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COMMISSION REGULATION (EC) No 358/2005

of 2 March 2005

concerning the authorisations without a time limit of certain additives and the authorisation of new uses of additives already authorised in feedingstuffs

(Text with EEA relevance)

(OJ L 57, 3.3.2005, p. 3)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) No 643/2013 of 4 July 2013	L 186	7	5.7.2013
►**M2**	Commission Implementing Regulation (EU) 2017/429 of 10 March 2017	L 66	4	11.3.2017

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COMMISSION REGULATION (EC) No 358/2005

of 2 March 2005

concerning the authorisations without a time limit of certain additives and the authorisation of new uses of additives already authorised in feedingstuffs

(Text with EEA relevance)

Article 1

The preparations belonging to the group ‘Enzymes’ as set out 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 substances belonging to the group ‘Colourants, including pigments, other colourants’ as set out 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 set out in Annex III are authorised provisionally for four years as additives in animal nutrition under the conditions laid down in that Annex.

Article 4

The preparation belonging to the group ‘Micro-organisms’, as set out in Annex IV is authorised provisionally for four years as additive in animal nutrition under the conditions laid down in that Annex.

Article 5

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.

ANNEX I

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content / Maximum content (Units of activity/kg of complete feedingstuff)		Other provisions	End of period of authorisation
Enzymes								
E 1619	Alpha-amylase EC 3.2.1.1 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of alpha-amylase and endo-1,3(4)-beta-glucanase produced by *Bacillus amyloliquefaciens* (DSM 9553) having minimum activities of: Coated form: Alpha-amylase: 200 KNU ([1])/g Endo-1,3(4)-beta-glucanase: 350 FBG ([2])/g Liquid form: Alpha-amylase: 130 KNU/ml Endo-1,3(4)-beta-glucanase: 225 FBG/ml	Chickens for fattening	—	alpha-amylase: 10 KNU	—	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: alpha-amylase: 20–40 KNU endo-1,3(4)-beta-glucanase: 35–70 FBG 3. For use in compound feed rich in starch and beta glucans, e.g. containing more than 40 % cereals (e.g. barley, oats, wheat, rye, triticale, or maize).	Without a time limit
					endo-1,3(4)-beta –glucanase: 17 FBG	—		
E 1620	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-glucanase EC 3.2.1.4 Alpha-amylase EC 3.2.1.1 Bacillolysin EC 3.4.24.28 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), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 2 350 U ([3])/g Endo-1,4-beta-glucanase: 4 000 U ([4])/g Alpha-amylase: 400 U ([5])/g Bacillolysin: 450 U ([6])/g Endo-1,4-beta-xylanase: 20 000 U ([7])/g	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 587 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: 1 175–2 350 U endo-1,4-beta-glucanase: 2 000–4 000 U alpha-amylase: 200–400 U bacillolysin: 225–450 U endo-1,4-beta-xylanase: 10 000–20 000 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 45 % wheat.	Without a time limit
					Endo-1,4-beta-glucanase: 1 000 U	—		
					Alpha-amylase: 100 U	—		
					Bacillolysin: 112 U	—		
					Endo-1,4-beta-xylanase: 5 000 U	—		

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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			
▼M2 ———								
▼B E 1622	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 and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CBS 357.94) having a minimum activity of: Granulated form: 6 000 BGU ([8])/g 8 250 EXU ([9])/g Liquid form: 2 000 BGU/ml 2 750 EXU/ml	Chickens for fattening	—	endo-1,3(4)-beta-glucanase: 500 BGU endo-1,4-beta-xylanase: 680 EXU	— —	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: 500 BGU endo-1,4-beta-xylanase: 680 EXU 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 30 % wheat and 30 % barley, or 20 % rye.	Without a time limit

([1]) 1 KNU is the amount of enzyme which liberates 672 micromoles of reducing sugars (glucose equivalent) from soluble starch per minute at pH 5,6 and 37 °C.
([2]) 1 FBG 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.
([3]) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 7,5 and 30 °C.
([4]) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from carboxymethylcellulose per minute at pH 4,8 and 50 °C.
([5]) 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from water insoluble cross-linked starch polymer per minute at pH 7,5 and 37 °C.
([6]) 1 U is the amount of enzyme which makes 1 microgram of azo-casein soluble in trichloracetic acid per minute at pH 7,5 and 37 °C.
([7]) 1 U is the amount of enzyme which liberates 0,0067 micromoles of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 5,3 and 50 °C.
([8]) 1 BGU is the amount of enzyme which liberates 0,278 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 3,5 and 40 °C.
([9]) 1 EXU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH 3,5 and 55 °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
					mg/kg of complete feedingstuff			
Colourants, including pigments								
2. **Other colourants**								
E 102	Tartrazine	$C_{16}H_9N_4O_9S_2Na_3$	Grain-eating ornamental birds	—	—	150	—	Without a time limit
			Small rodents	—	—	150	—	Without a time limit
E 110	Sunset yellow FCF	$C_{16}H_{10}N_2O_7S_2Na_2$	Grain-eating ornamental birds	—	—	150	—	Without a time limit
			Small rodents	—	—	150	—	Without a time limit

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E 141	Chlorophyll copper complex	—	Grain-eating ornamental birds	—	—	150	—	Without a time limit
			Small rodents	—	—	150	—	Without a time limit

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								
51	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) having a minimum activity of: Solid and liquid form: 100 IU (1)/g or ml	Laying hens	—	10 IU	—	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: 10 IU 3. For use in compound feed rich in arabinoxylan, e.g. containing minimum 40 % wheat or barley.	6 March 2009
28	3-Phytase EC 3.1.3.8	Preparation of 3-phytase produced by *Trichoderma reesei* (CBS 528.94) having a minimum activity of: Solid form: 5 000 PPU (2)/g Liquid form: 1 000 PPU/g	Turkeys for fattening	—	250 PPU	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended dose per kg of complete feedingstuff: 250-1 000 PPU 3. For use in compound feed containing more than 0,22 % phytin bound phosphorus.	6 March 2009
			Sows	—	250 PPU	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended dose per kg of complete feedingstuff: 500-1 000 PPU 3. For use in compound feed containing more than 0,22 % phytin bound phosphorus.	6 March 2009

(1) 1 IU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 4,5 and 30 °C.
(2) 1 PPU is the amount of enzyme which liberates 1 micromole of inorganic phosphate from sodium phytate per minute at pH 5 and 37 °C.

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ANNEX IV

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								
10	*Enterococcus faecium* NCIMB 10415	Preparation of *Enterococcus faecium* containing a minimum of microencapsulated form: 5×10^9 CFU/g	Dogs	—	$4{,}5 \times 10^6$	2×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting	6 March 2009
			Cats	—	5×10^6	8×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting	6 March 2009