

COMMISSION REGULATION (EC) No 516/2007
of 10 May 2007
concerning the permanent authorisation of an additive in feedingstuffs
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ⁽¹⁾, and in particular Articles 3, 9d(1) thereof,

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 ⁽²⁾, and in particular Article 25 thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.
- (2) Article 25 of Regulation (EC) No 1831/2003 lays down transitional measures for applications for the authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of Regulation (EC) No 1831/2003.
- (3) The application for the authorisation of the additive listed in the Annex to this Regulation was submitted before the date of application of Regulation (EC) No 1831/2003.
- (4) Initial comments on those applications, as provided for in Article 4(4) of Directive 70/524/EEC, were forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. Those applications are therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

(5) The use of the enzyme preparation of endo-1,4-beta-xylanase EC 3.2.1.8, produced by *Bacillus subtilis* (LMG S-15136) was provisionally authorised for the first time for pigs for fattening by Commission Regulation (EC) No 261/2003 ⁽³⁾ and turkeys for fattening by Commission Regulation (EC) No 2188/2002 ⁽⁴⁾. New data were submitted in support of an application for authorisation without a time limit of that enzyme preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex to this Regulation, should be authorised without a time limit.

(6) The assessment of this application shows that certain procedures should be required to protect workers from exposure to the additives set out in the Annex. Such protection should be assured by the application of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ⁽⁵⁾.

(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 belonging to the group 'Enzymes', as specified in the Annex, is authorised without a time limit as an additive in animal nutrition under the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1800/2004 (OJ L 317, 16.10.2004, p. 37).

⁽²⁾ 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).

⁽³⁾ OJ L 37, 13.3.2003, p. 12.

⁽⁴⁾ OJ L 333, 10.12.2002, p. 5.

⁽⁵⁾ OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

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

Done at Brussels, 10 May 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	End of period of authorisation
					Units of activity/kg of complete feedstuff	Units of activity/kg of complete feedstuff			
Enzymes									
E 1606	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Bacillus subtilis</i> (LMG S-15136) having a minimum activity of: Solid and liquid: endo-1,4-beta-xylanase: 100 IU (1)/g or ml	Pigs for fattening	—	10 IU	—	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 feedstuff: 10 IU 3. For use in compound feed rich in arabinoxylan, e.g. minimum 40 % wheat.	Without a time limit	
			Turkeys for fattening	—	10 IU	—	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 feedstuff: 10 IU 3. For use in compound feed rich in arabinoxylan, e.g. minimum 40 % wheat.	Without a time limit	

(1) 1 IU is the amount of enzyme which liberates 1 micromole of reducing sugars (expressed in equivalent xylose) from birchwood xylan per minute at pH 4,5 and 30 °C.