COMMISSION REGULATION (EC) No 379/2009

of 8 May 2009

concerning the authorisation of a new use of 6-phytase EC 3.1.3.26 as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening and sows (holder of the authorisation Danisco Animal Nutrition, legal entity Danisco (UK) 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 a new use of the preparation of 6-phytase EC 3.1.3.26 produced by *Schizosaccharomyces pombe* (ATCC 5233), as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening and sows to be classified in the additive category 'zootechnical additives'.

(4) The use of 6-phytase EC 3.1.3.26 produced by *Schizosaccharomyces pombe* (ATCC 5233) was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 1743/2006 [2] and for 10 years by Commission Regulation (EC) No 785/2007 [3] for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening and sows.

(5) New data were submitted in support of an application for authorisation of a new formulation of 6-phytase EC 3.1.3.26, produced by *Schizosaccharomyces pombe* (ATCC 5233), for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening and sows.

(6) The European Food Safety Authority ('the Authority') stated in its opinion of 10 December 2008 [4], that its former opinion adopted on 17 October 2006 [5] fully applies to this new formulation of 6-phytase EC 3.1.3.26. Therefore, the Authority concluded that the preparation 6-phytase EC 3.1.3.26, new formulation, produced by *Schizosaccharomyces pombe* (ATCC 5233), is effective for target species and it is safe for animal health, human health or the environment. 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.

(7) 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.

(8) 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*.

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 329, 25.11.2006, p. 16.
[3] OJ L 175, 5.7.2007, p. 5.
[4] *The EFSA Journal* (2008) 915, pp. 1-10.
[5] *The EFSA Journal* (2006) 404, pp. 1-20.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 May 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

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 — Unit of activity/kg of complete feedingstuff with a moisture content of 12 %		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1640	Danisco Animal Nutrition (legal entity Danisco (UK) Limited)	6-phytase EC 3.1.3.26	**Additive composition:** Preparation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) having a minimum activity of: Solid coated form: 10 000 FTU [1]/g Liquid form: 10 000 FTU/ml **Characterisation of the active substance:** 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) **Analytical method** [2] Colorimetric method measuring inorganic phosphate released by the enzyme from phytate substrate.	Chickens for fattening	—	250 FTU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For use in feed containing more than 0,23 % phytin bound phosphorus. 3. For piglets (weaned) up to 35 kg of body weight. 4. Recommended doses per kilogram of complete feedingstuffs: — chickens for fattening: 500-750 FTU, — turkeys for fattening: 250-1 000 FTU, — laying hens: 150-900 FTU, — ducks for fattening: 250-1 000 FTU, — piglets (weaned): 500-1 000 FTU, — pigs for fattening: 500-1 000 FTU, — sows: 500 FTU. 5. For safety: breathing protection glasses and gloves shall be used during handling.	29 May 2019
				Turkeys for fattening	—	250 FTU	—		
				Laying hens	—	150 FTU	—		
				Ducks for fattening	—	250 FTU	—		
				Piglets (weaned)	—	250 FTU	—		
				Pigs for fattening	—	250 FTU	—		
				Sows	—	500 FTU	—		

[1] One FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from a sodium phytate substrate at pH 5,5 and 37 °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