

COMMISSION IMPLEMENTING REGULATION (EU) 2019/929

of 5 June 2019

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 chickens for fattening and weaned piglets (holder of authorisation Berg and 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) 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.
- (3) The 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 chickens for fattening and weaned piglets to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 25 January 2017 ⁽²⁾ and 2 October 2018 ⁽³⁾ 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 was also concluded that the additive may have a skin and respiratory sensitisation potential. Therefore, the Commission considers that 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 that the additive is considered efficacious in improving final body weight and feed to gain ratio in chickens for fattening and weaned piglets. 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.
- (5) 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.
- (6) 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

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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2017;15(2):4707

⁽³⁾ EFSA Journal 2018;16(10):5457.

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 June 2019.

For the Commission

The President

Jean-Claude JUNKER

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.

4a26	Berg and Schmidt GmbH Co. KG	Endo-1,4-beta-xylanase (EC 3.2.1.8)	<i>Additive composition</i> Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> (BCCM/MUCL 49755) with a minimum activity of 15 000 EPU ⁽¹⁾/g Solid form <i>Characterisation of active substance</i> endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> (BCCM/MUCL 49755) <i>Analytical method</i> ⁽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-β-xylanase from azurine cross-linked wheat arabinoxylan substrates.	Chickens for fattening Weaned piglets	—	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 use in weaned piglets up to approximately 35 kg body weight. 3. 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.	26.6.2029
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⁽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>