COMMISSION REGULATION (EC) No 773/2006

of 22 May 2006

concerning the provisional and permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised 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) and 9e(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 applications for the authorisation of the additives listed in the Annexes to this Regulation were 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) Data were submitted in support of an application for authorisation of the use of the micro-organism preparation of *Kluyveromyces marxianus-fragilis B0399* MUCL 41579 for piglets. The European Food Safety Authority (EFSA) expressed its opinion on the use of this preparation on 28 January 2004. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex I to this Regulation, should be authorised for four years.

(6) The use of the enzyme preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 600.94) is authorised without a time limit for chickens for fattening, turkeys for fattening and piglets, as enzyme E1609 in coated, liquid and solid forms by Commission Regulation (EC) No 1453/2004 [3]. New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to ducks and to include in the authorisation for this animal species a granulate form. EFSA delivered an opinion on 30 November 2005 on the use of this preparation which concludes that it does not present a risk for this additional animal category. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for an authorisation of that preparation for that use are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex II to this Regulation, should be authorised for four years.

(7) Data were submitted in support of an application for authorisation of a granulate form of the enzyme E1609 for chickens for fattening, turkeys for fattening and piglets. EFSA expressed its opinion on the use of this preparation on 30 November 2005. 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 III to this Regulation, should be authorised without a time limit.

[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 269, 17.8.2004, p. 3.

(8) The assessment of these applications shows that certain procedures should be required to protect workers from exposure to the additives set out in the Annexes. 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 [1].

(9) 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 'Micro-organisms', as specified in Annex I, is authorised for four years as additive in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparation belonging to the group 'Enzymes', as specified in Annex II, is authorised for four years as additive in animal nutrition under the conditions laid down in that Annex.

Article 3

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

Article 4

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, 22 May 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

[1] 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).

ANNEX I

No (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU/kg of complete feedingstuff			
Micro-organisms								
26	*Kluyveromyces marxianus-fragilis B0399* MUCL 41579	Preparation of *Kluyveromyces marxianus-fragilis B0399* containing a minimum of: Powder and granulated form: 5×10^6 CFU/g additive	Piglets (weaned)	—	6×10^6	6×10^6	In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. For use in weaned piglets until approximately 35 kg.	12 June 2010

ANNEX II

No (or 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 feedingstuff			
Enzymes								
7	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,4-beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 600.94) having a minimum activity of: Coated, solid and granulate forms: Endo-1,4-beta-xylanase: 36 000 FXU (1)/g Endo-1,4-beta-glucanase: 15 000 BGU (2)/g Liquid form: Endo-1,4-beta-xylanase: 36 000 FXU/ml Endo-1,4-beta-glucanase: 15 000 BGU/ml	Ducks	—	6 000 FXU 2 500 BGU	— —	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 kg of complete feedingstuff: — 6 000 FXU — 2 500 BGU 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 60 % wheat.	12 June 2010

(1) 1 FXU is the amount of enzyme which liberates 0,15 micromoles of xylose from azurine-cross-linked xylan per minute at pH 5,0 and 40 °C.
(2) 1 BGU is the amount of enzyme which liberates 0,15 micromoles of glucose from azurine-cross-linked beta-glucan per minute at pH 5,0 and 40 °C.

ANNEX III

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 feedingstuff			
Enzymes								
E 1609	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,4-beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 600.94) having a minimum activity of: Granulate forms: Endo-1,4-beta-xylanase: 36 000 FXU [1]/g Endo-1,4-beta-glucanase: 15 000 BGU [2]/g	Chickens for fattening	—	4 860 FXU 2 025 BGU	— —	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 kg of complete feedingstuff: — 4 860-6 000 FXU — 2 025-2 500 BGU 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 35 % barley and 20 % wheat.	Without a time limit
			Turkeys for fattening	—	6 000 FXU 2 500 BGU	— —	1. In the directions for use of the additive and premixtures, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dose per kg of complete feedingstuff: — 6 000 FXU — 2 500 BGU 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % wheat.	Without a time limit

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 feedingstuff			
			Piglets (weaned)	—	6 000 FXU 2 500 BGU	— —	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 kg of complete feedingstuff: — 6 000 FXU — 2 500 BGU 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 30 % wheat and 30 % barley. 4. For use in weaned piglets until approximately 35 kg.	Without a time limit

(1) 1 FXU is the amount of enzyme which liberates 0,15 micromoles of xylose from azurine-cross-linked xylan per minute at pH 5,0 and 40 °C.
(2) 1 BGU is the amount of enzyme which liberates 0,15 micromoles of glucose from azurine-cross-linked beta-glucan per minute at pH 5,0 and 40 °C.