

COMMISSION REGULATION (EC) No 866/1999
of 26 April 1999
concerning the authorisation of new additives and new additive uses in feeding-
stuffs

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/EC⁽²⁾, and in particular Articles 3 and 9j thereof,

- (1) Whereas Directive 70/524/EEC provides that new additives or new additive uses may be authorised, taking account of advances in scientific and technical knowledge;
- (2) Whereas 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⁽³⁾, as last amended by Directive 97/40/EC⁽⁴⁾, 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) Whereas 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;

(4) Whereas the Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the harmlessness of these preparations;

(5) Whereas 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' and listed in Annex I to this Regulation may be authorised according to Directive 70/524/EEC as additives in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparations belonging to the group 'micro-organisms' and listed in Annex II to this Regulation may be authorised according to Directive 70/524/EEC as additives in animal nutrition under the conditions laid down in that Annex.

Article 3

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

It shall apply from 1 July 1999.

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

Done at Brussels, 26 April 1999.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 270, 14.12.1970, p. 1.

⁽²⁾ OJ L 80, 25.3.1999, p. 20.

⁽³⁾ OJ L 334, 31.12.1993, p. 17.

⁽⁴⁾ OJ L 180, 9.7.1997, p. 21.

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			
2	3-phytase EC 3.1.3.8	Preparation of 3-phytase produced by <i>Aspergillus oryzae</i> (DSM 10 289) having a minimum activity of: Coated form: 2 500 FYT ⁽¹⁾ /g Liquid form: 5 000 FYT/g	Laying hens	—	500 FYT	1 000 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: 750 FYT. 3. For use in compound feed rich in phytates, e.g. containing more than 40 % cereals (corn, barley, oats, wheat, rye, triticale), oilseeds and pulses.	30. 9. 1999
8	Endo-1,4-betaglucanase EC 3.2.1.4 Endo-1,4-betaxylanase EC 3.2.1.8	Preparation of endo-1,4-beta-glucanase and endo-1,4-beta-xylanase produced by <i>Aspergillus niger</i> (CBS 600.94) having a minimum activity of: Solid and liquid forms: Endo-1,4-beta-glucanase: 10 000 BGU ⁽²⁾ /g Endo-1,4-beta-xylanase: 4 000 FXU ⁽³⁾ /g	Piglets	Four months	3 000 BGU 1 200 FXU	5 000 BGU 2 000 FXU	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: 3 000 to 5 000 BGU 1 200 to 2 000 FXU. 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. 1999

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			
29	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Geosmithia emersonii</i> (IMI SD 133) having a minimum activity of: 5 500 U (°)/g	Chickens for fattening	—	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: 250 U. 3. For use in compound feed rich in non-starch polysaccharides. (mainly beta-glucans), e.g. containing more than 50 % barley.	30. 9. 1999
30	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>Penicillium funiculosum</i> (IMI SD 101) having a minimum activity of: Powder form Endo-1,3(4)-beta-glucanase: 2 000 U (°)/g Endo-1,4-beta-xylanase: 1 400 U (°)/g Liquid form Endo-1,3(4)-beta-glucanase: 500 U/ml Endo-1,4-beta-xylanase: 350 U/ml	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 100 U Endo-1,4-beta-xylanase: 70 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: 100 U Endo-1,4-beta-xylanase: 70 U. 3. For use in compound feed rich in non-starch polysaccharides, (mainly beta-glucans and arabinoxylans), e.g. containing more than 50 % barley or 60 % wheat.	30. 9. 1999

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			
31	Endo-1,4-betaxylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (CBS 614-94) having a minimum activity of: Solid form: 300 EU (7)/g Liquid form: 1 000 EU/g	Chickens for fattening	—	600 EU	—	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: 600 EU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 60 % wheat.	30. 9. 1999
			Laying hens	—	300 EU	—	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: 600 EU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 60 % wheat.	30. 9. 1999

(1) One FYT is the amount of enzyme which liberates one micromole of inorganic phosphate per minute using Na-phytate as substrate at pH 5,5 and 37 °C.

(2) One BGU is the amount of enzyme which liberates 0,15 micromoles of glucose per minute from azurine-crosslinked beta-glucan at pH 5,0 and 40 °C

(3) One FXU is the amount of enzyme which liberates 0,15 micromoles of xylose per minute from azurine-crosslinked xylan at pH 5,0 and at 40 °C

(4) One U is the amount of enzyme which liberates 2,78 micromoles of reducing sugars (maltose equivalents) from barley beta-glucan per minute at pH 5,0 and 50 °C

(5) One U is the amount of enzyme which liberates 5,55 micromoles of reducing sugars (maltose equivalents) from barley beta-glucan per minute at pH 5,0 and 50 °C

(6) One U is the amount of enzyme which liberates 4,00 micromoles of reducing sugars (maltose equivalents) from birchwood xylan per minute at pH 5,5 and 50 °C

(7) One EU is the amount of enzyme which liberates one micromole of reducing sugars (xylose equivalents) from oat xylan per minute at pH 4,5 and 40 °C

ANNEX II

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			
5	<i>Saccharomyces cerevisiae</i> CBS 493.94	Preparation of <i>Saccharomyces cerevisiae</i> containing a minimum of 1 ×10 ⁸ CFU/g additive	Cattle for fattening	—	1,7 × 10 ⁸	1,7 × 10 ⁸	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. The quantity of <i>Saccharomyces cerevisiae</i> in the daily ration must not exceed 7,5 × 10 ⁸ CFU for 100 kg body weight. Add 1 × 10 ⁸ CFU for each extra 100 kg body weight.	30.9.1999
9	<i>Pediococcus acidilactici</i> CNCM MA 18/5M	Preparation of <i>Pediococcus acidilactici</i> containing a minimum of 1 × 10 ¹⁰ CFU/g of additive	Chickens for fattening	—	1 × 10 ⁹	1 × 10 ¹⁰	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, meticlorpindol, decoquinate, halofuginone, narasin, salinomycin sodium, nicarbazin, maduramicin ammonium, diclazuril.	30.9.1999
			Piglets	Four months	1 × 10 ⁹	1 × 10 ⁹	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.1999
			Pigs	—	1 × 10 ⁹	1 × 10 ⁹	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.1999

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			
10	<i>Enterococcus faecium</i> NCIMB 10415	Preparation of <i>Enterococcus faecium</i> containing a minimum of: Microencapsulated form: 1,0 × 10 ¹⁰ CFU/g additive 1,75 × 10 ¹⁰ CFU/g additive	Chickens for fattening	—	0,3 × 10 ⁹	2,8 × 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 coccidio-stats: amprolium, amprolium/ethopa-bate, diclazuril, halofuginone, madur-amicin ammonium, meticlorpindol, meticlorpindol/methylbenzoate, monensin sodium, robenidine, sal-inomycin sodium	30.9.1999
			Pigs	—	0,35 × 10 ⁹	1,5 × 10 ⁹	In the directions for use of the addi-tive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.1999
			Sows	—	0,2 × 10 ⁹	1,25 × 10 ⁹	In the directions for use of the addi-tive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.1999
			Cattle for fattening	—	0,25 × 10 ⁹	0,6 × 10 ⁹	In the directions for use of the addi-tive and premixture, indicate the storage temperature, storage life and stability to pelleting. The quantity of <i>Enterococcus faecium</i> in the daily ration must not exceed 1 × 10 ⁹ CFU for 100 kg body weight. Add 1 × 10 ⁹ CFU for each additional 100 kg body weight.	30.9.1999

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			
		Preparation of <i>Enterococcus faecium</i> containing a minimum of: Microencapsulated form: 1,0 × 10 ¹⁰ CFU/g additive 1,75 × 10 ¹⁰ CFU/g additive and Granulated form: 3,5 × 10 ¹⁰ CFU/g additive	Piglets	Four months	0,3 × 10 ⁹	1,4 × 10 ⁹	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Granulated form to be used exclusively in milk replacers.	30.9.1999
		Calves	Six months	0,35 × 10 ⁹	6,6 × 10 ⁹	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Granulated form to be used exclusively in milk replacers.	30.9.1999	
11	<i>Enterococcus faecium</i> DSM 5464	Preparation of <i>Enterococcus faecium</i> containing a minimum of: 5 × 10 ¹⁰ CFU/g additive	Piglets	Four months	0,5 × 10 ⁹	1 × 10 ⁹	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.1999