COMMISSION REGULATION (EC) No 1520/2007

of 19 December 2007

concerning 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 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 microorganism preparation of *Saccharomyces cerevisiae* (MUCL 39885) was provisionally authorised for the first time for dairy cows by Commission Regulation (EC) No 879/2004 [3]. New data were submitted in support of an application for authorisation without a time limit of that microorganism preparation for dairy cows. 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 microorganism preparation, as specified in Annex I to this Regulation, should be authorised without a time limit.

(6) The use of the microorganism preparation of *Enterococcus faecium* (DSM 10663/NCIMB 10415) was provisionally authorised for the first time for turkeys for fattening by Commission Regulation (EC) No 1801/2003 [4]. New data were submitted in support of an application for authorisation without a time limit of that microorganism 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 microorganism preparation, as specified in Annex II to this Regulation, should be authorised without a time limit.

(7) The use of the microorganism preparation of *Enterococcus faecium* (DSM 10663/NCIMB 10415) was provisionally authorised for the first time for dogs by Commission Regulation (EC) No 1288/2004 [5]. New data were submitted in support of an application for authorisation without a time limit of that microorganism 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 microorganism preparation, as specified in Annex III to this Regulation, should be authorised without a time limit.

(8) The use of the microorganism preparation of *Lactobacillus acidophilus* (D2/CSL CECT 4529) was provisionally authorised for the first time for laying hens by Commission Regulation (EC) No 2154/2003 [6]. New data were submitted in support of an application for authorisation without a time limit of that microorganism 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 microorganism preparation, as specified in Annex IV to this Regulation, should be authorised without a time limit.

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[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 162, 30.4.2004, p. 65.

[4] OJ L 264, 15.10.2003, p. 16.

[5] OJ L 243, 15.7.2004, p. 10. Regulation as amended by Regulation (EC) No 1812/2005 (OJ L 291, 5.11.2005, p. 18).

[6] OJ L 324, 11.12.2003, p. 11.

(9) The use of the enzyme preparation of endo-1,4-beta-glucanase, EC 3.2.1.4 produced by *Trichoderma longibrachiatum* (IMI SD 142) was provisionally authorised for the first time for piglets by Commission Regulation (EC) No 1436/98 [1]. 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 V to this Regulation, should be authorised without a time limit.

(10) 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].

(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 'Microorganisms', as specified in Annex I, is authorised without a time limit as an additive in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparation belonging to the group 'Microorganisms', as specified in Annex II, is authorised without a time limit as an additive in animal nutrition under the conditions laid down in that Annex.

Article 3

The preparation belonging to the group 'Microorganisms', as specified in Annex III, is authorised without a time limit as an additive in animal nutrition under the conditions laid down in that Annex.

Article 4

The preparation belonging to the group 'Microorganisms', as specified in Annex IV, is authorised without a time limit as an additive in animal nutrition under the conditions laid down in that Annex.

Article 5

The preparation belonging to the group 'Enzymes', as specified in Annex V, is authorised without a time limit as an additive in animal nutrition under the conditions laid down in that Annex.

Article 6

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.

Done at Brussels, 19 December 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

[1] OJ L 191, 7.7.1998, p. 15.
[2] OJ L 183, 29.6.1989, p. 1. Directive as last amended by Directive 2007/30/EC of the European Parliament and of the Council (OJ L 165, 27.6.2007, p. 21).

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
					CFU/kg of complete feedingstuff			
Micro-organisms								
E 1710	*Saccharomyces cerevisiae* MUCL 39885	Preparation of *Saccharomyces cerevisiae* containing a minimum of: Powder, spheric and oval granulated forms: 1×10^9 CFU/g additive	Dairy cows	—	$1{,}23 \times 10^9$	$2{,}33 \times 10^9$	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. The quantity of *Saccharomyces cerevisiae* in the daily ration must not exceed $8{,}4 \times 10^9$ CFU per 100 kg. Body weight till 600 kg. Over 600 kg add $0{,}9 \times 10^9$ CFU for each additional 100 kg body weight.	Without a time limit

ANNEX II

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			
Microorganisms								
E 1707	*Enterococcus faecium* DSM 10663/ NCIMB 10415	Preparation of *Enterococcus faecium* containing a minimum of: Powder and granulated form: $3,5 \times 10^{10}$ CFU/g additive Coated form: $2,0 \times 10^{10}$ CFU/g additive Liquid form: 1×10^{10} CFU/ml additive	Turkeys for fattening	—	1×10^{7}	$1,0 \times 10^{9}$	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. May be used in compound feed containing the permitted coccidiostats: diclazuril, halofuginone, lasalocid sodium, maduramicin ammonium monensin sodium, robenidine.	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
					CFU/kg of complete feedingstuff			
Microorganisms								
E 1707	*Enterococcus faecium* DSM 10663/ NCIMB 10415	Preparation of *Enterococcus faecium* containing a minimum of: Powder and granulated form: $3,5 \times 10^{10}$ CFU/g additive Coated form: $2,0 \times 10^{10}$ CFU/g additive Liquid form: 1×10^{10} CFU/ml additive	Dogs	—	1×10^{9}	$3,5 \times 10^{10}$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.	Without a time limit

ANNEX IV

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			
Microorganisms								
E 1715	*Lactobacillus acidophilus* D2/CSL CECT 4529	Preparation of *Lactobacillus acidophilus* containing minimum of: 50×10^9 CFU/g additive	Laying hens	—	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.	Without time limit

ANNEX V

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 1616	Endo-1,4-beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (IMI SD 142) having a minimum activity of: Solid form: 2 000 CU [1]/g Liquid form: 2 000 CU/ml	Piglets (weaned)	—	350 CU	—	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: 350-1 000 CU. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley. 4. For use in weaned piglets up to approximately 35 kg.	Without a time limit

[1] 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.