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COMMISSION REGULATION (EC) No 1876/2006

of 18 December 2006

concerning the provisional and permanent authorisation of certain additives in feedingstuffs

(Text with EEA relevance)

(OJ L 360, 19.12.2006, p. 126)

Corrected by:

►**C1** Corrigendum, OJ L 43, 15.2.2007, p. 42 (1876/2006)

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COMMISSION REGULATION (EC) No 1876/2006

of 18 December 2006

concerning the provisional and 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 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 of the use of the micro-organism preparation of *Lactobacillus farciminis* CNCM MA 67/4R for chickens for fattening, turkeys for fattening and laying hens. The European Food Safety Authority (EFSA) expressed its opinion on the use of this preparation on 11 July 2006. 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 I to this Regulation, should be authorised for four years.

(6) Data were submitted in support of an application for authorisation of the use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), subtilisin produced by *Bacillus subtilis* (ATCC 2107), polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) for turkeys for fattening. On 15 June 2006 EFSA 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 9e(1) of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex II to this Regulation, should be authorised for four years.

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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).

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(7) The use of the enzyme preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 74252) was provisionally authorised for the first time for laying hens and piglets by Commission Regulation (EC) No 2188/2002 ([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 III to this Regulation, should be authorised without a time limit.

(8) The use of the preparation of sodium benzoate, propionic acid and sodium propionate was provisionally authorised for the first time for pigs and dairy cows by Commission Regulation (EC) No 1252/2002 ([2]). New data were submitted in support of an application for authorisation without a time limit of that preservative 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 preservative preparation, as specified in Annex IV to this Regulation, should be authorised without a 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 ([3]).

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

Article 2

The preparation belonging to the group ‘Enzymes’, as specified in Annex II, is authorised for four years as an additive 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, 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 ‘Preservatives’, 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.

([1]) OJ L 333, 10.12.2002, p. 5.
([2]) OJ L 183, 12.7. 2002, p. 10.
([3]) 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 5

This Regulation shall enter into force on the 20th 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.

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ANNEX I

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								
12	*Lactobacillus farciminis* CNCM MA 67/4R	Preparation of *Lactobacillus farciminis* containing a minimum of 1×10^9 CFU/g additive	Chickens for fattening Turkeys for fattening Laying hens	—	5×10^8	1×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	►C1 8.1.2011 ◄

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
					Units of activity/kg of complete feedingstuff			
Enzymes								
59	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Subtilisin EC 3.4.21.62 Alpha-amylase EC 3.2.1.1 Polygalacturonase EC 3.2.1.15	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), subtilisin produced by *Bacillus subtilis* (ATCC 2107), polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) having a minimum activity of: Endo-1,4-beta-xylanase: 300 U ([1])/g Endo-1,3(4)-beta-glucanase: 150 U ([2])/g Subtilisin: 4 000 U ([3])/g Alpha-amylase: 400 U ([4])/g Polygalacturonase: 25 U ([5])/g	Turkeys for fattening	—	Endo-1,4-beta-xylanase: 100 U Endo-1,3(4)-beta-glucanase: 50 U Subtilisin: 1 333 U Alpha-amylase: 133 U Polygalac-turonase: 8,3 U	— — — — —	1. In the directions for use of the additive and remixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended dose per kg of complete feedingstuff: — endo-1,4-beta-xylanase: 100-300 U — endo-1,3(4)-beta-glucanase: 50-150 U — subtilisin: 1 333-4 000 U — alpha-amylase: 133-400 U — polygalacturonase: 8,3-25 U 3. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans).	►C1 8.1.2011 ◄

([1]) 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.
([2]) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5,0 and 30 °C.
([3]) 1 U is the amount of enzyme which liberates 1 micromole of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7,5 and 40 °C.
([4]) 1 U is the amount of enzyme which liberates 1 micromole of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 6,5 and 37 °C.
([5]) 1 U is the amount of enzyme which liberates 1 micromole of reducing material (galacturonic acid equivalents) from a poly D-galacturonic substrate per minute at pH 5,0 and 40 °C.

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 1602	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 *Trichoderma longibrachiatum* (ATCC 74 252) having a minimum activity of: Liquid and Granular Form: Endo-1,4-beta-glucanase: 8 000 U ([1])/ml or g Endo-1,3(4)-beta-glucanase: 18 000 U ([2])/ml or g Endo-1,4-beta-xylanase: 26 000 U ([3])/ml or g	Laying hens	—	Endo-1,4-beta-glucanase: 640 U Endo-1,3(4)-beta-glucanase: 1 440 U Endo-1,4-beta-xylanase: 2 080 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: 640-800 U — Endo-1,3(4)-beta-glucanase: 1 440-1 800 U — Endo-1,4-beta-xylanase: 2 080-2 600 U 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and betaglucans), containing more than 30 % wheat, triticale or barley.	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 (weaned)	—	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 betaglucans). 4. For use in weaned piglets until approximately 35 kg.	

([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.

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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
					mg/kg of cereal			
Preservatives								
E 700	Sodium benzoate 140 g/kg Propionic acid 370 g/kg Sodium propionate 110 g/kg	Composition of the additive: Sodium benzoate: 140 g/kg Propionic acid: 370 g/kg Sodium propionate: 110 g/kg Water: 380 g/kg	Pigs	—	3 000	22 000	For the preservation of cereal with a humidity content of more than 15 %	Without a time limit
		Active ingredients: Sodium benzoate $C_7H_5O_2Na$ Propionic acid $C_3H_6O_2$ Sodium propionate $C_3H_5O_2Na$	Dairy cows		3 000	22 000	For the preservation of cereal with a humidity content of more than 15 %	