COMMISSION REGULATION (EC) No 1500/2007

of 18 December 2007

of concerning the authorisation of a new use of 6-phytase EC 3.1.3.26 (Ronozyme) 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 a new use of the preparation of 6-phytase EC 3.1.3.26 (Ronozyme) produced by *Aspergillus oryzae* (DSM 14223), as a feed additive for ducks, to be classified in the additive category 'zootechnical additives'.

(4) The use of the preparation of 6-phytase EC 3.1.3.26 produced by *Aspergillus oryzae* (DSM 14223) was authorised without a time limit for chickens for fattening, laying hens, turkeys for fattening, piglets, pigs for fattening and sows by Commission Regulation (EC) No 255/2005 [2] and provisionally authorised for salmonids by Commission Regulation (EC) No 521/2005 [3].

(5) New data were submitted in support of an application for authorisation for ducks. The European Food Safety Authority (the Authority) concluded in its opinion of 10 July 2007 that the preparation of 6-phytase EC 3.1.3.26 (Ronozyme) produced by *Aspergillus oryzae* (DSM 14223) does not have an adverse effect on animal health, human health or the environment [4]. It further concluded that the preparation does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation for this additional animal category. According to that opinion, the use of that preparation is efficacious in digestibility of feedingstuffs. 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.

[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 45, 16.2.2005, p. 3.

[3] OJ L 84, 2.4.2005, p. 3. Regulation as amended by Regulation (EC) No 1812/2005 (OJ L 291, 5.11.2005, p. 18).

[4] Opinion of the Scientific Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of the enzyme preparation Ronozyme P5000 (CT) and Ronozyme P20000 (L) (6-phytase) as feed additive for ducks according to Regulation (EC) No 1831/2003. Adopted on 10 July 2007, *The EFSA Journal* (2007) 519, 1-8.

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, 18 December 2007.

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									
4a1614(i)	DSM Nutritional Products Ltd.	6-phytase EC 3.1.3.26 (Bio-Feed Phytase CT 2X/Ronozyme P5000 (CT) and Bio-Feed Phytase L 4X/ Ronozyme P20000 (L)	Additive composition: Preparation of 6-phytase produced by *Aspergillus oryzae* (DSM 14223) having a minimum activity of: Coated form: 5 000 FYT (1)/g Liquid form: 20 000 FYT/ml Characterisation of the active substance: 6-phytase produced by *Aspergillus oryzae* (DSM 14223) Analytical method (2) Colorimetric method based on reaction of vanadomolybdate on inorganic phosphate produced by action of 6-phytase on phytate-containing substrate (sodium phytate) at pH 5,5 and 37 °C.	Ducks	—	250	—	1. In the directions for use of the additive and premixture, indicate storage temperature, storage life and stability to pelleting. 2. Recommended dose per kg of complete feedingstuff: 500-1 000 FYT/kg. 3. For use in compound feed containing more than 0,25 % phytin-bound phosphorus.	8.1.2018

(1) 1 FYT 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