Commission Regulation (EC) No 255/2005 of 15 February 2005 concerning the permanent authorisations of certain additives in feedingstuffs (Text with EEA relevance)

COMMISSION REGULATION (EC) No 255/2005

of 15 February 2005

concerning the permanent authorisations 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 and 9d(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 in the European Union.

(2) Article 25 of Regulation (EC) No 1831/2003 lays down the transitional measures for applications for authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of that Regulation.

(3) The applications for authorisation of additives listed in the annexes to this Regulation were submitted before the date of application of Regulation (EC) No 1831/2003.

(4) Initial comments by Member States on these applications were issued under Article 4(4) of Directive 70/524/EEC have been forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. Such applications therefore shall continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

(5) The use of the micro-organism preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012) was provisionally authorised, for the first time, for cattle for fattening by Commission Regulation (EC) No 1411/1999[(3)].

(6) The use of the micro-organism preparation of *Enterococcus faecium* (DSM 10663/NCIMB 10415) was provisionally authorised, for the first time, for calves by Commission Regulation (EC) No 1636/1999[(4)].

(7) New data were submitted in support of these applications for authorisation without a time limit of those two micro-organism preparations specified in Annex I to this

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 255/2005. (See end of Document for details)*

Regulation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(8) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (NRRL 25541) was provisionally authorised, for the first time, for laying hens, by Commission Regulation (EC) No 1436/98[(5)].

(9) New data were submitted in support of the application for authorisation without a time limit of this enzyme preparation.

(10) The European Food Safety Authority (EFSA) delivered an opinion dated on 14 September 2004 about the efficacy of the use of this preparation for laying hens.

(11) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(12) The use of the enzyme preparation of 6-phytase produced by *Aspergillus oryzae* (DSM 11857) was provisionally authorised, for the first time, for chickens for fattening, laying hens, turkeys for fattening, piglets and pigs for fattening by Commission Regulation (EC) No 1353/2000[(6)], and for sows by Commission Regulation (EC) No 261/2003[(7)]. The use of this enzyme preparation was authorised without a time limit for these animal categories by Commission Regulation (EC) No 1465/2004[(8)].

(13) New data were submitted in support of the application for authorisation without a time limit of a preparation of the same enzyme preparation produced by the strain DSM 14223 of *Aspergillus oryzae* for the same animal categories.

(14) The European Food Safety Authority (EFSA) has delivered an opinion on the use of this preparation when produced from *Aspergillus oryzae* strain DSM 14223 instead of strain DSM 11857 which concludes that this preparation does not present a risk to human health, the animal categories specified or the environment, under the conditions set out in the Annex II to this Regulation.

(15) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for an authorisation without a time limit of such preparation have been satisfied.

(16) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 270.95) was provisionally authorised, for the first time, for chickens for fattening, by Commission Regulation (EC) No 1436/98 and, for turkeys for fattening, by Commission Regulation (EC) No 654/2000[(9)].

(17) New data were submitted in support of the application for authorisation without a time limit of this enzyme preparation.

(18) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(19) Accordingly, the use of those three enzyme preparations as specified in Annex II, should be authorised without a time limit.

(20) 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[(10)].

(21) 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 ‘Micro-organisms’ are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in Annex I.

Article 2

The preparations belonging to the group ‘Enzymes’ are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in Annex II.

Article 3

This Regulation shall enter into force on the third 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 255/2005. (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
					CFU/kg of complete feedingstuff			
Micro-organisms								
[F1]								
[F2]								

Textual Amendments

F1 Deleted by Commission Implementing Regulation (EU) 2015/1399 of 17 August 2015 concerning the denial of authorisation of the preparation of Bacillus toyonensis (NCIMB 14858T) (formerly Bacillus cereus var. toyoi NCIMB 40112/CNCM I-1012) as a feed additive for cattle for fattening, rabbits for fattening, chickens for fattening, piglets (weaned), pigs for fattening, sows for reproduction and calves for rearing and the revocation of the authorisations of the preparation of Bacillus cereus var. toyoi (NCIMB 40112/CNCM I-1012) as a feed additive for turkeys for fattening and rabbit breeding does, amending Regulations (EC) No 256/2002, (EC) No 1453/2004, (EC) No 255/2005 and (EC) No 1200/2005 and repealing Regulations (EC) No 166/2008, (EC) No 378/2009 and Implementing Regulation (EU) No 288/2013 (Text with EEA relevance).

F2 Deleted by Commission Implementing Regulation (EU) 2015/1053 of 1 July 2015 concerning the authorisation of the preparation of Enterococcus faecium DSM 10663/NCIMB 10415 as a feed additive for calves for rearing, piglets, chickens for fattening, turkeys for fattening, cats and dogs and amending Regulations (EC) No 1259/2004, (EC) No 255/2005, (EC) No 1200/2005 and (EC) No 1520/2007 (holder of authorisation Chevita Tierarzneimittel-GmbH) (Text with EEA relevance).

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
					Units of activity/ kg of complete feedingstuff			
Enzymes								
[F3								
F3]								
[F4]								
a	[F3]							
b	[F3]							
c	[F4]							
d	[F5]							

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‘Laying hens	—	300 FYT	—	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: 450-1 000 FYT. 3. For use in compound feed containing more than 0,25 % phytin bound phosphorus.	Without time limit
Turkeys for fattening	—	250 FYT	—	1. In the directions for	Without time limit

a [F3]

b [F3]

c [F4]

d [F5]