COMMISSION REGULATION (EC) No 554/2008

of 17 June 2008

concerning the authorisation of 6-phytase (Quantum Phytase) 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 enzyme preparation 6-phytase (Quantum Phytase) produced by *Pichia pastoris* (DSM 15927) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening and piglets (weaned), to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority (the Authority) concluded in its opinion adopted on 1 February 2007 and on 30 January 2008 [2] that the enzyme preparation 6-phytase (Quantum Phytase) produced by *Pichia pastoris* (DSM 15927) does not have an adverse effect on animals, consumers, or the environment and that it is efficacious in improving digestibility of feedingstuffs, based on the data provided by the applicant. It further concluded that the product is a mild irritant and a dermal sensitiser and that it may be a potential respiratory sensitiser. The Authority does 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 a digestibility enhancer, as specified in the Annex to this Regulation. Measures should be provided for the protection of users from the risks identified in the opinion of the Authority.

(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*.

[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] Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) and of the Panel on Genetically Modified Organisms (GMO) on 'Safety and efficacy of the product Quantum Phytase 5000 L and Quantum Phytase 2500 D (6-phytase) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening and piglets (weaned)'. The EFSA Journal (2008) 627, pp. 1-27.

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

Done at Brussels, 17 June 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

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
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a5	AB Enzyme GmbH	6-phytase EC 3.1.3.26 (Quantum Phytase 2500 D Quantum Phytase 5000 L)	*Additive composition* 6-phytase produced by *Pichia pastoris* (DSM 15927) having a minimum activity of: Solid form: 2 500 FTU/g (1) Liquid form: 5 000 FTU/ml *Characterisation of the active substance* 6-phytase produced by *Pichia pastoris* (DSM 15927) *Analytical method* (2) Colorimetric method based on reaction of vanadomolybdate on organic phosphate produced by reaction on a phytate-contaning substrate (sodium phosphate) at pH 5,5 and 37 °C.	Chickens for fattening	—	500 FTU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting 2. Recommended dose per kilogram of complete feedingstuff: — chickens for fattening: 500-2 500 FTU — laying hens: 2 000 FTU — ducks for fattening: 250-2 000 FTU — turkeys for fattening: 1 000-2 700 FTU — piglets (weaned): 100-2 500 FTU 3. For use in compound feed containing more than 0,25 % phytin-bound phosphorus 4. For use in weaned piglets until approximately 35 kg 5. For safety: breathing protection glasses and gloves shall be used during handling	8.7.2018
				Laying hens	—	2 000 FTU	—		
				Ducks for fattening	—	250 FTU	—		
				Turkeys for fattening	—	1 000 FTU	—		
				Piglets (weaned)	—	100 FTU	—		

(1) 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate 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