COMMISSION REGULATION (EU) No 891/2010

of 8 October 2010

concerning the authorisation of a new use of 6-phytase as a feed additive for turkeys (holder of authorisation Roal Oy)

(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. That application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a new use of the enzyme preparation 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) as a feed additive for turkeys, to be classified in the additive category 'zootechnical additives'.

(4) The use of 6-phytase (EC 3.1.3.26) has been authorised for poultry for fattening and breeding other than turkeys for fattening, for poultry for laying and for pigs other than sows by Commission Regulation (EU) No 277/2010 ([2]).

(5) New data were submitted to support the application. The European Food Safety Authority ('the Authority') concluded in its opinion of 10 March 2010 ([3]) that 6-phytase (EC 3.1.3.26), under the proposed conditions of use, does not have an adverse effect on animal health, human health or the environment, and that its use can improve the performance of the animals. 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 6-phytase (EC 3.1.3.26) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this 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*.

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

Done at Brussels, 8 October 2010.

For the Commission
The President
José Manuel BARROSO

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 86, 1.4.2010, p. 13.
([3]) *The EFSA Journal* 2010; 8(3):1553.

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									
4a12	Roal Oy	6-phytase EC 3.1.3.26	*Additive composition* Preparation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) with a minimum activity of: 40 000 PPU [1]/g in solid form 10 000 PPU/g in liquid form *Characterisation of the active substance* of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) *Analytical method* [2] Colorimetric method quantifying the activity of 6-phytase by measuring released inorganic phosphate from sodium phytate by analysing the colour formed by reduction of a phosphomolybdate complex.	Turkeys	—	250 PPU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Maximum recommended dose per kilogram of complete feed for turkeys: 1 000 PPU. 3. For use in feed containing more than 0,23 % phytin-bound phosphorus. 4. For safety: breathing protection, glasses and gloves shall be used during handling.	29 October 2020

[1] 1 PPU is the amount of enzyme which liberates 1 µmol of inorganic phosphate from sodium phytate per minute at pH = 5,0 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