

Commission Regulation (EC) No 1087/2009 of 12 November 2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and alpha-amylase produced by *Bacillus amyloliquefaciens* (ATCC 3978) as a feed additive for chickens for fattening, for ducks and for 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 (EC) No 1087/2009

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concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and alpha-amylase produced by *Bacillus amyloliquefaciens* (ATCC 3978) as a feed additive for chickens for fattening, for ducks and for turkeys for fattening (holder of authorisation [F<sup>1</sup>Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.]

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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<sup>(1)</sup>, 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), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and alpha-amylase produced by *Bacillus amyloliquefaciens* (ATCC 3978) as a feed additive for chickens for fattening, turkeys for fattening and ducks, to be classified in the additive category 'zootechnical additives'.
- (4) The Authority concluded in its opinions of 17 June 2009<sup>(2)</sup> that the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and alpha-amylase produced by *Bacillus amyloliquefaciens* (ATCC 3978) does not have an adverse effect on animal health, human health or the environment and that the use of that preparation improves

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**Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 1087/2009. (See end of Document for details)

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the performance of the animals. The Authority did 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.

- (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.

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## ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Chemical formula, 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									
4a10	[ <sup>1</sup> 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 Subtilisin EC 3.4.21.62 Alpha-amylase EC 3.2.1.1		Chickens — composition: Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i>		Endo-1,4-beta-xylanase 187,5 U Subtilisin 2 500 U Alpha-amylase 250 U		1.	3 December 2019 Directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.
						Endo-1,4-beta-xylanase 75 U Subtilisin 1 000 U Alpha-amylase 100 U			
				Ducks (ATCC 5588), subtilisin produced by <i>Bacillus subtilis</i> (ATCC 2107)		Endo-1,4-beta-xylanase 300 U Subtilisin 4 000 U Alpha-amylase 400 U		2.	For use in feed rich in non-starch polysaccharides (mainly beta-glucans)

**a** 1 U of endo-1,4-β-xylanase is the amount of enzyme that liberates 0,5 μmol of reducing sugar (xylose equivalents) per minute from a cross-linked oat spelt xylan at pH 5,3 and 50 °C.

**b** 1 U of subtilisin is the amount of enzyme that liberates 1 μmol of phenolic compound (tyrosine equivalents) per minute from a casein substrate at pH 7,5 and 40 °C.

**c** 1 U of α-amylase is the amount of enzyme that liberates 1 μmol of glucosidic linkages per minute from a water insoluble cross-linked starch polymer substrate at pH 6,5 and 37 °C.

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			activity of Solid form:	Endo-1,4-beta-xylanase 1 500 U <sup>a</sup> /g Subtilisin (protease) 20 000 U <sup>b</sup> /g Alpha-amylase 2 000 U <sup>c</sup> /g			and arabinoxylans), e. g. containing more than 40 % maize.
			Characterisation of the active substance:	Endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> (ATCC PTA 5588), subtilisin produced by <i>Bacillus subtilis</i> (ATCC 2107) and alpha-amylase produced		3.	For safety reasons: breathing protection, glasses and gloves shall be used during handling.
						4.	An appropriate method for control purposes shall be developed.

**a** 1 U of endo-1,4-β-xylanase is the amount of enzyme that liberates 0,5 μmol of reducing sugar (xylose equivalents) per minute from a cross-linked oat spelt xylan at pH 5,3 and 50 °C.

**b** 1 U of subtilisin is the amount of enzyme that liberates 1 μmol of phenolic compound (tyrosine equivalents) per minute from a casein substrate at pH 7,5 and 40 °C.

**c** 1 U of α-amylase is the amount of enzyme that liberates 1 μmol of glucosidic linkages per minute from a water insoluble cross-linked starch polymer substrate at pH 6,5 and 37 °C.

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			by <i>Bacillus amyloliquefaciens</i> (ATCC 3978)				
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- a** 1 U of endo-1,4- $\beta$ -xylanase is the amount of enzyme that liberates 0,5  $\mu$ mol of reducing sugar (xylose equivalents) per minute from a cross-linked oat spelt xylan at pH 5,3 and 50 °C.
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- b** 1 U of subtilisin is the amount of enzyme that liberates 1  $\mu$ mol of phenolic compound (tyrosine equivalents) per minute from a casein substrate at pH 7,5 and 40 °C.
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- c** 1 U of  $\alpha$ -amylase is the amount of enzyme that liberates 1  $\mu$ mol of glucosidic linkages per minute from a water insoluble cross-linked starch polymer substrate at pH 6,5 and 37 °C.
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- (1) [OJ L 268, 18.10.2003, p. 29.](#)
- (2) *The EFSA Journal* (2009) 1154, p. 1, and *The EFSA Journal* (2009) 1156, p. 1.

**Changes to legislation:**

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