COMMISSION IMPLEMENTING REGULATION (EU) 2015/2305

of 10 December 2015

concerning the authorisation of a preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma citrinoviride* Bisset (IM SD142) as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, and amending Regulations (EC) No 2148/2004 and (EC) No 1520/2007 (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-glucanase (EC 3.2.1.4) produced by *Trichoderma citrinoviride* Bisset (IM SD142) (formerly *Trichoderma longibrachiatum*) hereinafter referred to as 'the preparation specified in the Annex' was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening by Commission Regulation (EC) No 2148/2004 ([3]) and for weaned piglets by Commission Regulation (EC) No 1520/2007 ([4]). That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) 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-glucanase (EC 3.2.1.4) produced by *Trichoderma citrinoviride* Bisset (IM SD142) (formerly *Trichoderma longibrachiatum)* as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets. 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 17 April 2013 ([5]) and 10 March 2015 ([6]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma citrinoviride* Bisset (IM SD142) (formerly *Trichoderma longibrachiatum)* does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the use of that preparation has the potential to be efficacious in chickens for fattening and weaned piglets. The Authority further considered that the conclusions on the efficacy can be extrapolated to minor poultry species for fattening. It 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.

(5) The assessment of the preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma citrinoviride* Bisset (IM SD142) (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.

(6) Regulations (EC) No 2148/2004 and (EC) No 1520/2007 should be amended accordingly.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Regulation (EC) No 2148/2004 of 16 December 2004 concerning the permanent and provisional authorisations of certain additives and the authorisation of new uses of an additive already authorised in feedingstuffs (OJ L 370, 17.12.2004, p. 24).
([4]) Commission Regulation (EC) No 1520/2007 of 19 December 2007 concerning the permanent authorisations of certain additives in feedingstuffs (OJ L 335, 20.12.2007, p. 17).
([5]) EFSA Journal 2013; 11(7):3207.
([6]) EFSA Journal 2015; 13(3):4054.

(7) 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.

(8) 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 1616, endo-1,4-beta-glucanase, is deleted.

Article 3

Amendment to Regulation (EC) No 1520/2007

Regulation (EC) No 1520/2007 is amended as follows:

(1) Article 5 is deleted;

(2) Annex V is deleted.

Article 4

Transitional measures

The preparation specified in the Annex, and feed containing that preparation, which is produced and labelled before 30 June 2016 in accordance with the rules applicable before 31 December 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

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.

Done at Brussels, 10 December 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a1616	Huvepharma NV	Endo-1,4-beta-glucanase EC 3.2.1.4	*Additive composition:* Preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma citrinoviride* Bisset (IM SD142) with a minimum activity of 2 000 CU (1)/g (solid and liquid form). *Characterisation of the active substance:* Endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma citrinoviride* Bisset (IM SD142). *Analytical method* (2)*:* For the determination of endo-1,4-beta-glucanase in feed additive, premixtures and feedingstuffs: — colorimetric method based on the quantification of water soluble dyed fragments (azurine) produced by the action of endo-1,4-beta-glucanase on azurine-crosslinked cellulose.	Chickens for fattening and minor poultry species for fattening	—	500 CU	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. For safety: breathing protection, glasses and gloves shall be used during handling. 3. For use in weaned piglets until approximately 35 kg.	31 December 2025
				Weaned piglets		350 CU			

(1) 1 CU is the amount of enzyme that liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.
(2) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports