

COMMISSION REGULATION (EC) No 1353/2000

of 26 June 2000

concerning the permanent authorisation of an additive and the provisional authorisation of new additives, new additive uses and new preparations 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 Directive 1999/20/CE ⁽²⁾ and in particular Article 3 thereof,

Whereas:

- (1) Directive 70/524/EEC provides that new additives or new uses of additives shall be authorised, taking account of advances in scientific and technical knowledge.
- (2) A permanent authorisation of a preparation belonging to the group of enzymes shall be given if all conditions laid down in Article 3(a) of Directive 70/524/EEC are met.
- (3) Data were submitted for the permanent authorisation of the 3-phytase (EC 3.1.3.8) produced by *Aspergillus niger* (CBS 114.94), which is described in the Annex.
- (4) A provisional authorisation of new additives, or new uses of additives shall be given if, at the level permitted in feedingstuffs, it does not adversely affect human or animal health or the environment, nor harm the consumer by altering the characteristics of livestock product, if its presence in feedingstuffs can be controlled, and it is reasonable to assume, in view of the available results, that it has favourable effect on the characteristics of those feedingstuffs or on livestock production when incorporated in such feedingstuffs.
- (5) Data were submitted for the provisional authorisations of new enzymes and micro-organisms, of new uses of enzymes and for the replacement of authorised preparations of enzymes by new preparations of the same enzymes.
- (6) Council Directive 89/391/EEC ⁽³⁾ on the introduction of measures to encourage improvements in the safety and health of workers at work and its relevant individual directives, in particular Council Directive 90/679/EC ⁽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 applic-

able to the use and manipulation by workers of the additives in feedingstuffs.

- (7) The Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the harmlessness of these enzyme and micro-organism preparations and with regard to the favourable effect on animal production of the enzyme preparation for which an authorisation without a time limit is proposed.
- (8) 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 'Enzymes' listed in Annex I 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 Annex.

Article 2

The conditions for the authorisation of the preparations No 16 and No 17 belonging to the group 'Enzymes' listed in Annex II to the present Regulation are hereby replaced by those set out in the said Annex according to Directive 70/524/EEC.

Article 3

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 4

The preparation belonging to the group 'Micro-organisms' listed in Annex IV 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 5

This Regulation shall enter into force on the twentieth 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 80, 25.3.1999, p. 20.

⁽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, 26 June 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
					Units of activity/kg of complete feedstuff	Units of activity/kg of complete feedstuff			
E 1600	3-phytase EC 3.1.3.8	Preparation of 3-phytase produced by <i>Aspergillus niger</i> (CBS 114.94) having a minimum activity of: Solid form: 5 000 FTU/g (!) Liquid form: 5 000 FTU/ml	Piglets	2 months	500 FTU	—	—	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. Recommended dose per kilogram of complete feedstuff: 500 FTU. For use in compound feed containing more than 0,23 % phytin bound phosphorus. 	Without a time limit
			Pigs for fattening	—	280 FTU	—	—	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. Recommended dose per kilogram of complete feedstuff: 400-500 FTU. For use in compound feed containing more than 0,23 % phytin bound phosphorus. 	Without a time limit
			Sows	—	500 FTU	—	—	—	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. Recommended dose per kilogram of complete feedstuff: 500 FTU. For use in compound feed containing more than 0,36 % phytin bound phosphorus.

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorisation
					Units of activity/kg of complete feedingsstuff				
			Chickens for fattening	—	375 FTU	—		<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. Recommended dose per kilogram of complete feedingsstuff: 500-700 FTU. For use in compound feed containing more than 0,23 % phytin bound phosphorus. 	Without a time limit
			Laying hens	—	250 FTU	—		<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. Recommended dose per kilogram of complete feedingsstuff: 300-400 FTU. For use in compound feed containing more than 0,23 % phytin bound phosphorus. 	Without a time limit

(¹) 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute sodium phytate at pH 5.5 and 37 °C.

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
					Units of activity/kg of complete feedingsstuff	—			
16	Endo-1,4-beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 142) having a minimum activity of: Solid form: 2 000 CU/g (°) Liquid form: 2 000 CU/ml	Chickens for fattening	—	250 CU	—	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 feedingsstuff: 500-1 000 CU. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley.	30.9.2000	
			Laying hens	—	250 CU	—	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 feedingsstuff: 500-1 000 CU. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley.	30.9.2000	
			Piglets	4 months	250 CU	—	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 feedingsstuff: 500-1 000 CU. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley.	30.9.2000	

No (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorisation
					Units of activity/kg of complete feedstuff	Units of activity/kg of complete feedstuff			
			Pigs for fattening	—	250 CU	—	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Recommended dose per kg of complete feedstuff: 500-1 000 CU. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley. 	30.9.2000	
17	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135) having a minimum activity of: Solid form: 6 000 EPU/g (?) Liquid form: 2 000 EPU/ml	Chickens for fattening	—	750 EPU	—	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Recommended dose per kg of complete feedstuff: 1 500-3 000 EPU. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat. 	30.9.2000	
			Laying hens	—	750 EPU	—	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Recommended dose per kg of complete feedstuff: 1 500-3 000 EPU. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat. 	30.9.2000	

No (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorisation
					Units of activity/kg of complete feedingsstuff				
			Piglets	4 months	750 EPU	—		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 feedingsstuff: 1 500-3 000 EPU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.	30.9.2000
			Pigs for fattening	—	750 EPU	—		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 feedingsstuff: 1 500-3 000 EPU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.	30.9.2000

(1) 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.

(2) 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.

ANNEX III

No. (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorisation
					Units of activity/kg of complete feedingstuff				
12	Endo-1,4- beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-glucanase, endo-1,3 (4)-beta-glucanase and endo-1,4- beta-xylanase produced by <i>Trichoderma</i> <i>viride</i> (FERM BP-4447) having a minimum activity	Turkeys for fattening	—	Endo-1,4- beta-glucanase 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-glucanase: 800-1 200 U Endo-1,3(4)-beta-glucanase: 1 800-2 700 U Endo-1,4-beta-xylanase: 2 600-3 900 U.	30.9.2001
	Endo-1,3(4)- beta-glucanase EC 3.2.1.6	Endo-1,3(4)- beta-glucanase: 1 800 U			—				
	Endo-1,4-beta- xylanase EC 3.2.1.8	Endo-1,4- beta-xylanase: 2 600 U			—	3. For use in compound feed rich in non- starch polysaccharides (mainly arabi- nylans and beta-glucans), e.g. containing more than 20 % wheat and 20 % barley.			
17	Endo-1,4- beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 1 35) having a minimum activity of: Solid form: 6 000 EPU/g (*) Liquid form: 6 000 EPU/ml	Turkeys for fattening	—	750 EPU	—	—	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: 1 500-3 000 EPU. 3. For use in compound feed rich in non- starch polysaccharides (mainly arabi- noxylyans), e.g. containing more than 35 % wheat.	30.9.2001

No. (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorisation
					Units of activity/kg of complete feedingsstuff				
42	Endo-1,4(4)-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135) having a minimum activity of: Solid form: 4 000 U/g (5) Characteristic of the authorised preparation: endo-1,4-beta-xylanase: 1,99 % wheat: 97,7 % calcium propionate: 0,3 % lecithin: 0,01 %	Pigs for fattening	—	4 000 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: 4 000 U 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 60 % wheat.	30.9.2001	
49	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Alfa-amylase EC 3.2.1.1 Bacilolysin EC 3.4.24.28 Polygalacturonase EC 3.2.1.15	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106), endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135) alpha-amylase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9554) and polygalacturonase produced by <i>Aspergillus aculeatus</i> (CBS 589,94) having a minimum activity of: endo-1,3(4)-beta-glucanase: 150 U/g (6) endo-1,4-beta-xylanase: 1 500 U/g (7) alfa-amylase: 500 U/g (8) bacilolysin: 800 U/g (9) polygalacturonase: 50 U/g (10)	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 150 U Endo-1,4-beta-xylanase: 1 500 U Alfa-amylase: 500 U Bacilolysin: 800 U Polygalacturonase: 50 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: 1 500 U alpha-amylase: 800 U bacilolysin: 800 U polygalacturonase: 50 U 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and betagalucans), e.g. containing more than 30 % wheat.	30.9.2001	

No. (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorisation
					Units of activity/kg of complete feedingstuff				
			Layinghens	—	endo-1,3(4)- beta-glucanase: 150 U endo-1,4- beta-xylanase: 1 500 U alpha- amylase: 1 000 U bacillolysin: 800 U polygalacturo- nase: 50 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 feedingstuffs: endo-1,3(4)-beta-glucanase: 150 U endo-1,4-beta-xylanase: 1 500 U alpha-amylase: 1 000 U polygalacturonase: 25 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and betaglucans), e.g. containing more than 30 % wheat.	30.9.2001
50	6-phytase EC 3.1.3.26	Preparation of 6-phytase produced by <i>Aspergillus oryzae</i> (DSM 11857) having a minimum activity of: Coated form: 2 500 FYT/g ⁽¹⁾ Liquid form: 5 000 FYT/g	Chickens for fattening	—	250 FYT	—		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: 500-1 000 FYT 3. For use in compound feed containing more than 0,25 % phytin bound phosphorus.	30.9.2001

No. (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorisation
					Units of activity/kg of complete feedingstuff				
			Laying hens	—	250 FYT	—		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: 500-1 000 FYT 3. For use in compound feed containing more than 0,25 % phytin bound phosphorus.	30.9.2001
			Turkeys for fattening	—	250 FYT	—		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: 500-1 000 FYT 3. For use in compound feed containing more than 0,25 % phytin bound phosphorus.	30.9.2001
			Piglets	2 months	500 FYT	—		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: 500-1 000 FYT 3. For use in compound feed containing more than 0,25 % phytin bound phosphorus.	30.9.2001

No. (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	Period of authorisation
					Units of activity/kg of complete feedstuff				
51	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Bacillus subtilis</i> (LMG-S 15136) having a minimum activity of: 100 IU/g ^(1,2)	Pigs for fattening	—	500 FYT	—	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 feedstuff: 500-1 000 FYT 3. For use in compound feed containing more than 0,25 % phytin bound phosphorus.	30.9.2001	
			Chickens for fattening	—	10 IU	—	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 feedstuff: 10- IU 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.	30.9.2001	
52	Endo-1,3(4)-beta-glucanase: EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Aspergillus aculeatus</i> (CBS 589,94), endo-1,4-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (CBS 592,94) and alpha-amylase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9553), having a minimum activity of: Liquid form: Endo-1,3(4)-beta-glucanase: 10 000 U/m ^(1,3) Endo-1,4-beta-glucanase: 120 000 U/m ^(1,4) Alpha-amylase: 400 U/ml ^(1,5)	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 1 000 U Endo-1,4-beta-glucanase: 12 000 U Alpha-amylase: 40 U	—	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 feedstuff: endo-1,3(4)-beta-glucanase: 1 000-2 000 U endo-1,4-beta-glucanase: 12 000-24 000 U 3. For use in compound feed rich in non starch polysaccharides (mainly arabinoxylans and betaglucans) e.g. containing more than 20 % wheat and 15 % sorghum and 5 % maize.	30.9.2001	
				—	—	—			

- (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 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °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 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.
- (8) 1 U is the amount of enzyme which liberates 1 micromole of glucosidic linkages from water insoluble cross-linked starch polymer per minute at pH 6,5 and 37 °C.
- (9) 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from casein substrate per minute at pH 7,5 and 40 °C.
- (10) 1 U is the amount of enzyme which liberates 1 micromole of reducing material (galacturonic acid equivalents) from poly D-galacturonic substrate per minute at pH 5,0 and 40 °C.
- (11) 1 FVT is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5,5 and 37 °C.
- (12) 1 IU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 4,5 and 30 °C.
- (13) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from barley-glucan per minute at pH 7,5 and 30 °C.
- (14) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from carboxymethylcellulose per minute at pH 7,5 and 30 °C.
- (15) 1 U is the amount of enzyme which liberates 1 micromole of glucose from a cross-linked starch polymer per minute at pH 7,4 and 37 °C.

ANNEX IV

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 feedstuff				
19	<i>Streptococcus infantarius</i> CNCM I-841 <i>Lactobacillus plantarum</i> CNCM I-840	Mixture of: <i>Streptococcus infantarius</i> and <i>Lactobacillus plantarum</i> containing a minimum of: <i>Streptococcus infantarius</i> $0,5 \times 10^9$ CFU/g and: <i>Lactobacillus plantarum</i> 2×10^9 CFU/g	Calves	6 months	<i>Streptococcus infantarius</i> 1×10^9 <i>Lactobacillus plantarum</i> : $0,5 \times 10^9$	<i>Streptococcus infantarius</i> 1×10^9 <i>Lactobacillus plantarum</i> : $0,5 \times 10^9$		In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.2001