COMMISSION REGULATION (EU) No 335/2011

of 7 April 2011

amending Regulation (EC) No 1091/2009 as regards the minimum content of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MUCL 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MUCL 49754) as a feed additive in feed for chickens for fattening

(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 use of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MUCL 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MUCL 49754) was authorised for 10 years for chickens for fattening by Commission Regulation (EC) No 1091/2009 of 13 November 2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MUCL 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MUCL 49754) as a feed additive for chickens for fattening (holder of authorisation Aveve NV) ([2]).

(2) The holder of the authorisation submitted an application for changing the terms of the authorisation of this feed additive when used in chickens for fattening by reducing the minimum recommended dose of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MUCL 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MUCL 49754) from 4 000 XU ([3])/kg and 900 BGU ([4])/kg to 2 000 XU/kg and 450 BGU/kg. That application was accompanied by the relevant data supporting the request for the change.

(3) The European Food Safety Authority (the Authority) concluded in its opinion of 10 November 2010 that the data provided from three trials in chickens for fattening do not support the reduction of the minimum recommended dose from 4 000 XU and 900 BGU/kg feed to 2 000 XU and 450 BGU/kg feed because analyses of the feeds showed that the intended doses were considerably exceeded. However, the data showed that the product is efficacious at a lower dose than the one currently authorised. According to the Authority the data indicates, as an approximation, that 3 000 XU and 600 BGU/kg feed has the potential to improve growth rate and feed to gain ratio in chickens for fattening ([5]).

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

(5) Regulation (EC) No 1091/2009 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

The Annex to Regulation (EC) No 1091/2009 is replaced by the text in the Annex to this Regulation.

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, 7 April 2011.

For the Commission
The President
José Manuel BARROSO

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 299, 14.11.2009, p. 6.
([3]) 1 XU is the amount of enzyme which releases 1 µmol of reducing sugar (xylose equivalent) per minute from xylan of oat spelt at pH 5,0 and 50 °C.
([4]) 1 BGU is the amount of enzyme which releases 1 µmol of reducing sugar (cellobiose equivalent) per minute from ß-glucan of barley at pH 4,8 and 50 °C.
([5]) *EFSA Journal 2010; 8(12):1919.*

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									
4a9	Aveve NV	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	*Additive composition* Preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MUCL 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MUCL 49754) having a minimum activity of 40 000 XU/g and 9 000 BGU/g *Characterisation of the active substance* endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MUCL 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MUCL 49754) *Analytical method* (1) Characterisation of the active substance in the additive: — colorimetric method based on reaction of dinitrosalicylic acid on reducing sugar produced by action of endo-1,4-β-*xylanase* on a xylan containing substrate, — colorimetric method based on reaction of dinitrosalicylic acid on reducing sugar produced by action of endo-1,3(4)-β-*glucanase* on a β-glucan containing substrate. Characterisation of the active substances in the feedingstuffs: — colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from dye cross-linked wheat arabinoxylan substrate,	Chickens for fattening	—	3 000 XU 675 BGU		1. In the directions for use of the additive and premixture indicate the storage temperature, storage life, and stability to pelleting. 2. For use in feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 30 % wheat, barley, rye and/or triticale. 3. For safety reasons: breathing protection, glasses and gloves shall be used during handling.	4 December 2019

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 %			
			— colorimetric method measuring water soluble dye released by action of endo-1,3(4)-beta-glucanase from dye cross-linked barley beta-glucan substrate.						

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory: www.irmm.jrc.be/crl-feed-additives