Commission Implementing Regulation (EU) No 1088/2011 of 27 October 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by Trichoderma reesei (MULC 49755) and endo-1,3(4)-beta-glucanase produced by Trichoderma reesei (MULC 49754) as a feed additive for weaned piglets (holder of authorisation Aveve NV) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1088/2011

of 27 October 2011

concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) as a feed additive for weaned piglets (holder of 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 enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754). The application was accompanied by the particulars and documents required pursuant to 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* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) as a feed additive for weaned piglets, to be classified in the additive category ‘zootechnical additives’.

(4) The use of that preparation was authorised for 10 years for chickens for fattening by Commission Regulation (EC) No 1091/2009[(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* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) for weaned piglets. The European Food Safety Authority (‘the Authority’) concluded in its opinion of 16 June 2011[(3)] that, under the proposed

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1088/2011. (See end of Document for details)

conditions of use, the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) does not have an adverse effect on animal health, human health or the environment, and that the use of that preparation can significantly increase the body weight gain and can improve feed to gain ratio in weaned piglets. 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 the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) 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*.

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

Done at Brussels, 27 October 2011.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1088/2011. (See end of Document for details)*

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 consisting of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) having a minimum activity of: 40 000 XU[a] and 9	*Piglets (weaned)*	—	4 000 XU 900 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 weaned piglets up to approximately 35 kg. 3. For safety: breathing protection, glasses and	17.11.2021

a 1 XU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) per minute from xylan of oat spelt at pH 4,8 and 50 °C.

b 1 BGU is the amount of enzyme which liberates 1 micromole of reducing sugars (cellobiose equivalents) per minute from ß-glucan of barley at pH 5,0 and 50 °C.

c 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

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				000 BGU[b]/g *Characterisation of the active substance* endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MULC 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) *Analytical method*[c] Characterisation of the active substance in the additive: —	colorimetric method based on reaction of dinitrosalicylic acid on		gloves shall be used during handling.

a 1 XU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) per minute from xylan of oat spelt at pH 4,8 and 50 °C.

b 1 BGU is the amount of enzyme which liberates 1 micromole of reducing sugars (cellobiose equivalents) per minute from ß-glucan of barley at pH 5,0 and 50 °C.

c 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