

COMMISSION IMPLEMENTING REGULATION (EU) No 1196/2012

of 13 December 2012

amending Regulation (EU) No 9/2010 as regards the minimum content of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive in feed for laying hens (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 13(3) thereof,

Whereas:

- (1) The use of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (ATCC PTA 5588), belonging to the additive category of 'zoo-technical additives', was authorised for 10 years as a feed additive for use on chickens for fattening, laying hens, ducks and turkeys for fattening by Commission Regulation (EU) No 9/2010⁽²⁾, for weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) No 528/2011⁽³⁾ and for minor poultry species other than ducks by Commission Implementing Regulation (EU) No 1021/2012⁽⁴⁾.
- (2) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of the preparation concerned by reducing its minimum content from 2 500 U/kg to 625 U/kg as regards the use on laying hens. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter 'the Authority').

- (3) The Authority concluded in its opinion of 22 May 2012⁽⁵⁾ that, under the new proposed conditions of use, the preparation concerned is efficacious at the requested minimum dose of 625 U/kg. 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.
- (4) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.
- (5) Regulation (EU) No 9/2010 should therefore be amended accordingly.
- (6) 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 Annex to Regulation (EU) No 9/2010 is amended in accordance with the Annex to this Regulation.

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, 13 December 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⁾ OJ L 307, 7.11.2012, p. 68.

⁽⁵⁾ *EFSA Journal* 2012; 10(6):2739.

ANNEX

The Annex to Regulation (EU) No 9/2010 is replaced by the following:

'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 ⁽¹⁾/g</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>	Chickens for fattening		625 U		<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 non-starch polysaccharides (mainly beta- arabinoxylans).</p>	13 January 2020
				Laying hens		625 U			
				Ducks		625 U			
				Turkeys for fattening		1 250 U			

⁽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