COMMISSION IMPLEMENTING REGULATION (EU) No 1110/2011

of 3 November 2011

concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for laying hens, minor poultry species and pigs for fattening (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 enzyme preparation of endo-1, 4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044). 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 the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for laying hens, minor poultry species and pigs for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The use of that preparation has been authorised for 10 years for chickens for fattening and chickens reared for laying, turkeys for fattening, turkeys reared for breeding and for weaned piglets by Commission Regulation (EC) No 902/2009 ([2]).

(5) New data were submitted in support of the application for the authorisation of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) for laying hens, minor poultry species and pigs for fattening. The European Food Safety Authority ('the Authority') concluded in its opinion of 14 June 2011 ([3]) that, under the proposed conditions of use, 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 improve the laying performance of the hens and the growth performance of other minor poultry species and pigs for fattening. 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 Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) 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*.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 256, 29.9.2009, p. 23.
([3]) *EFSA Journal 2011*;9(6):2277.

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

Done at Brussels, 3 November 2011.

For the Commission
The President
José Manuel BARROSO

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									
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	Minor poultry species other than laying birds thereof	—	8 000 BXU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For safety: breathing protection, glasses and gloves shall be used during handling.	24 November 2021
				Laying hens and laying birds of minor poultry species		24 000 BXU			
				Pigs for fattening		24 000 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 Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx