

## I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

## REGULATIONS

## COMMISSION REGULATION (EC) No 242/2007

of 6 March 2007

**concerning the authorisation of endo-1,4-beta xylanase EC 3.2.1.8 (Belfeed B1100MP and Belfeed B1100ML) 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<sup>(1)</sup>, 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. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The application concerns a new use of the preparation of endo-1,4-beta xylanase EC 3.2.1.8 produced by *Bacillus subtilis* (LMG S-15136), as a feed additive for ducks, to be classified in the additive category 'zootechnical additives'.
- (4) The method of analysis included in the application for authorisation in accordance with Article 7(3)(c) of

Regulation (EC) No 1831/2003 concerns the determination of the active substance of the feed additive in feed. The method of analysis referred to in the Annex to this Regulation is therefore not to be understood as a Community method of analysis within the meaning of Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules<sup>(2)</sup>.

- (5) The use of endo-1,4-beta xylanase EC 3.2.1.8 produced by *Bacillus subtilis* (LMG S-15136) was authorised without a time limit for piglets (weaned) by Commission Regulation (EC) No 1206/2005<sup>(3)</sup> and for chickens for fattening by Commission Regulation (EC) No 1259/2004<sup>(4)</sup>. New data were submitted in support of an application for authorisation for ducks. The European Food Safety Authority (the Authority) concluded in its opinion of 15 June 2006<sup>(5)</sup> that the safety of this additive for the consumer, the user and the environment have already been established and will not be changed by the proposed new use. It further concluded, that the use of the preparation does not have an adverse effect on this additional animal category and that the use of that preparation can improve the zootechnical parameters in ducks. 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

<sup>(1)</sup> 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).

<sup>(2)</sup> OJ L 165, 30.4.2004, p. 1; corrected by OJ L 191, 28.5.2004, p. 1. Regulation as last amended by Council Regulation (EC) No 1791/2006 (OL L 363, 20.12.2006, p. 1).

<sup>(3)</sup> OJ L 197, 28.7.2005, p. 12.

<sup>(4)</sup> OJ L 239, 9.7.2004, p. 8.

<sup>(5)</sup> Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the enzyme preparation Belfeed B1100MP and belfeed B1100ML (endo-1-4-beta xylanase) authorised as a feed additive in accordance with Council Directive 70/524/EEC. Adopted on 15 June 2006. The EFSA Journal (2006) 368, 1.

Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

HAS ADOPTED THIS REGULATION:

*Article 1*

- (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.

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*

- (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,

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, 6 March 2007.

*For the Commission*  
Markos KYPRIANOU  
*Member of the Commission*

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## 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
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
<b>Category of zootechnical additives. Functional group: digestibility enhancers.</b>									
4a1606	Beldem SA	endo-1,4-beta-xylanase EC 3.2.1.8 (Belfeed B1100MP Belfeed B1100ML)	<p><b>Additive composition</b> Preparation of endo-1,4-beta-xylanase EC 3.2.1.8 having a minimum of activity solid and liquid form 100 IU <sup>(1)</sup> /g or ml</p> <p><b>Characterisation of the active substance</b> endo-1,4-beta-xylanase EC 3.2.1.8 produced by <i>Bacillus subtilis</i> (LMG S-15136)</p> <p><b>Analytical method <sup>(2)</sup></b> Colorimetric method measuring water soluble dye released by the enzyme from azurine crosslinked wheat arabinoxylan substrate</p>	Ducks	—	10 IU	—	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</li> <li>2. Recommended dose per kg of complete feedingstuffs: endo-1,4-beta-xylanase: 10 IU</li> <li>3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.</li> <li>4. If the product is handled or mixed in a confined atmosphere, it is recommended to use safety glasses and masks for mixing if the mixers are not equipped with exhaust systems.</li> </ol>	2.4.2017

<sup>(1)</sup> One IU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 4,5 and 30 °C.

<sup>(2)</sup> Details of the analytical methods are available at the following address of the Community Reference Laboratory: [www.irmm.jrc.be/html/crlfaa/](http://www.irmm.jrc.be/html/crlfaa/)