COMMISSION REGULATION (EC) No 833/2005

of 31 May 2005

concerning the permanent authorisation of additives 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 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 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 *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) was provisionally authorised for the first time for weaned piglets, by Commission Regulation (EC) No 2690/1999 ([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 the Annex, 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), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) was provisionally authorised for the first time for weaned piglets, by Regulation (EC) No 2690/1999. 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 the Annex, should be authorised without a time limit.

(7) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) was provisionally authorised for the first time for weaned piglets, by Commission Regulation (EC) No 1636/1999 ([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 the Annex, 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.
([3]) OJ L 326, 18.12.1999, p. 33.
([4]) OJ L 194, 27.7.1999, p. 17.

(8) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) was provisionally authorised for the first time for pigs for fattening, by Regulation (EC) No 1636/1999. 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 the Annex, should be authorised without a time limit.

(9) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) was provisionally authorised for the first time for chickens for fattening, by Commission Regulation (EC) No 1411/1999 ([1]). 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 the Annex, should be authorised without a time limit.

(10) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and 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 418/2001 ([2]). 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 the Annex, should be authorised without a time limit.

(11) The assessment of those 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 ([3]).

(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 the Annex, are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the third 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, 31 May 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

([1]) OJ L 164, 30.6.1999, p. 56.
([2]) OJ L 62, 2.3.2001, p. 3.
([3]) 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

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 1624	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Alpha-amylase EC 3.2.1.1	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 250 U [1]/g Endo-1,4-beta-xylanase: 400 U [2]/g Alpha-amylase: 1 000 U [3]/g	Piglets (weaned)	—	endo-1,3(4)-beta-glucanase: 250 U endo-1,4-beta-xylanase: 400 U alpha-amylase: 1 000 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 kg of complete feedingstuff: endo-1,3(4)-beta-glucanase: 250 U endo-1,4-beta-xylanase: 400 U alpha-amylase: 1 000 U. 3. For use in compound feed containing cereals rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 35 % barley. 4. For use in weaned piglets until approximately 35 kg in weight.	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			
E 1625	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Alpha-amylase EC 3.2.1.1 Polygalacturonase EC 3.2.1.15	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 150 U [1]/g Endo-1,4-beta-xylanase: 4 000 U [2]/g Alpha-amylase: 1 000 U [3]/g Polygalacturonase: 25 U [4]/g	Piglets (weaned)	—	endo-1,3(4)-beta-glucanase: 150 U endo-1,4-beta-xylanase: 4 000 U alpha-amylase: 1 000 U polygalactu-ronase: 25 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 kg of complete feedingstuff: endo-1,3(4)-beta-glucanase: 150 U endo-1,4-beta-xylanase: 4 000 U alpha-amylase: 1 000 U polygalacturonase: 25 U. 3. For use in compound feed containing cereals rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 20 % barley and 35 % wheat. 4. For use in weaned piglets until approxi-mately 35 kg in weight.	Without a time limit
E 1626	Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) having a minimum activity of: Endo-1,4-beta-xylanase: 5 000 U [2]/g Subtilisin: 500 U [5]/g	Piglets (weaned)	—	endo-1,4-beta-xylanase: 5 000 U subtilisin: 500 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 kg of complete feedingstuff: endo-1,4-beta-xylanase: 5 000 U subtilisin: 500 U. 3. For use in compound feed e.g. containing more than 40 % wheat. 4. For use in weaned piglets until approxi-mately 35 kg in weight.	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			
E 1627	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 800 U [1]/g Endo-1,4-beta-xylanase: 800 U [2]/g	Pigs for fattening	—	endo-1,3(4)-beta-glucanase: 400 U endo-1,4-beta-xylanase: 400 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 kg of complete feedingstuff: endo-1,3(4)-beta-glucanase: 400 U endo-1,4-beta-xylanase: 400 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans) e.g. containing more than 65 % barley.	Without a time limit
E 1628	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) having a minimum activity of: Powder form: Endo-1,4-beta-xylanase: 2 000 U [2]/g Liquid form: Endo-1,4-beta-xylanase: 5 000 U/ml	Chickens for fattening	—	endo-1,4-beta-xylanase: 500 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 kg of complete feedingstuff: endo-1,4-beta-xylanase: 500-2 500 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 55 % wheat or 60 % rye.	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			
E 1629	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 longibrachiatum* (ATCC 2105) and endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) having a minimum activity of: Endo-1,4-beta-xylanase: 5 000 U [2]/ml Endo-1,3(4)-beta-glucanase: 50 U [1]/ml	Chickens for fattening	—	endo-1,4-beta-xylanase: 1 250 U endo-1,3(4)-beta-glucanase: 12 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 kg of complete feedingstuff: endo-1,4-beta-xylanase: 1 250-2 500 U endo-1,3(4)-beta-glucanase: 12-25 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 20 % barley and 40 % wheat.	Without a time limit

[1] 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.
[2] 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 5,3 and 50 °C.
[3] 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from a water insoluble cross linked starch polymer substrate per minute at pH 6,5 and 37 °C.
[4] 1 U is the amount of enzyme which liberates 1 micromole of reducing material (galacturonic acid equivalents) from a poly D-galacturonic substrate per minute at pH 5,0 and 40 °C.
[5] 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7,5 and 40 °C.