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COMMISSION REGULATION (EC) No 600/2005

of 18 April 2005

concerning a new authorisation for 10 years of a coccidiostat as an additive in feedingstuffs, the provisional authorisation of an additive and the permanent authorisation of certain additives in feedingstuffs

(Text with EEA relevance)

(OJ L 99, 19.4.2005, p. 5)

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concerning a new authorisation for 10 years of a coccidiostat as an additive in feedingstuffs, the provisional authorisation of an additive and the permanent authorisation of certain 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]), and in particular Articles 3, 9d (1) and 9e(1) thereof,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([2]) and in particular Article 25 thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.

(2) Article 25 of Regulation (EC) No 1831/2003 lays down transitional measures for applications for the authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of Regulation (EC) No 1831/2003.

(3) The applications for authorisation of the additives listed in the Annexes to this Regulation were submitted before the date of application of Regulation (EC) No 1831/2003.

(4) Initial comments on those applications, as provided for in Article 4(4) of Directive 70/524/EEC, were forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. Those applications are therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

(5) The person responsible for putting into circulation Salinomax 120G submitted an application for authorisation for 10 years, as a coccidiostat for chickens for fattening, according to Article 4 of that Directive. The European Food Safety Authority (EFSA) has delivered an opinion on the safety of the use of this preparation for humans, animals and the environment, under the conditions set out in Annex I to this Regulation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of this preparation, as specified in Annex I, should be authorised for 10 years.

(6) Data were submitted in support of an application of the new additive *Lactobacillus acidophilus* DSM 13241 for dogs and cats. The EFSA delivered favourable opinions on 15 April 2004 and 27 October 2004 on the safety for the target animals, the user and the environment. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex II, should be provisionally authorised.

(7) The use of the micro-organism preparation *Enterococcus faecium* ATCC 53519 and *Enterococcus faecium* ATCC 55593 was provi-

([1]) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1800/2004 (OJ L 317, 16.10.2004, p. 37).

([2]) OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

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sionally authorised, for the first time, for chickens for fattening by Commission Regulation (EC) No 1436/98 ([1]). New data were submitted in support of an application for authorisation without time limit of that micro-organism preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex III, should be authorised without a time limit.

(8) The use of the micro-organism preparation *Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750 was provisionally authorised, for the first time, for turkeys for fattening by Commission Regulation (EC) No 2437/2000 ([2]) and for calves by Commission Regulation (EC) No 418/2001 ([3]). New data were submitted in support of an application for authorisation without time limit of that micro-organism preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex III, should be authorised without a time limit.

(9) The use of the micro-organism preparation *Saccharomyces cerevisiae* NCYC Sc 47 was provisionally authorised, for the first time, for rabbits by the Regulation (EC) No 1436/98. New data were submitted in support of an application for authorisation without time limit of that micro-organism preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex III, should be authorised without a time limit.

(10) The assessment of this application shows that certain procedures should be required to protect workers from exposure to the additive set out in the Annex. Such protection should 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 ([4]).

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation belonging to the group ‘Coccidiostats and other medicinal substances’, as specified in Annex I, is authorised for use for 10 years as additive in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparation belonging to the group ‘Micro-organisms’, as specified in Annex II, is authorised provisionally for four years as an additive in animal nutrition under the conditions laid down in that Annex.

([1]) OJ L 191, 7.7.1998, p. 15.
([2]) OJ L 280, 4.11.2000, p. 28.
([3]) OJ L 62, 2.3.2001, p. 3.
([4]) OJ L 183, 29.6.1989, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

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Article 3

The preparations belonging to the group 'Micro-organisms', as specified in Annex III, are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in that Annex.

Article 4

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

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

ANNEX I

Registration number of additive	Name and registration number of person responsible for putting the additive into circulation	Additive (trade name)	Composition, chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff			
Coccidiostats and other medicinal substances									
‘E 766	Alpharma (Belgium) BVBA	Salinomycin sodium 120 g/kg (Salinomax 120G)	Additive composition: Salinomycin sodium 120 g/kg Calcium lignosulfonate: 40 g/kg Calcium sulphate dihydrate to 1 000 g/kg Active substance: Salinomycin sodium, $C_{42}H_{69}O_{11}Na$, Sodium salt of a polyether monocarboxylic acid produced by fermentation of *Streptomyces albus* (ATCC 21838/US 9401-06), CAS No: 55 721-31-8 Related impurities: < 42 mg elaiophylin/kg salinomycin sodium. < 40 g 17-epi-20 desoxysalinomycin /kg salinomycin sodium	Chickens for fattening	—	50	70	Use prohibited at least 5 days before slaughter. Indicate in the instructions for use: “Dangerous for equines and turkeys” “This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contra-indicated”	22.4.2015’

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ANNEX II

No (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU/kg of complete feedingstuff			
Micro-organisms								
'25	*Lactobacillus acidophilus* DSM 13241	Preparation of *Lactobacillus acidophilus* containing a minimum of: 1×10^{11} CFU/g additive	Dogs	—	6×10^{9}	2×10^{10}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. For use in dry feed with a water content at or below 2 %.	22.4.2009
			Cats	—	3×10^{9}	2×10^{10}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. For use in dry feed with a water content at or below 2 %.	22.4.2009'

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ANNEX III

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU/kg of complete feedingstuff			
Micro-organisms								
‘E 1709	*Enterococcus faecium* ATCC 53519 *Enterococcus faecium* ATCC 55593 (In a 1/1 ratio)	Mixture of encapsulated *Enterococcus faecium* and *Enterococcus faecium* containing a minimum of 2×10^8 CFU/g additive. (i.e. a minimum of 1×10^8 CFU/g of each bacterium)	Chickens for fattening	—	1×10^8	1×10^8	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. May be used in compounded feed containing coccidiostats: decoquinate, halofuginone, lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, narasin/nicarbazin, and salinomycin sodium.	Without a time limit
▼M1 E 1700	*Bacillus licheniformis* DSM 5749 and *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 additive ($1{,}6 \times 10^9$ of each bacterium)	Turkeys for fattening	—	$1{,}28 \times 10^9$	$1{,}28 \times 10^9$	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: — diclazuril, halofuginone, monensin sodium, robenidine and maduramicin ammonium.	Without a time limit
▼B			Calves	3 months	$1{,}28 \times 10^9$	$1{,}28 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	Without a time limit

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EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU/kg of complete feedingstuff			
E 1702	*Saccharomyces cerevisiae* NCYC Sc 47	Preparation *of Saccharomyces cerevisiae* containing 5×10^9 CFU/g additive	Rabbits for fattening	—	$2{,}5 \times 10^9$	$7{,}5 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting	Without a time limit’