COMMISSION REGULATION (EC) No 2036/2005

of 14 December 2005

concerning the permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of certain additives 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 micro-organism preparation of *Saccharomyces cerevisiae* (CNCM I-1079) was provisionally authorised, for the first time, for sows 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 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 I, should be authorised without a time limit.

(6) The use of the micro-organism preparation of *Pediococcus acidilactici* (CNCM MA 18/5M) was provisionally authorised, for the first time, for pigs for fattening by Commission Regulation (EC) No 866/1999 [4]. 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 I, should be authorised without a time limit.

(7) The use of the micro-organism preparation of *Enterococcus faecium* (CECT 4515) was provisionally authorised, for the first time, for piglets by Commission Regulation (EC) No 654/2000 [5]. 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 I, 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 191, 7.7.1998, p. 15.
[4] OJ L 108, 27.4.1999, p. 21.
[5] OJ L 79, 30.3.2000, p. 26.

(8) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 526.94) was provisionally authorised for the first time for chickens for fattening by Commission Regulation (EC) No 2374/98 [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 Annex II, 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), endo-1,3(4)-beta-glucanase and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) 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 Annex II, should be authorised without a time limit.

(10) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287) was authorised without a time limit for chickens for fattening, turkeys for fattening and piglets by Commission Regulation (EC) No 1332/2004 [3]. New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to ducks and pigs for fattening. 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 III, should be authorised for four years.

(11) 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 authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 943/2005 [4]. New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to ducks. The 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 III, should be authorised for four years.

(12) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) was provisionally authorised for chickens for fattening by Regulation (EC) No 418/2001. New data were submitted in support of two applications to extend the authorisation of the use of this enzyme preparation to ducks and laying hens. The EFSA has delivered an opinion on the use of this preparation on each of the two animal categories which conclude in both cases that it does not present a risk for them. 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 for ducks and laying hens, as specified in Annex III, should be authorised for four years.

(13) 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 [5].

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

[1] OJ L 295, 4.11.1998, p. 3.
[2] OJ L 62, 2.3.2001, p. 3.
[3] OJ L 247, 21.7.2004, p. 8.
[4] OJ L 159, 22.6.2005, p. 6.
[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).

HAS ADOPTED THIS REGULATION:

Article 1

The preparations belonging to the group 'Micro-organisms', 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 without a time limit as additives in animal nutrition under the conditions laid down in that Annex.

Article 3

The preparations belonging to the group 'Enzymes', as specified in Annex III, are authorised for use for four years 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, 14 December 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

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
					CFU/kg of complete feedingstuff			
Micro-organisms								
E 1703	*Saccharomyces cerevisiae* CNCM I-1079	Preparation of *Saccharomyces cerevisiae* containing a minimum of: 2×10^{10} CFU/g additive	Sows	—	1×10^{9}	6×10^{9}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	Without a time limit
E 1712	*Pediococcus acidilactici* CNCM MA 18/5M	Preparation of *Pediococcus acidilactici* containing a minimum of: 1×10^{10} CFU/g additive	Pigs for fattening	—	1×10^{9}	1×10^{9}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	Without a time limit
E 1713	*Enterococcus faecium* CECT 4515	Preparation of *Enterococcus faecium* containing a minimum of: 1×10^{9} CFU/g additive	Piglets (weaned)	—	1×10^{9}	1×10^{9}	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 until approximately 35 kg.	Without a time limit

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 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	Chickens for fattening	—	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. Recommended dose per kg of complete feedingstuff: 17 500-50 000 BU. 3. For use in compound feed rich in non-starch polysaccharides (mainly glucans), e.g. containing more than 20 % barley or 30 % rye.	Without a time limit
E 1637	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Subtilisin EC 3.4.21.62 Alpha-amylase EC 3.2.1.1 Polygalacturonase EC 3.2.1.15	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), subtilisin produced by *Bacillus subtilis* (ATCC 2107), polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) having a mimimum activity of: Endo-1,4-beta-xylanase: 300 U (2)/g Endo-1,3(4)-beta-glucanase: 150 U (3)/g Subtilisin: 4 000 U (4)/g Alpha-amylase: 400 U (5)/g Polygalacturonase: 25 U (6)/g	Chickens for fattening	—	endo-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalacturonase: 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-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalacturonase: 25 U. 3. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % maize or 60 % wheat.	Without a time limit

(1) 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.
(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 liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5,0 and 30 °C.
(4) 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.
(5) 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.
(6) 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.

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								
5	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287) having a minimum activity of: Coated form: 1 000 FXU [1]/g Liquid form: 650 FXU/ml	Pigs for fattening	—	200 FXU	—	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: 200-400 FXU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 50 % cereals (e.g. wheat, barley, rye or triticale).	4.1.2010
			Ducks	—	100 FXU	—	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: 100-200 FXU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 50 % cereals (e.g. wheat, barley, rye or triticale).	4.1.2010

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			
37	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: 1 600 U [3]/g	Ducks	—	endo-1,4-beta-xylanase: 2 500 U subtilisin: 800 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: 2 500 U subtilisin: 800 U. 3. For use in compound feed e.g. containing more than 65 % wheat.	4.1.2010
59	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Subtilisin EC 3.4.21.62 Alpha-amylase EC 3.2.1.1 Polygalacturonase EC 3.2.1.15	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), subtilisin produced by *Bacillus subtilis* (ATCC 2107), polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) having a mimimum activity of: Endo-1,4-beta-xylanase: 300 U [2]/g Endo-1,3(4)-beta-glucanase: 150 U [4]/g Subtilisin: 4 000 U [3]/g Alpha-amylase: 400 U [5]/g Polygalacturonase: 25 U [6]/g	Ducks	—	endo-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalac-turonase: 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-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalacturonase: 25 U. 3. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % maize.	4.1.2010

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			
			Laying hens	—	endo-1,4-beta-xylanase: 225 U endo-1,3(4)-beta-glucanase: 112 U subtilisin: 3 000 U alpha-amylase: 300 U polygalac-turonase: 18 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: 225 U endo-1,3(4)-beta-glucanase: 112 U subtilisin: 3 000 U alpha-amylase: 300 U polygalacturonase: 18 U. 3. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % maize.	4.1.2010

([1]) 1 FXU is the amount of enzyme which liberates 7,8 micromoles of reducing sugars (xylose equivalents) from azo-wheat arabinoxylan per minute at pH 6,0 and 50 °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 liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7,5 and 40 °C.
([4]) 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.
([5]) 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.
([6]) 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.