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COMMISSION REGULATION (EC) No 1380/2007

of 26 November 2007

concerning the authorisation of endo-1,4-beta-xylanase (Natugrain Wheat TS) as a feed additive

(Text with EEA relevance)

(OJ L 309, 27.11.2007, p. 21)

Amended by:

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		No	page	date
►**M1**	Commission Regulation (EC) No 516/2008 of 10 June 2008	L 151	3	11.6.2008

Corrected by:

►**C1** Corrigendum, OJ L 310, 28.11.2007, p. 22 (1380/2007)

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concerning the authorisation of endo-1,4-beta-xylanase (Natugrain Wheat TS) as a feed additive

(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 a new use of the preparation of endo-1,4-beta-xylanase (Natugrain Wheat TS) produced by *Aspergillus niger* (CBS 109.713), as a feed additive for turkeys for fattening to be classified in the additive category ‘zootechnical additives’.

(4) The use of the preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) was provisionally authorised for chickens for fattening by Commission Regulation (EC) No 1458/2005 of 8 September 2005 concerning the permanent and provisional authorisations of certain additives in feedingstuffs and the provisional authorisation of new uses of certain additives already authorised in feedingstuffs ([2]).

(5) New data were submitted in support of the application for authorisation for turkeys for fattening. The European Food Safety Authority (the Authority) concluded in its opinion of 18 April 2007 that the preparation of endo-1,4-beta-xylanase (Natugrain Wheat TS) produced by *Aspergillus niger* (CBS 109.713) does not have an adverse effect on animal health, human health or the environment ([3]). It further concluded that the preparation does not present any other risk which would, in accordance with Article 5 (2) of Regulation (EC) No 1831/2003, exclude authorisation. According to that opinion, the use of that preparation does not have an adverse effect on these additional animal categories. It does not consider that there is a need for specific requirements of post-market monitoring. This opinion also verifies the report on the method of analysis of the feed additive submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of that preparation shows that the conditions for authorisation, provided for in Article 5 of Regulation (EC)

([1]) OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

([2]) OJ L 233, 9.9.2005, p. 3.

([3]) Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the enzymatic preparation of Natugrain Wheat TS (endo-1,4-beta-xylanase), as a feed additive for turkeys for fattening, in accordance with Regulation (EC) No 1831/2003. Adopted on 18 October 2007. The EFSA Journal (2007) 474, 1-11.

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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 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 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.

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: Digestibility enhancers.									
►C1 4a 62 ◄	►M1 BASF SE ◄	Endo-1,4-beta-xylanase EC 3.2.1.8 (Natugrain Wheat TS)	*Additive composition* Preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) having a minimum activity of: Solid form: 5 600 TXU (1)/g Liquid form: 5 600 TXU/ml *Characterisation of the active substance*: Preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) *Analytical methods* (2) Viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta-xylanase on the xylan-containing substrate (wheat arabinoxylan) at pH 3,5 and 55 °C.	Turkeys for fattening	—	560 TXU	—	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Recommended dose per kilogram of complete feedingstuff: Turkeys for fattening: 560-840 TXU For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e. g. containing more than 40 % wheat.	17 December 2017

(1) 1 TXU is the amount of enzyme which liberates 5 micromole of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH 3,5 and 55 °C.
(2) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives