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COMMISSION REGULATION (EC) No 786/2007

of 4 July 2007

concerning the authorisation of endo-1,4-beta-mannanase EC 3.2.1.78 (Hemicell) as a feed additive

(Text with EEA relevance)

(OJ L 175, 5.7.2007, p. 8)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) No 103/2013 of 4 February 2013	L 34	12	5.2.2013

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concerning the authorisation of endo-1,4-beta-mannanase EC 3.2.1.78 (Hemicell) 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 the preparation of endo-1,4-beta-mannanase EC 3.2.1.78 (Hemicell), produced by *Bacillus lentus* (ATCC 55045), as a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 21 November 2006 that the preparation of endo-1,4-beta-mannanase EC 3.2.1.78 produced by *Bacillus lentus* (ATCC 55045) (Hemicell) does not have an adverse effect on animal health, human health or the environment ([2]). It further concluded that that preparation does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. The opinion of the Authority recommends appropriate measures for user safety. 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 in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

([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]) Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the enzymatic preparation Hemicell® Feed Enzyme (beta-D-mannanase) as a feed additive for chickens for fattening in accordance with Regulation (EC) No 1831/2003. Adopted on 21 November 2006. The EFSA Journal (2006) 412, 1-12.

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(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.

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									
4a3	►**M1** Eli Lilly and Company Ltd ◄	Endo-1,4-beta-mannanase EC 3.2.1.78 (Hemicell)	Additive composition: Preparation of endo-1,4-beta-mannanase produced by *Bacillus lentus* (ATCC 55045) having a minimum activity of: Liquid form: $7{,}2 \times 10^5$ U (1)/ml Characterisation of the active substance: Endo-1,4-beta-mannanase produced by *Bacillus lentus* (ATCC 55045) Analytical method (2) Reducing sugar assay for Endo-1,4-beta-mannanase by colorimetric reaction of dinitrosalicylic acid reagent on reducing sugar yield	Chickens for fattening	—	79 200 U	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Breathing protection during handling and safety glasses shall be used. 3. For use in compound feed rich of galactomannan-containing hemicelluloses (e.g. soya, maize)	25 July 2017

(1) One unit activity is defined as the amount of enzyme that generates 0,72 micrograms of reducing sugar (mannose equivalents) from mannan containing substrate (locust bean gum) per minute at pH 7,5 and 40 °C.
(2) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/html/crlfaa/