

COMMISSION REGULATION (EC) No 785/2007
of 4 July 2007

**concerning the authorisation of 6-phytase EC 3.1.3.26 (Phyzyme XP 5000G Phyzyme XP 5000L) 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 the authorisation of a new use of the preparation of 6-phytase EC 3.1.3.26 produced by *Schizosaccharomyces pombe* (ATCC 5233) (Phyzyme XP 5000G Phyzyme XP 5000L), as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening, and sows to be classified in the additive category 'zootechnical additives'.
- (4) The use of 6-phytase EC 3.1.3.26 produced by *Schizosaccharomyces pombe* (ATCC 5233) was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 1743/2006 (⁽²⁾).

(5) New data were submitted in support of an application for authorisation for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening, and sows. The European Food Safety Authority (the Authority) concluded in its opinion of 17 October 2006 that the preparation 6-phytase EC 3.1.3.26 produced by *Schizosaccharomyces pombe* (ATCC 5233) (Phyzyme XP 5000G Phyzyme XP 5000L) does not have an adverse effect on animal health, human health or the environment (⁽³⁾). It further concluded that that preparation does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. According to that opinion, the use of that preparation does not have an adverse effect on these additional animal categories. 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 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 329, 25.11.2006, p. 16.

⁽³⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the enzyme preparation Phyzyme™ XP 5000L and Phyzyme™ XP 5000G as feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening, sows in accordance with Regulation (EC) No 1831/2003. Adopted on 17 October 2006. The EFSA Journal (2006) 404, p. 1.

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, 4 July 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	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.										
4a1640	Danisco Animal Nutrition	6-phytase EC 3.1.3.26 (Phyzyme XP 5000G Phyzyme XP 5000L)	Additive composition: Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Schizosaccharomyces pombe</i> (ATCC 5233) having a minimum activity of: Solid form: 5 000 FTU ⁽¹⁾ /g Liquid form: 5 000 FTU/ml Characterisation of the active substance: 6-phytase (EC 3.1.3.26) produced by <i>Schizosaccharomyces pombe</i> (ATCC 5233) Analytical method ⁽²⁾ Colorimetric method measuring inorganic phosphate released by the enzyme from phytate substrate.	Chickens for fattening Turkeys for fattening Laying hens Ducks for fattening Piglets (weaned) Pigs for fattening Sows	— — — — — — —	250 FTU 250 FTU 150 FTU 250 FTU 250 FTU 250 FTU 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 feed containing more than 0,23 % phytin bound phosphorus. 3. For piglets (weaned) up to 35 kg of body weight. 4. Recommended doses for kilogram of complete feedingstuffs: — chickens for fattening: 500-750 FTU; — turkeys for fattening: 250-1 000 FTU; — laying hens: 150-900 FTU; — ducks for fattening: 250-1 000 FTU; — piglets (weaned) 500-1 000 FTU; — pigs for fattening 500-1 000 FTU; — sows: 500 FTU.	25 July 2017	

⁽¹⁾ One FTU is the amount of enzyme which liberates one micromole of inorganic phosphate per minute from a sodium phytate substrate 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/html/crifaa/