Commission Regulation (EC) No 1811/2005 of 4 November 2005 concerning the provisional and permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1811/2005

of 4 November 2005

concerning the provisional and permanent authorisations of certain additives in feedingstuffs and 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, 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 enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94) was provisionally authorised for the first time for piglets 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 enzyme preparation. 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, should be authorised without a time-limit.

(6) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) was provisionally authorised for the first time for chickens for fattening by Commission Regulation (EC) No 1411/1999[(4)]. New data were submitted in support of an application for authorisation without a time-limit of that enzyme preparation. 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, should be authorised without a time-limit.

(7) The use of the enzyme preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 74 252) was provisionally authorised for turkeys for fattening by Commission Regulation (EC) No 937/2001[(5)] and for laying hens by Commission Regulation (EC) No 2188/2002[(6)] and was authorised without a time-limit for chickens for fattening by Commission Regulation (EC) No 1259/2004[(7)] and for turkey for fattening by Commission Regulation (EC) No 1206/2005[(8)]. New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to ducks. The European Food Safety Authority (EFSA) has delivered an opinion on the use of this preparation which concludes that it does not present a risk for this additional animal category. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for an authorisation of that preparation for that use are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex II, should be authorised for four years.

(8) Data were submitted in support of an application for authorisation of the use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 529.94) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 526.94) for chickens for fattening and for turkeys for fattening. EFSA has delivered an opinion on the use of this preparation which concludes that it does not present a risk for the consumer, the user, the animal category or the environment. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for an authorisation of that preparation for that use are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex II, should be authorised for four years.

(9) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (NCYC Sc 47) was provisionally authorised, for the first time, for dairy cows by Regulation (EC) No 937/2001. New data were submitted in support of an application for authorisation without a time-limit of that micro-organism preparation. 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 micro-organism preparation, as specified in Annex III, should be authorised without a time-limit.

(10) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (CBS 493.94) was provisionally authorised, for the first time, for dairy cows by Regulation (EC) No 937/2001. New data were submitted in support of an application for authorisation

without a time-limit of that micro-organism preparation. 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 micro-organism preparation, as specified in Annex III, should be authorised without a time-limit.

(11) 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[9].

(12) 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 group ‘Enzymes’, as specified in Annex I, are authorised for use without a time-limit as additives in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparations belonging to the group ‘Enzymes’, as specified in Annex II, are authorised for use for four years as additives in animal nutrition under the conditions laid down in that Annex.

Article 3

The preparations belonging to the group ‘Micro-organisms’, as specified in Annex III, are authorised for use without a time-limit as additives 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1811/2005. (See end of Document for details)*

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 1603	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94) having a minimum activity of:	Piglets (weaned)	—	Endo-1,3(4)-beta-glucanase: 10 FBG		1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life, and stability to pelleting 2. Recommended dose per kg of complete feedingstuff: Endo-1,3(4)-beta-glucanase: 10-25 FBG 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more	Without a time-limit
			Coated form: Endo-1,3(4)-beta-glucanase: 50 FBG[a]/g Liquid form: Endo-1,3(4)-beta-glucanase: 120 FBG/ml					

a 1 FBG 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.

b [F1]

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 1811/2005. (See end of Document for details)*

							than 60 % vegetable ingredients (maize, lupin, wheat, barley, soya, oilseed rape or peas)	
							4. For use in weaned piglets until approximately 35 kg	

[F1]]

a 1 FBG 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.

b [F1]]

Textual Amendments

F1 Deleted by Commission Implementing Regulation (EU) 2017/1145 of 8 June 2017 on the withdrawal from the market of certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those feed additives (Text with EEA relevance).

ANNEX II

EC No or 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			

a 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from carboxymethylcellulose per minute at pH 5,0 and 40 °C.

b 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from barley beta-glucan per minute at pH 5,0 and 40 °C.

c 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from oat spelt xylan per minute at pH 5,0 and 40 °C.

d [F1

e F1]