Commission Implementing Regulation (EU) 2015/1043 of 30 June 2015 concerning the authorisation of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma citrinoviride Bisset (IM SD135) as a feed additive for chickens for fattening, turkeys for fattening, laying hens, weaned piglets, pigs for fattening and minor poultry species for fattening and for laying, and amending Regulations (EC) No 2148/2004, (EC) No 828/2007 and (EC) No 322/2009 (holder of authorisation Huvepharma NV) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1043

of 30 June 2015

concerning the authorisation of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IM SD135) as a feed additive for chickens for fattening, turkeys for fattening, laying hens, weaned piglets, pigs for fattening and minor poultry species for fattening and for laying, and amending Regulations (EC) No 2148/2004, (EC) No 828/2007 and (EC) No 322/2009 (holder of authorisation Huvepharma NV)

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) The preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IM SD135) (formerly *Trichoderma longibrachiatum*) was authorised in accordance with Directive 70/524/EEC without a time limit as a feed additive for chickens for fattening by Commission Regulation (EC) No 2148/2004[(3)], for turkeys for fattening by Commission Regulation (EC) No 828/2007[(4)] and for laying hens and weaned piglets by Commission Regulation (EC) No 322/2009[(5)]. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IM SD135) (formerly *Trichoderma longibrachiatum*) as a feed

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1043. (See end of Document for details)*

additive for chickens for fattening, turkeys for fattening, laying hens, weaned piglets, pigs for fattening and minor poultry species for fattening and for laying. The applicant requested that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 31 January 2013[6] and 10 December 2014[7] that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IM SD135) (formerly *Trichoderma longibrachiatum*) does not have an adverse effect on animal health, human health or the environment.

(5) The Authority also concluded that the use of that preparation has the potential to be efficacious in turkeys for fattening, chickens for fattening, laying hens, weaned piglets and pigs for fattening. The Authority further considered that the conclusions on the efficacy can be extrapolated to minor poultry species for fattening and for laying. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IM SD135) (formerly *Trichoderma longibrachiatum*) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(7) Regulations (EC) No 2148/2004, (EC) No 828/2007 and (EC) No 322/2009 should therefore be amended accordingly.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(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

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment to Regulation (EC) No 2148/2004

In Annex IV to Regulation (EC) No 2148/2004 the entry on E 1617, endo-1,4-beta-xylanase EC 3.2.1.8, is deleted.

Article 3

Amendment to Regulation (EC) No 828/2007

Regulation (EC) No 828/2007 is amended as follows:

(1) Article 2 is deleted;

(2) Annex II is deleted.

Article 4

Amendment to Regulation (EC) No 322/2009

Regulation (EC) No 322/2009 is amended as follows:

(1) Article 2 is deleted;

(2) Annex II is deleted.

Article 5

Transitional measures

The preparation specified in the Annex, and feed containing that preparation, which are produced and labelled before 21 January 2016 in accordance with the rules applicable before 21 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 6

Entry into force

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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1043. (See end of Document for details)*

Done at Brussels, 30 June 2015.

For the Commission

The President

Jean-Claude JUNCKER