COMMISSION IMPLEMENTING REGULATION (EU) 2020/993

of 9 July 2020

concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) as a feed additive for all avian species for fattening other than chickens for fattening, ornamental birds, all weaned porcine species other than weaned piglets and all porcine species for fattening other than pigs for fattening (holder of authorisation Berg und Schmidt GmbH Co. KG)

(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) The preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) was authorised for 10 years by Commission Implementing Regulation (EU) 2018/130 ([2]) for pigs for fattening and by Commission Implementing Regulation (EU) 2019/929 ([3]) for chickens for fattening and weaned piglets.

(3) 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 reesei* (BCCM/MUCL 49755). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) That application concerns the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) as a feed additive for all other avian species for fattening, ornamental birds and all other weaned porcine species and for fattening, to be classified in the additive category 'zootechnical additives'.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 July 2019 ([4]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive should be regarded as a potential skin and a respiratory sensitiser. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded in its previous opinions ([5]) that the additive has the potential to be efficacious in improving zootechnical performance in chickens for fattening, weaned piglets and pigs for fattening and that these conclusions can be extrapolated to all birds for fattening and ornamental birds and to all weaned porcine species and all porcine species for fattening. 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 reesei* (BCCM/MUCL 49755) 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]) OJ L 22, 26.1.2018, p. 120.
([3]) OJ L 148, 6.6.2019, p. 25.
([4]) *EFSA Journal* 2019;17(7):5781.
([5]) *EFSA Journal* 2017;15(2):4707 and *EFSA Journal* 2018;16(10):5457.

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, 9 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

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 — Units of activity/kg of complete feedingstuff with a moisture content of 12 %		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a26	Berg and Schmidt GmbH Co. KG	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 reesei* (BCCM/MUCL 49755) with a minimum activity of 15 000 EPU (1)/g Solid form ***Characterisation of active substance*** Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) ***Analytical method*** (2) For quantification of endo-1,4-beta-xylanase activity in the feed additive, premixtures and feedingstuffs: — Colorimetric method measuring water soluble dye released by action of endo-1,4- beta-xylanase from azurine cross-linked wheat arabinoxylan substrates.	All avian species for fattening other than chickens for fattening Ornamental birds All weaned porcine species other than weaned piglets All porcine species for fattening other than pigs for fattening	-	1 500 EPU	-	1. In the directions for use of the additive and premixture, 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 protection.	30.7.2030

(1) One Endopentosanase Unit (EPU) corresponds to the amount of enzyme which liberates 0,0083 µmol of reducing sugars (xylose equivalents) from oat spelt xylan per minute 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