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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)

(OJ L 155, 28.6.2000, p. 15)

Amended by:

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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*.

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

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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 feedingstuff			
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 ⁽¹⁾ Liquid form: 2 000 CU/ml	Chickens for fattening	—	250 CU	—	<ol style="list-style-type: none"> 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 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	—	<ol style="list-style-type: none"> 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 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	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 	30.9.2000

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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			
							<p>2. Recommended dose per kg of complete feedingstuff: 500-1 000 CU.</p> <p>3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley.</p>	
			Pigs for fattening	—	250 CU	—	<p>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>2. Recommended dose per kg of complete feedingstuff: 500-1 000 CU.</p> <p>3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley.</p>	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 (2) Liquid form: 2 000 EPU/ml	Chickens for fattening	—	750 EPU	—	<p>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>2. Recommended dose per kg of complete feedingstuff: 1 500-3 000 EPU.</p> <p>3. For use in compound feed rich in non-starch polysaccharides (mainly arabi-noxylans), e.g. containing more than 40 % wheat.</p>	30.9.2000

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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	—	750 EPU	—	<ol style="list-style-type: none"> 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 arabinoxylans), e.g. containing more than 40 % wheat. 	30.9.2000
			Piglets	4 months	750 EPU	—	<ol style="list-style-type: none"> 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 arabinoxylans), e.g. containing more than 40 % wheat. 	30.9.2000
			Pigs for fattening	—	750 EPU	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 	30.9.2000

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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			
							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 arabinoxylans), e.g. containing more than 40 % wheat.	

(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 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-glucanase, endo-1,3 (4)-beta-glucanase and endo-1,4-beta-xylanase produced by <i>Trichoderma viride</i> (FERM BP-4447) having a minimum activity Endo-1,4-beta-glucanase: 8 000 U/g ⁽¹⁾ Endo-1,3(4)-glucanase: 18 000 U/g ⁽²⁾ Endo-1,4-beta-xylanase: 26 000 U/g ⁽³⁾	Turkeys for fattening	—	Endo-1,4-beta-glucanase 800 U Endo-1,3(4)-beta-glucanase: 1 800 U Endo-1,4-beta-xylanase: 2 600 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. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 20 % wheat and 20 % barley.	30.9.2001
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 ⁽⁴⁾ 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 arabinoxylans), e.g. containing more than 35 % wheat.	30.9.2001

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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			
42	Endo-1,4(4)- betaxylanase 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- xylanasa EC 3.2.1.8 Alfa-amylase EC 3.2.1.1 Bacillolysin EC 3.4.24.28 Polygalactu- ronase C 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⁾ bacillolysin: 800 U/g ⁽⁹⁾ polygalacturonase: 50 U/g ⁽¹⁰⁾	Chickens for fattening	—	Endo-1,3(4)- beta-gluc- anase: 150 U Endo-1,4- beta-xylanase: 1 500 U Alfa-amylase: 500 U Bacillolysin 800 U Polygalactu- ronase 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: 800 U. bacillolysin: 800 U polygalacturonase: 50 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

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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-gluc- anase: 150 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

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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	—	<ol style="list-style-type: none"> 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	—	<ol style="list-style-type: none"> 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	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 	30.9.2001

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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			
							<p>2. Recommended dose per kg of complete feedingstuff: 500-1 000 FYT</p> <p>3. For use in compound feed containing more than 0,25 % phytin bound phosphorus.</p>	
			Pigs for fattening	—	500 FYT	—	<p>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>2. Recommended dose per kg of complete feedingstuff: 500-1 000 FYT</p> <p>3. For use in compound feed containing more than 0,25 % phytin bound phosphorus.</p>	30.9.2001
51	Endo-1,4- betaxylanase 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 ⁽¹²⁾	Chickens for fattening	—	10 IU	—	<p>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>2. Recommended dose per kg of complete feedingstuff: 10- IU</p> <p>3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.</p>	30.9.2001

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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			
52	Endo-1,3(4)- beta-glucanase: EC 3.2.1.6 Endo-1,4-beta- glucanase: EC 3.2.1.4 Alpha-amylase EC 3.2.2.1	Preparation of endo-1,3(4)-beta-glucanasa 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 ⁽¹³⁾ Endo-1,4-beta-glucanase: 120 000 U/m ⁽¹⁴⁾ Alpha-amylase: 400 U/ml ⁽¹⁵⁾	Chickens for fattening	—	Endo-1,3(4)- beta-gluc- anase: 1 000 U Endo-1,4- beta-gluc- anase: 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 feedingstuff: 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 arabin-oxylans 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 FYT 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 feedingstuff			
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