COMMISSION REGULATION (EC) No 828/2007

of 13 July 2007

concerning the permanent and provisional 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 Articles 3, 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.

(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 the 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 preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (MUCL 39203) was provisionally authorised for the first time for chickens for fattening by Commission Regulation (EC) No 1436/98 [3]. New data were submitted in support of an application for authorisation without a time limit of that preparation for chickens for fattening. 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 preparation, as specified in Annex I to this Regulation, should be authorised without a time limit.

(6) The use of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) was provisionally authorised for the first time for turkeys for fattening by Commission Regulation (EC) No 1353/2000 [4]. New data were submitted in support of an application for authorisation without a time limit of that preparation for turkeys. 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 preparation, as specified in Annex II to this Regulation, should be authorised without a time limit.

(7) Data were submitted in support of an application for authorisation for four years of the preparation Astaxanthin-rich *Phaffia rhodozyma* (ATCC SD-5340) for salmon and trout. The European Food Safety Authority (EFSA) expressed its opinion on the use of this preparation on 25 January 2006. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that preparation, as specified in Annex III to this Regulation, should be provisionally authorised for four years.

(8) 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 [5].

(9) 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 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 as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

[3] OJ L 191, 7.7.1998, p. 15.

[4] OJ L 155, 28.6.2000, p. 15.

[5] OJ L 183, 29.6.1989, p. 1. Directive as last amended by Directive 2007/30/EC of the European Parliament and of the Council (OJ L 165, 27.6.2007, p. 21).

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 an 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 an additive in animal nutrition under the conditions laid down in that Annex.

Article 3

The preparation belonging to the group 'Colorants, including pigments', as specified in Annex III, is authorised provisionally for four years as an 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, 13 July 2007.

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
					Units of activity/kg of complete feedingstuff			
Enzymes								
E 1641	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (MUCL 39203) having a minimum activity of: Solid form: 1 500 AXC/g ([1]) Liquid form: 200 AXC/ml	Chickens for fattening	—	55 AXC	—	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 kilogram of complete feedingstuff: 55-100 AXC. 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 AXC is the amount of enzyme which liberates 17,2 micromoles of reducing sugars (maltose equivalents) from oat Xylan per minute at pH 4,7 and 30 °C.

ANNEX II

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/g [1] Liquid form: 6 000 EPU/ml	Turkeys for fattening	—	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: 1 050-3 000 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 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
					mg/kg of complete feedingstuff			
Colorants, including pigments								
E 161y	Astaxanthin-rich *Phaffia rhodozyma* (ATCC SD-5340)	Concentrated biomass of the yeast *Phaffia rhodozyma* (ATCC SD-5340), killed, and containing at least 10,0 g astaxanthin per kilogram of additive.	Salmon	—	—	100	The maximum content is expressed as astaxanthin. Use permitted only from the age of six months onwards. The mixture of the additive with canthaxanthin is allowed provided that the total concentration of astaxanthin and canthaxanthin does not exceed 100 mg/kg in the complete feedingstuff.	3 August 2011
			Trout		—	100		