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COMMISSION REGULATION (EC) No 943/2005

of 21 June 2005

concerning the permanent authorisation of additives in feedingstuffs

(Text with EEA relevance)

(OJ L 159, 22.6.2005, p. 6)

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COMMISSION REGULATION (EC) No 943/2005

of 21 June 2005

concerning the permanent authorisation of 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 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 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 of *Enterococcus faecium* (NCIMB 10415) was provisionally authorised, for the first time, for chickens for fattening and for pigs for fattening by the Commission Regulation (EC) No 866/1999 ([3]). New data were submitted in support of an application for authorisation without time-limit of that micro-organism 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 micro-organism preparation, as specified in Annex I, 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 amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).
([3]) OJ L 108, 27.4.1999, p. 21.

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(6) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Penicillium funiculosum* (IMI SD 101) was provisionally authorised for the first time for laying hens and for turkeys for fattening, by Commission Regulation (EC) No 418/2001 ([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 II, should be authorised without a time-limit.

(7) 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 turkeys for fattening, by Regulation (EC) No 418/2001. 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 II, should be authorised without a time-limit.

(8) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and *subtilisin* produced by *Bacillus subtilis* (ATCC 2107) was provisionally authorised for the first time for chickens for fattening, by Commission Regulation (EC) No 1636/1999 ([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 II, should be authorised without a time-limit.

(9) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta- xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) was provisionally authorised for the first time for chickens for fattening, by Regulation (EC) No 1636/1999. 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 II, should be authorised without a time-limit.

([1]) OJ L 62, 2.3.2001, p. 3.
([2]) OJ L 194, 27.7.1999, p. 17.

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(10) The use of the enzyme preparation of 3-phytase produced by *Trichoderma reesei* (CBS 528.94) was provisionally authorised for the first time for piglets (weaned) and for pigs for fattening, by Commission Regulation (EC) No 2374/98 ([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 II, should be authorised without a time-limit.

(11) The assessment of those 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]).

(12) 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 use without a time-limit as an additive in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparations belonging to the group 'Enzymes', as specified in Annex II, are authorised for use without a time-limit as additives in animal nutrition under the conditions laid down in that Annex.

Article 3

This Regulation shall enter into force on the third 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.

([1]) OJ L 295, 4.11.1998, p. 3.
([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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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 1705		*Enterococcus faecium* NCIMB 10415	Preparation of *Enterococcus faecium* containing a minimum of: Microencapsulated form: $1,0 \times 10^{10}$ CFU/g of additive; Granulated form: $3,5 \times 10^{10}$ CFU/g additive	Pigs for fattening	—	$0,35 \times 10^{9}$	$1,0 \times 10^{9}$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	Without a time limit

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
					Units of activity/kg of complete feedingstuff			
Enzymes								
E 1604	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 and endo-1,4-beta-xylanase produced by *Penicillium funiculosum* (IMI SD 101) having a minimum activity of: Powder form: endo-1,3(4)-beta-glucanase: 2 000 U ([1])/g endo-1,4-beta-xylanase: 1 400 U ([2])/g Liquid form: endo-1,3(4)-beta-glucanase: 500 U/ml endo-1,4-beta-xylanase: 350 U/ml	Laying hens	—	Endo-1,3(4)-beta-glucanase: 100 U Endo-1,4-beta-xylanase: 70 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: 100 U endo-1,4-beta-xylanase: 70 U 3. For use in compound feed rich in non-starch polysaccharides, (mainly beta-glucans and arabinoxylans), e.g. containing more than 60 % barley or 30 % wheat.	Without a time-limit
			Turkeys for fattening	—	Endo-1,3(4)-beta-glucanase: 100 U Endo-1,4-beta-xylanase: 70 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: 100 U endo-1,4-beta-xylanase: 70 U 3. For use in compound feed rich in non-starch polysaccharides, (mainly beta-glucans and arabinoxylans), e.g. containing more than 30 % barley or 20 % wheat.	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 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 ([3])/g Powder form: 7 000 IFP/ml	Turkeys for fattening	—	1 400 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: 1 400 IFP 3. For use in compound feed rich in non-starch polysaccharides (mainly arabin-oxylans), e.g. containing more than 38 % wheat.	Without a time-limit
E 1630	Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) with a minimum activity of: endo-1,4-beta-xylanase: 5 000 U ([4])/g subtilisin: 1 600 U ([5])/g	Chickens for fattening	—	Endo-1,4-beta-xylanase: 500 U Subtilisin: 160 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: 500-2 500 U subtilisin: 160-800 U 3. For use in compound feed e.g. containing more than 65 % wheat.	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 1631	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 *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) having a minimum activity of: endo-1,3(4)-beta-glucanase: 300 U ([6])/g endo-1,4-beta-xylanase: 300 U ([7])/g	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 300 U Endo-1,4-beta-xylanase: 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 dose per kg of complete feedingstuff: endo-1,3(4)-beta-glucanase: 300 U endo-1,4-beta-xylanase: 300 U. 3. For use in compound feed rich in non-starch polysaccharides, (mainly beta-glucans and arabinoxylans), e.g. containing more than 40 % barley.	Without a time-limit
E 1632	3-phytase EC 3.1.3.8	Preparation of 3-phytase produced by *Trichoderma reesei* (CBS 528.94) having a minimum activity of: Solid form: 5 000 PPU ([8])/g Liquid form: 5 000 PPU/g	Piglets (weaned)	—	250 PPU	—	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: 250-750 PPU 3. For use in compound feed containing more than 0,25 % phytin bound phosphorus. 4. For weaned piglets up to approximately 35 kg.	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			
			Pigs for fattening	—	250 PPU	—	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: 250-750 PPU 3. For use in compound feed containing more than 0,23 % phytin bound phosphorus.	Without a time-limit

([1]) 1 U is the amount of enzyme which liberates 5,55 micromoles of reducing sugars (maltose equivalents) from barley beta-glucan per minute at pH 5,0 and 50 °C.
([2]) 1 U is the amount of enzyme which liberates 4,00 micromoles of reducing sugars (maltose equivalents) from birchwood xylan per minute at pH 5,5 and 50 °C.
([3]) 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.
([4]) 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.
([5]) 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.
([6]) 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.
([7]) 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.
([8]) 1 PPU is the amount of enzyme which liberates 1 micromole of inorganic phosphate from sodium phytate per minute at pH 5 and 37 °C.