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COMMISSION REGULATION (EC) No 521/2005

of 1 April 2005

concerning the permanent authorisation of an additive and the provisional authorisation of new uses of certain additives already authorised in feedingstuffs

(Text with EEA relevance)

(OJ L 84, 2.4.2005, p. 3)

Amended by:

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		No	page	date
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concerning the permanent authorisation of an additive and the provisional authorisation of new uses of certain additives 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 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 *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) was provisionally authorised for the first time for chickens for fattening, by Commission Regulation (EC) No 1636/1999 ([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 6-phytase produced by *Aspergillus oryzae* (DSM 14223) was authorised without a time limit for chickens for fattening, laying hens, turkeys for fattening, piglets, pigs for fattening and sows by Commission Regulation (EC) No 255/2005 ([4]). New data were submitted in support of an application to extend the authorisation of the use of that enzyme preparation to salmonids. The European Food Safety Authority (EFSA) has delivered an opinion on the use of that preparation which concludes that it does not present a risk to salmonids under the conditions set out in Annex II to this Regulation. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for such authorisation

([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 Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).
([3]) OJ L 194, 27.7.1999, p. 17.
([4]) OJ L 45, 16.2.2005, p. 3.

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are satisfied. Accordingly, the use of that enzyme preparation as specified in Annex II, should be provisionally authorised for four years.

(7) The use of the micro-organism preparation of *Enterococcus faecium* (DSM 7134) was provisionally authorised, for the first time, for piglets and pigs for fattening by Commission Regulation (EC) No 666/2003 ([1]). New data were submitted in support of an application to extend the authorisation of the use of that micro-organism preparation to chickens for fattening. The EFSA has delivered a favourable opinion on 28 October 2004 on the safety of that additive when used in the animal category chickens for fattening, under the conditions of use set out in Annex III to this Regulation. 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 micro-organism preparation as specified in Annex III, should be provisionally authorised for four years.

(8) The assessment of those 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]).

(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,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation belonging to the group ‘Enzymes’, as specified in Annex I, is authorised for use 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 provisionally authorised for four years as an additive in animal nutrition under the conditions laid down in that Annex.

Article 3

The preparation belonging to the group ‘Micro-organisms’, 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 third 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.

([1]) OJ L 96, 12.4.2003, p. 11.

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

ANNEX I

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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 1623	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) having a minimum activity of: endo-1,3(4)-beta-glucanase: 200 U (1)/g endo-1,4-beta-xylanase: 5 000 U (2)/g subtilisin: 1 600 U (3)/g	Chickens for fattening	—	endo-1,3(4)-beta-glucanase: 25 U endo-1,4-beta-xylanase: 625 U subtilisin: 200 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: 25-100 U endo-1,4-beta-xylanase: 625-2 500 U subtilisin: 200-800 U. 3. For use in compound feed, e.g. containing more than 30 % wheat and 10 % barley.	Without a time-limit

(1) 1 U 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.

(2) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 5,3 and 50 °C.

(3) 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7,5 and 40 °C.

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ANNEX II

No (or 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								
‘50	6-phytase EC 3.1.3.26	Preparation of 6-phytase produced by *Aspergillus oryzae* (DSM 14223) having a minimum activity of: Liquid form: 20 000 FYT ([1])/g	Salmonids	—	500 FYT	—	1. In the directions for use of the additive, indicate the storage temperature and storage life 2. Recommended dose per kg of complete feedingstuff: 500-2 000 FYT. 3. For use in compound feed rich in phytin-bound phosphorus.	5.4.2009

([1]) 1 FYT is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5,5 and 37 °C.’

ANNEX III

No (or 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								
'22	*Enterococcus faecium* DSM 7134	Preparation of *Enterococcus faecium* containing a minimum of: Powder: 1×10^{10} CFU/g additive Granules (micro-encapsulated form): 1×10^{10} CFU/g additive	Chickens for fattening	—	$0{,}2 \times 10^{9}$	2×10^{9}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	5.4.2009'