

Commission Regulation (EU) No 9/2010 of 23 December 2009 concerning the authorisation of the endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for chickens for fattening, laying hens, ducks and turkeys for fattening (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 9/2010

of 23 December 2009

concerning the authorisation of the endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for chickens for fattening, laying hens, ducks and turkeys for fattening (holder of authorisation [F1Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.]

(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 the preparation set out in the Annex to this Regulation. 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 the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for chickens for fattening, laying hens, ducks and turkeys for fattening, to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority (the Authority) concluded in its opinions of 12 and 19 September 2007⁽²⁾, of 22 November 2007⁽³⁾ and of 2 July 2009⁽⁴⁾ that the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) does not have an adverse effect on animal health, human health or the environment and that the use of that preparation improves the performance of the animals. 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.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 9/2010. (See end of Document for details)

- (5) The assessment of that preparation shows that the conditions for authorisation, 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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Textual Amendments

- F1** Substituted by Commission Implementing Regulation (EU) 2019/221 of 6 February 2019 amending Regulations (EC) No 785/2007, (EC) No 379/2009, (EC) No 1087/2009, (EU) No 9/2010, (EU) No 337/2011 and Implementing Regulations (EU) No 389/2011, (EU) No 528/2011, (EU) No 840/2012, (EU) No 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 as regards the name of the holder of the authorisation and the representative of the holder of the authorisation for certain feed additives (Text with EEA relevance).

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 20th day following 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.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 9/2010. (See end of Document for details)

[^{F2} ANNEX

Textual Amendments

F2 Substituted by 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).

Identification number of the additive	Name of the holder of authorisation	Additive	Chemical formula, description, analytical method	Species, category, 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	[^{F1} Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.]	Endo-1,4-beta-xylanase EC 3.2.1.8	<p><i>Characterisation of the composition of Laying hens 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^a/g</i></p> <p><i>Characterisation of the composition of Laying hens 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^a/g</i></p>			625 U		1.	13 January 2020 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
						625 U			
						625 U			
						1 250 U		2.	For use in feed rich

a 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.

b 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

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 9/2010. (See end of Document for details)

			<p><i>active substance</i> endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> (ATCC PTA 5588) <i>Analytical method^b</i> For quantification of endo-1,4-beta-xylanase activity: 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</p>			<p>in non-starch polysaccharides (mainly beta-arabinoxylans).</p>
--	--	--	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--	--	-------------------------------------------------------------------

a 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.

b 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

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 9/2010. (See end of Document for details)

			pH 4,25 and 50 °C.					
--	--	--	-----------------------------	--	--	--	--	--

a 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.

b 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

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 9/2010. (See end of Document for details)

- (1) [OJ L 268, 18.10.2003, p. 29.](#)
- (2) *The EFSA Journal* (2007) 548, p. 1.
- (3) *The EFSA Journal* (2007) 586, p. 1.
- (4) *The EFSA Journal* (2009) 1183, p. 1.

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 9/2010.