REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 527/2011

of 30 May 2011

concerning the authorisation of a preparation of endo-1,4-β-xylanase produced by *Trichoderma reesei* (MUCL 49755), endo-1,3(4)-β-glucanase produced by *Trichoderma reesei* (MUCL 49754) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) as feed additive for weaned piglets (holder of the authorisation Aveve NV)

(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 preparation of endo-1,4-β-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (MUCL 49755), endo-1,3(4)-β-glucanase (EC 3.2.1.6) produced by *Trichoderma reesei* (MUCL 49754) and polygalacturonase (EC 3.2.1.15) produced by *Aspergillus aculeatus* (CBS 589.94), as set out in the Annex. 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 the preparation set out in the Annex as a feed additive for weaned piglets, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 8 July 2009 [2] and 2 February 2011 [3] that the preparation set out in the Annex, under the proposed conditions of use, does not have an adverse effect on animal health, consumer health or the environment, and that this additive has the potential to increase the body weight and feed to gain ratio in the 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 Reference Laboratory for Feed Additives set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation set out in the Annex 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.

(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 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* (2009) 1186, 1-17.
[3] EFSA Journal (2011); 9(2):2010.

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

Done at Brussels, 30 May 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 (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									
4a 14	Aveve NV	Endo-1,4-β-xylanase EC 3.2.1.8 Endo-1,3(4)-β-glucanase EC 3.2.1.6 Polygalacturonase EC 3.2.1.15	*Additive composition* Preparation of endo-1,4-β-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (MUCL 49755), endo-1,3(4)-β-glucanase (EC 3.2.1.6) produced by *Trichoderma reesei* (MUCL 49754) and polygalacturonase (EC 3.2.1.15) produced by *Aspergillus aculeatus* (CBS 589.94) having a minimum activity of: solid form: Endo-1,4-β-xylanase: 21 400 XU (1)/g Endo-1,3(4)-β-glucanase: 12 300 BGU (2)/g Polygalacturonase: 460 PGLU (3)/g. liquid form: Endo-1,4-β-xylanase: 10 700 XU/g Endo-1,3(4)-β-glucanase: 6 150 BGU/g Polygalacturonase: 230 PGLU/g. *Characterisation of the active substance* Endo-1,4-β-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei*, endo-1,3(4)-β-glucanase (EC 3.2.1.6) produced by *Trichoderma reesei* and polygalacturonase (EC 3.2.1.15) produced by *Aspergillus aculeatus* *Method of Analysis* (4) Characterisation of the active substances in the additive and feedingstuffs:	Piglets (weaned)		Endo-1,4-β-xylanase: 2 140 XU Endo-1,3(4)-β-glucanase: 1 230 BGU Polygalacturonase: 46 PGLU	—	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. 3. For use in compound feed rich in non-starch polysaccharides.	20 June 2021

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-1,4-β-xylanase from dye cross-linked wheat arabinoxylan substrate, — colorimetric method measuring water soluble dye released by action of endo-1,3(4)-β-glucanase from dye cross-linked barley betaglucan substrate, — viscosimetric method based on a decrease of viscosity produced by action of polygalacturonase on the pectin-containing substrate, poly-methylgalacturonic acid.						

([1]) 1 XU is the amount of enzyme which releases 1 μmol of reducing sugar (xylose equivalent) per minute from xylan of oat spelt at 50 °C and pH 4,8.
([2]) 1 BGU is the amount of enzyme which releases 1 μmol of reducing sugar (cellobiose equivalent) per minute from β-glucan of barley at 50 °C and pH 5,0.
([3]) 1 PGLU is the amount of enzyme which releases 1 μmol of reducing sugar (glucose equivalent) per minute from polymethylgalacturonic acid (pectin containing substrate) at 35 °C and pH 4,8.
([4]) 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