

COMMISSION REGULATION (EC) No 937/2001

of 11 May 2001

concerning the authorisation of new additive uses, new additive preparation, the prolongation of provisional authorisations and the 10 year authorisation of an additive 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 and new 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 a new additive or new use of an additive may be given if the conditions of Article 3a(b) to (e) are satisfied and if it is 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 the dossiers submitted in respect of the new uses of the enzyme and micro-organism preparations described in Annexes I and II shows that they satisfy the abovementioned conditions and may therefore be authorised on a provisional basis for a four-year period.
- (4) New data were submitted to extend the authorisation of an enzyme preparation provisionally listed under No 11 to a new physical form. The assessment of the dossier submitted shows that the new physical form may be provisionally authorised.
- (5) On 1 October 2000, the authorisation of the micro-organism preparation No 1 *Bacillus cereus* var. *toyoi* (NCIMB 40 112) was provisionally renewed for a limited period, in order to provide sufficient time for the safety reassessment of the strain with regard to production of toxins, as requested in the opinion of the Scientific Committee for Animal Nutrition (SCAN) on the safety of use of bacillus species in animal nutrition adopted on 17 February 2000.

- (6) According to the SCAN opinion on *Bacillus cereus* var. *toyoi* (NCIMB 40 112) adopted on 21 March 2001, the assessment of the dossiers submitted shows that the product may be considered safe as regard toxin production. The provisional authorisation of the product may therefore be resumed.
- (7) Article 2(aaa) of Directive 70/524/EEC requires authorisations for coccidiostats to be linked to the person responsible for putting them into circulation.
- (8) 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.
- (9) The assessment of the dossier submitted shows that the coccidiostat described in Annex IV satisfies all the requirements of Article 3a, when used in the animal category and under the conditions described in the said Annex.
- (10) The assessment of the dossier 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⁾.
- (11) The Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the safety 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 Annex.
- (12) 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 'Enzymes' listed in Annex I to the present Regulation are authorised for use as additives in animal nutrition under the conditions laid down in the Annex.

⁽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.

Article 2

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

Article 3

The provisional authorisations of the preparation belonging to the group 'Micro-organisms' listed in Annex III are resumed under the conditions laid down in the Annex.

Article 4

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

Article 5

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 June 2001.

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

Done at Brussels, 11 May 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
					Units of activity/kg of complete feedingstuff			
11	Endo-1,4-beta-glucanase EC 3.2.1.4 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 74 252) having a minimum activity of: Granular and Liquid form: Endo-1,4-beta-glucanase: 8 000 U ⁽¹⁾ /g or ml Endo-1,3(4)-beta-glucanase: 18 000 U ⁽²⁾ /g or ml Endo-1,4-beta-xylanase: 26 000 U ⁽³⁾ /g or ml	Chickens for fattening	—	Endo-1,4-beta-glucanase: 400 U Endo-1,3(4)-beta-glucanase: 900 U Endo-1,4-beta-xylanase: 1 300 U	— — —	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dosages per kilogram of complete feedingstuff: Endo-1,4-beta-glucanase: 400-1 600 U Endo-1,3(4)-beta-glucanase: 900-3 600 U Endo-1,4-beta-xylanase: 1 300-5 200 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e. g. containing more than 30 % wheat or barley and more than 10 % rye.	30.6.2004

No (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					Units of activity/kg of complete feedingstuff			
			Turkeys for fattening	—	Endo-1,4-beta-glucanase: 400 U Endo-1,3(4)-beta-glucanase: 900 U Endo-1,4-beta-xylanase: 1 300 U	— — —	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. Recommended dosages per kilogram of complete feedingstuff: endo-1,4-beta-glucanase: 400-800 U endo-1,3(4)-beta-glucanase: 900-1 800 U endo-1,4-beta-xylanase: 1 300-2 600 U. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e. g. containing more than 40 % wheat. 	31.5.2005
51	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Bacillus subtilis</i> (LMG S-15136) having a minimum activity of 100 IU ^(*) /g	Piglets	2 months	10 IU	—	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. Recommended dose per kilogram of complete feedingstuff: 10 IU. For use in compound feed rich in arabinoxylan, e. g. containing more than 40 % wheat. 	31.5.2005

(¹) 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from carboxymethylcellulose per minute at pH 5,0 and 40 °C.

(²) 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from barley beta-glucan per minute at pH 5,0 and 40 °C.

(³) 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from oat spelt xylan per minute at pH 5,0 and 40 °C.

(⁴) 1 IU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 4,5 and 30 °C.

ANNEX II

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			
3	<i>Saccharomyces cerevisiae</i> NCYC Sc 47	Preparation of <i>Saccharomyces cerevisiae</i> containing a minimum of 5×10^9 CFU/g of additive	Dairy cows	—	4×10^8	2×10^9	In the directions for use of the additive and the 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 $5,6 \times 10^9$ CFU per 100 kg of body weight. Add $8,75 \times 10^9$ per each additional 100 kg body weight.	31.5.2005
5	<i>Saccharomyces cerevisiae</i> CBS 493.94	Preparation of <i>Saccharomyces cerevisiae</i> containing a minimum of 1×10^8 CFU/g additive	Dairy cows	—	5×10^7	$3,5 \times 10^8$	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 $1,2 \times 10^9$ CFU for 100 kg body weight. Add $1,7 \times 10^8$ CFU per each additional 100 kg body weight.	31.5.2005

ANNEX III

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			
1	<i>Bacillus cereus</i> var. <i>toyoi</i> NCIMB 40112/ CNCM I-1012	Preparation of <i>Bacillus cereus</i> var. <i>toyoi</i> 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 temperature, storage life and stability to pelleting. May be used in compound feed containing the permitted coccidiostats: monensin sodium, lasolacid sodium, salinomycin sodium, deco-quinat, robenidine, narasin, halofuginone.	1.3.2002
			Laying hens	—	$0,2 \times 10^9$	1×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	1.3.2002
			Calves	6 months	$0,5 \times 10^9$	1×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	1.3.2002
			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 <i>Bacillus cereus</i> var. <i>toyoi</i> 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.	1.3.2002

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			
			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 coccidiostat: robenidine.	1.3.2002
			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: robenidine, salinomycin sodium.	1.3.2002

ANNEX IV

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			
Coccidiostats and other medicinal substances									
E 766	Intervet International bv	Salinomycin sodium 120 g/kg (Sacox 120)	<p><i>Additive composition:</i> Salinomycin sodium ≥ 120 g/kg Silicon dioxide 10-100 g/kg Calcium carbonate 350-700 g/kg</p> <p><i>Active substance:</i> Salinomycin sodium, C₄₂H₆₉O₁₁Na, CAS number: 53003-10-4 sodium salt of a polyether monocarboxylic acid produced by fermentation of <i>Streptomyces albus</i> (DSM 12217)</p> <p><i>Related impurities:</i> < 42 mg elaiophylin/kg salinomycin sodium, < 40 g de 17-epi-20-desoxy-salinomycin/kg salinomycin sodium.</p>	Rabbits for fattening	—	20	25	Use prohibited at least 5 days before slaughter. Indicate in the instructions for use: 'Dangerous for equines'. 'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contra-indicated'	31.5.2011