COMMISSION IMPLEMENTING REGULATION (EU) 2018/327

of 5 March 2018

concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IMI SD135) as a feed additive for carp (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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IMI SD135). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IMI SD135) as a feed additive for carp, to be classified in the additive category 'zootechnical additives'.

(4) That preparation was already authorised as a feed additive for 10 years by Commission Implementing Regulation (EU) 2015/1043 ([2]) for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and laying, weaned piglets and pigs for fattening and by Commission Implementing Regulation (EU) 2017/1906 ([3]) for chickens reared for laying and minor poultry species reared for laying.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 July 2017 ([4]) 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 (IMI SD135) does not have an adverse effect on animal health, human health or the environment. The Authority concluded that the additive is considered efficacious in improving the zootechnical performance of carp. 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 a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IMI SD135) 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) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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([1]) OJ L 268, 18.10.2003, p. 29.

([2]) 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 SD 135) 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) (OJ L 167, 1.7.2015, p. 63).

([3]) Commission Implementing Regulation (EU) 2017/1906 of 18 October 2017 concerning the authorisation of a preparation of endo-1,4-b-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IM SD135) as a feed additive for chickens reared for laying and minor poultry species reared for laying (holder of authorisation Huvepharma NV) (OJ L 269, 19.10.2017, p. 33).

([4]) *EFSA Journal* 2017;15(7):4942.

HAS ADOPTED THIS REGULATION:

Article 1

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

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, 5 March 2018.

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									
4a1617	Huvepharma NV	Endo-1,4-beta-xylanase EC 3.2.1.8	*Additive composition:* Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IMI SD135) with a minimum activity of 6 000 EPU (1)/g (solid and liquid form) *Characterisation of the active substance:* endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma citrinoviride* Bisset (IMI SD135) *Analytical method* (2) For characterisation of endo-1,4-beta-xylanase activity: colorimetric method measuring water-soluble dye released by action of endo-1,4-β-xylanase from azurine cross-linked wheat arabinoxylan substrates.	Carp	—	1 050 EPU		1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eyes and breathing protections.	26.3.2028

(1) 1 EPU is the amount of enzyme which releases 0,0083 µmol of reducing sugars (xylose equivalent) per minute from oat spelt xylan at pH 4,7 and 50 °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