COMMISSION REGULATION (EC) No 322/2009

of 20 April 2009

concerning the permanent authorisations 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 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/EEC before the date of application of Regulation (EC) No 1831/2003.

(3) The applications for authorisation of the additives set out 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 enzyme preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) was provisionally authorised for laying hens by Commission Regulation (EC) No 358/2005 [3]. It was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 1259/2004 [4], for piglets (weaned) by Commission Regulation (EC) No 1206/2005 [5], for pigs for fattening and turkeys for fattening by Commission Regulation (EC) No 516/2007 [6] and for 10 years for ducks by Commission Regulation (EC) No 242/2007 [7]. New data were submitted in support of an application for authorisation without a time limit of that enzyme preparation for laying hens. 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 I to this Regulation, should be authorised without a time limit.

(6) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) was provisionally authorised for laying hens, pigs for fattening and weaned piglets by Commission Regulation (EC) No 1436/1998 [8]. It was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 2148/2004 [9], for turkeys for fattening by Commission Regulation (EC) No 828/2007 [10]. New data were submitted in support of an application for authorisation without a time limit of that enzyme preparation for laying hens and weaned piglets. 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 to this Regulation, should be authorised without a time limit.

(7) 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 piglets (weaned) and ducks for fattening by Regulation (EC) No 2148/2004. It was authorised for chickens for fattening without a time limit by Regulation (EC) No 1259/2004, for laying hens and turkeys for fattening by Commission Regulation (EC) No 943/2005 [11] and for pigs for fattening by Regulation (EC) No 1206/2005. New data were submitted in support of an application for authorisation without a time limit of that enzyme preparation for ducks for fattening and weaned piglets. 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 to this Regulation, should be authorised without a time limit.

[1] OJ L 270, 14.12.1970, p. 1.
[2] OJ L 268, 18.10.2003, p. 29.
[3] OJ L 57, 2.3.2005, p. 3.
[4] OJ L 239, 9.7.2004, p. 8.
[5] OJ L 197, 28.7.2005, p. 12.
[6] OJ L 122, 11.5.2007, p. 22.
[7] OJ L 73, 13.3.2007, p. 1.
[8] OJ L 191, 7.7.1998, p. 15.
[9] OJ L 370, 17.12.2004, p. 24.
[10] OJ L 184, 14.7.2007, p. 12.
[11] OJ L 159, 22.6.2005, p. 6.

(8) 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 'Enzymes', as specified in Annex I, is authorised without a time limit as additive in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparation belonging to the group 'Enzymes', as specified in Annex II, is authorised without a time limit as additive in animal nutrition under the conditions laid down in that Annex.

Article 3

The preparation belonging to the group 'Enzymes', as specified in Annex III, is authorised without a time limit as additive in animal nutrition under the conditions laid down in that Annex.

Article 4

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, 20 April 2009.

For the Commission
Androulla VASSILIOU
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
					Units of activity/kg of complete feedingstuff			
Enzymes								
'E 1606	Endo-1,4-beta-xylanase 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	Laying hens	-	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 arabinoxylan, e.g. containing minimum 40 % wheat or barley.	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.'

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 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 [1]/g Liquid form: 6 000 EPU/ml	Laying hens	-	1 050 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: 1 050 – 1 500 EPU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat or maize.	Without a time limit.
			Piglets (weaned)	-	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. 4. For use in weaned piglets until approximately 35 kg	Without a time limit.

[1] 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 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 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 from *Penicillium funiculosum* (IMI SD101) 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	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 betaglucans and arabinoxylans), e.g. containing more than 50 % barley or 60 % wheat.	Without a time limit.
			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 betaglucans and arabinoxylans), e.g. containing more than 30 % barley or 20 % wheat. 4. For use in weaned piglets until approximately 35 kg.	Without a time limit.

(1) 1 U is the amount of enzyme which liberates 5,55 micromoles of reducing sugars (maltose equivalents) from barley betaglucan 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.’