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COMMISSION REGULATION (EC) No 1810/2005

of 4 November 2005

concerning a new authorisation for 10 years of an additive in feedingstuffs, the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of new uses of certain additives already authorised in feedingstuffs

(Text with EEA relevance)

(OJ L 291, 5.11.2005, p. 5)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 184/2007 of 20 February 2007	L 63	1	1.3.2007

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COMMISSION REGULATION (EC) No 1810/2005

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concerning a new authorisation for 10 years of an additive in feedingstuffs, the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of new uses of certain additives already authorised 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, 9, 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 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) The use of the growth promoter 'Formi LHS (potassium diformate)' was provisionally authorised, for the first time, for piglets and pigs for fattening by Commission Regulation (EC) No 1334/2001 ([3]). The person responsible for putting into circulation 'Formi LHS (potassium diformate)' submitted an application to obtain a definitive authorisation for 10 years. 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) The use of the additive 'clinoptilolite of sedimentary origin' as a member of the group of binders, anti-caking agents and coagulants was provisionally authorised, for the first time, for pigs, chickens and turkeys for fattening and for bovines and salmon by Commission Regulation (EC) No 1887/2000 ([4]). New data were submitted in support of an application for authorisation without time-limit of that additive. 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

([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 180, 3.7.2001, p. 18. Regulation as amended by Regulation (EC) No 676/2003 (OJ L 97, 15.4.2003, p. 29).
([4]) OJ L 227, 7.9.2000, p. 13.

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that additive, as specified in Annex II, should be authorised without a time-limit.

(7) The use of the additive 'sodium ferrocyanide' as a member of the group of binders, anti-caking agents and coagulants was provisionally authorised, for the first time, for all species or categories of animals by Commission Regulation (EC) No 256/2002 ([1]). New data were submitted in support of an application for authorisation without time-limit of that additive. 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 additive, as specified in Annex II, should be authorised without a time-limit.

(8) The use of the additive 'potassium ferrocyanide' as a member of the group of binders, anti-caking agents and coagulants was provisionally authorised, for the first time, for all species or categories of animals by Regulation (EC) No 256/2002. New data were submitted in support of an application for authorisation without time-limit of that additive. 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 additive, as specified in Annex II, should be authorised without a time-limit.

(9) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10 W) was provisionally authorised for the first time for laying hens, by Commission Regulation (EC) No 418/2001 ([2]). New data were submitted in support of an application for authorisation without a time-limit of that enzyme 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 enzyme preparation, as specified in Annex III, should be authorised without a time-limit.

(10) The use of the micro-organism preparation of *Enterococcus faecium* (NCIMB 11181) was authorised without a time-limit for calves and for piglets by Commission Regulation (EC) No 1333/2004 ([3]). New data were submitted in support of an application to extend the authorisation of the use of that micro-organism preparation to chickens for fattening. The European Food Safety Authority (EFSA) delivered a favourable opinion on 13 April 2005 on the safety of that additive when used in the animal category chickens for fattening, under the conditions of use set out in Annex IV to this Regulation. 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 IV, should be provisionally authorised for four years.

(11) The use of the micro-organism preparation of *Enterococcus faecium* (CECT 4515) was provisionally authorised, for the first time, for piglets and for calves by Commission Regulation (EC) No 654/2000 ([4]). New data were submitted in support of an application to extend the authorisation of the use of that micro-organism preparation to chickens for fattening. The EFSA delivered a favourable opinion on 13 April 2005 on the safety of that additive when used in the animal category chickens for fattening, under the conditions of use set out in Annex IV to this Regulation. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for such authorisation

([1]) OJ L 41, 13.2.2002, p. 6.
([2]) OJ L 62, 2.3.2001, p. 3.
([3]) OJ L 247, 21.7.2004, p. 11.
([4]) OJ L 79, 30.3.2000, p. 26. Regulation as amended by Regulation (EC) No 2200/2001 (OJ L 299, 15.11.2001, p. 1).

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are satisfied. Accordingly, the use of that micro-organism preparation as specified in Annex IV, should be provisionally authorised for four years.

(12) 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 [1].

(13) 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:

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Article 2

The additives belonging to the group 'Binders, anti-caking agents and coagulants', as specified in Annex II, are authorised without a time limit for use as additives in animal nutrition under the conditions laid down in that Annex.

Article 3

The preparation belonging to the group 'Enzymes', 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

The preparations belonging to the group 'Micro-organisms', as specified in Annex IV, are authorised provisionally for four years as additives in animal nutrition under the conditions laid down in that Annex.

Article 5

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.

[1] 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).

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			
Growth promoters									
E 800	BASF Aktiengesellschaft	Potassium diformate (Formi LHS)	**Additive composition** Potassium diformate, solid min. 98 % Silicate max. 1,5 % Water max. 0,5 % **Active substance:** Potassium diformate, solid $KH(COOH)_2$ CAS No 20642-05-1	Piglets (weaned)	—	6 000	18 000	For use in weaned piglets until approximately 35 kg	25.11.2015
				Pigs for fattening	—	6 000	12 000	—	25.11.2015

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
					mg/kg of complete feedingstuff			
Binders, anti-caking agents and coagulants								
E 568	Clinoptilolite of sedimentary origin	Hydrated calcium aluminosilicate of sedimentary origin containing at least 80 % clinoptilolite and a maximum 20 % of clay minerals, free of fibres and quartz	Pigs for fattening	—	—	20 000	All feedingstuffs	Without a time-limit
			Chickens for fattening	—	—	20 000	All feedingstuffs	Without a time-limit
			Turkeys for fattening	—	—	20 000	All feedingstuffs	Without a time-limit
			Bovines	—	—	20 000	All feedingstuffs	Without a time-limit
			Salmon	—	—	20 000	All feedingstuffs	Without a time-limit
E 535	Sodium Ferrocyanide	$Na_4[Fe(CN)_6]. 10H_2O$	All species or categories of animals	—	—	—	Maximum content: 80 mg/kg NaCl (calculated as ferrocyanide anion)	Without a time-limit
E 536	Potassium Ferrocyanide	$K_4[Fe(CN)_6]. 3H_2O$	All species or categories of animals	—	—	—	Maximum content: 80 mg/kg NaCl (calculated as ferrocyanide anion)	Without a time-limit

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
					Units of activity/kg of complete feedingstuff			
Enzymes								
E 1613	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10 W) having a minimum activity of: Powder form: 70 000 IFP (1)/g Liquid form: 7 000 IFP/ml	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 kg 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.	Without a time-limit

(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.

ANNEX IV

EC No or 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								
15	*Enterococcus faecium* NCIMB 11181	Preparation of *Enterococcus faecium* containing a minimum of: Powder form: 4×10^{11} CFU/g additive Coated form: 5×10^{10} CFU/g additive	Chickens for fattening	—	$2{,}5 \times 10^{8}$	15×10^{9}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	25.11.2009
18	*Enterococcus faecium* CECT 4515	Preparation of *Enterococcus faecium* containing a minimum of: 1×10^{9} CFU/g additives	Chickens for fattening	—	1×10^{9}	1×10^{9}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	25.11.2009