COMMISSION IMPLEMENTING REGULATION (EU) No 1019/2012

of 6 November 2012

amending Commission Regulation (EC) No 1096/2009 as regards the minimum content of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) as a feed additive in feed for chickens for fattening and for ducks (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 13(3) thereof,

Whereas:

(1) The enzyme endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713), belonging to the additive category of 'zootechnical additives' was authorised for 10 years as a feed additive for use on chickens for fattening and for ducks by Commission Regulation (EC) No 1096/2009 [2] and for use on turkeys for fattening by Commission Regulation (EC) No 1380/2007 [3].

(2) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of the enzyme concerned by reducing its minimum content from 560 TXU/kg to 280 TXU/kg as regards use on chickens for fattening and ducks. The application was accompanied by the relevant supporting data.

(3) The European Food Safety Authority (hereinafter 'the Authority') concluded in its opinion of 2 February 2012 [4] that, under the new proposed conditions of use, the enzyme concerned is efficacious at the requested minimum dose of 280 TXU/kg. The Authority does not consider that there is a need for specific requirements of post-market monitoring.

(4) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.

(5) Commission Regulation (EC) No 1096/2009 should therefore be amended accordingly.

(6) 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

Regulation (EC) No 1096/2009 is amended in accordance with the Annex to this Regulation.

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*.

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

Done at Brussels, 6 November 2012.

For the Commission
The President
José Manuel BARROSO

[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.

ANNEX

The Annex to Regulation (EC) No 1096/2009 is replaced by the following:

'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	Chickens for fattening	—	280 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 chickens for fattening and ducks: 800 TXU. 3. For use in feed rich in starch and non-starch polysaccharides (mainly beta-glucans and arabinoxylans).	7.12.2019
				Ducks		280 TXU			

[1] 1 TXU is the amount of enzyme which liberates 5 micromole 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'