Commission Regulation (EC) No 2036/2005 of 14 December 2005 concerning the permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of certain additives already authorised in feedingstuffs (Text with EEA relevance)

COMMISSION REGULATION (EC) No 2036/2005

of 14 December 2005

concerning the permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use 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 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 micro-organism preparation of *Saccharomyces cerevisiae* (CNCM I-1079) was provisionally authorised, for the first time, for sows 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 micro-organism preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 2036/2005. (See end of Document for details)*

EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex I, should be authorised without a time limit.

(6) The use of the micro-organism preparation of *Pediococcus acidilactici* (CNCM MA 18/5M) was provisionally authorised, for the first time, for pigs for fattening by Commission Regulation (EC) No 866/1999[(4)]. 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 I, should be authorised without a time limit.

(7) The use of the micro-organism preparation of *Enterococcus faecium* (CECT 4515) was provisionally authorised, for the first time, for piglets by Commission Regulation (EC) No 654/2000[(5)]. 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 I, should be authorised without a time limit.

(8) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 526.94) was provisionally authorised for the first time for chickens for fattening by Commission Regulation (EC) No 2374/98[(6)]. 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 II, should be authorised without a time limit.

(9) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) was provisionally authorised for the first time for chickens for fattening by Commission Regulation (EC) No 418/2001[(7)]. 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 II, should be authorised without a time limit.

(10) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287) was authorised without a time limit for chickens for fattening, turkeys for fattening and piglets by Commission Regulation (EC) No 1332/2004[(8)]. New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to ducks and pigs for fattening. 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 III, should be authorised for four years.

(11) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 943/2005[(9)]. New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to ducks. The 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 III, should be authorised for four years.

(12) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) was provisionally authorised for chickens for fattening by Regulation (EC) No 418/2001. New data were submitted in support of two applications to extend the authorisation of the use of this enzyme preparation to ducks and laying hens. The EFSA has delivered an opinion on the use of this preparation on each of the two animal categories which conclude in both cases that it does not present a risk for them. 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 for ducks and laying hens, as specified in Annex III, should be authorised for four years.

(13) 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)].

(14) 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’, 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.

[F1]Article 2

. . . . . .

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 2036/2005. (See end of Document for details)*

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).

Article 3

The preparations belonging to the group ‘Enzymes’, as specified in Annex III, are authorised for use for four years 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 2036/2005. (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								
[F2]								
[F3]								
[F4]								

Textual Amendments

F2 Deleted by Commission Implementing Regulation (EU) 2018/347 of 5 March 2018 concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for piglets and sows and amending Regulations (EC) No 1847/2003 and (EC) No 2036/2005 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (Text with EEA relevance).

F3 Deleted by Commission Implementing Regulation (EU) 2017/2299 of 12 December 2017 concerning the authorisation of a preparation of Pediococcus acidilactici CNCM MA 18/5M as a feed additive for pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, minor poultry species for fattening and minor poultry species for laying, the authorisation of that feed additive for use in water for drinking and amending Regulations (EC) No 2036/2005, (EC) No 1200/2005 and Implementing Regulation (EU) No 413/2013 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (Text with EEA relevance).

F4 Deleted by Commission Implementing Regulation (EU) 2017/961 of 7 June 2017 concerning the authorisation of a preparation of Enterococcus faecium CECT 4515 as a feed additive for weaned piglets, and a new use in water for drinking for weaned piglets and chickens for fattening, and amending Regulation (EC) No 2036/2005 and Regulation (EU) No 887/2011 (holder of authorisation Evonik Nutrition & Care GmbH) (Text with EEA relevance).

F1ANNEX II

[F1]