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COMMISSION REGULATION (EC) No 1259/2004

of 8 July 2004

concerning the permanent authorisation of certain additives already authorised in feedingstuffs

(Text with EEA relevance)

(OJ L 239, 9.7.2004, p. 8)

Amended by:

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COMMISSION REGULATION (EC) No 1259/2004

of 8 July 2004

concerning the permanent authorisation 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]), as last amended by Regulation (EC) No 1756/2002 ([2]), and in particular Articles 3 and 9d(1) thereof,

Whereas:

(1) Directive 70/524/EEC provides that no additive may be put into circulation unless a Community authorisation has been granted.

(2) In the case of additives referred to in part II of Annex C to Directive 70/524/EEC, which includes micro-organisms and enzymes, authorisation without a time limit of an additive already authorised may be given if the conditions laid down in Article 3(a) are satisfied.

(3) The use of the micro-organism preparation of *Enterococcus faecium* (DSM 10663/NCIMB 10415) was provisionally authorised, for the first time, for chickens for fattening by Commission Regulation (EC) No 1636/1999 ([3]).

(4) New data were submitted in support of the application for authorisation without a time limit of this micro-organism.

(5) The assessment of the application for authorisation submitted in respect of this micro-organism, shows that the conditions provided for in Directive 70/524/EEC for authorisation without a time limit are satisfied.

(6) The use of this micro-organism for chickens for fattening, specified in Annex I, should therefore be authorised without a time limit.

(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 74 252) was provisionally authorised, for the first time, for chickens for fattening in liquid form by Commission Regulation (EC) No 1436/1998 ([4]), and in granular form by Commission Regulation (EC) No 937/2001 ([5]).

([1]) OJ L 270, 14.12.1970, p. 1.
([2]) OJ L 265, 3.10.2002, p. 1.
([3]) OJ L 194, 27.7.1999, p. 17.
([4]) OJ L 191, 7.7.1998, p. 15.
([5]) OJ L 130, 12.5.2001, p. 25.

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(8) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94) was provisionally authorised, for the first time, for chickens for fattening by Commission Regulation (EC) No 654/2000 ([1]).

(9) The use of the enzyme preparation 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 chickens for fattening by Commission Regulation (EC) No 866/1999 ([2]).

(10) The use of the enzyme preparation endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 520.94) was provisionally authorised, for the first time, for chickens for fattening by Commission Regulation (EC) No 1436/1998 ([3]).

(11) The use of the enzyme preparation endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG-S 15136) was provisionally authorised, for the first time, for chickens for fattening in solid form by Commission Regulation (EC) No 1353/2000 ([4]) and in liquid form by Commission Regulation (EC) No 2188/2002 ([5]).

(12) New data were submitted in support of the applications for authorisation without a time limit of each of these enzyme preparations.

(13) The assessment of the applications for authorisation submitted in respect of each of these enzyme preparations, shows that the conditions provided for in Directive 70/524/EEC for authorisation without time limit are satisfied.

(14) The use of these enzyme preparations for chickens for fattening under the conditions set out in Annexes II, III, IV, V and VI should therefore be authorised without a time limit.

(15) 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 ([6]), as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([7]).

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

([1]) OJ L 79, 30.3.2000, p. 26.
([2]) OJ L 108, 27.4.1999, p. 21.
([3]) OJ L 191, 7.7.1998, p. 15.
([4]) OJ L 155, 28.6.2000, p. 15.
([5]) OJ L 333, 10.12.2002, p. 5.
([6]) OJ L 183, 29.6.1989, p. 1.
([7]) OJ L 284, 31.10.2003, p. 1.

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HAS ADOPTED THIS REGULATION:

Article 1

The preparation belonging to the group ‘micro-organisms’ as set out in Annex I is authorised for use as additive in animal nutrition under the conditions laid down in that Annex.

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Article 2

The preparations belonging to the group ‘Enzymes’, as set out in Annexes III, IV, V and VI are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in those Annexes.

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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

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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 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	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 May be used in compound feed containing the permitted coccidiostats: diclazuril, halofuginone, lasalocid sodium, maduramicin ammonium, monensin sodium, robenidine	Without a time limit

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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 1603	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94) having a minimum activity of: coated form: 50 FBG ([1])/g liquid form: 120 FBG/ml	Chickens for fattening	—	10 FBG	—	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: 15-20 FBG 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 60 % vegetable ingredients (maize, lupin, wheat, barley, soya, rice, oilseed rape or peas)	Without a time limit

([1]) 1 FBG 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 ºC.

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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
					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	Chickens 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-glucan and arabinoxylans), e.g. containing more than 50 % barley or 60 % wheat	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.

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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 1605	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 520.94) having a minimum activity of: solid form: Endo-1,4-beta-xylanase: 600 U ([1])/g liquid form: Endo-1,4-beta-xylanase: 300 U/ml	Chickens for fattening	—	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-1,4-beta-xylanase: 300-600 U 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 50 % wheat	Without a time limit

([1]) 1 U is the amount of enzyme which liberates 1 micromole of xylose from birchwood xylan per minute at pH 5,3 and 50 °C.

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ANNEX VI

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 1606	Endo-1,4-beta-xilanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG-S 15136) having a minimum activity of: Solid and liquid form: 100 IU ([1])/g or ml	Chickens for fattening	—	10 IU	—	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: 10 IU 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 IU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 4,5 and 30 °C.