

**COMMISSION REGULATION (EC) No 654/2000**  
**of 29 March 2000**  
**concerning the authorisation of new additives, new additive uses and new additive 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 <sup>(1)</sup>, as last amended by Commission Regulation (EC) No 2690/1999 <sup>(2)</sup> and in particular Article 3 thereof,

Whereas:

- (1) Directive 70/524/EEC provides that new additives or new additive uses shall be authorised, taking account of advances in scientific and technical knowledge.
- (2) Council Directive 93/113/EC of 14 December 1993 concerning the use and the marketing of enzymes, micro-organisms and their preparations in animal nutrition <sup>(3)</sup>, as last amended by Directive 97/40/EC <sup>(4)</sup>, by derogation from Directive 70/524/EEC, authorised Member States to permit provisionally the use and marketing of enzymes, micro-organisms and their preparations.
- (3) New data were submitted for the replacement of authorised preparations of enzymes by new preparations of the same enzymes.
- (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 products, if its presence in feedingstuffs can be controlled, and it is reasonable to assume, in view of the available results, that it has a favourable effect on the characteristics of those feedingstuffs or on livestock production when incorporated in such feedingstuffs.
- (5) 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 <sup>(5)</sup> and its

relevant individual directives, in particular Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work <sup>(6)</sup>, as last amended by Commission Directive 75/65/EC <sup>(7)</sup>, are fully applicable to the use and manipulation by workers of the additives in feedingstuffs.

- (6) The examination of the dossiers, submitted by the Member States in accordance with Article 3 of Directive 93/113/EC, indicates that a certain number of preparations belonging to the groups of enzymes and micro-organisms can be provisionally authorised.
- (7) The Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the harmlessness of these enzyme <sup>(8)</sup> and micro-organism <sup>(9)</sup> preparations.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Feedingstuffs,

HAS ADOPTED THIS REGULATION:

*Article 1*

The preparations belonging to the group 'Enzymes' listed in Annex I 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 2*

The particulars concerning the composition of the enzymes authorised under Nos '7' and '8' are modified, as indicated in Annex I, under the heading 'Chemical formula, description'.

*Article 3*

The preparations belonging to the group 'Micro-organisms' listed in Annex II 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.

<sup>(1)</sup> OJ L 270, 14.12.1970, p. 1.

<sup>(2)</sup> OJ L 326, 18.12.1999, p. 33.

<sup>(3)</sup> OJ L 334, 31.12.1993, p. 17.

<sup>(4)</sup> OJ L 180, 9.7.1997, p. 21.

<sup>(5)</sup> OJ L 183, 29.6.1989, p. 1.

<sup>(6)</sup> OJ L 374, 31.12.1990, p. 1.

<sup>(7)</sup> OJ L 335, 6.12.1997, p. 17.

<sup>(8)</sup> Report of the Scientific Committee for Animal Nutrition on the use of certain enzymes as additives in feedingstuffs, adopted on 4 June 1998, updated on 21 October 1999.

<sup>(9)</sup> Report of the Scientific Committee for Animal Nutrition on the use of certain micro-organisms as additives in feedingstuffs, adopted on 26 September 1997, updated on 22 October 1999.

*Article 4*

This Regulation shall enter into force on the third day following publication in the *Official Journal of the European Communities*.

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

Done at Brussels, 29 March 2000.

*For the Commission*  
David BYRNE  
*Member of the Commission*

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## ANNEX I

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity per kg of complete feedingstuff			
4	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) having a minimum activity of:  Coated form: 50 FBG (1)/g Liquid form: 120 FBG/ml	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase 10 FBG	Endo-1,3(4)-beta-glucanase: 100 FBG	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: 20 FBG  3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 60 % maize.	30.11.2000
7	Endo-1,4-beta-xylanase EC 3.2.1.8  Endo-1,4-beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by <i>Aspergillus niger</i> (CBS 600.94) having a minimum activity of:  Coated form: 36 000 FXU (2)/g 15 000 BGU (2)/g  Liquid form: 36 000 FXU/g 15 000 BGU/g	Chicken for fattening	—	Endo-1,4-beta-xylanase: 3 600 FXU  Endo-1,4-beta-glucanase: 1 500 BGU	Endo-1,4-beta-xylanase: 12 000 FXU  Endo-1,4-beta-glucanase: 5 000 BGU	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-1,4-beta-xylanase: 3 600-6 000 FXU Endo-1,4-beta-glucanase: 1 500-2 500 BGU  3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 35 % barley and 20 % wheat.	30.11.2000

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity per kg of complete feedingstuff			
			Piglets	four months	Endo-1,4-beta-xylanase: 6 000 FXU  Endo-1,4-beta-glucanase: 2 500 BGU	—  —	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.</li> <li>2. Recommended dose per kilogram of complete feedingstuff: Endo-1,4-beta-xylanase: 6 000 FXU Endo-1,4-beta-glucanase: 2 500 BGU</li> <li>3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 30 % wheat and 30 % barley.</li> </ol>	30.11.2000
			Turkeys for fattening	—	Endo-1,4-beta-xylanase: 6 000 FXU  Endo-1,4-beta-glucanase: 2 500 BGU	Endo-1,4-beta-xylanase: 12 000 FXU  Endo-1,4-beta-glucanase: 5 000 BGU	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.</li> <li>2. Recommended dose per kilogram of complete feedingstuff: Endo-1,4-beta-xylanase: 6 000-12 000 FXU Endo-1,4-beta-glucanase: 2 500-5 000 BGU</li> <li>3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % wheat.</li> </ol>	30.11.2000

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity per kg of complete feedingstuff			
			Laying hens	—	Endo-1,4-beta-xylanase: 12 000 FXU  Endo-1,4-beta-glucanase: 5 000 BGU	—  —	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.</li> <li>Recommended dose per kilogram of complete feedingstuff: Endo-1,4-beta-xylanase: 12 000 FXU Endo-1,4-beta-glucanase: 5 000 BGU</li> <li>For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 20 % wheat, 10 % barley and 20 % sunflower.</li> </ol>	30.11.2000
8	Endo-1,4-beta-glucanase EC 3.2.1.4 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of Endo-1,4-beta-glucanase and Endo-1,4-beta-xylanase produced <i>Aspergillus niger</i> (CBS 600.94) having a minimum activity of: Coated form: 10 000 BGU (3)/g 4 000 FXU (2)/g Liquid form: 20 000 BGU/g 8 000 FXU/g	Chickens for fattening	—	Endo-1,4-beta-glucanase: 3 000 BGU  Endo-1,4-beta-xylanase: 1 200 FXU	Endo-1,4-beta-glucanase: 10 000 BGU  Endo-1,4-beta-xylanase: 4 000 FXU	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.</li> <li>Recommended dose per kilogram of complete feedingstuff: Endo-1,4-beta-glucanase: 3 000-10 000 BGU Endo-1,4-beta-xylanase: 1 200-4 000 FXU</li> <li>For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 60 % barley.</li> </ol>	30.11.2000

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity per kg of complete feedingstuff			
			Piglets	Four months	Endo-1,4-beta-glucanase: 3 000 BGU  Endo-1,4-beta-xylanase: 1 200 FXU	Endo-1,4-beta-glucanase: 5 000 BGU  Endo-1,4-beta-xylanase: 2 000 FXU	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.</li> <li>2. Recommended dose per kilogram of complete feedingstuff: Endo-1,4-beta-glucanase: 3 000-5 000 BGU Endo-1,4-beta-xylanase: 1 200-2 000 FXU</li> <li>3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 30 % barley.</li> </ol>	30.11.2000
			Laying hens	—	Endo-1,4-beta-glucanase: 5 000 BGU  Endo-1,4-beta-xylanase: 2 000 FXU	—  —	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.</li> <li>2. Recommended dose per kilogram of complete feedingstuff: Endo-1,4-beta-glucanase: 5 000 BGU Endo-1,4-beta-xylanase: 2 000 FXU</li> <li>3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 60 % barley.</li> </ol>	30.11.2000

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity per kg of complete feedingstuff			
9	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of Endo-1,4-beta-xylanase produced by <i>Aspergillus niger</i> (CBS 270.95) having a minimum activity of: Solid form: Endo-1,4-beta-xylanase: 28 000 EXU (*)/g Liquid form: Endo-1,4-beta-xylanase: 14 000 EXU/ml	Laying hens	—	Endo-1,4-beta-xylanase: 2 400 EXU	—	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</li> <li>Recommended dose per kg of complete feedingstuff: Endo-1,4-beta-xylanase: 2 400 - 7 400 EXU</li> <li>For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans) e.g. containing more than 30 % wheat and 30 % rye.</li> </ol>	30.11.2000
			Turkeys for fattening	—	Endo-1,4-beta-xylanase: 2 400 EXU	—	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</li> <li>Recommended dose per kg of complete feedingstuff: Endo-1,4-beta-xylanase: 2 400-5 600 EXU</li> <li>For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans) e.g. containing more than 30 % wheat and 30 % rye.</li> </ol>	30.11.2000

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity per kg of complete feedingstuff			
13	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of Endo-1,3(4)-beta-glucanase and Endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (CBS 357.94) having a minimum activity of:  Powder form: Endo-1,3(4)-beta-glucanase: 8 000 BGU (°)/g Endo-1,4-beta-xylanase: 11 000 EXU (°)/g  Granulated form: Endo-1,3(4)-beta-glucanase: 6 000 BGU/g Endo-1,4-beta-xylanase: 8 250 EXU/g  Liquid form: Endo-1,3(4)-beta-glucanase: 2 000 BGU/ml Endo-1,4-beta-xylanase: 2 750 EXU/ml	Laying hens	—	Endo-1,3(4)-beta-glucanase: 600 BGU  Endo-1,4-beta-xylanase: 800 EXU	—  —	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: 600 BGU Endo-1,4-beta-xylanase: 800 EXU  3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % wheat and more than 30 % barley.	30.11.2000
			Turkeys for fattening	—	Endo-1,3(4)-beta-glucanase: 600 BGU  Endo-1,4-beta-xylanase: 800 EXU	—  —	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: 600 BGU Endo-1,4-beta-xylanase: 800 EXU  3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 30 % wheat or more than 30 % rye.	30.11.2000



No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity per kg of complete feedingstuff			
48	Alpha-amylase EC 3.2.1.1 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of Alpha-amylase and Endo-1,3(4)-beta-glucanase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9553) having a minimum activity of:  Coated form: Alpha-amylase: 200 KNU <sup>(6)</sup> /g Endo-1,3(4)-beta-glucanase: 350 FBG <sup>(1)</sup> /g  Liquid form: Alpha-amylase: 130 KNU/ml Endo-1,3(4)-beta-glucanase: 225 FBG/ml	Chickens for fattening	—	Alpha-amylase: 10 KNU  Endo-1,3(4)-beta-glucanase: 17 FBG	Alph-amylase: 40 KNU  Endo-1,3(4)-beta-glucanase: 70 FBG	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: Alpha-amylase: 20 KNU Endo-1,3(4)-beta-glucanase: 35 FBG  3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % barley.	30.11.2000
			Turkeys for fattening	—	Alpha-amylase: 40 KNU  Endo-1,3(4)-beta-glucanase: 70 FBG	Alpha-amylase: 80 KNU  Endo-1,3(4)-beta-glucanase: 140 FBG	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: Alpha-amylase: 40 KNU Endo-1,3(4)-beta-glucanase: 70 FBG  3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans) and beta-glucans), e.g. containing more than 40 % barley.	30.11.2000

<sup>(1)</sup> One FBG is the amount of enzyme which liberates one micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5,0 and 30 °C.

<sup>(2)</sup> One FXU is the amount of enzyme which liberates 0,15 micromole of xylose from azurine-cross-linked xylan per minute at pH 5,0 and 40 °C.

<sup>(3)</sup> One BGU is the amount of enzyme which liberates 0,15 micromoles of glucose from azurine-cross-linked beta-glucan per minute at pH 5,0 and 40 °C.

<sup>(4)</sup> One EXU is the amount of enzyme which liberates one micromole of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH 3,5 and 55 °C.

<sup>(5)</sup> One BGU is the amount of enzyme which liberates 0,278 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 3,5 and 40 °C.

<sup>(6)</sup> One KNU is the amount of enzyme which liberates 672 micromoles of reducing sugars (glucose equivalent) from soluble starch per minute at pH 5,6 and 37 °C.

## ANNEX II

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	CFU/kg of complete feedingstuff		Other provisions	Period of authorisation
					Minimum content	Maximum content		
11	<i>Enterococcus faecium</i> DSM 5464	Preparation of <i>Enterococcus faecium</i> containing a minimum of: $5 \times 10^{10}$ CFU/g additive	Chickens for fattening	—	$0,5 \times 10^9$	$1 \times 10^9$	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.  2. May be used in compound feed containing the permitted coccidiostats: amprolium, diclazuril, halofuginone, monensin-sodium, metil-clorpindol, methylbenzoquate, nicarbazin.	30.11.2000
			Calves	four months	$0,5 \times 10^{10}$	$1 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.11.2000
17	<i>Lactobacillus casei</i> NCIMB 30096  <i>Enterococcus faecium</i> NCIMB 30098	Mixture of <i>Lactobacillus casei</i> and <i>Enterococcus faecium</i> containing a minimum of:  <i>Lactobacillus casei</i> $20 \times 10^9$ CFU/g and:  <i>Enterococcus faecium</i> $6 \times 10^9$ CFU/g additive	Calves	six months	<i>Lactobacillus casei</i> $0,5 \times 10^9$  <i>Enterococcus faecium</i> $1,5 \times 10^9$	<i>Lactobacillus casei</i> $1 \times 10^9$  <i>Enterococcus faecium</i> $3 \times 10^9$	In the directions for use of the additive and premixture indicate the storage temperature storage life and stability to pelleting.	30.11.2000
18	<i>Enterococcus faecium</i> CECT 4515	Preparation of <i>Enterococcus faecium</i> containing a minimum of $1 \times 10^{10}$ CFU/g additive	Piglets	four months	$1 \times 10^9$	$1 \times 10^9$	In the directions for use of the additive and premixture indicate the storage temperature, storage life and stability to pelleting.	30.11.2000
			Calves	six months	$1 \times 10^9$	$1 \times 10^9$	In the directions for use of the additive and premixture indicate the storage temperature, storage life and stability to pelleting.	30.11.2000