COMMISSION REGULATION (EC) No 2437/2000

of 3 November 2000

concerning the permanent authorisation of an additive and the provisional authorisation of new 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], as last amended by Commission Regulation (EC) No 1887/2000 [2], and in particular Article 3 thereof,

Whereas:

(1) Directive 70/524/EEC provides that new additives shall be authorised, taking account of advances in scientific and technical knowledge.

(2) Article 9d of the Directive provides that an additive of a type listed in Part II of Annex C to the Directive shall be authorised, where, following an evaluation of the dossier, all the conditions laid down in Article 3a of the Directive are met.

(3) Article 9e of the Directive provides that an additive of the same type may be provisionally authorised for a period of up to four years where, following an evaluation of the dossier referred to above, the conditions of Article 3a(b) to (e) of the Directive are satisfied and if it is reasonable to assume, in view of the available results, that the conditions laid down in Article 3a(a) are also met.

(4) The assessment of the dossier submitted shows that the micro-organism preparation described in Annexes I and II to this Regulation satisfies the conditions of Article 3a(b) to (e) of the Directive. Further, it satisfies the conditions of Article 3a(a) when used in relation to piglets.

(5) It is also reasonable to assume, in view of the available results, that the conditions laid down in Article 3a(a) are met in relation to the use of the same micro-organism preparation for the categories of animals listed in Annex II to the Regulation.

(6) The assessment of the dossiers submitted shows that the enzyme preparations described in Annex III to this Regulation satisfy the conditions for preliminary authorisation specified in Article 9e of the Directive, when used in relation to the categories of animal, and in accordance with the other provisions, specified in Annex III to this Regulation.

(7) 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] and its relevant individual directives, in particular Council Directive 90/679/EEC [4], as last amended by Commission Directive 97/65/EC [5], on the protection of workers from risks related to exposure to biological agents at work, are fully applicable to the use and manipulation by workers of the additives in feedingstuffs.

(8) The Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the harmlessness of the enzyme and micro-organism preparations and with regard to the favourable effect on piglets of the micro-organism preparation.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Feedingstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation belonging to the group 'micro-organisms' listed in Annexes I and II to the present Regulation shall be authorised according to Directive 70/524/EEC as additive in animal nutrition under the conditions laid down in the said Annexes.

Article 2

The preparations belonging to the group 'enzymes' listed in Annex III to the present Regulation shall be authorised according to Directive 70/524/EEC as additives in animal nutrition under the conditions laid down in the said Annex.

Article 3

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

[1] OJ L 270, 14.12.1970, p. 1.
[2] OJ L 227, 7.9.2000, p. 13.
[3] OJ L 183, 29.6.1989, p. 1.
[4] OJ L 374, 31.12.1990, p. 1.
[5] OJ L 335, 6.12.1997, p. 17.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 November 2000.

For the Commission
David BYRNE
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	Period of authorisation
					CFU/kg of complete feedingstuff			
E 1700	*Bacillus licheniformis* (DSM 5749) *Bacillus subtilis* (DSM 5750) (In a 1/1 ratio)	Mixture of *Bacillus licheniformis* and *Bacillus subtilis* containing a minimum of $3,2 \times 10^9$ CFU/g of the additive ($1,6 \times 10^9$ CFU/g of each bacterium)	Piglets	2 months	$1,28 \times 10^9$	$3,2 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	Without a time limit

ANNEX II

No (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					CFU/kg of complete feedingstuff			
20	*Bacillus licheniformis* (DSM 5749) *Bacillus subtilis* (DSM 5750) (In a 1/1 ratio)	Mixture of *Bacillus licheniformis* and *Bacillus subtilis* containing a minimum of $3,2 \times 10^9$ CFU/g of the additive ($1,6 \times 10^9$ CFU/g of each bacterium)	Sows	15 days pre partum and during lactation period	$0,96 \times 10^9$	$1,92 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.2001
			Pigs for fattening	—	$0,48 \times 10^9$	$1,28 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.2001
			Chickens for fattening	—	$3,2 \times 10^9$	$3,2 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. May be used in compound feed containing the permitted coccidiostats: amprolium ethopabate, diclazuril, halofuginone, methylbenzoquate/meticlorpindol, monensin sodium, nifursol and robenidine.	30.9.2001
			Turkeys for fattening	—	$1,28 \times 10^9$	$3,2 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. May be used in compound feed containing the permitted coccidiostats: amprolium ethopabate, diclazuril, halofuginone, methylbenzoquate/meticlorpindol, monensin sodium, nifursol and robenidine.	30.9.2001

ANNEX III

No (or EC-No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum	Maximum	Other provisions	Period of authorisation
					Units of activity/kg complete feedingstuff			
53	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 Bacillolysine 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]	Piglets	2 months	Endo-1,3(4)-beta-glucanase: 2 350 U Endo-1,4-beta-glucanase: 4 000 U Alpha-amylase: 400 U Bacillolysin: 450 U Endo-1,4-beta-xylanase: 20 000 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: 2 350 U endo-1,4-beta-glucanase: 4 000 U alpha-amylase: 400 U bacillolysin: 450 U endo-1,4-beta-xylanase: 20 000 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 25 % barley and 20 % maize.	30.9.2001
			Chickens for fattening	—	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. 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 arabinoxylans), e.g. containing more than 45 % wheat	30.9.2001

No (or EC-No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum	Maximum	Other provisions	Period of authorisation
					Units of activity/kg complete feedingstuff			
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 3.4.1.1 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/g (1) Endo-1,4-beta-glucanase: 120 000 U/g (2) Alpha-amylase: 400 U/g (3) Endo-1,4-beta-xylanase: 210 000 U/g (5)	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 1 000 U Endo-1,4-beta-glucanase: 12 000 U Alpha-amylase: 40 U Endo-1,4-beta-xylanase: 21 000 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: 1 000 - 2 000 U endo-1,4-beta-glucanase: 12 000 - 24 000 U alpha-amylase: 40 - 80 U endo-1,4-beta-xylanase: 21 000 - 42 000 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 45 % wheat	30.9.2001
55	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	Preparation of endo-1,3(4)-beta-glucanase, producerd by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produceerd by *Trichoderma longibrachiatum* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) and bacillolysine, produced by *Bacillus amyloliquefaciens* (DSM 9554) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 3 000 U/g (1) Endo-1,4-beta-glucanase: 5 000 U/g (2) Alpha-amylase: 540 U/g (3) Bacillolysin: 450 U/g (4)	Piglets	2 months	Endo-1,3(4)-beta-glucanase: 1 500 U Endo-1,4-beta-glucanase: 2 500 U Alpha-amylase: 270 U Bacillolysin: 225 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: 1 500 - 3 000 U endo-1,4-beta-glucanase: 2 500 - 5 000 U alpha-amylase: 270 - 540 U bacillolysin: 225 - 450 U 3. For use in compound feed rich in starch and non-starch polysaccharides, e.g. containing more than 35 % wheat and 15 % barley	30.9.2001

No (or EC-No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum	Maximum	Other provisions	Period of authorisation
					Units of activity/kg complete feedingstuff			
55 *(cont'd)*			Pigs for fattening	—	Endo-1,3(4)-beta-glucanase: 1 500 U Endo-1,4-beta-glucanase: 2 500 U Alpha-amylase: 270 U Bacillolysin: 225 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: 1 500 - 3 000 U endo-1,4-beta-glucanase: 2 500 - 5 000 U alpha-amylase: 270 - 540 U bacillolysin: 225 - 450 U 3. For use in compound feed rich in starch and non-starch polysaccharides, e.g. containing more than 50 % barley	30.9.2001
			Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 1 500 U Endo-1,4-beta-glucanase: 2 500 U Alpha-amylase: 270 U Bacillolysin: 225 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: 1 500 - 3 000 U endo-1,4-beta-glucanase: 2 500 - 5 000 U alpha-amylase: 270 - 540 U bacillolysin: 225 - 450 U 3. For use in compound feed rich in starch and non-starch polysaccharides, e.g. containing more than 50 % maize or 50 % wheat	30.9.2001

No (or EC-No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum	Maximum	Other provisions	Period of authorisation
					Units of activity/kg complete feedingstuff			
55 *(cont'd)*			Laying hens	—	Endo-1,3(4)-beta-glucanase: 1 500 U Endo-1,4-beta-glucanase: 2 500 U Alpha-amylase: 270 U Bacillolysin: 225 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: 1 500 - 3 000 U endo-1,4-beta-glucanase: 2 500 - 5 000 U alpha-amylase: 270 - 540 U bacillolysin: 225 - 450 U 3. For use in compound feed rich in starch and non-starch polysaccharides, e.g. containing more than 40 % maize and 10 % rye	30.9.2001
56	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	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 bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 6 000 U/g [1] Endo-1,4-beta-glucanase: 3 500 U/g [2] Alpha-amylase 1 400 U/g [3] Bacillolysin: 450 U/g [4]	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 6 000 U Endo-1,4-beta-glucanase: 3 500 U Alpha-amylase: 1 400 U Bacillolysin: 450 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: 6 000 U endo-1,4-beta-glucanase: 3 500 U alpha-amylase: 1 400 U bacillolysin: 450 U 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % barley	30.9.2001

No (or EC-No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum	Maximum	Other provisions	Period of authorisation
					Units of activity/kg complete feedingstuff			
57	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 Bacillolysine: EC 3.4.24.28	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 bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 3 000 U/g (1) Endo-1,4-beta-glucanase: 9 000 U/g (2) Alpha-amalyse 540 U/g (3) Bacillolysin: 450 U/g (4)	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 3 000 U Endo-1,4-beta-glucanase: 9 000 U Alpha-amylase: 540 U Bacillolysin: 450 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: 3 000 U endo-1,4-beta-glucanase: 9 000 U alpha-amylase: 540 U bacillolysin: 450 U 3. For use in compound feed rich in starch and non-starch polysaccharides (mainly cellulose and hemicellulose), e.g. containing more than 20 % sunflower meal and 10 % soya meal	30.9.2001
58	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	Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum 7* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) and bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 2 350 U/g (1) Endo-1,4-beta-glucanase: 5 000 U/g (2) Alpha-amylase 400 U/g (3) Bacillolysin: 5 000 U/g (4)	Piglets	2 months	Endo-1,3(4)-beta-glucanase: 2 350 U Endo-1,4-beta-glucanase: 5 000 U Alpha-amylase: 400 U Bacillolysin: 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: 2 350 U endo-1,4-beta-glucanase: 5 000 U alpha-amylase: 400 U bacillolysin: 5 000 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 30 % barley.	30.9.2001

(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 hydrolises 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 makes 1 microgram of azo-casein soluble in trichloracetic acid 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.