COMMISSION REGULATION (EU) No 327/2010

of 21 April 2010

concerning the authorisation of a new use of 3-phytase as a feed additive for all minor avian species, other than ducks, and for ornamental birds (holder of authorisation BASF SE)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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. The 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 3-phytase, an enzyme preparation produced by *Aspergillus niger* (CBS 101.672), as a feed additive for minor avian species and for ornamental birds, 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]), for laying hens and turkeys for fattening by Commission Regulation (EC) No 1142/2007 ([3]), for ducks by Commission Regulation (EC) No 165/2008 ([4]) and for sows by Commission Regulation (EC) No 505/2008 ([5]).

(5) New data were submitted in support of the application for authorisation for minor avian species and for ornamental birds. The European Food Safety Authority (the Authority) concluded in its opinion of 9 December 2009 ([6]) that 3-phytase does not have an adverse effect on animal health, human health or the environment, and that it is efficacious in improving digestibility of feed. 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 3-phytase shows that the conditions for authorisation, as 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 enhancer', 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, 21 April 2010.

For the Commission
The President
José Manuel BARROSO

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 73, 13.3.2007, p. 4.
([3]) OJ L 256, 2.10.2007, p. 20.
([4]) OJ L 50, 23.2.2008, p. 8.
([5]) OJ L 149, 7.6.2008, p. 33.
([6]) *The EFSA Journal* 2010; 8(1):1427.

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	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 SE	3-phytase	Additive composition 3-phytase (EC 3.1.3.8) 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 (EC 3.1.3.8) produced by *Aspergillus niger* (CBS 101.672) Analytical method (2) Colorimetric method measuring inorganic phosphate released by the enzyme from phytate substrate.	Ornamental birds and all minor avian species, other than ducks	—	250 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 feed for all species: 300-500 FTU 3. For use in feed containing more than 0,23 % phytin-bound phosphorus.	12.5.2020

(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