COMMISSION REGULATION (EC) No 1140/2007

of 1 October 2007

concerning the provisional authorisation of a new use 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 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 application for the authorisation of a new use of the additive listed in the Annex to this Regulation was submitted before the date of application of Regulation (EC) No 1831/2003.

(4) Initial comments on this application, 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. This application is therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

(5) The use of the enzyme preparation endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 358/2005 ([3]).

(6) New data were submitted in support of an application for authorisation for four years of that preparation for laying hens. The European Food Safety Authority (EFSA) delivered its opinion on that use on 18 April 2007. 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 to this Regulation, should be provisionally authorised for four years.

(7) The assessment of this application 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]).

(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,

([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 57, 3.3.2005, p. 3.

([4]) 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 the Annex, is authorised provisionally for four years as an additive in animal nutrition under the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the 20th 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, 1 October 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Unit of activity/kg of complete feedingstuff			
Enzymes								
53	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-glucanase EC 3.2.1.4 Alpha-amylase EC 3.2.1.1 Bacillolysin EC 3.4.24.28 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 2 350 U/g (1) Endo-1,4-beta-glucanase: 4 000 U/g (2) Alpha-amylase: 400 U/g (3) Bacillolysin: 450 U/g (4) Endo-1,4-beta-xylanase: 20 000 U/g (5)	Laying hens	—	Endo-1,3(4)-beta-glucanase: 587 Endo-1,4-beta-glucanase: 1 000 U Alpha-amylase: 100 U Bacillolysin: 112 U Endo-1,4-beta-xylanase: 5 000 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 kilogram of complete feedingstuff: — endo-1,3(4)-beta-glucanase: 587-2 350 U — endo-1,4-beta-glucanase: 1 000-4 000 U — alpha-amylase: 100-400 U — bacillolysin: 112-450 U — endo-1,4-beta-xylanase: 5 000-20 000 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and especially arabinoxylans), e.g. containing more than 30 % of wheat.	22 October 2011

(1) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 7,5 and 30 °C.
(2) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from carboxymethylcellulose per minute at pH 4,8 and 50 °C.
(3) 1 U is the amount of enzyme which liberates 1 micromole of glucose from a cross-linked starch polymer per minute at pH 7,5 and 37 °C.
(4) 1 U is the amount of enzyme which solubilises one microgram of azo-casein substrate per minute at pH 7,5 and 37 °C.
(5) 1 U is the amount of enzyme which liberates 0,0067 micromoles of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 5,3 and 50° C.