T. harzianum* IMI 206040) in Annex I of Directive 91/414/EEC. SANCO/1866/08 – rev. 6, 11 July 2014.
- ¹³ Review report for the active substance *Trichoderma atroviride* (formerly *T. harzianum*) T-11. 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 *Trichoderma atroviride* (formerly *T. harzianum*) T-11 in Annex I of Directive 91/414/EEC. SANCO/1841/08 – rev. 6, 11 July 2014.
- ¹⁴ Review report for the active substance *Trichoderma harzianum* T-22. 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 *Trichoderma harzianum* T-22 in Annex I of Directive 91/414/EEC. SANCO/1839/08 – rev. 5, 11 July 2014.
- ¹⁵ Review report for the active substance *Trichoderma harzianum* ITEM 908. 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 *Trichoderma harzianum* ITEM 908 in Annex I of Directive 91/414/EEC. SANCO/1840/08 – rev. 6, 11 July 2014.
- ¹⁶ Review report for the active substance *Trichoderma asperellum* T34. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 20 November 2012 in view of the inclusion of *Trichoderma asperellum* T34 in Annex I of Directive 91/414/EEC. SANCO/12614/2012 – rev. 4, 20 November 2012.
- ¹⁷ Review report for the active substance *Trichoderma atroviride* strain I-1237. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 20 November 2012 in view of the inclusion of *Trichoderma atroviride* strain I-1237 in Annex I of Directive 91/414/EEC. SANCO/12620/2012 – rev. 4, 20 November 2012.

- (3) For thymol¹⁸, the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and, in accordance with Commission Implementing Regulation (EU) No 568/2013¹⁹ the substance was approved subject to the submission of confirmatory information. Thymol is naturally occurring in plants. In view of this, it is considered appropriate to include this substance temporarily in Annex IV to Regulation (EC) No 396/2005 pending submission of the reasoned opinion of the Authority in accordance with Article 12(1).
- (4) For geraniol²⁰, the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and, in accordance with Commission Implementing Regulation (EU) No 570/2013²¹ the substance was approved subject to the submission of confirmatory information. Geraniol is naturally occurring in plants. In view of this, it is considered appropriate to include this substance temporarily in Annex IV to Regulation (EC) No 396/2005 pending submission of the reasoned opinion of the Authority in accordance with Article 12(1).
- (5) Sucrose is approved as basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council²². In view of Commission Implementing Regulation (EU) No 916/2014²³, the Commission considers that the inclusion of such substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (6) Ferric sulphate (Iron (III) sulphate) is not an active substance under Regulation (EC) No 1107/2009. Therefore, this substance does not fall within the scope of Regulation (EC) No 396/2005. In view of this, it is considered appropriate to delete this substance from Annex IV to Regulation (EC) No 396/2005.
- (7) Commission Decision 2007/442/EC²⁴ provided for a non-inclusion of folic acid in Annex I to Council Directive 91/414/EEC. Since Article 12 of Regulation (EC) No 396/2005 therefore does not apply to folic acid, it is appropriate to delete after the entry for folic acid the footnote 1 referring to that provision.

¹⁸ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance thymol. EFSA Journal 2012;10(11):2916. [43 pp.] doi:10.2903/j.efsa.2012.2916.

¹⁹ Commission Implementing Regulation (EU) No 568/2013 of 18 June 2013 approving the active substance thymol, 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 167, 19.6.2013, p. 33).

²⁰ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance geraniol. EFSA Journal 2012;10(11):2915. [44 pp.] doi:10.2903/j.efsa.2012.2915.

²¹ Commission Implementing Regulation (EU) No 570/2013 of 17 June 2013 approving the active substance geraniol, 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 Implementing Regulation (EU) No 540/2011 (OJ L 168, 20.6.2013, p. 18).

²² 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).

²³ Commission Implementing Regulation (EU) No 916/2014 of 22 August 2014 approving the basic substance sucrose 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 251, 23.8.2014, p. 16).

²⁴ Commission Decision 2007/442/EC of 21 June 2007 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances (OJ L 166, 28.6.2007, p. 16).

- (8) Ferrous sulphate (iron II sulphate) and folic acid are food supplements under Directive 2002/46/EC of the European Parliament and of the Council²⁵. Other substances listed in Annex IV are food additives or flavourings. In view of this, it is appropriate to modify the wording of footnote 2 to refer more broadly to other specific food and feed legislation.
- (9) 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.
- (10) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (11) 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.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

²⁵ 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).