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COMMISSION REGULATION (EC) No 1453/2004

of 16 August 2004

concerning the permanent authorisation of certain additives in feedingstuffs

(Text with EEA relevance)

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COMMISSION REGULATION (EC) No 1453/2004

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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 Article 3 and Article 9d(1) thereof,

Whereas:

(1) Directive 70/524/EEC provides for the authorisation of additives to be used in the Community. The additives referred to in Part II of Annex C to that Directive may be authorised without a time limit subject to certain conditions being satisfied.

(2) The use of the micro-organism preparation of *Bacillus licheniformis* (DSM 5749) and *Bacillus subtilis* (DSM 5750) was provisionally authorised, for the first time, for sows, by Commission Regulation (EC) No 2437/2000 [2].

(3) New data were submitted in support of the application for authorisation without a time limit of that preparation. The assessment shows that the conditions laid down in Directive 70/524/EEC for such authorisation are satisfied.

(4) Accordingly, the use of that preparation for sows, as specified in the Annex I, should be authorised without a time limit.

(5) The use of the micro-organism preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I–1012) was provisionally authorised, for the first time, for pigs for fattening by Commission Directive 94/17/EC [3].

[1] OJ L 270, 14.12.1970, p. 1 Directive as last amended by Commission Regulation (EC) No 1289/2004 (OJ L 243, 15.7.2004, p. 15).
[2] OJ L 280, 4.11.2000, p. 28.
[3] OJ L 105, 26.4.1994, p. 19.

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(6) The Scientific Committee on Animal Nutrition (SCAN), in its report on *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I–1012) adopted on 5 December 2001, confirmed that preparation, when used in the animal categories piglets, pigs for fattening and sows, satisfies the conditions of Article 3a(b) of Directive 70/524/EEC. The SCAN report also concluded favourably on the efficacy of that preparation when used in the animal categories piglets to two months and sows.

(7) New data were submitted in support of the application for authorisation without a time limit of that preparation.

(8) The European Food Safety Authority (EFSA) was asked to issue on opinion on the efficacy of that preparation when used as feed additive for pigs for fattening. In its opinion adopted on 7 May 2004, the EFSA concluded favourably on the efficacy regarding that preparation and the whole assessment shows that the conditions laid down in Directive 70/524/EEC for such authorisation are satisfied.

(9) Accordingly, the use of that preparation for pigs for fattening, as specified in Annex I, should be authorised without a time limit.

(10) The use of the enzyme preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 600.94) set out in the first row of Annex II was provisionally authorised, for the first time, for chickens for fattening, turkeys for fattening and piglets by Commission Regulation (EC) No 654/2000 ([1]).

(11) The use of the enzyme preparation of endo-1,4-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 600.94) set out in the second row of Annex II was provisionally authorised, for the first time, for chickens for fattening, by Commission Regulation (EC) No 654/2000.

(12) 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) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) was provisionally authorised, for the first time, for pigs for fattening by Commission Regulation (EC) No 2690/1999 ([2]).

([1]) OJ L 79, 30.3.2000, p. 26.
([2]) OJ L 326, 18.12.1999, p. 33.

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(13) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger (phoenicis)* (NRRL 25541) and of alpha-amylase produced by *Aspergillus oryzae* (ATCC 66222) was provisionally authorised, for the first time, for piglets by Commission Regulation (EC) No 1636/1999 ([1]).

(14) The use of the enzyme preparation of endo-1,4-beta-xylanase, produced from *Trichoderma longibrachiatum* (CNCM MA 6–10W) was provisionally authorised, for the first time, for chickens for fattening by Commission Regulation (EC) No 1436/98 ([2]).

(15) New data were submitted in support of the application for authorisation without a time limit of those five enzyme preparations. The assessment shows that the conditions laid down in Directive 70/524/EEC for such authorisation are satisfied.

(16) Accordingly, the use of those five enzyme preparations as specified in Annex II, should be authorised without a time limit.

(17) The assessment of those seven 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]).

(18) 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 preparations belonging to the groups 'Micro-organisms' and 'Enzymes', as set out in Annexes I and II are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in those Annexes.

Article 2

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 194, 27.7.1999, p. 17.
([2]) OJ L 191, 7.7.1998, p. 15.
([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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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 feeding-stuff			
Micro-organisms								
E 1700	*Bacillus licheniformis* DSM 5749 *Bacillus subtilis* DSM 5750 (In 1/1 ratio)	Mixture of *Bacillus licheniformis* and *Bacillus subtilis* containing a minimum of: $3{,}2 \times 10^9$ CFU/g additive ($1{,}6 \times 10^9$ CFU/g additive of each bacterium)	Sows	—	$1{,}28 \times 10^9$	$1{,}28 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. For sows two weeks before farrowing and during the lactation.	Without a time limit
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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 1609	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,4-beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 600.94) having minimum activities of: Coated form: Endo-1,4-beta-xylanase: 36 000 FXU ([1])/g Endo-1,4-beta-glucanase: 15 000 BGU ([2])/g Liquid form: Endo-1,4-beta-xylanase: 36 000 FXU/ml Endo-1,4-beta-glucanase: 15 000 BGU/ml Solid form: Endo-1,4-beta-xylanase: 36 000 FXU/g Endo-1,4-beta-glucanase: 15 000 BGU/g	Chickens for fattening	—	4 860 FXU	—	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: 4 860–6 000 FXU 2 025–2 500 BGU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabino-xylans and beta-glucans), e.g. containing more than 35 % barley and 20 % wheat.	Without a time limit
					2 025 BGU	—		
			Turkeys for fattening	—	6 000 FXU	—	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: 6 000 FXU 2 500 BGU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabino-xylans and beta-glucans), e.g. containing more than 40 % wheat.	Without a time limit
					2 500 BGU	—		

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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)	—	6 000 FXU	—	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: 6 000 FXU 2 500 BGU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabino-xylans and beta-glucans), e.g. containing more than 30 % wheat and 30 % barley. 4. For use in weaned piglets until approximately 35 kg.	Without a time limit
					2 500 BGU	—		
E 1610	Endo-1,4-beta-glucanase EC 3.2.1.4 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 600.94) having minimum activities of: Coated form: Endo-1,4-beta-glucanase: 10 000 BGU/ ([3])g Endo-1,4-beta-xylanase: 4 000 FXU ([4])/g Liquid form: Endo-1,4-beta-glucanase: 20 000 BGU/ml Endo-1,4-beta-xylanase: 8 000 FXU/ml Solid form: Endo-1,4-beta-glucanase: 20 000 BGU/g Endo-1,4-beta-xylanase: 8 000 FXU/g	Chickens for fattening	—	5 000 BGU	—	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: 5 000–10 000 BGU 2 000–4 000 FXU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabino-xylans and beta-glucans), e.g. containing more than 60 % barley.	Without a time limit
					2 000 FXU	—		

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EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content / Maximum content Units of activity/kg of complete feedingstuff		Other provisions	End of period of authorisation
E 1611	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Polygalacturonase EC 3.2.1.15	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) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 400 U ([5])/g Endo-1,4-beta-xylanase: 400 U ([6])/g Polygalacturonase: 50 U ([7])/g	Pigs for fattening	—	endo-1,3(4)-beta-glucanase: 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 polygalacturonase: 50 U. 3. For use in compound feed containing cereals rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % barley.	Without a time limit
					endo-1,4-beta-xylanase: 400 U	—		
					polygalacturonase: 50 U	—		
E 1612	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Alpha-amylase EC 3.2.1.1	Preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger (phoenicis)* (NRRL 25541) and of alpha-amylase produced by *Aspergillus oryzae* (ATCC 66222) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 275 U ([8])/g Endo-1,4-beta-xylanase: 400 U ([9])/g Alpha-amylase: 3 100 U ([10])/g	Piglets (weaned)	—	endo-1,3(4)-beta-glucanase: 138 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: 138 U endo-1,4-beta-xylanase: 200 U alpha-amylase: 1 550 U 3. For use in compound feeds rich in starch and non-starch polysaccharides, for example mixed diets containing barley, maize, wheat. 4. For use in weaned piglets until approximately 35 kg.	Without a time limit
					endo-1,4-beta-xylanase: 200 U	—		
					alpha-amylase: 1 550 U	—		

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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 from *Trichoderma longibrachiatum* (CNCM MA 6 - 10W), having a minimum activity of: Powder form: 70 000 IFP ([11])/g Liquid form: 7 000 IFP/ml	Chickens for fattening	—	1 050 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 feeds rich in non-starch polysaccharides (mainly arabinoxylans), for example more than 40 % wheat.	Without a time limit

([1]) 1 FXU is the amount of enzyme which liberates 0,15 micromoles of xylose from azurine-cross-linked xylan per minute at pH 5,0 and 40 °C.
([2]) 1 BGU is the amount of enzyme which liberates 0,15 micromoles of xylose from azurine-cross-linked beta-glucan per minute at pH 5,0 and 40 °C.
([3]) 1 BGU is the amount of enzyme which liberates 0,15 micromoles of xylose from azurine-cross-linked beta-glucan per minute at pH 5,0 and 40 °C.
([4]) 1 FXU is the amount of enzyme which liberates 0,15 micromoles of xylose from azurine-cross-linked xylan per minute at pH 5,0 and 40 °C.
([5]) 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.
([6]) 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.
([7]) 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.
([8]) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from oat beta-glucan per minute at pH 5,0 and 40 °C.
([9]) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from oat xylan per minute at pH 4,0 and 30 °C.
([10]) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from wheat starch per minute at pH 4,0 and 30 °C.
([11]) 1 IFP is the quantity of enzyme which liberates 1 micromole of reducing sugars (measured as xylose equivalent) from oat xylan per minute at pH 4,8 and 50 °C.