

COMMISSION IMPLEMENTING REGULATION (EU) No 1021/2012

of 6 November 2012

concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for minor poultry species other than ducks (holder of authorisation Danisco Animal Nutrition)

(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) and Article 13(3) 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 use of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) was authorised for 10 years for chickens for fattening, laying hens, ducks and turkeys for fattening by Commission Regulation (EU) No 9/2010 ⁽²⁾ and for weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) No 528/2011 ⁽³⁾.
- (3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new use of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) for minor poultry species other than ducks requesting that the additive be classified in the additive category 'zootechnical additives'.
- (4) The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003, and by the relevant data to support its requests.
- (5) The European Food Safety Authority ('the Authority') focused its assessment on safety and efficacy for the new target species. The Authority concluded in its opinion of 22 May 2012 ⁽⁴⁾ that, under the proposed

conditions of use, since safety of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) has been established in the major poultry species with a wide margin of safety, this conclusion can be extended to all poultry species requested. They stated that a similar conclusion on efficacy can be extrapolated from major poultry species to all minor poultry species. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (6) The assessment of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (ATCC PTA 5588) 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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The enzyme as 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, 6 November 2012.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 3, 7.1.2010, p. 10.

⁽³⁾ OJ L 143, 31.5.2011, p. 10.

⁽⁴⁾ EFSA Journal 2012; 10(6):2739.

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

4a11	Danisco Animal Nutrition (legal entity Danisco (UK) Limited)	Endo-1,4-beta-xylanase EC 3.2.1.8	<p><i>Additive composition</i></p> <p>Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> (ATCC PTA 5588) with a minimum activity of 40 000 U/g ⁽¹⁾</p> <p><i>Characterisation of the active substance</i></p> <p>endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> (ATCC PTA 5588)</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>For quantification of endo-1,4-beta-xylanase activity:</p> <p>colorimetric method based on the quantification of water soluble dyed fragments produced by the action of endo-1,4-beta-xylanase on azurine cross-linked wheat arabinoxylan at pH 4,25 and 50 °C.</p>	Minor poultry species other than ducks	—	625U		<p>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>2. For use in feed rich in starch and non-starch polysaccharides (mainly beta-arabinoxylans).</p>	27 November 2022
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⁽¹⁾ 1 U is the amount of enzyme which liberates 0,5 µmol of reducing sugar (expressed as xylose equivalents) from a cross-linked oat spelt arabinoxylan substrate at pH 5,3 and 50 °C in one minute.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx