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COMMISSION REGULATION (EC) No 1443/2006

of 29 September 2006

concerning the permanent authorisations of certain additives in feedingstuffs and an authorisation for 10 years for a coccidiostat

(Text with EEA relevance)

(OJ L 271, 30.9.2006, p. 12)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 887/2009 of 25 September 2009	L 254	68	26.9.2009

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concerning the permanent authorisations of certain additives in feedingstuffs and an authorisation for 10 years for a coccidiostat

(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, 9 and 9d(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 the 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) Data were submitted in support of an application for authorisation without a time limit of the enzyme preparation of 3-phytase produced by *Hansenula polymorpha* (DSM 15087) for chickens for fattening, turkeys for fattening, laying hens, piglets, pigs for fattening and sows. On 7 March 2006 the European Food Safety Authority (the Authority) delivered its opinion on the use of this preparation which concludes that it does not present a risk for the consumer, the user, the animal category targeted or the environment. 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 enzyme preparation, as specified in Annex I to this Regulation, should be authorised without a time limit.

(6) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) was provisionally authorised for the first time for piglets by Commission Regulation (EC) No 1411/1999 ([3]). New data were submitted in support of an application for authorisation without a time limit of that enzyme preparation. The assessment shows that

([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).
([3]) OJ L 164, 30.6.1999, p. 56.

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the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex I to this Regulation, should be authorised without a time limit.

(7) The use of the coccidiostat preparation of semduramicin sodium (AVIAX 5 %) was provisionally authorised for the first time for chickens for fattening, by Commission Regulation (EC) No 1041/2002 ([1]). New data were submitted in support of an application for authorisation for 10 years of that coccidiostat. 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 substance, as specified in the Annex II, should be authorised for 10 years.

(8) Data were submitted in support of an application for authorisation without a time limit of 25-hydroxycholecalciferol, belonging to the group 'Vitamins, provitamins and chemically well-defined substances having similar effect' for chickens for fattening, laying hens and turkeys. On 26 May 2005 the Authority has delivered an opinion on the use of this preparation which concludes that it does not present a risk for the consumer, the user, the animal category targeted or the environment. 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 vitamin preparation, as specified in Annex III, should be authorised without time limit.

(9) The assessment of these applications shows that certain procedures should be required to protect workers from exposure to the additives set out in the Annexes. 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 ([2]).

(10) 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 preparations belonging to the group 'Enzymes', as specified in Annex I, are authorised without a time limit as additives in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparation belonging to the group 'Coccidiostat and other medicinal substances', as specified in Annex II, is authorised for 10 years as additive in animal nutrition under the conditions laid down in that Annex.

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([1]) OJ L 157, 15.6.2002, p. 41.
([2]) OJ L 183, 29.6.1989, p. 1. Directive as 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 4

This Regulation shall enter into force on the 20th day following 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

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity/kg of complete feedingstuff			
Enzymes								
E 1639	3-phytase EC 3.1.3.8	Preparation of 3-phytase produced by *Hansenula polymorpha* (DSM 15087) having a minimum activity of: Coated form: 2 500 U ([1])/g Liquid forms: 5 000 U/g	Chickens for fattening	—	250 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: 250-1 000 U/kg 3. For use in compound feed rich in phytin-bound phosphorus such as maize, soya, wheat, barley, rye.	Without a time limit
			Turkeys for fattening	—	250 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: 250-1 000 U/kg 3. For use in compound feed rich in phytin-bound phosphorus such as maize, soya, wheat, barley, rye.	Without a time limit
			Laying hens	—	250 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: 250-1 000 U/kg 3. For use in compound feed rich in phytin-bound phosphorus such as maize, soya, wheat, barley, rye.	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
					Units of activity/kg of complete feedingstuff			
			Piglets	Four months	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: 500-1 000 U/kg 3. For use in compound feed rich in phytinbound phosphorus such as maize, soya, wheat, barley, rye.	Without a time limit
			Pigs for fattening	—	250 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: 250-1 000 U/kg 3. For use in compound feed rich in phytinbound phosphorus such as maize, soya, wheat, barley, rye.	Without a time limit
			Sows	—	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: 500-1 000 U/kg 3. For use in compound feed rich in phytinbound phosphorus such as maize, soya, wheat, barley, rye.	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
					Units of activity/kg of complete feedingstuff			
E 1628	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) having a minimum activity of: Powder form: Endo-1,4-beta-xylanase: 8 000 U ([2])/g Liquid form: Endo-1,4-beta-xylanase: 8 000 U/ml	Piglets (weaned)	—	Endo-1,4-beta-xylanase: 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: Endo-1,4-beta-xylanase: 4 000 U. 3. For use in compound feed rich in nonstarch polysaccharides (mainly arabinoxylans), e.g. containing more than 35 % wheat. 4. For use in weaned piglets until approximately 35 kg.	Without a time limit

([1]) 1 U is the amount of enzyme which liberates 1micromole of inorganic phosphate from phytate per minute at pH 5,5 and 37 °C.
([2]) 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.

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ANNEX II

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	End of period of authorisation
						mg of active substance/kg of complete feedingstuff			
Coccidiostats and other medicinal substances									
E 773	Phibro Animal Health, s.a.	Semduramicin sodium (Aviax 5 %)	**Additive composition**: Semduramicin sodium: 51,3 g/kg Sodium carbonate: 40 g/kg Mineral oil: 30-50 g/kg Sodium aluminosilicate: 20 g/kg Soybean mill run: 838,7-858,7 g/kg **Active substance**: Semduramicin $C_{45}H_{76}O_{16}$ CAS number: 113378-31-7 Semduramicin sodium $C_{45}H_{75}O_{16}Na$ CAS number: 119068-77-8 sodium salt of a monocarboxylic acid polyether ionophore produced by *Actinomadura roseorufa* (ATCC 53664) Related impurities: Descarboxylsemduramicin, ≤ 2 % Desmethoxylsemduramicin, ≤ 2 % Hydroxysemduramicin, ≤ 2 % Total: ≤ 5 %	Chickens for fattening	—	20	25	Use prohibited at least five days before slaughter. Simultaneous use of semduramicin and tiamulin may induce a temporary reduction of feed consumption and water intake.	10 years from the date to entry into force of Regulation

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