COMMISSION REGULATION (EU) 2015/896

of 11 June 2015


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


Whereas:

(1) For *Trichoderma polysporum* strain IMI 206039, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1 (1), *Trichoderma atroviride* (formerly *T. harzianum*) strains IMI 206040 and T11 (1), *Trichoderma harzianum* strains T-22 and ITEM 908 (1), *Trichoderma gamsii* (formerly *T. viride*) strain ICC080 (1), *Trichoderma asperellum* (strain T34) (1) and *Trichoderma atroviride* strain I-1237 (1) the substance was approved subject to the submission of confirmatory information. 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 (1) 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.

(2) As regards *Trichoderma polysporum* strain IMI 206039 (1), *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1 (1), *Trichoderma atroviride* (formerly *T. harzianum*) strains IMI 206040 and T11 (1), *Trichoderma harzianum* strains T-22 and ITEM 908 (1), *Trichoderma gamsii* (formerly *T. viride*) strain ICC080 (1), *Trichoderma asperellum* (strain T34) (1) and *Trichoderma atroviride* strain I-1237 (1) 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 916/2014 (1), the substance was approved subject to the submission of confirmatory information. The European Food Safety Authority (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 916/2014 (1), the substance was approved subject to the submission of confirmatory information. The substance was approved subject to the submission of confirmatory information. 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).

(3) For thymol (1), 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 568/2013 (1) 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 geraniol (1), 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 570/2013 (1) 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 Council (1). In view of Commission Implementing Regulation (EU) No 916/2014 (1), the substance was approved subject to the submission of confirmatory information. Sucrose is naturally occurring in plants. In view of this, it is considered appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.

(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.
Commission Decision 2007/442/EC (1) provided for a non-inclusion of folic acid in Annex I to Council Directive 91/414/EEC (2). 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.

Ferrous sulphate (iron II sulphate) and folic acid are food supplements under Directive 2002/46/EC of the European Parliament and of the Council (3). 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.

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.

Regulation (EC) No 396/2005 should therefore be amended accordingly.

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, 11 June 2015.

For the Commission

The President

Jean-Claude JUNCKER


Annex IV to Regulation (EC) No 396/2005 is amended as follows:

(1) the text of footnote 2 is replaced by the following:

‘(2) Substances included in Annex IV without prejudice to other specific food and feed legislation, e.g. on food additives, food supplements, flavourings, etc.;


(3) the entry ‘Ferric sulphate (Iron (III) sulphate)’ is deleted;

(4) the reference to footnote 1 behind the entry ‘Folic acid’ is replaced by a reference to footnote 2;

(5) a reference to footnote 2 behind the entry ‘Ferrous sulphate (Iron II sulphate)’ is added.

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