COMMISSION REGULATION (EC) No 1458/2005

of 8 September 2005

concerning the permanent and provisional authorisations of certain additives in feedingstuffs and the provisional authorisation of new uses 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 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 niger* (MUCL 39199) was provisionally authorised for the first time for chickens for fattening, 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 *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) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) is authorised for chickens for fattening without a time limit by Commission Regulation (EC) No 358/2005 [4], and provisionally for turkeys for fattening by Commission Regulation (EC) No 2013/2001 [5]. New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to laying hens. 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.

(7) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) is authorised for chickens for fattening without a time limit by Commission Regulation (EC) No 833/2005 [6]. New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to turkeys for fattening. 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

[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 57, 3.3.2005, p. 3.
[5] OJ L 272, 13.10.2001, p. 24.
[6] OJ L 138, 1.6.2005, p. 5.

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 *Aspergillus niger* (CBS 109.713) for chickens 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 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 [1].

(10) 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 for use without a time limit as additive 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 additive in animal nutrition under the conditions laid down in that Annex.

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, 8 September 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 1634	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus niger* (MUCL 39199) having a minimum activity of: Solid form: 1 500 AGL [1]/g Liquid form: 200 AGL/ml	Chickens for fattening	—	25 AGL	—	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: 25-100 AGL 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 50 % barley	Without a time limit

[1] 1 AGL is the amount of enzyme which liberates 5,55 micromoles of reducing sugars (maltose equivalents) from barley beta-glucan per minute at pH 4,6 and 30 °C.

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								
54	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 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) 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: 10 000 U ([1])/g Endo-1,4-beta-glucanase: 120 000 U ([2])/g Alpha-amylase: 400 U ([3])/g Endo-1,4-beta-xylanase: 210 000 U ([4])/g	Laying hens	—	Endo-1,3(4)-beta-glucanase: 500 U endo-1,4-beta-glucanase: 6 000 U alpha-amylase: 20 U endo-1,4-beta-xylanase: 10 500 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-1,3(4)-beta-glucanase: 500-1 500 U endo-1,4-beta-glucanase: 6 000-18 000 U alpha-amylase: 20-60 U endo-1,4-beta-xylanase: 10 500-31 500 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 30 % wheat	29.9.2009
60	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), endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) having a minimum activity of: Liquid form: Endo-1,4-beta-xylanase: 5 000 U ([5])/ml Endo-1,3(4)-beta-glucanase: 50 U ([6])/ml	Turkeys 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 pelletting 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	29.9.2009

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			
62	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) having a minimum activity of: Solid form: 5 600 TXU ([7])/g Liquid form 5 600 TXU/ml	Chickens for fattening	—	200 TXU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelletting 2. Recommended dose per kg of complete feedingstuff: 400-800 TXU 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 40 % wheat	29.9.2009

([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 hydrolyses 1 micromole of glucosidic linkages from water insoluble cross-linked starch polymer per minute at pH 7,5 and 37 °C.
([4]) 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.
([5]) 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.
([6]) 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.
([7]) 1 TXU is the amount of enzyme which liberates 5 micromoles of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH 3,5 and 55 °C.