COMMISSION REGULATION (EC) No 165/2008

of 22 February 2008

concerning the authorisation of a new use 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 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 a new use of the enzyme preparation 3-phytase (Natuphos 5000, Natuphos 5000 G, Natuphos 5000 L, Natuphos 10000 G and Natuphos 10000 L) produced by *Aspergillus niger* (CBS 101.672) as a feed additive for ducks, to be classified in the additive category 'zootechnical additives'.

(4) The use of that preparation was authorised for weaned piglets, pigs for fattening and chickens for fattening by Commission Regulation (EC) No 243/2007 [2] and for laying hens and turkeys for fattening by Commission Regulation (EC) No 1142/2007 [3].

(5) New data were submitted in support of the application for authorisation for ducks. The European Food Safety Authority (the Authority) concluded in its opinions of 18 September 2007 that the enzyme preparation 3-phytase (Natuphos 5000, Natuphos 5000 G, Natuphos 5000 L, Natuphos 10000 G and Natuphos 10000 L) produced by *Aspergillus niger* (CBS 101.672) does not have an adverse effect on consumers, users or the environment [4]. According to that opinion, the use of that preparation does not have an adverse effect on this additional animal category and it is efficacious in improving digestibility of feedingstuffs. 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.

(6) 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.

(7) 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] OJ L 73, 13.3.2007, p. 4.
[3] OJ L 256, 2.10.2007, p. 20.
[4] Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on the safety and efficacy of the enzyme preparation of Natuphos (3-phytase) as a feed additive for ducks. *The EFSA Journal* (2007) 544, 1-10.

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

Done at Brussels, 22 February 2008.

For the Commission
Markos KYPRIANOU
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									
4a1600	BASF Aktien-gesellschaft	3-phytase EC 3.1.3.8 (Natuphos 5000, Natuphos 5000 G, Natuphos 5000 L, Natuphos 10000 G, Natuphos 10000 L)	Additive composition: 3-phytase produced by *Aspergillus niger* (CBS 101.672) having a minimum activity of: Solid form: 5 000 FTU (1)/g Liquid form: 5 000 FTU/ml Characterisation of the active substance: 3-phytase produced by *Aspergillus niger* (CBS 101.672) Analytical method (2) Colorimetric method measuring inorganic phosphate released by the enzyme from phytate substrate	Ducks	—	300 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: 300-750 FTU. 3. For use in feed containing more than 0,23 % phytin bound phosphorus.	14 March 2018

(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