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COMMISSION REGULATION (EC) No 2148/2004

of 16 December 2004

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

(Text with EEA relevance)

(OJ L 370, 17.12.2004, p. 24)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 1980/2005 of 5 December 2005	L 318	3	6.12.2005
►**M2**	Commission Implementing Regulation (EU) No 1018/2012 of 5 November 2012	L 307	56	7.11.2012
►**M3**	Commission Implementing Regulation (EU) 2015/1043 of 30 June 2015	L 167	63	1.7.2015
►**M4**	Commission Implementing Regulation (EU) 2015/2305 of 10 December 2015	L 326	43	11.12.2015
►**M5**	Commission Implementing Regulation (EU) 2017/447 of 14 March 2017	L 69	18	15.3.2017

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COMMISSION REGULATION (EC) No 2148/2004

of 16 December 2004

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

(Text with EEA relevance)

Article 1

The preparation belonging to the group ‘Binders, anti-caking agents and coagulants’, is authorised for use without a time limit as additive in animal nutrition under the conditions laid down in Annex I.

Article 2

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 II.

Article 3

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

Article 4

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 IV.

Article 5

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

Article 6

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.

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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
					mg/kg of complete feedingstuff			
Binders, anti-caking agents and coagulants								
E 567	Clinoptilolite of volcanic origin	Calcium hydrated aluminosilicate of volcanic origin containing a minimum of 85 % of clinoptilolite and a maximum of 15 % of feldspar, micas and clays free of fibres and quartz ►M1 ——————— ◄	Pigs	—	—	20 000	All feedingstuffs	Without a time limit
			Rabbits	—	—	20 000	All feedingstuffs	Without a time limit
			Poultry	—	—	20 000	All feedingstuffs	Without a time limit

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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
					CFU/kg of complete feedingstuff			
Micro-organisms								
▼M5 —								
▼B E 1702	*Saccharomyces cerevisiae* NCYC Sc 47	Preparation of *Saccharomyces cerevisiae* containing a minimum of: 5×10^9 CFU/g additive	Piglets (weaned)	—	5×10^9	►M2 — ◄	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. For use in weaned piglets until approximately 35 kg.	Without a time limit
E 1706	*Enterococcus faecium* DSM 7134 *Lactobacillus rhamnosus* DSM 7133	Mixture of: *Enterococcus faecium* containing a minimum of: 7×10^9 CFU/g and of *Lactobacillus rhamnosus* containing a minimum of: 3×10^9 CFU/g	Piglets (weaned)	—	$2{,}5 \times 10^9$	5×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. For use in weaned piglets until approximately 35 kg.	Without a time limit

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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								
24	*Kluyveromyces marxianus* var. *lactisK1* BCCM/MUCL 39434	Preparation of *Kluyveromyces marxianus* var. *lactisK1* having a minimum activity of: $1,0 \times 10^8$ CFU/g	Dairy cows	—	$0,25 \times 10^6$	$1,0 \times 10^6$	In directions for use of the additive and premixture, indicate the storage temperature and storage life. Do not use in pelleted premixture and feedingstuffs. Use in dairy cows, in particular when they are reaching the maximum of daily milk production, for minimum period of 14 days. The amount of daily ration administered to each cow is $1,0 \times 10^7$ CFU.	20 December 2008

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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
					Units of activity/kg of complete feedingstuff			
Enzymes								
E 1615	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10 W) having a minimum activity of: Solid form: 70 000 BGN (1)/g Liquid form: 14 000 BGN/ml	Chickens for fattening	—	1 050 BGN	—	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: 2 800 BGN. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 35 % barley.	Without a time limit
▼M4 —								
▼M3 —								

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(1) 1 BGN is the amount of enzyme which liberates 1 micromole of reducing sugar (glucose equivalents) from barley beta-glucan per minute at pH 4,8 and 50 °C.

ANNEX V

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								
30 (or E 1604)	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 *Penicillium funiculosum* (IMI SD 101) having a minimum activity of: Powder form: Endo-1,3(4)-beta-glucanase: 2 000 U ([1])/g Endo-1,4-beta-xylanase: 1 400 U ([2])/g Liquid form: Endo-1,3(4)-beta-glucanase: 500 U/ml Endo-1,4-beta-xylanase: 350 U/ml	Piglets (weaned)		endo-1,3(4)-beta-glucanase: 100 U endo-1,4-beta-xylanase: 70 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: 100 U endo-1,4-beta-xylanase: 70 U 3. For use in compound feed rich in non-starch polysaccharides, (mainly beta-glucan and arabinoxylans), e.g. containing more than 30 % barley or 20 % wheat. 4. For weaned piglets up to approximately 35 kg.	20.12.2008

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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			
			Ducks for fattening	—	endo-1,3(4)-beta-glucanase: 100 U endo-1,4-beta-xylanase: 70 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: 100 U endo-1,4-beta-xylanase: 70 U 3. For use in compound feed rich in non-starch polysaccharides, (mainly beta-glucan and arabinoxylans), e.g. containing more than 50 % barley or 60 % wheat.	20.12.2008

([1]) 1 U is the amount of enzyme which liberates 5,55 micromoles of reducing sugars (maltose equivalents) from barley beta-glucan per minute at pH 5,0 and 50 °C.
([2]) 1 U is the amount of enzyme which liberates 4,00 micromoles of reducing sugars (maltose equivalents) from birchwood xylan per minute at pH 5,5 and 50 °C.