

**COMMISSION REGULATION (EC) No 2690/1999**  
**of 17 December 1999**  
**concerning the authorisation of new additives in feedingstuffs**

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 2562/1999 <sup>(2)</sup>, 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) 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) A provisional authorisation of new additives or 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 a favourable effect on the characteristics of those feedingstuffs or on livestock production when incorporated in such feedingstuffs.
- (4) Council Directive 89/391/EEC <sup>(5)</sup> 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/EEC <sup>(6)</sup> as last amended by Commission Directive 97/65/CE <sup>(7)</sup>

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.

- (5) 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.
- (6) The Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the harmlessness of these preparations.
- (7) 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 preparation 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.

*Article 3*

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

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

<sup>(2)</sup> OJ L 310, 4.12.1999, p. 11.

<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.

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

Done at Brussels, 17 December 1999.

*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			
43	Endo-1,4-betaxylanase EC 3.2.1.8	Preparation of endo-1,4-betaxylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135), endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106) and alpha-amylase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9553) having a minimum activity of: endo-1,4-beta-xylanase: 3 975 U/g <sup>(1)</sup> endo-1,3(4)-beta-glucanase: 125 U/g <sup>(2)</sup> alpha-amylase: 1 000 U/g <sup>(3)</sup>	Piglets	4 months	endo-1,4-beta-xylanase: 3 975 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-xylanase: 3 975 U endo-1,3(4)-beta-glucanase: 125 U alpha-amylase: 1 000 U  3. For use in compound feed containing cereals rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 30 % wheat and 20 % barley and 20 % rye.	30.9.2000
	endo-1,3(4)-beta-glucanase: 125 U				—			
	alpha-amylase: 1 000 U				—			
44	Endo-1,4-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106), and endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2105) and alpha-amylase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9553) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 250 U/g <sup>(2)</sup> Endo-1,4-beta-xylanase: 400 U/g <sup>(1)</sup> Alpha-amylase: 1 000 U/g <sup>(3)</sup>	Piglets	4 months	endo-1,3(4)-beta-glucanase: 250 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: 250 U endo-1,4-beta-xylanase: 400 U alpha-amylase: 1 000 U.  3. For use in compound feed containing cereals rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 50 % barley.	30.9.2000
	endo-1,4-beta-xylanase: 400 U				—			
	alpha-amylase: 1 000 U				—			

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			
45	Endo-1,3(4)-beta-glucanase EC 3.2.1.6  Endo-1,4-beta-xylanase EC 3.2.1.8  Alpha-amylase EC 3.2.1.1	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106), and endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD.135) and alphaamylase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9553) having a minimum activity of: endo-1,3(4)-beta-glucanase: 250 U/g <sup>(2)</sup> endo-1,4-beta-xylanase: 400 U/g <sup>(1)</sup> alpha-amylase: 1 000 U/g <sup>(3)</sup>	Piglets	4 months	endo-1,3(4)-beta-glucanase: 250 U  endo-1,4-beta-xylanase: 400 U  alpha-amylase: 1 000 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: endo-1,3(4)-beta-glucanase: 250 U endo-1,4-beta-xylanase: 400 U alpha-amylase: 1 000 U.  3. For use in compound feed containing cereals rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 35 % barley.	30.9.2000
46	Endo-1,3(4)-beta-glucanase EC 3.2.1.6  Endo-1,4-beta-xylanase EC 3.2.1.8  Polygalacturonase EC 3.2.1.15	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106), and endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD.135) and polygalacturonase produced by <i>Aspergillus aculeatus</i> (CBS 589.94) having a minimum activity of: endo-1,3(4)-beta-glucanase: 400 U/g <sup>(2)</sup> endo-1,4-beta-xylanase: 400 U/g <sup>(1)</sup> polygalacturonase: 50 U/g <sup>(4)</sup>	Pigs for fattening	—	endo-1,3(4)-beta-glucanase: 400 U  endo-1,4-beta-xylanase: 400 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: 400 U endo-1,4-beta-xylanase: 400 U polygalacturonase: 50 U.  3. For use in compound feed containing cereals rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % barley.	30.9.2000

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			
47	Endo-1,3(4)-beta-glucanase EC 3.2.1.6  Endo-1,3(4)-beta-xylanase EC 3.2.1.8  Alpha-amylase EC 3.2.1.1  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 9553), polygalacturonase produced by <i>Aspergillus aculeatus</i> (CBS 589.94) having a minimum activity of: endo-1,3(4)-beta-glucanase: 150 U/g <sup>(2)</sup> endo-1,4-beta-xylanase: 4 000 U/g <sup>(1)</sup> alpha-amylase: 1 000 U/g <sup>(3)</sup> polygalacturonase: 25 U/g <sup>(4)</sup>	Piglets	4 months	endo-1,3(4)-beta-glucanase: 150 U  endo-1,4-beta-xylanase: 4 000 U  alpha-amylase: 1 000 U  polygalacturonase: 25 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: 4 000 U alpha-amylase: 1 000 U polygalacturonase: 25 U.  3. For use in compound feed containing cereals rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 20 % barley and 35 % wheat.	30.9.2000

<sup>(1)</sup> 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.

<sup>(2)</sup> 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.

<sup>(3)</sup> 1 U is the amount of enzyme which liberates 1 micromole of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 6,5 and 37 °C.

<sup>(4)</sup> 1 U is the amount of enzyme which liberates 1 micromole of reducing material (galacturonic acid equivalents) from a poly D-galacturonic substrate per minute at pH 5,0 and 40 °C.

## ANNEX II

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	CFu/kg (kg of complete feedingstuffs)		Other provisions	Period of authorisation
					Minimum content	Maximum content		
15	<i>Enterococcus faecium</i> NCIMB 11181	Preparation of <i>Enterococcus faecium</i> containing a minimum of:  Powder form: $4 \times 10^{11}$ CFU/g additive  Coated form: $5 \times 10^{10}$ CFU/g additive	Calves	6 months	$5 \times 10^8$	$2 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.2000
			Piglets	4 months	$5 \times 10^8$	$2 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.2000
16	<i>Enterococcus faecium</i> DSM 7134  <i>Lactobacillus rhamnosus</i> DSM 7133	Mixture of: <i>Enterococcus faecium</i> containing a minimum of: $7 \times 10^9$ CFU/g and of <i>Lactobacillus rhamnosus</i> containing a minimum of: $3 \times 10^9$ CFU/g	Calves	6 months	$1 \times 10^9$	$6 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.2000
			Piglets	4 months	$1 \times 10^9$	$5 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.2000