COMMISSION REGULATION (EC) No 243/2007

of 6 March 2007

concerning the authorisation of 3-phytase (Natuphos) 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. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns authorisation of the enzyme preparation 3-phytase produced by *Aspergillus niger* (CBS 101.672) for weaned piglets, pigs for fattening, and chickens for fattening to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority (the Authority) concluded in its opinions of 15 June 2006 and of 17 May 2006 that 3-phytase produced by *Aspergillus niger* (CBS 101.672) does not have an adverse effect on animal health, human health or the environment ([2]). It further concluded that the enzyme preparation 3-phytase produced by *Aspergillus niger* (CBS 101.672) 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. 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.

(5) 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.

Done at Brussels, 6 March 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

([1]) OL 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 and of the Scientific Panel on Genetically Modified Organisms on the safety and efficacy of the enzyme preparation Natuphos® (3-phytase) produced by *Aspergillus niger*. Adopted by FEEDAP Panel on 15 June 2006 and by the GMO Panel on 17 May 2006. *The EFSA Journal* (2006) 369, p. 1.

ANNEX

Identi-fication 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 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.									
4a 1600	BASF Aktiengesellschaft	3-phytase EC 3.1.3.8 (Natuphos 5 000 G Natuphos 5 000 L Natuphos 10 000 G Natuphos 10 000 L)	**Additive composition** 3-phytase produced by *Aspergillus niger* (CBS 101.672) having a minimum activity of: Solid form: 5 000 FTU/g Liquid form: 5 000 FTU/ml **Characterisation of the active substance** 3-phytase produced by *Aspergillus niger* (CBS 101.672) **Analytical method** (1) Colorimetric method measuring inorganic phosphate released by the enzyme from phytate substrate.	Piglets (weaned)	—	500 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 weaned piglets up to 35 kg. 3. Recommended dose per kilogram of complete feedingstuff: 500 FTU. 4. For use in feed containing more than 0,23 % phytin bound phosphorus.	2.4.2017
				Pigs for fattening		280 FTU		1. In the direction of use of the additive and premixtures, indicate the storage life and stability in pelleting. 2. Recommended dose per kilogram of complete feedingstuff: 400500 FTU. 3. For use in feed containing more than 0,23 % phytin bound phosphorus.	
				Chickens for fattening	—	375 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: 500700 FTU. 3. For use in feed containing more than 0,23 % phytin bound phosphorus.	

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/html/crlfaa/