Commission Implementing Regulation (EU) No 1195/2012 of 13 December 2012 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by Trichoderma koningii (MUCL 39203) for turkeys for fattening and turkeys reared for breeding (holder of authorisation Lyven) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1195/2012

of 13 December 2012

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma koningii* (MUCL 39203) for turkeys for fattening and turkeys reared for breeding (holder of authorisation Lyven)

(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) The use of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma koningii* (MUCL 39203) was authorised without time limit for chickens for fattening by Commission Regulation (EC) No 828/2007[(2)].

(3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new use of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma koningii* (MUCL 39203) for turkeys for fattening and turkeys reared for breeding requesting that the additive be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 July 2012[(3)] that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma koningii* (MUCL 39203) does not have an adverse effect on animal health, human health or the environment, and that it has the potential to improve feed to gain ratio in turkeys for fattening. It also concluded that this conclusion can be extended to turkeys reared for breeding. 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.

(5) The assessment of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma koningii* (MUCL 39203) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that 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 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, 13 December 2012.

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**	**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									
4a1642	Lyven	Endo-1,4-beta-xylanase EC 3.2.1.8	*Additive composition* Preparation of endo-1,4-beta-xylanase produced by *Trichoderma koningii* (MUCL 39203) having a minimum activity of: *Characterisation of the active substance*	*Turkeys for fattening* Turkeys for breeding	— Solid form: 1 500 AXC[a]/g Liquid form: 200 AXC/ml	75 AXC	—	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 turkeys for fattening and turkeys	3 January 2023

a 1 AXC is the amount of enzyme which liberates 17,2 micromoles of reducing sugars (maltose equivalents) from oat xylan per minute at pH 4,7 and 30 °C.

b 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

				endo-1,4-beta-xylanase produced by *Trichoderma koningii* (MUCL 39203) *Analytical method*[b] For quantification of endo-1,4-beta-xylanase produced by *Trichoderma koningii* (MUCL 39203) in feed: Colorimetric method based on the quantification of dyed oligomers produced by the action of endo-1,4-beta-xylanase on Remazol-Brilliant-Blue-R xylan at				reared for breeding: 100 AXC. 3. For use in feed rich in non-starch polysaccharides (mainly arabinoxylans) 4. For safety: breathing protection, glasses and gloves shall be used during handling.

a 1 AXC is the amount of enzyme which liberates 17,2 micromoles of reducing sugars (maltose equivalents) from oat xylan per minute at pH 4,7 and 30 °C.

b 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

				pH 4,7 and 30 °C					

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(**1**) OJ L 268, 18.10.2003, p. 29.

(**2**) OJ L 184, 14.7.2007, p. 12.

(**3**) *EFSA Journal* 2012; 10(7):2843

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1195/2012.