COMMISSION REGULATION (EC) No 1088/2009

of 12 November 2009

concerning the authorisation of a new use of an enzyme preparation of 6-phytase produced by *Aspergillus oryzae* (DSM 17594) as a feed additive for weaned piglets, pigs for fattening, poultry for fattening and poultry for laying (holder of authorisation DSM Nutritional Products Ltd., represented by DSM Nutritional Products Sp. Z.o.o.)

(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 the authorisation of a new use of the enzyme preparation of 6-phytase produced by *Aspergillus oryzae* (DSM 17594) as a feed additive for weaned piglets, pigs for fattening, poultry for fattening and poultry for laying, to be classified in the additive category 'zootechnical additives'.

(4) The use of that preparation was authorised for ten years by Commission Regulation (EC) No 270/2009 [2] for chickens for fattening.

(5) New data were submitted in support of the application for authorisation for weaned piglets, pigs for fattening, poultry for fattening and poultry for laying. The European Food Safety Authority ('the Authority') concluded in its opinion of 14 May 2009 [3] that the enzyme preparation of 6-phytase produced by *Aspergillus oryzae* (DSM 17594) does not have an adverse effect on animal health, human health or the environment and that the use of that preparation improves the digestibility of dietary phosphorus. The Authority did 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) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulation (EC) No 270/2009 should be repealed.

(8) 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.
[2] OJ L 91, 3.4.2009, p. 3.
[3] *The EFSA Journal* (2009) 1097, p. 1.

Article 2

Regulation (EC) No 270/2009 is repealed.

Article 3

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, 12 November 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

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									
4a6	DSM Nutritional Products Ltd. represented by DSM Nutritional Products Sp. Z.o.o.	6-phytase EC 3.1.3.26	Additive composition: Preparation of 6-phytase produced by *Aspergillus oryzae* (DSM 17594) having a minimum activity of: Solid form: 10 000 FYT ([1])/g Liquid form: 20 000 FYT/g Characterisation of the active substance: 6-phytase produced by *Aspergillus oryzae* (DSM 17594) Analytical method ([2]) Colorimetric method based on reaction of vanadomolybdate on inorganic phosphate produced by action of 6-phytase on a phytate-containing substrate (sodium phytate) at pH 5,5 and 37 °C, quantified against a standard curve from inorganic phosphate.	Piglets (weaned)	—	1 500 FYT		1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting 2. For piglets (weaned) up to 35 kg of body weight 3. Recommended dose per kilogram of complete feedingstuff: — poultry for fattening: 1 500-3 000 FYT; — poultry for laying: 600-1 500 FYT; — piglets (weaned) and pigs for fattening: 1 500-3 000 FYT 4. For use in compound feed containing more than 0,23 % phytin-bound phosphorus 5. For safety: breathing protection, glasses and gloves shall be used during handling	1 December 2019
				Pigs for fattening		1 500 FYT			
				Poultry for fattening		1 500 FYT			
				Poultry for laying		600 FYT			

([1]) One FYT is the amount of enzyme that releases 1 μmol of inorganic phosphate from phytase per minute under reaction conditions with a phytate concentration of 5,0 mM at pH 5,5 and a temperature of 37 °C during 30 minutes of incubation.

([2]) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives