COMMISSION REGULATION (EC) No 1811/2005

of 4 November 2005

concerning the provisional and permanent authorisations 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) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94) was provisionally authorised for the first time for piglets by Commission Regulation (EC) No 1436/98 ([3]). 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 I, should be authorised without a time-limit.

(6) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) was provisionally authorised for the first time for chickens for fattening by Commission Regulation (EC) No 1411/1999 ([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 I, should be authorised without a time-limit.

(7) The use of the enzyme preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 74 252) was provisionally authorised for turkeys for fattening by Commission Regulation (EC) No 937/2001 ([5]) and for laying hens by Commission Regulation (EC) No 2188/2002 ([6]) and was authorised without a time-limit for chickens for fattening by Commission Regulation (EC) No 1259/2004 ([7]) and for turkey for fattening by Commission Regulation (EC) No 1206/2005 ([8]). New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to ducks. The European Food Safety Authority (EFSA) has delivered an opinion 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, should be authorised for four years.

(8) Data were submitted in support of an application for authorisation of the use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 529.94) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 526.94) for chickens for

([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 191, 7.7.1998, p. 15.
([4]) OJ L 164, 30.6.1999, p. 56.
([5]) OJ L 130, 12.5.2001, p. 25.
([6]) OJ L 333, 10.12.2002, p. 5.
([7]) OJ L 239, 9.7.2004, p. 8.
([8]) OJ L 197, 28.7.2005, p. 12.

fattening and for turkeys for fattening. EFSA has delivered an opinion on the use of this preparation which concludes that it does not present a risk for the consumer, the user, the animal category or the environment. 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, should be authorised for four years.

(9) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (NCYC Sc 47) was provisionally authorised, for the first time, for dairy cows by Regulation (EC) No 937/2001. New data were submitted in support of an application for authorisation without a time-limit of that micro-organism 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 micro-organism preparation, as specified in Annex III, should be authorised without a time-limit.

(10) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (CBS 493.94) was provisionally authorised, for the first time, for dairy cows by Regulation (EC) No 937/2001. New data were submitted in support of an application for authorisation without a time-limit of that micro-organism 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 micro-organism preparation, as specified in Annex III, should be authorised without a time-limit.

(11) 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].

(12) 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 preparations belonging to the group 'Enzymes', as specified in Annex I, are authorised for use without a time-limit as additives in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparations belonging to the group 'Enzymes', as specified in Annex II, are authorised for use for four years as additives in animal nutrition under the conditions laid down in that Annex.

Article 3

The preparations belonging to the group 'Micro-organisms', as specified in Annex III, are authorised for use without a time-limit as additives 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, 4 November 2005.

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

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 1603	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94) having a minimum activity of: Coated form: Endo-1,3(4)-beta-glucanase: 50 FBG [1]/g Liquid form: Endo-1,3(4)-beta-glucanase: 120 FBG/ml	Piglets (weaned)	—	Endo-1,3(4)-beta-glucanase: 10 FBG	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life, and stability to pelleting 2. Recommended dose per kg of complete feedingstuff: Endo-1,3(4)-beta-glucanase: 10-25 FBG 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 60 % vegetable ingredients (maize, lupin, wheat, barley, soya, oilseed rape or peas) 4. For use in weaned piglets until approximately 35 kg	Without a time-limit
E 1635	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) having a minimum activity of: Liquid form: Endo-1,3(4)-beta-glucanase: 200 U [2]/ml	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 75 U	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting 2. Recommended dose per kg of complete feedingstuff: 75-100 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 30 % barley etc.	Without a time-limit

[1] 1 FBG is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5,0 and 30 °C.
[2] 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5,0 and 30 °C.

ANNEX II

EC No or 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								
11	Endo-1,4-beta-glucanase EC 3.2.1.4 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 74 252) having a minimum activity of: Liquid and granular form: Endo-1,4-beta-glucanase: 8 000 U ([1])/ml or g Endo-1,3(4)-beta-glucanase: 18 000 U ([2])/ml or g Endo-1,4-beta-xylanase: 26 000 U ([3])/ml or g	Ducks	—	Endo-1,4-beta-glucanase: 400 U Endo-1,3(4)-beta-glucanase: 900 U Endo-1,4-beta-xylanase: 1 300 U	— — —	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life, and stability to pelleting 2. Recommended dose per kg of complete feedingstuff: endo-1,4-beta-glucanase: 400-1 600 U endo-1,3(4)-beta-glucanase: 900-3 600 U endo-1,4-beta-xylanase: 1 300-5 200 U 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 45 % of either barley and/or triticale	25.11.2009
63	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 529.94) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 526.94) having minimum activities of: Solid form: Endo-1,4-beta-xylanase: 800 000 BXU ([4])/g Endo-1,3(4)-beta-glucanase: 200 000 BU ([5])/g Liquid form: Endo-1,4-beta-xylanase: 120 000 BXU/ml Endo-1,3(4)-beta-glucanase: 30 000 BU/ml	Chickens for fattening	—	Endo-1,4-beta-xylanase: 6 000 BXU Endo-1,3(4)-beta-glucanase: 1 500 BU	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting 2. Recommended dose per kg of complete feedingstuff: Endo-1,4-beta-xylanase: 16 000-24 000 BXU Endo-1,3(4)-beta-glucanase: 4 000-6 000 BU 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and glucans), e.g. containing more than 54 % wheat	25.11.2009

EC No or 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			
			Turkeys for fattening	—	Endo-1,4-beta-xylanase: 16 000 BXU Endo-1,3(4)-beta-glucanase: 4 000 BU	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting 2. Recommended dose per kg of complete feedingstuff: Endo-1,4-beta-xylanase: 16 000-40 000 BXU Endo-1,3(4)-beta-glucanase: 4 000-10 000 BU 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and glucans), e.g. containing more than 44 % wheat	25.11.2009

(1) 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from carboxymethylcellulose per minute at pH 5,0 and 40 °C.
(2) 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from barley beta-glucan per minute at pH 5,0 and 40 °C.
(3) 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from oat spelt xylan per minute at pH 5,0 and 40 °C.
(4) 1 BXU is the amount of enzyme which liberates 0,06 micromoles of reducing sugars (xylose equivalents) from birch xylan per minute at pH 5,3 and 50 °C.
(5) 1 BU is the amount of enzyme which liberates 0,06 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,8 and 50 °C.

ANNEX III

EC No or 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								
E 1702	*Saccharomyces cerevisiae* NCYC Sc 47	Preparation of *Saccharomyces cerevisiae* containing a minimum of: 5×10^9 CFU/g additive	Dairy cows	—	4×10^8	2×10^9	In the directions for use of the additive and the pre-mixture, indicate the storage temperature, storage life and stability to pelleting. The quantity of *Saccharomyces cerevisiae* in the daily ration must not exceed $5{,}6 \times 10^9$ CFU per 100 kg of body weight. Add $8{,}75 \times 10^9$ CFU per each additional 100 kg body weight.	Without a time-limit
E 1704	*Saccharomyces cerevisiae* CBS 493.94	Preparation of *Saccharomyces cerevisiae* containing a minimum of: 1×10^9 CFU/g additive	Dairy cows	—	5×10^7	$3{,}5 \times 10^8$	In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting. The quantity of *Saccharomyces cerevisiae* in the daily ration must not exceed $1{,}2 \times 10^9$ CFU for 100 kg of body weight. Add $1{,}7 \times 10^8$ CFU per each additional 100 kg body weight.	Without a time-limit