COMMISSION REGULATION (EC) No 902/2009

of 28 September 2009

concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (holder of authorisation Roal Oy)

(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) This Regulation authorises an enzyme preparation of endo-1,4-beta-xylanase as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding.

(3) 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.

(4) The European Food Safety Authority (the Authority) performed the risk assessment in accordance with Article 8(3) of Regulation (EC) No 1831/2003.

(5) The application concerns the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding, to be classified in the additive category 'zootechnical additives'.

(6) The Authority concluded in its opinions of 21 May 2008 [2] and 21 April 2009 [3] that the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) does not have an adverse effect on animal health, human health or the environment and that the use of that preparation can have a significant benefit on body weight gain and feed conversion. 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.

(7) 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.

(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.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

[1] OJ L 268, 18.10.2003, p. 29.

[2] *The EFSA Journal* (2008) 712, pp. 1-20.

[3] *The EFSA Journal* (2009) 1058, pp. 1-6.

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

Done at Brussels, 28 September 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 (Units 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									
4a8	Roal Oy	Endo-1,4-beta-xylanase EC 3.2.1.8	Additive composition: Preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) having a minimum activity of: solid form: 4×10^6 BXU (1)/g liquid form: 4×10^5 BXU/g Characterisation of the active substance: endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) Analytical method (2): In the additive and the premixture: reducing sugar assay for endo-1,4-beta-xylanase by colorimetric reaction of dinitrosalicylic acid reagent on reducing sugar yield at pH 5,3 and 50 °C In the feedingstuffs: colorimetric method measuring water soluble dye released by the enzyme from azurine crosslinked wheat arabinoxylan substrate	Piglets (weaned)	—	24 000 BXU	—	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. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 20 % wheat. 4. For safety reasons: breathing protection, glasses and gloves shall be used during handling.	19 October 2019
				Chickens for fattening		8 000 BXU			
				Chickens reared for laying		8 000 BXU			
				Turkeys for fattening		16 000 BXU			
				Turkeys reared for breeding		16 000 BXU			

(1) 1 BXU is the amount of enzyme which liberates 1 nmol reducing sugars as xylose from birch xylan per second at pH 5,3 and 50 °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