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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)

(OJ L 328, 15.12.2005, p. 13)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) No 1018/2012 of 5 November 2012	L 307	56	7.11.2012
►**M2**	Commission Implementing Regulation (EU) No 1206/2012 of 14 December 2012	L 347	12	15.12.2012
►**M3**	Commission Implementing Regulation (EU) 2017/961 of 7 June 2017	L 145	7	8.6.2017

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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)

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.

Article 2

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

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.

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								
E 1703	*Saccharomyces cerevisiae* CNCM I-1079	Preparation of *Saccharomyces cerevisiae* containing a minimum of: 2×10^{10} CFU/g additive	Sows	—	1×10^{9}	►M1 —— ◄	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	Without a time limit
E 1712	*Pediococcus acidilactici* CNCM MA 18/5M	Preparation of *Pediococcus acidilactici* containing a minimum of: 1×10^{10} CFU/g additive	Pigs for fattening	—	1×10^{9}	►M1 —— ◄	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	Without a time limit
▼M3 ——								

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								
E 1636	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 526.94) having a minimum activity of: Solid form: 700 000 BU ([1])/g Liquid form: 300 000 BU/g	Chickens for fattening	—	17 500 BU	—	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: 17 500-50 000 BU. 3. For use in compound feed rich in non-starch polysaccharides (mainly glucans), e.g. containing more than 20 % barley or 30 % rye.	Without a time limit
E 1637	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Subtilisin EC 3.4.21.62 Alpha-amylase EC 3.2.1.1 Polygalacturonase EC 3.2.1.15	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), polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) having a mimimum activity of: Endo-1,4-beta-xylanase: 300 U ([2])/g Endo-1,3(4)-beta-glucanase: 150 U ([3])/g Subtilisin: 4 000 U ([4])/g Alpha-amylase: 400 U ([5])/g Polygalacturonase: 25 U ([6])/g	Chickens for fattening	—	endo-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalacturonase: 25 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-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalacturonase: 25 U. 3. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % maize or 60 % wheat.	Without a time limit

([1]) 1 BU is the amount of enzyme which liberates 0,06 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,8 and 50 °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 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5,0 and 30 °C.
([4]) 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.
([5]) 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 6,5 and 37 °C.
([6]) 1 U is the amount of enzyme which liberates 1 micromole of reducing material (galacturonic acid equivalents) from a poly D-galacturonic substrate per minute at pH 5,0 and 40 °C.

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ANNEX III

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								
▼M2 ———								
▼B 37	Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62	Preparation of 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-1,4-beta-xylanase: 5 000 U ([2])/g Subtilisin: 1 600 U ([3])/g	Ducks	—	endo-1,4-beta-xylanase: 2 500 U subtilisin: 800 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-1,4-beta-xylanase: 2 500 U subtilisin: 800 U. 3. For use in compound feed e.g. containing more than 65 % wheat.	4.1.2010
59	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Subtilisin EC 3.4.21.62 Alpha-amylase EC 3.2.1.1 Polygalacturonase EC 3.2.1.15	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), polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) having a mimimum activity of: Endo-1,4-beta-xylanase: 300 U ([2])/g Endo-1,3(4)-beta-glucanase: 150 U ([4])/g Subtilisin: 4 000 U ([3])/g Alpha-amylase: 400 U ([5])/g Polygalacturonase: 25 U ([6])/g	Ducks	—	endo-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalacturonase: 25 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-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalacturonase: 25 U. 3. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % maize.	4.1.2010

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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			
			Laying hens	—	endo-1,4-beta-xylanase: 225 U endo-1,3(4)-beta-glucanase: 112 U subtilisin: 3 000 U alpha-amylase: 300 U polygalacturonase: 18 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-1,4-beta-xylanase: 225 U endo-1,3(4)-beta-glucanase: 112 U subtilisin: 3 000 U alpha-amylase: 300 U polygalacturonase: 18 U. 3. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % maize.	4.1.2010

►M2 ——————— ◄

(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.
(4) 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.
(5) 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 6,5 and 37 °C.
(6) 1 U is the amount of enzyme which liberates 1 micromole of reducing material (galacturonic acid equivalents) from a poly D-galacturonic substrate per minute at pH 5,0 and 40 °C.