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COMMISSION REGULATION (EC) No 537/2007

of 15 May 2007

concerning the authorisation of the fermentation product of *Aspergillus oryzae* (NRRL 458) (Amaferm) as a feed additive

(Text with EEA relevance)

(OJ L 128, 16.5.2007, p. 13)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 905/2009 of 28 September 2009	L 256	30	29.9.2009

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concerning the authorisation of the fermentation product of *Aspergillus oryzae* (NRRL 458) (Amaferm) 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 authorisation of the fermentation product of *Aspergillus oryzae* NRRL 458 (Amaferm), as a feed additive for dairy cows, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 8 March 2006 that the fermentation product of *Aspergillus oryzae* NRRL 458 (Amaferm) does not have an adverse effect on animal health, human health or the environment ([2]). It further concluded that that fermentation product does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. Amaferm has shown to produce positive effects on milk yield of dairy cows. 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.

(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:

([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 product 'Amaferm' authorised as a feed additive for dairy cows and cattle for fattening in accordance with Regulation (EC) No 1831/2003 Adopted on 18 March 2006. *The EFSA Journal* (2006) 337, pp. 1 to 17.

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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
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a2	►**M1** Biozyme Incorporated ◄	Fermentation product of *Aspergillus oryzae* NRRL 458 (Amaferm)	Additive composition: Fermentation product of *Aspergillus oryzae* NRRL 458: 4 to 5 % Wheat bran: 94 to 95 % Stainless grit containing 5 % cobalt carbonate 1 % Characterisation of the active substance: Fermentation product of *Aspergillus oryzae* (NRRL 458) containing: Endo-1,4-beta-glucanase EC 3.2.1.4: 3 IU (1)/g; Alpha-amylase EC 3.2.1.1: 40 IU (2)/g. Analytical method: Alpha amylase AOAC 17th Ed. 2002.01 Endo-1,4-beta-glucanase (based on supernatant protein and cellulase activities of the anaerobic fungus (*Neocallimastix frontalis* EB 188) (Barichievich, EB, Calza RE (1990)).	Dairy cows	—	85	300	1. Recommended dose: the quantity of the additive in daily ration should be 3 to 5 g/cow/day. 2. For user safety: shall be used breathing protection during handling and safety glasses shall be worn.	5 June 2017

(1) 1 IU refers to the cellulase that liberates 1 micromole of glucose per minute from carboxymethylcellulose at pH 6,5 and at 39 °C.
(2) 1 IU refers to the amylase that liberates 1 micromole of glucose per minute from potato starch at pH 6,5 and at 39 °C.