COMMISSION REGULATION (EU) No 1270/2009

of 21 December 2009

concerning the permanent authorisations of certain additives in feedingstuffs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs [1], and in particular Articles 3 and 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 applications for authorisation of the additives set out 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) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 526,94) was provisionally authorised for piglets by Commission Regulation (EC) No 2374/1998 [3]. It was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 2036/2005 [4]. New data were submitted in support of an application for authorisation without a time limit of that enzyme preparation for weaned piglets. 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 I to this Regulation, should be authorised without a time limit.

(6) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589,94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592,94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) was provisionally authorised for piglets by Commission Regulation (EC) No 2200/2001 [5]. It was provisionally authorised for turkeys for fattening by Commission Regulation (EC) No 252/2006 [6]. It was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 358/2005 [7] and it was provisionally authorised for laying hens by Commission Regulation (EC) No 1140/2007 [8]. New data were submitted in support of an application for authorisation without a time limit of that enzyme preparation for turkeys for fattening and weaned piglets. 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 II to this Regulation, should be authorised without a time limit.

(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 Annex I, is authorised without a time limit 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 without a time limit as additive in animal nutrition under the conditions laid down in that Annex.

[1] OJ L 270, 14.12.1970, p. 1.
[2] OJ L 268, 18.10.2003, p. 29.
[3] OJ L 295, 4.11.1998, p. 3.
[4] OJ L 328, 15.12.2005, p. 13.
[5] OJ L 299, 15.11.2001, p. 1.
[6] OJ L 44, 15.2.2006, p. 3.
[7] OJ L 57, 3.3.2005, p. 3.
[8] OJ L 256, 2.10.2007, p. 14.

Article 3

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, 21 December 2009.

For the Commission
The President
José Manuel BARROSO

ANNEX I

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 1636	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 526.94) having a minimum activity of: Solid form: 700 000 BU [1]/g Liquid form: 300 000 BU/g	Piglets (weaned)	—	17 500 BU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. For use in weaned piglets up to 35 kg. 3. Recommended dose per kilogram of complete feedingstuff: 17 500-50 000 BU. 4. For use in compound feed rich in non-starch polysaccharides (mainly glucans), e.g. containing more than 60 % barley or wheat.	Without a time limit

[1] 1 BU is the amount of enzyme which liberates 0,06 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,8 and 50 °C.

ANNEX II

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 1620	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-glucanase EC 3.2.1.4 Alpha-amylase EC 3.2.1.1 Bacillolysin EC 3.4.24.28 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 2 350 U/g [1] Endo-1,4-beta-glucanase: 4 000 U/g [2] Alpha-amylase: 400 U/g [3] Bacillolysin: 450 U/g [4] Endo-1,4-beta-xylanase: 20 000 U/g [5]	Turkeys for fattening	—	Endo-1,3(4)-beta-glucanase: 587 U Endo-1,4-beta-glucanase: 1 000 U Alpha-amylase: 100 U Bacillolysin: 112 U Endo-1,4-beta-xylanase: 5 000 U	— — — — —	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: — endo-1,3(4)-beta-glucanase: 1 175-2 350 U, — endo-1,4-beta-glucanase: 2 000-4 000 U, — alpha-amylase: 200-400 U, — bacillolysin: 225-450 U, — endo-1,4-beta-xylanase: 10 000-20 000 U, 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and especially arabinoxylans), e.g. containing more than 30 % wheat.	Without a time limit
			Piglets (weaned)	—	Endo-1,3(4)-beta-glucanase: 1 175 U Endo-1,4-beta-glucanase: 2 000 U Alpha-amylase: 200 U Bacillolysin: 225 U Endo-1,4-beta-xylanase: 10 000 U	— — — — —	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For use in weaned piglets up to 35 kg 3. Recommended dose per kilogram of complete feedingstuff: — endo-1,3(4)-beta-glucanase: 1 175 U, — endo-1,4-beta-glucanase: 2 000 U, — alpha-amylase: 200 U, — bacillolysin: 225 U, — endo-1,4-beta-xylanase: 10 000 U, 4. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and especially arabinoxylans), e.g. containing more than 35 % wheat.	

(1) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 7,5 and 30 °C.
(2) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from carboxymethylcellulose per minute at pH 4,8 and 50 °C.
(3) 1 U is the amount of enzyme which liberates 1 micromole of glucose from a cross-linked starch polymer per minute at pH 7,5 and 37 °C.
(4) 1 U is the amount of enzyme which solubilises one microgram of azo-casein substrate per minute at pH 7,5 and 37 °C.
(5) 1 U is the amount of enzyme which liberates 0,0067 micromoles of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 5,3 and 50 °C.