COMMISSION IMPLEMENTING REGULATION (EU) No 843/2012

of 18 September 2012

concerning the authorisation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) as a feed additive for turkeys reared for breeding, minor avian species for fattening and reared for laying or breeding and ornamental birds (holder of authorisation BASF SE)

(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 endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (CBS 109.713). 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 endo-1, 4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (CBS 109.713) as a feed additive for chickens reared for laying, turkeys reared for breeding, minor avian species for fattening and reared for laying or breeding and ornamental birds, to be classified in the additive category 'zootechnical additives'.

(4) The use of that preparation was authorised for 10 years for chickens for fattening and for ducks by Commission Regulation (EC) No 1096/2009 ([2]) and for turkeys for fattening by Commission Regulation (EC) No 1380/2007 ([3]).

(5) New data were submitted in support of the application for the authorisation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (CBS 109.713) for chickens reared for laying, turkeys reared for breeding, minor avian species for fattening and reared for laying or breeding and ornamental birds. The European Food Safety Authority ('the Authority') concluded in its opinion of 2 February 2012 ([4]) that, under the proposed conditions of use, endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (CBS 109.713) does not have an adverse effect on animal health, human health or the environment, and that its use can improve the feed to gain ratio in all target species. 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 endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* (CBS 109.713) shows that the conditions for authorisation, as 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.

Article 2

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 301, 17.11.2009, p. 3.
([3]) OJ L 309, 27.11.2007, p. 21.
([4]) *EFSA Journal* 2012; 10(2):2575.

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

Done at Brussels, 18 September 2012.

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									
4a62	BASF SE	Endo-1,4-beta-xylanase EC 3.2.1.8	*Additive composition* Preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) having a minimum activity of: Solid form: 5 600 TXU (1)/g Liquid form: 5 600 TXU/ml *Characterisation of the active substance* Endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) *Analytical method* (2) Viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta-xylanase on the xylan-containing substrate (wheat arabinoxylan) at pH 3,5 and 55 °C	Turkeys reared for breeding	—	560 TXU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended maximum dose per kilogram of complete feedingstuff for all species falling within the scope of this Regulation: 840 TXU. 3. For use in feed rich in starch and non-starch polysaccharides (mainly beta-glucans and arabinoxylans).	9 October 2022
				Ornamental birds, minor avian species except ducks and laying birds.		280 TXU			

(1) 1 TXU is the amount of enzyme which liberates 5 micromoles of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH 3,5 and 55 °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