

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 Animal Nutrition, legal entity Finnfeeds International Limited)

(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⁽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), 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⁽²⁾ 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 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:

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.

Done at Brussels, 12 November 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

⁽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.

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									
4a10	Danisco Animal Nutrition (legal entity Finnfeeds International Limited)	Endo-1,4-beta-xylanase	<p>Additive composition:</p> <p>Preparation of 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 by <i>Bacillus amyloliquefaciens</i> (ATCC 3978) having a minimum activity of</p> <p>Solid form:</p> <p>Endo-1,4-beta-xylanase 1 500 U ⁽¹⁾/g Subtilisin (protease) 20 000 U ⁽²⁾/g Alpha-amylase 2 000 U ⁽³⁾/g</p> <p>Characterisation of the active substance:</p> <p>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 by <i>Bacillus amyloliquefaciens</i> (ATCC 3978)</p>	Chickens for fattening	—	Endo-1,4-beta-xylanase 187,5 U		<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. For use in feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e. g. containing more than 40 % maize. For safety reasons: breathing protection, glasses and gloves shall be used during handling. An appropriate method for control purposes shall be developed. 	3 December 2019
		EC 3.2.1.8		Ducks		Subtilisin 2 500 U			
		Subtilisin				Alpha-amylase 250 U			
		EC 3.4.21.62				Endo-1,4-beta-xylanase 75 U			
		Alpha-amylase				Subtilisin 1 000 U			
		EC 3.2.1.1		Turkeys for fattening		Alpha-amylase 100 U			
						Endo-1,4-beta-xylanase 300 U			
						Subtilisin 4 000 U			
						Alpha-amylase 400 U			

⁽¹⁾ 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.

⁽²⁾ 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.

⁽³⁾ 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.