COMMISSION REGULATION (EC) No 1411/1999

of 29 June 1999

concerning the authorisation of new additives and new additive uses 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 [1], as last amended by Commission Regulation (EC) No 1245/1999 [2], and in particular Articles 9j and 3 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 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, 29 June 1999.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 270, 14.12.1970, p. 1.
[2] OJ L 150, 17.6.1999, p. 15.
[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			
6	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-betaxylanase and endo-1,4-beta-glucananase produced by *Humicola insolens* (DSM 10442) having a minimum activity of: — Coated: 800 FXU ([1])/g 75 FBG ([2])/g — Microgranulate: 800 FXU/g 75 FBG/g — Liquid: 550 FXU/ml 50 FBG/ml	Pigs for fattening	—	200 FXU 19 FBG	800 FXU 75 FBG	1. In the conditions of use of the additive and premixture, indicate the storage temperature, storage life, and the stability to pelleting 2. Recommended dose per kg of feedingstuff: — 400 FXU — 37 FBG 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 30 % barley, and/or oats, wheat	30.9.1999
32	Endo-1,3(4)-beta-glucanase EC 3.2.1.6)	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) having a minimum activity of: — 200 U ([3])/ml	Chickens for fattening	—	100 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: 100 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 30 % barley	30.9.1999
		1 200 U/ml	Piglets	Four months	400 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: 400 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 55 % 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			
			Pigs for fattening	—	500 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: 500 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 70 % barley	30.9.1999
33	Endo-1,4-betax-ylanasa EC 3.2.1.8	Preparation of endo-1,4-beta-xylanasa produced by *Trichoderma longibrachiatum* (ATCC 2105) having a minimum activity of: — Powder form: 2 000 U/ml [4] — Liquid form: 5 000 U/ml	Chickens for fattening	—	500 U	—	1. In the directions for use of the additive and premixture, indicate the storage temeprature, storage life, and stability to pelleting 2. Recommended dose per kg of complete feedingstuff: 500 to 2 500 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing maore than 55 % wheat or 60 % rye	30.9.1999
			Laying hens	—	2 000 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: 2 000 U 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 35 % 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			
		— Powder form: 4 000 U/g — Liquid form: 10 000 U/ml	Piglets	Four months	5 000 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: 5 000 U 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 45 % wheat	30.9.1999
		— Powder form: 4 000 U/g — Liquid form: 8 000 U/ml	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 feedingstaff: 4 000 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 35 % wheat	30.9.1999

(1) 1 FXU is the amount of enzyme which liberates 3,1 micromoles of reducing sugars (xylose equivalents) from azo-wheat arabinoxylan per minute at pH 6,0 and 50 °C.
(2) 1 FBG is the amount of enzyme which liberates one micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 6,0 and 50 °C.
(3) 1 U 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.
(4) 1 U is the amount of enzyme which liberates one micromole of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 5,3 and 50 °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			
1	*Bacillus cereus* var. *toyoi* NCIMB 40112	Preparation of *Bacillus cereus* var. *toyoi* containing a minimum of 1×10^{10} CFU/g additive	Chickens for fattening	—	$0{,}2 \times 10^{9}$	1×10^{9}	In the directions for use of the additive and premixture, indicate the storage life and stability to pelleting May be used in compound feed containing the permitted coccidiostats: monensin sodium, lasolacid sodium, salinomycin sodium, amprolium- ethopabate, meticlorpindol-methyl benzoquate, decoquinate, robenidine, dinitolmide, narasin, halofuginone	30.9.1999
			Laying hens	—	$0{,}2 \times 10^{9}$	1×10^{9}	In the directions for use of the additive and premixture, indicate the storage life and stability to pelleting.	30.9.1999
			Calves	six months	$0{,}5 \times 10^{9}$	1×10^{9}	In the directions for use of the additive and premixture, indicate the 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			
			Cattle for fattening	—	$0,2 \times 10^9$	$0,2 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting The quantity of *Bacillus cereus* var. *toyoi* in the daily ration must not exceed $1,0 \times 10^9$ CFU for 100 kg, body weight. Add $0,2 \times 10^9$ CFU for each additional 100 kg body weight	30.9.1999
			Breeding does	—	$0,1 \times 10^9$	5×10^9	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 coccidiostats: robenidine	30.9.1999
			Rabbits for fattening	—	$0,1 \times 10^9$	5×10^9	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 coccidiostats: meticlorpindol, robenidine, salinomycin sodium	30.9.1999

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content (CFU/kg of complete feedingstuff)	Maximum content (CFU/kg of complete feedingstuff)	Other provisions	Period of authorisation
12	*Lactobacillus farciminis* CNCM MA 67/4R	Preparation of *Lactobacillus farciminis* containing a minimum of 1×10^9 CFU/g additive	Piglets	four months	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	30.9.1999
13	*Enteroccocus faecium* DSM 10 663	Preparation of *Enteroccocus faecium* containing a minimum of: — Powder and granulated forms: $3{,}5 \times 10^{10}$ CFU/g additive — Coated form: $2{,}0 \times 10^{10}$ CFU/g additive — Liquid form: 1×10^{10} CFU/ml additive	Piglets	four months	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	30.9.1999
14	*Saccharomyces cerevisiae* MUCL 39 885	Preparation of *Saccharomyces cerevisiae* containing a minimum of: — Powder, spheric and oval granulated forms: 1×10^9 CFU/g additive	Piglets	four months	3×10^9	3×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting	30.9.1999
			Cattle for fattening		9×10^9	9×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting The quantity of *Saccharomyces cerevisiae* in the daily ration must not exceed $1{,}6 \times 10^{10}$ CFU per 100 kg/body weight. Add $3{,}2 \times 10^9$ CFU for each additional 100 kg body weight	30.9.1999