COMMISSION REGULATION (EC) No 1636/1999
of 26 July 1999
concerning the authorisation of new additives 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 1411/1999 ([2]), and in particular Articles 9j and 3 thereof,

(1) Whereas Directive 70/524/EEC provides that new additives or uses of additives 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 a provisional authorisation of new additives or uses of additives may 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) Whereas the provisions of Council Directive 89/391/EEC of 12 June 1989 ([5]) 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 of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work ([6]), as last amended by Directive 97/65/EC ([7]), are fully applicable to the use and manipulation by workers of the additives in feedingstuffs;

(5) 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 provisonally authorised;

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

(7) Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Committe on Feedingstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

The preparations belonging to the group 'Enzymes' listed in Annex I to the present Regulation may 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 may be authorised according to Directive 70/524/EEC as additive in animal nutrition under the conditions laid down in the said Annex.

Article 3

This Regulation shall enter into force on the day 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.

Done at Brussels, 26 July 1999.

For the Commission
Franz FISCHLER
Member of the Commission

([1]) OJ L 270, 14.12.1970, p. 1.
([2]) OJ L 164, 30.6.1999, p. 56.
([3]) OJ L 334, 31.12.1993, p. 17.
([4]) OJ L 180, 9.7.1997, p. 21.
([5]) OJ L 183, 29.6.1989, p. 1.
([6]) OJ L 374, 31.12.1990, p. 1.
([7]) OJ L 335, 6.12.1997, p. 17.

ANNEX I

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content Units of activity per kg of complete feedingstuff	Maximum content	Other provisions	Period of authorisation
34	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-betaxylanase EC 3.2.1.8 Alpha-amylase EC 3.2.1.1	Preparation of endo-1,3 (4)-beta-glucanasa and endo 1,4-beta-xylanase produced by *Aspergillus niger* (NRRL 25541) and of alpha-amylase produced by *Aspergillus oryzae* (ATCC 66 222) having a minimum activity of: Endo-1,3 (4)-beta-glucanase: 275 U/g [1] Endo-1,4-beta-xylanase: 400 U/g [2] Alpha-amylase: 3 100 U/g [3]	Piglets	4 months	Endo-1,3 (4)-beta-glucanase: 165 U Endo-1,4-beta-xylanase: 240 U Alpha-amylase: 1 860 U	— — —	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and the stability to pelleting. 2. Recommended dose per kg of complete feedingstuffs: endo-1,3(4)-beta-glucanase: 165 U endo-1,4-beta-xylanase: 240 U alpha-amylase: 1 860 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 45 % barley and 10 % wheat or 10 % maize.	30.9.1999
35	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 produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) having a minimum acitivity of: Endo-1,3(4)-beta-glucanase: 80 U/g [4] Endo-1,4-beta-xylanase: 180 U/g [5]	Laying hens	—	Endo-1,3(4)-beta-glucanase: 80 U Endo-1,4-beta-xylanase: 180 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: 80 U endo-1,4-beta-xylanase: 180 U 3. For use in compound feed rich in non-starch polysaccharides, (mainly betaglucans and arabinoxylans), e. g. containing more than 60 % barley.	30.9.1999

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content Units of activity per kg of complete feedingstuff	Maximum content	Other provisions	Period of authorisation
36	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 produced by *Trichoderma longibrachiatum* (ATTC 2106) and endo-1,4-beta-xylanasee produced by *Trichoderma longibrachiatum* (IMI SD 135) having a minimum activity of: endo-1,3(4)-beta-glucanase: 300 U/g [6] endo-1,4-beta-xylanase: 300 U/g [7]	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase 300 U Endo-1,4-beta-xylanase: 300 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: 300 U endo-1,4-beta-xylanase: 300 U 3. For use in compound feed rich in non-starch polysaccharides, (mainly beta-glucans and arabinoxylans), e.g. containing more than 40 % barley.	30.9.1999
			Laying hens		Endo-1,3(4)-beta-glucanase: 300 U Endo-1,4-beta-xylanase: 300 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: 300 U endo-1,4-beta-xylanase: 300 U 3. For use in compound feed rich in non-starch polysaccharides, (mainly beta-glucans and arabinoxylans), e.g. containing more than 35 % barley.	30.9.1999

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content Units of activity per kg of complete feedingstuff	Maximum content	Other provisions	Period of authorisation
37	Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107), with a minimum activity of: Endo-1,4-beta-xylanase: 2 500 U/g (8) Subtilisin: 800 U/g (9)	Chickens for fattening	—	Endo-1,4-beta-xylanase: 500 U Subtilisin: 160 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: 500-2 500 U subtilisin: 160-800 U 3. For use in compound feed e.g. containing morew than 65 % wheat.	30.9.1999
			Turkeys	—	Endo-1,4-beta-xylanase: 825 U Subtilisin: 265 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: 825-2 500 U subtilisin: 265-800 U 3. For use in compound feed e.g. containing more than 45 % wheat.	30.9.1999

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content Units of activity per kg of complete feedingstuff	Maximum content	Other provisions	Period of authorisation
38	Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62.	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) having a minimum activity of: Endo-1,4-beta-xylanase: 5 000 U/g [10] Subtilisin: 500 U/g [11]	Piglets	4 months	Endo-1,4-beta-xylanase: 5 000 U Subtilisin: 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: endo-1,4-beta-xylanase: 5 000 U subtilisin: 500 U 3. For use in compound feed e.g. containing more than 40 % wheat.	30.9.1999
39	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 produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) having a minimum activity of: endo-1,3(4)-beta-glucanase: 400 U/g [12] endo-1,4-beta-xylanase: 400 U/g [13]	Pigs for fattening	—	Endo-1,3(4)-beta-glucanase: 400 U Endo-1,4-beta-xylanase: 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: endo-1,3(4)-beta-glucanase: 400 U endo-1,4-beta-xylanase: 400 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylns) e.g. containing more than 65 % 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			
40	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) having a minimum activity of: endo-1,3(4)-beta-glucanase: 100 U/g [14] endo-1,4-beta-xylanase: 300 U/g [15] subtilisin: 800 U/g [16]	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 30 U Endo-1,4-beta-xylanase: 90 U Subtilisin: 240 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: 30-100 U endo-1,4-beta-xylanase: 90-300 U subtilising: 240-800 U 3. For use in compound feed e.g. containing more than 60 % barley.	30.9.1999
41	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) having a minimum activity of: endo-1,3(4)-beta-glucanase: 100 U/g [17] endo-1,4-beta-xylanase: 2 500 U/g [18] subtilisin: 800 U/g [19]	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 25 U Endo-1,4-beta-xylanase: 625 U Subtilisin: 200 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: 25-100 U endo-1,4-beta-xylanase: 625-2 500 U subtilising: 200-800 U 3. For use in compound feed e.g. containing more than 30 % wheat and 10 % barley.	30.9.1999

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content Units of activity per kg of complete feedingstuff	Maximum content	Other provisions	Period of authorisation
			Laying hens	—	Endo-1,3(4)-beta-glucanase: 100 U Endo-1,4-beta-xylanase: 2 500 U Substilisin: 800 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: 2 500 U subtilisin: 800 U 3. For use in compound feed e.g. containing more than 50 % wheat and 25 % barley.	30.9.1999
42	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) having a minimum activity of: Solid form: 4 000 U/g ([20]) Characteristics of the authorised preparation: endo-1,4-beta-xylanase: 1,99 % wheat: 97,7 % calcium propionate: 0,3 % lecithin: 0,01 %	Piglets	4 months	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.	30.9.1999

(1) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugar (glucose equivalent) from oat beta-glucan per minute at pH 4,0 and 30 °C.
(2) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugar (glucose equivalent) from oat xylan per minute at pH 4,0 and 30 °C.
(3) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugar (glucose equivalent) from wheat starch per minute at pH 4,0 and 30 °C.
(4) 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.
(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 reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 5,3 and 50 °C.
(9) 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a 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 sugars (xylose equivalents) from oat spelt xylan per minute at pH 5,3 and 50 °C.
(11) 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7,5 and 40 °C.
(12) 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.
(13) 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.
(14) 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.
(15) 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.
(16) 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7,5 and 40 °C.
(17) 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.
(18) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from a oat spelt xylan per minute at pH 5,3 and 50 °C.
(19) 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7,5 and 40 °C.
(20) 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.

ANNEX II

No	Additive	Chimcal formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					CFU/kg of complete feedingstuff			
13	*Enteroccocus faecium* DSM 10 663 NCIMB 10 415	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	Calves	6 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
			Chickens for fattening	—	1×10^{9}	1×10^{10}	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, Amprolium-Ethopabat, Arprinocid, Decoquinate, Diclazuril, Dinitolmid, Halofuginone, Lasalocid sodium, Maduramicin ammonium, Meticlorpindol/Methylbenzoquate, Monensin sodium Narasin, Nicarbarin, Robenidine, Salinomycin sodium.	30.9.1999