Commission Implementing Regulation (EU) No 989/2012 of 25 October 2012 concerning the authorisation 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 laying hens and minor poultry species for fattening and laying (holder of authorisation Aveve NV) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 989/2012

of 25 October 2012

concerning the authorisation 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 laying hens and minor poultry species for fattening and laying (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 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 under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation 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 laying hens and minor poultry species for fattening and laying, to be classified in the additive category ‘zootechnical additives’.

(4) The use of those enzymes was authorised for 10 years for chickens for fattening by Commission Regulation (EC) No 1091/2009[(2)] and for 10 years for weaned piglets by Commission Implementing Regulation (EU) No 1088/2011[(3)].

(5) New data were submitted in support of the application for the authorisation 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 laying hens and minor poultry species for fattening and laying. The European Food Safety Authority (‘the

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 989/2012. (See end of Document for details)*

Authority') concluded in its opinion of 23 May 2012[4] that the use 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 egg mass and can improve feed to eggs mass ratio in laying hens and minor poultry species for laying and can improve the zootechnical parameters in minor poultry species for fattening. 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 that preparation 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

Endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase as specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', are 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*.

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

Done at Brussels, 25 October 2012.

For the Commission

The President

José Manuel BARROSO

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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	Liquid preparation containing 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 900 BGU[b] per kg 12 000 XU and 2 700 BGU per litre Characterisation of active substance: Endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MULC 49755) Endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MULC 49754) Analytical method[c]: Spectrophotometric determination of reducing sugars released from oat spelt xylan (endo-1,4-beta-xylanase) and barley ß-glucan (endo-1,3(4)-beta-glucanase)	—	Minor poultry species for fattening	4 000 XU 900 BGU 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 starch and non-starch polysaccharides (mainly beta-glucans and arabinoxylans).	15 November 2022

a 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 reducing		3. For safety: breathing protection, glasses and gloves shall be used during handling.	

a 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