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COMMISSION REGULATION (EC) No 492/2006

of 27 March 2006

concerning the provisional and permanent authorisation of certain additives in feedingstuffs

(Text with EEA relevance)

(OJ L 89, 28.3.2006, p. 6)

Amended by:

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COMMISSION REGULATION (EC) No 492/2006

of 27 March 2006

concerning the provisional and permanent 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) Data were submitted in support of an application for authorisation of the use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94) and endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287) for chickens for fattening and for piglets. On 20 July 2005, the European Food Safety Authority (EFSA) 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 these uses are satisfied. Accordingly, the uses of that enzyme preparation, as specified in Annex I, should be authorised for four years.

([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).

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(6) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (MUCL 39 885) was provisionally authorised for the first time for cattle for fattening by Commission Regulation (EC) No 1411/1999 ([1]). 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 II, should be authorised without a time-limit.

(7) The use of the micro-organism preparation of *Lactobacillus farciminis* (CNCM MA 67/4R) was provisionally authorised for the first time for piglets by Commission Regulation (EC) No 1411/1999. 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 II, should be authorised without a time-limit.

(8) Data were submitted in support of an application for authorisation without a time-limit of the use of the substance 'potassium diformate' as feed additive under the category 'Preservatives' for all animal species. The Commission asked EFSA to give an opinion on the efficacy and the safety for humans, animals and environment. EFSA delivered a favourable opinion with regard to the safety and to the efficacy of potassium diformate for all animal species on 8 December 2004. The assessment of potassium diformate showed that the relevant conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that substance as preservative, as specified in Annex III, should be authorised without a time-limit.

(9) 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 ([2]).

(10) 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 provisionally for four years as additive in animal nutrition under the conditions laid down in that Annex.

([1]) OJ L 164, 30.6.1999, p. 56.
([2]) OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

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Article 2

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

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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.

ANNEX I

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			
Enzymes								
64	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 produced by *Aspergillus aculeatus* (CBS 589.94) and endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287), having a minimum activity of: Coated form: 60 FBG/g ([1]) 600 FXU/g ([2]) Liquid form: 40 FBG/g 400 FXU/g	Chickens for fattening	—	6 FBG	—	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: 6-18 FBG — endo-1,4-beta-xylanase: 60-180 FXU 3. For use in compound feed with a high content of non-starch polysaccharides (mainly beta-glucans, arabinoxylans and more complex hemicelluloses), e.g. containing more than 15 % vegetable ingredients (e.g. barley, oats, rye, triticale, maize, soya beans, rape seed, peas, sunflower or lupin)	17.4.2010
					60 FXU	—		
			Piglets (weaned)	—	6 FBG	—	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: 6-18 FBG — endo-1,4-beta-xylanase: 60-180 FXU 3. For use in compound feed with a high content of non-starch polysaccharides (mainly beta-glucans, arabinoxylans and more complex hemicelluloses), e.g. containing more than 15 % vegetable ingredients (e.g. barley, oats, rye, triticale, maize, soya beans, rape seed, peas, sunflower or lupin) 4. For use in weaned piglets up to approximately 35 kg	17.4.2010
					60 FXU	—		

([1]) 1 FBG is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley ß-glucan per minute at pH 5,0 and 30 °C.
([2]) 1 FXU is the amount of enzyme which liberates 7,8 micromoles of reducing sugars (xylose equivalents) from azo-wheat arabinoxylan per minute at pH 6,0 and 50 °C.

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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 1710	*Saccharomyces cerevisiae* MUCL 39 885	Preparation of *Saccharomyces cerevisiae* containing a minimum of: Powder, spheric and oval granulated forms: 1×10^9 UFC/g additive	Cattle for fattening		9×10^9	9×10^9	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting 2. The quantity of *Saccharomyces cerevisiae* in the daily ration must not exceed 1,6 x 10^{10} CFU per 100 kg. body weight. Add 3,2 x 10^9 CFU for each additional 100 kg body weight	Without a time-limit
E 1714	*Lactobacillus farciminis* CNCM MA 67/4R	Preparation of *Lactobacillus farciminis* containing a minimum of 1×10^9 UFC/g additive	Piglets (weaned)	—	1×10^9	1×10^{10}	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting 2. For use in weaned piglets up to approximately 35 kg	Without a time-limit

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