COMMISSION IMPLEMENTING REGULATION (EU) No 1040/2013

of 24 October 2013

concerning the authorisation of a 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 pigs for fattening and minor porcine species for fattening other than *Sus scrofa domesticus* and turkeys for fattening (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 a new use of a 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). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a new use of a 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 pigs for fattening and minor porcine species for fattening other than *Sus scrofa domesticus*, and turkeys for fattening, 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]), for weaned piglets by Commission Implementing Regulation (EU) No 1088/2011 ([3]) and for laying hens and minor poultry species for fattening and laying by Commission Implementing Regulation (EU) No 989/2012 ([4]).

(5) The European Food Safety Authority ('the Authority') in its opinions of 12 March 2013 ([5]) confirmed its previous conclusions that, under the proposed conditions of use, the 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) does not have an adverse effect on animal health, human health or the environment. The Authority concluded that the additive has the potential to improve the zootechnical performance in pigs for fattening and that this conclusion can be extrapolated to minor porcine species for fattening other than *Sus scrofa domesticus*. The Authority also concluded that the additive has the potential to improve the final body weight and feed to gain ratio in turkeys 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 the 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) 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.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) 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) (OJ L 299, 14.11.2009, p. 6).

([3]) 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) (OJ L 281, 28.10.2011, p. 14).

([4]) 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) (OJ L 297, 26.10.2012, p. 11).

([5]) *EFSA Journal 2013*; 11(4):3171 and *EFSA Journal 2013*; 11(4):3172.

(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 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, 24 October 2013.

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									
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 [1] and 9 000 BGU [2]/g Solid and liquid forms *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* [3] 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-beta-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)-beta-glucanase on a beta-glucan containing substrate. Characterisation of the active substances in the feedingstuffs:	Pigs for fattening Minor porcine species for fattening other than *Sus scrofa domesticus* Turkeys for fattening	—	4 000 XU 900 BGU	—	1. In the directions for use of the additive and premixture, indicate the storage conditions, and stability to pelleting. 2. For use in feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans) 3. For safety: breathing protection, glasses and gloves shall be used during handling.	14 November 2023

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						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-beta-xylanase from dye cross-linked wheat arabinoxylan substrate; — colorimetric method measuring water soluble dye released by action of endo-1,3(4)-beta-glucanase from dye cross-linked barley betaglucan substrate.						

([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.
([2]) 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.
([3]) 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