COMMISSION REGULATION (EC) No 497/2007

of 4 May 2007

concerning the authorisation of endo-1,4-beta-xylanase EC 3.2.1.8 (Safizym X) as a feed additive

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns a new use of the preparation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma longibrachiatum* (CNCM MA 6-10) (Safizym X), as a feed additive for piglets (weaned), to be classified in the additive category 'Zootechnical additives'.

(4) The use of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma longibrachiatum* (CNCM MA 6-10) was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 1453/2004 ([2]), without a time limit for turkeys for fattening by Commission Regulation (EC) No 943/2005 ([3]) and without a time limit for laying hens by Commission Regulation (EC) No 1810/2005 ([4]).

(5) New data were submitted in support of an application for authorisation for piglets (weaned). The European Food Safety Authority (the Authority) concluded in its opinion of 17 October 2006 that the preparation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma longibrachiatum* (CNCM MA 6-10) (Safizym X) does not have an adverse effect on animal health, human health or the environment ([5]). It further concluded that that preparation does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. According to that opinion, the use of that preparation does not have an adverse effect on these additional animal categories. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of that preparation shows that the conditions for authorisation, 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.

(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.

([1]) OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).
([2]) OJ L 269, 17.8.2004, p. 3.
([3]) OJ L 159, 22.6.2005, p. 6.
([4]) OJ L 291, 5.11.2005, p. 5. Regulation as amended by Regulation (EC) No 184/2007 (OJ L 63, 1.3.2007, p. 1).
([5]) Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the enzyme preparation Safizym X (endo-1,4-beta-xylanase) as feed additive for piglets in accordance with Regulation (EC) No 1831/2003. Adopted on 17 October 2006, *The EFSA Journal* (2006) 405, 1-10.

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, 4 May 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1613	Société Industrielle Lesaffre	Endo-1,4-beta-xylanase EC 3.2.1.8 (Safizym X)	**Additive composition:** Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10W) having a minimum activity of: Powder form: 70 000 IFP (1)/g Liquid form: 7 000 IFP/ml **Characterisation of the active substance:** endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10W) **Analytical method** (2) Reducing sugar assay for endo-1,4-beta-xylanase by colorimetric reaction of dinitrosalicylic acid reagent on reducing sugar yield.	Piglets (weaned)	—	840 IFP		1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dose per kilogram of complete feedingstuff: 1 680 IFP. 3. For piglets (weaned) up to 35 kg of body weight. 4. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 20 % wheat.	25.5.2017

(1) 1 IFP is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat xylan per minute at pH 4,8 and 50 °C.
(2) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/html/crlfaa/