

COMMISSION REGULATION (EC) No 1812/2005

of 4 November 2005

amending Regulations (EC) Nos 490/2004, 1288/2004, 521/2005 and 833/2005 as regards the conditions for the authorisation of certain additives in feedingstuffs belonging to the groups of enzymes and micro-organisms

(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 use of the micro-organism preparation No 5 of *Saccharomyces cerevisiae* (CBS 493.94) has been authorised

for horses provisionally for four years by Commission Regulation (EC) No 490/2004 ⁽³⁾. New data were submitted in support of an increase of the Colony Forming Units minimum content of this preparation in the column 'chemical formula, description' without changing the maximum, minimum or recommended contents in complete feedingstuffs in the conditions of authorisation. 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 I, should be authorised until 20 March 2008.

- (6) The use of the micro-organism preparation No E 1704 of *Saccharomyces cerevisiae* (CBS 493.94) has been authorised for calves and cattle for fattening without a time-limit by Commission Regulation (EC) No 1288/2004 ⁽⁴⁾. New data were submitted in support of an increase of the Colony Forming Units minimum content of this preparation in the column 'chemical formula, description' without changing the maximum, minimum or recommended contents in complete feedingstuffs in the conditions of authorisation. 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 II, should be authorised without a time-limit.
- (7) The use of the enzyme preparation No E 1623 of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) has been authorised for chickens for fattening without a time-limit by Commission Regulation (EC) No 521/2005 ⁽⁵⁾. New data were submitted in support of a change of the minimum enzyme activity in this preparation as described in the column 'chemical formula, description' without changing the maximum, minimum or recommended contents in complete feedingstuffs in the conditions of authorisation. 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.

⁽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 79, 17.3.2004, p. 23.

⁽⁴⁾ OJ L 243, 15.7.2004, p. 10.

⁽⁵⁾ OJ L 84, 2.4.2005, p. 3.

- (8) The use of the enzyme preparation No E 1627 of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) has been authorised for pigs for fattening without a time-limit by Commission Regulation (EC) No 833/2005 ⁽¹⁾. New data were submitted in support of a change in the formulation of this preparation as described in the column 'chemical formula, description' without changing the maximum, minimum or recommended contents in complete feedingstuffs in the conditions of authorisation. 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 IV, should be authorised without a time-limit.
- (9) Regulations (EC) Nos 490/2004, 1288/2004, 521/2005 and 833/2005 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 490/2004 is replaced by Annex I to this Regulation.

Article 2

Annex I to Regulation (EC) No 1288/2004 is amended in accordance with Annex II to this Regulation.

Article 3

Annex I to Regulation (EC) No 521/2005 is replaced by Annex III to this Regulation.

Article 4

The Annex to Regulation (EC) No 833/2005 is amended in accordance with Annex IV to this Regulation.

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.

Done at Brussels, 4 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ OJ L 138, 1.6.2005, p. 5.

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									
5	<i>Saccharomyces cerevisiae</i> CBS 493,94	Preparation of <i>Saccharomyces cerevisiae</i> containing a minimum of 1×10^9 CFU/g additive	Horses	—	4×10^9	$2,5 \times 10^{10}$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. The quantity of <i>Saccharomyces cerevisiae</i> in the daily ration must not exceed $4,17 \times 10^{10}$ CFU for 100 kg of body weight. Use permitted from two months post weaning onwards.	20.3.2008	

ANNEX II

In Annex I to Regulation (EC) No 1288/2004, the entry for E 1704 is replaced by the following:

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								
E 1704	Saccharomyces cerevisiae CBS 493,94	Preparation of Saccharomyces cerevisiae containing a minimum of 1 × 10 ⁹ CFU/g additive	Calves	6 months	2 × 10 ⁸	2 × 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
			Cattle for fattening	—	1,7 × 10 ⁸	1,7 × 10 ⁸	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. The quantity of Saccharomyces cerevisiae in the daily ration must not exceed 7,5 × 10 ⁸ CFU for 100 kg body weight. Add 1 × 10 ⁸ CFU for each additional 100 kg of body weight.	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 feedstuff			
Enzymes								
E 1623	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106), endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2105) and subtilisin produced by <i>Bacillus subtilis</i> (ATCC 2107) having a minimum activity of: endo-1,3(4)-beta-glucanase: 200 U ⁽¹⁾ /g endo-1,4-beta-xylanase: 5 000 U ⁽²⁾ /g subtilisin: 1 600 U ⁽³⁾ /g	Chickens for fattening	—	endo-1,3(4)-beta-glucanase: 25 U endo-1,4-beta-xylanase: 625 U subtilisin: 200 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 feedstuff: endo-1,3(4)-beta-glucanase: 25-100 U endo-1,4-beta-xylanase: 625-2 500 U subtilisin: 200-800 U. 3. For use in compound feed, e.g. containing more than 30 % wheat and 10 % barley.	Without a time-limit

⁽¹⁾ 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.

⁽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.

⁽³⁾ 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7.5 and 40 °C.

⁽¹⁾ 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.

⁽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.

⁽³⁾ 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7.5 and 40 °C.

ANNEX IV

In the Annex to Regulation (EC) No 833/2005, the entry for E 1627 is replaced by the following:

E 1627	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106) and endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2105) having a minimum activity of: powder form: endo-1,3(4)-beta-glucanase: 800 U ⁽¹⁾ /g endo-1,4-beta-xylanase: 800 U ⁽²⁾ /g liquid form: endo-1,3(4)-beta-glucanase: 800 U/ml endo-1,4-beta-xylanase: 800 U/ml	Pigs for fattening	—	endo-1,3(4)-beta-glucanase: 400 U endo-1,4-beta-xylanase: 400 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-1,3(4)-beta-glucanase: 400 U endo-1,4-beta-xylanase: 400 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans) e.g. containing more than 65 % barley.	Without a time-limit
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⁽¹⁾ 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.
⁽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.