COMMISSION REGULATION (EC) No 418/2001
of 1 March 2001
concerning the authorisations of new additives and uses of additives 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 [1], as last amended by Commission Regulation (EC) No 2697/2000 [2], and in particular Article 4 thereof,

Whereas:

(1) Directive 70/524/EEC provides that new additives or uses of additives may be authorised following the review of an application made in accordance with article 4 of the Directive.

(2) Article 9e(1) of the Directive provides that provisional authorisation of new additives or uses of additives may be given if the conditions of Articles 3a(b) to (e) of Directive 70/524/EEC are satifisfied and if its reasonable to assume, in view of the available results, that when used in animal nutrition it has one of the effects referred to in Article 2(a). Such provisional authorisation may be given for a period up to four years in the case of additives referred to in Part II of Annex C to the Directive.

(3) The assessment of dossiers submitted shows that the new micro-organism and enzyme preparations and the new uses of the micro-organism and enzyme preparations described in Annex I and II satisfy the abovementioned conditions and may therefore be authorised on a provisional basis for a four-year period.

(4) Article 2(aaa) of Directive 70/524/EEC requires authorisations for coccidiostats to be linked to the person responsible for putting them into circulation.

(5) Article 9b of Directive 70/524/EEC provides that the authorisations of such substances shall be given for a period of 10 years from the date on which final authorisation takes effect, if all conditions laid down in Article 3a of Directive 70/524/EEC are met.

(6) The assessment of the dossier submitted shows that the coccidiostat described in Annex III satisfies all the requirements of Article 3a, when used in the anidmal category and under the conditions described in the said Annex.

(7) The assessment of the dossiers shows that certain procedures may be required to protect workers from exposure to the additives. Such protection should however be assured by the application of 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 [3] and the Directives made under it.

(8) The Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the harmlessness of the enzyme and micro-organism preparations and of the coccidiostat, and with regard to the favourable effect on animal production of the latter, under the conditions described in the said Annexes.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Feedingstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

The preparations belonging to the group 'Micro-organisms' listed in Annex I to the present Regulation are authorised for use as additives in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparations belonging to the group 'Enzymes' listed in Annex II to the present Regulation are authorised for use as additives in animal nutrition under the conditions laid down in that Annex.

Article 3

The additive belonging to the group 'Coccidiostats and other medicinal substances' listed in Annex III to the present Regulation is authorised for use as additive in animal nutrition under the conditions laid down in that Annex.

Article 4

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

It shall apply from 1 March 2001.

[1] OJ L 270, 14.12.1970, p. 1.
[2] OJ L 319, 16.12.2000, p. 1.
[3] OJ L 183, 29.6.1989, p. 1.

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

Done at Brussels, 1 March 2001.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

No (or EC 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			
20	*Bacillus licheniformis* DSM 5749 *Bacillus subtilis* DSM 5750 (In a 1/1 ratio)	Mixture of *Bacillus licheniformis* and *Bacillus subtilis* containing a minimum of $3,2 \times 10^9$ CFU/g of the additive ($1,6 \times 10^9$ UFC/g of each bacterium)	Calves	6 month	$1,28 \times 10^9$	$1,6 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temeprature, storage life, and stability to pelleting.	28.2.2005
21	*Enterococcus faecium* DSM 3530	Preparation of *Enterococcus faecium* containing a minimum of $2,5 \times 10^9$ CFU/g	Calves	6 months	1×10^9	1×10^9	In the directions for use of the additive and premixture, indicate the storage temeprature, storage life, and stability to pelleting	28.2.2005

No (or EC No)	Additive	Chemical formula, decription	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity/kg complete feedingstuff			
23	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10W) having a minimum of activity of: Solid form: 70 000 IFP [1]/g Liquid form: 7 000 IFP/ml	Turkeys for fattening	—	700 IFP	—	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: 1 400 IFP 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat	28.2.2005
			Laying hens	—	840 IFP	—	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: 840 IFP 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat	28.2.2005
27	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 529.94) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 526.94) having a minimum activity of: Solid form: 200 000 BXU [2]/g 200 000 BU [3]/g Liquid form: 30 000 BXU/g 30 000 BU/g	Piglets	2 months	7 500 BXU 7 500 BU	— —	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: 7 500 to 15 000 BXU 7 500 to 15 000 BU 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 50 % wheat	28.2.2005

No (or EC No)	Additive	Chemical formula, decription	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity/kg complete feedingstuff			
28	3-Phytase EC 3.1.3.8	Preparation of 3-phytase produced by *Trichoderma reesei* (CBS 528.94) having a minimum activity of Solid form: 5 000 PPU [4]/g Liquid form: 1 000 PPU/g	Chickens for fattening	—	500 PPU	—	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: 500 to 750 PPU 3. For use in compound feed containing more than 0,22 % phytin bound phosphorus	28.2.2005
30	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,-beta-xylanase EC 3.2.1.8	Preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Penicillium funiculosum* (IMI SD 101) having a minimum activity of: Powder form: Endo-1,3(4)-beta-glucanase: 2 000 U [5]/g Endo-1,4-beta-xylanase: 1 400 U/g [6]/g Liquid form: Endo-1,3(4)-beta-glucanase: 500 U/ml Endo-1,4-beta-xylanase: 350 U/ml	Turkeys 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 kilogram 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 % wheat	28.2.2005
			Laying hens	—	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 stabiltiy to pelleting 2. Recommended dose per kilogram 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. continaing more than 60 % barley or 30 % wheat	28.2.2005

No (or EC No)	Additive	Chemical formula, decription	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity/kg complete feedingstuff			
			Pigs 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 kilogram 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	28.2.2005
59	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Subtilisin EC 3.4.21.62 Alpha-amylase EC 3.2.1.1 Polygalacturonase EC 3.2.1.15	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), subtilisin produced by *Bacillus subtilis* (ATCC 2107), polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) having a minimum activity of: Endo-1,4-beta-xylanase: 300 U [7]/g Endo-1,3(4)-beta-glucanase: 150 U [8]/g Subtilisin: 4 000 U [9]/g Alpha-amylase: 400 U [10]/g Polygalacturonase: 25 U [11]/g	Chickens for fattening	—	Endo-1,4-beta-xylanase: 300 U Endo-1,3(4)-beta-glucanase: 150 U Subtilisin: 4 000 U Alpha-amylase: 400 U Polygalacturonase: 25 U	— — — — —	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stbility to pelleting 2. Recommended dose per kilogram of complete feedingstuff: endo-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalacturonase: 25 U 3. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % maize	28.2.2005
60	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) having a minimum activitiy of: Endo-1,4-beta-xylanase: 5 000 U [7]/g Endo-1,3(4)-beta-glucanase: 50 U [8]/g	Chickens for fattening	—	Endo-1,4-beta-xylanase: 500 U Endo-1,3(4)-beta-glucanase: 5 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 kilogram of complete feedingstuff: endo-1,4-beta-xylanase: 500 to 2 500 U endo-1,3(4)-beta-glucanase: 5 to 25 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 20 % barley and 40 % wheat	28.2.2005

No (or EC No)	Additive	Chemical formula, decription	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity/kg complete feedingstuff			
61	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 526.94) having a minimum activity of: Powder form: Endo-1,(4)-beta-xylanase: 17 000 BXU (2)/g Endo-1,3(4)-beta-xylanase: 11 000 BU/ (3)/g Liquid form: Endo-1,4-beta-xylanase: 22 000 U/ml Endo-1,3(4)-beta-glucanase: 15 000 U/ml	Chickens for fattening	—	Endo-1,4-beta-xylanase: 17 000 BXU Endo-1,3(4)-beta-glucanase: 11 000 BU	— —	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: 17 000 BXU endo-1,3(4)-beta-glucanase: 11 000 BU 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 40 % barley or 55 % wheat	28.2.2005

(1) 1 IFP is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat xylan per minute at pH 4,8 and 50°C.
(2) 1 BXU is the amount of enzyme which liberates 0,06 micromoles of reducing sugars (xylose equivalents) from birch xylan per minute at pH 5,3 and 50 °C.
(3) 1 BU is the amount of enzyme which liberates 0,06 micromoles of reducing sugars (glucose equivalents) from barley-glucan per minute at pH 4,8 and 50 °C.
(4) 1 PPU is the amount of enzyme which liberates 1 micromole of inorganic phosphate from sodium phytate per minute at pH 5,0 and 37 °C.
(5) 1 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) 1 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) 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 (glucose equivalents) from barley beta-glucan per minute at pH 5,0 and 30 °C.
(9) 1 U is the amount of enzyme which liberates 1 micromole 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 glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 6,5 and 37 °C.
(11) 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 III

Registration number of additive	Name and registration number of person responsible for putting additive into circulation	Additive (trade name)	Composition, chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
						mg of active substance/kg of complete feedingstuff			
E771	Janssen Animal Health B.V.B.A	Diclazuril 0,5 g/100 g (Clinacox 0,5 % Premix)	**Additive composition** Diclazuril: 0,5 g/100 g Soybean meal: 99,25 g/100 g Polyvidone K 30: 0,2 g/100 g Sodium hydroxyde: 0,0538 g/100 g	Turkeys for fattening	12 weeks	1	1	Use prohibited at least five days before slaughter	28.2.2011
		Diclazuril 0,2 g/100 g (Clinacox 0,2 % Premix)	Diclazuril: 0,2 g/100 g Soybean meal: 39,7 g/100 g Polyvidone K 30: 0,08 g/100 g Sodium hydroxide: 0,0215 g/100 g Wheat middlings: 60 g/100 g **Active substance:** Diclazuril, $C_{17}H_9Cl_3N_4O_2$, (±)-4-chlorophenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile, CAS number: 101831-37-2, Related impurities: Degradation compound (R064318): ≤ 0,2 % Other related impurities (R066891, R066896, R068610, R070156, R068584, R070016): ≤ 0,5 % individually Total impurities ≤ 1,5 %						