COMMISSION REGULATION (EC) No 2148/2004

of 16 December 2004

concerning the permanent and provisional authorisations of certain additives and the authorisation of new uses of an additive 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], and in particular Articles 3 and 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 in the European Union.

(2) Article 25 of Regulation (EC) No 1831/2003 lays down the transitional measures for applications for authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of that Regulation.

(3) The applications for authorisation of additives listed in the annexes to this Regulation were submitted before the date of application of Regulation (EC) No 1831/2003.

(4) Initial comments by Member States on these applications were issued under Article 4(4) of Directive 70/524/EEC have been forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. Such applications therefore shall continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

(5) The use of the product, clinoptilolite of volcanic origin, as feed additive belonging to the category of 'binders, anti-caking agents and coagulants', was provisionally authorised, for the first time, for pigs, rabbits and poultry by Commission Regulation (EC) No 1245/1999 [3].

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

(7) Accordingly, the use of this product, clinoptilolite of volcanic origin, should be authorised without a time limit, under certain conditions set out in Annex I to this Regulation.

(8) The use of the micro-organism preparation of *Bacillus licheniformis* (DSM 5749) and *Bacillus subtilis* (DSM 5750) was provisionally authorised for pigs for fattening and without a time limit for piglets by Commission Regulation (EC) No 2437/2000 [4].

(9) New data were submitted in support of the application for authorisation without a time limit of that micro-organism preparation for pigs for fattening. The assessment shows that the conditions laid down in Directive 70/524/EEC for such authorisation are satisfied. New data were submitted in support of the application to modify the maximum age of that micro-organism preparation for piglets. The assessment shows that the conditions for such modification of the authorisation are satisfied.

(10) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (NCYC Sc 47) was provisionally authorised, for the first time, for piglets by Commission Regulation (EC) No 1436/98 [5].

(11) The use of the micro-organism preparation of *Enterococcus faecium* (DSM 7134) and *Lactobacillus rhamnosus* (DSM 7133) was provisionally authorised, for the first time, for piglets by Commission Regulation (EC) No 2690/99 [6].

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

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[1] OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation 1800/2004 (OJ L 317, 16.10.2004, p. 37).
[2] OJ L 268, 18.10.2003, p. 29.
[3] OJ L 150, 17.6.1999, p. 15.
[4] OJ L 280, 4.11.2000, p. 28.
[5] OJ L 191, 7.7.1998, p. 15.
[6] OJ L 326, 18.12.1999, p. 33.

(13) Accordingly, the use of those three micro-organism preparations, as specified in Annex II, should be authorised without a time limit.

(14) Data were submitted in support of an application to obtain an authorisation for a new additive belonging to the group micro-organisms, *Kluyveromyces marxianus* variety *lactisK1* (BCCM/MUCL 39434) for dairy cows.

(15) The assessment of the application for authorisation submitted, in respect of the micro-organism preparation specified in Annex III to this Regulation, shows that the conditions referred to in Article 9e(1) of Directive 70/524/EEC are satisfied.

(16) The Scientific Committee on Animal Nutrition (SCAN) has delivered an opinion on the use of this additive in feedingstuffs 'Opinion on the use of certain micro-organisms as additives in feedingstuffs' on 25 April 2003, which concludes that this additive does not present a risk to animal health, human health or the environment, under the conditions set out in Annex III to this Regulation.

(17) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10 W) was provisionally authorised for the first time for chickens for fattening by Commission Regulation (EC) No 1436/98.

(18) The use of the enzyme preparation of endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (IMI SD 142) was provisionally authorised for the first time for chickens for fattening, by Regulation (EC) No 1436/98 (liquid form) and by Commission Regulation (EC) No 1353/2000 [1] (solid form).

(19) The use of the enzyme preparation of 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 1436/98 (liquid form) and by Regulation (EC) No 1353/2000 (solid form).

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

(21) Accordingly, the use of those three enzyme preparations as specified in Annex IV, should be authorised without a time limit.

(22) 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) is authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 1259/2004 [2]. The use of this preparation was provisionally authorised for turkeys for fattening, for laying hens and for pigs for fattening by Commission Regulation (EC) No 418/2001 [3].

(23) New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to piglets and ducks for fattening.

(24) The European Food Safety Authority (EFSA) has delivered an opinion on the use of this preparation which concludes that this preparation does not present a risk for these additional animal categories, under the conditions set out in Annex V to this Regulation.

(25) The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for an authorisation of such preparation have been satisfied.

(26) Accordingly, the use of this enzyme preparation as specified in Annex V, should be provisionally authorised for four years.

(27) 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 [4].

(28) 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 155, 28.6.2000 p. 15.

[2] OJ L 239, 9.7.2004, p. 8.

[3] OJ L 62, 2.3.2001, p. 3.

[4] OJ L 183, 29.6.1989, p. 1.

HAS ADOPTED THIS REGULATION

Article 1

The preparation belonging to the group 'Binders, anti-caking agents and coagulants', is authorised for use without a time limit as additive in animal nutrition under the conditions laid down in Annex I.

Article 2

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

Article 3

The preparation belonging to the group 'Micro-organisms', is authorised provisionally for four years as additive in animal nutrition under the conditions laid down in Annex III.

Article 4

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

Article 5

The preparation belonging to the group 'Enzymes', is authorised provisionally for four years as additive in animal nutrition under the conditions laid down in Annex V.

Article 6

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.

Done at Brussels, 16 December 2004.

For the Commission
Markos KYPRIANOU
Member of the Commission

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
					mg/kg of complete feedingstuff			
Binders, anti-caking agents and coagulants								
E 567	Clinoptilolite of volcanic origin	Calcium hydrated aluminosilicate of volcanic origin containing a minimum of 85 % of clinoptilolite and a maximum of 15 % of feldspar, micas and clays free of fibres and quartz Maximum lead content: 80 mg/kg	Pigs	—	—	20 000	All feedingstuffs	Without a time limit
			Rabbits	—	—	20 000	All feedingstuffs	Without a time limit
			Poultry	—	—	20 000	All feedingstuffs	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
					CFU/kg of complete feedingstuff			
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)	Pigs for fattening	—	$1{,}28 \times 10^9$	$1{,}28 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.	Without a time limit
			Piglets	—	$1{,}28 \times 10^9$	$3{,}2 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. For use in piglets until approximately 35 kg.	Without a time limit
E 1702	*Saccharomyces cerevisiae* NCYC Sc 47	Preparation of *Saccharomyces cerevisiae* containing a minimum of: 5×10^9 CFU/g additive	Piglets (weaned)	—	5×10^9	1×10^{10}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. For use in weaned piglets until approximately 35 kg.	Without a time limit
E 1706	*Enterococcus faecium* DSM 7134 *Lactobacillus rhamnosus* DSM 7133	Mixture of: *Enterococcus faecium* containing a minimum of: 7×10^9 CFU/g and of *Lactobacillus rhamnosus* containing a minimum of: 3×10^9 CFU/g	Piglets (weaned)	—	$2{,}5 \times 10^9$	5×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. For use in weaned piglets until approximately 35 kg.	Without a time limit

ANNEX III

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								
24	*Kluyveromyces marxianus* var. *lactisK1* BCCM/MUCL 39434	Preparation of *Kluyveromyces marxianus* var. *lactisK1* having a minimum activity of: $1,0 \times 10^8$ CFU/g	Dairy cows	—	$0,25 \times 10^6$	$1,0 \times 10^6$	In directions for use of the additive and premixture, indicate the storage temperature and storage life. Do not use in pelleted premixture and feedingstuffs. Use in dairy cows, in particular when they are reaching the maximum of daily milk production, for minimum period of 14 days. The amount of daily ration administered to each cow is $1,0 \times 10^7$ CFU.	20 December 2008

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 1615	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10 W) having a minimum activity of: Solid form: 70 000 BGN [1]/g Liquid form: 14 000 BGN/ml	Chickens for fattening	—	1 050 BGN	—	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: 2 800 BGN. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 35 % barley.	Without a time limit
E 1616	Endo-1,4-beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (IMI SD 142) having a minimum activity of: Solid form: 2 000 CU [2]/g Liquid form: 2 000 CU/ml	Chickens for fattening	—	500 CU	—	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: 500-1 000 CU. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley.	Without a time limit

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 1617	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) having a minimum activity of: Solid form: 6 000 EPU [3]/g Liquid form: 6 000 EPU/ml	Chickens for fattening	—	1 500 EPU	—	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: 1 500-3 000 EPU. 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 BGN is the amount of enzyme which liberates 1 micromole of reducing sugar (glucose equivalents) from barley beta-glucan per minute at pH 4,8 and 50 °C.
[2] 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.
[3] 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.

ANNEX V

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								
30 (or 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	Piglets (weaned)		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 30 % barley or 20 % wheat. 4. For weaned piglets up to approximately 35 kg.	20.12.2008

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			
			Ducks 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.	20.12.2008

([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.