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COMMISSION REGULATION (EC) No 1453/2004

of 16 August 2004

concerning the permanent authorisation of certain additives in feedingstuffs

(Text with EEA relevance)

(OJ L 269, 17.8.2004, p. 3)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Implementing Regulation (EU) 2015/1399 of 17 August 2015	L 217	1	18.8.2015
► <u>M2</u>	Commission Implementing Regulation (EU) 2017/447 of 14 March 2017	L 69	18	15.3.2017



COMMISSION REGULATION (EC) No 1453/2004
of 16 August 2004
concerning the permanent authorisation of certain additives in
feedingstuffs
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Article 1

The preparations belonging to the groups ‘Micro-organisms’ and ‘Enzymes’, as set out in Annexes I and II are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in those Annexes.

Article 2

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 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 1609	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,4-beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by <i>Aspergillus niger</i> (CBS 600.94) having minimum activities of: Coated form: Endo-1,4-beta-xylanase: 36 000 FXU ⁽¹⁾ /g Endo-1,4-beta-glucanase: 15 000 BGU ⁽²⁾ /g Liquid form: Endo-1,4-beta-xylanase: 36 000 FXU/ml Endo-1,4-beta-glucanase: 15 000 BGU/ml Solid form: Endo-1,4-beta-xylanase: 36 000 FXU/g Endo-1,4-beta-glucanase: 15 000 BGU/g	Chickens for fattening	—	4 860 FXU	—	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: 4 860–6 000 FXU 2 025–2 500 BGU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabino-xylans and beta-glucans), e.g. containing more than 35 % barley and 20 % wheat.	Without a time limit		
					2 025 BGU	—				
			Turkeys for fattening	—	6 000 FXU	—			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: 6 000 FXU 2 500 BGU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabino-xylans and beta-glucans), e.g. containing more than 40 % wheat.	Without a time limit
					2 500 BGU	—				

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			
			Piglets (weaned)	—	6 000 FXU	—	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: 6 000 FXU 2 500 BGU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabino-xylans and beta-glucans), e.g. containing more than 30 % wheat and 30 % barley. 4. For use in weaned piglets until approximately 35 kg.	Without a time limit
					2 500 BGU	—		
E 1610	Endo-1,4-beta-glucanase EC 3.2.1.4 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-glucanase and endo-1,4-beta-xylanase produced by <i>Aspergillus niger</i> (CBS 600.94) having minimum activities of: Coated form: Endo-1,4-beta-glucanase: 10 000 BGU/ (³)g Endo-1,4-beta-xylanase: 4 000 FXU (⁴)g Liquid form: Endo-1,4-beta-glucanase: 20 000 BGU/ml Endo-1,4-beta-xylanase: 8 000 FXU/ml Solid form: Endo-1,4-beta-glucanase: 20 000 BGU/g Endo-1,4-beta-xylanase: 8 000 FXU/g	Chickens for fattening	—	5 000 BGU	—	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: 5 000–10 000 BGU 2 000–4 000 FXU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabino-xylans and beta-glucans), e.g. containing more than 60 % barley.	Without a time limit
					2 000 FXU	—		

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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			
E 1611	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Polygalacturonase EC 3.2.1.15	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106) and endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135) and polygalacturonase produced by <i>Aspergillus aculeatus</i> (CBS 589.94) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 400 U ⁽⁵⁾ /g Endo-1,4-beta-xylanase: 400 U ⁽⁶⁾ /g Polygalacturonase: 50 U ⁽⁷⁾ /g	Pigs for fattening	—	endo-1,3(4)-beta-glucanase: 400 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: 400 U endo-1,4-beta-xylanase: 400 U polygalacturonase: 50 U. 3. For use in compound feed containing cereals rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % barley.	Without a time limit
					endo-1,4-beta-xylanase: 400 U	—		
					polygalacturonase: 50 U	—		
E 1612	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Alpha-amylase EC 3.2.1.1	Preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by <i>Aspergillus niger (phoenicis)</i> (NRRL 25541) and of alpha-amylase produced by <i>Aspergillus oryzae</i> (ATCC 66222) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 275 U ⁽⁸⁾ /g Endo-1,4-beta-xylanase: 400 U ⁽⁹⁾ /g Alpha-amylase: 3 100 U ⁽¹⁰⁾ /g	Piglets (weaned)	—	endo-1,3(4)-beta-glucanase: 138 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: 138 U endo-1,4-beta-xylanase: 200 U alpha-amylase: 1 550 U 3. For use in compound feeds rich in starch and non-starch polysaccharides, for example mixed diets containing barley, maize, wheat. 4. For use in weaned piglets until approximately 35 kg.	Without a time limit
					endo-1,4-beta-xylanase: 200 U	—		
					alpha-amylase: 1 550 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			
E 1613	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase, produced from <i>Trichoderma longibrachiatum</i> (CNCM MA 6 - 10W), having a minimum activity of: Powder form: 70 000 IFP ⁽¹¹⁾ /g Liquid form: 7 000 IFP/ml	Chickens for fattening	—	1 050 IFP	—	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: 1 400 IFP. 3. For use in compound feeds rich in non-starch polysaccharides (mainly arabinoxylans), for example more than 40 % wheat.	Without a time limit

⁽¹⁾ 1 FXU is the amount of enzyme which liberates 0,15 micromoles of xylose from azurine-cross-linked xylan per minute at pH 5,0 and 40 °C.

⁽²⁾ 1 BGU is the amount of enzyme which liberates 0,15 micromoles of xylose from azurine-cross-linked beta-glucan per minute at pH 5,0 and 40 °C.

⁽³⁾ 1 BGU is the amount of enzyme which liberates 0,15 micromoles of xylose from azurine-cross-linked beta-glucan per minute at pH 5,0 and 40 °C.

⁽⁴⁾ 1 FXU is the amount of enzyme which liberates 0,15 micromoles of xylose from azurine-cross-linked xylan per minute at pH 5,0 and 40 °C.

⁽⁵⁾ 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.

⁽⁶⁾ 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.

⁽⁷⁾ 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.

⁽⁸⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from oat beta-glucan per minute at pH 5,0 and 40 °C.

⁽⁹⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from oat xylan per minute at pH 4,0 and 30 °C.

⁽¹⁰⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from wheat starch per minute at pH 4,0 and 30 °C.

⁽¹¹⁾ 1 IFP is the quantity of enzyme which liberates 1 micromole of reducing sugars (measured as xylose equivalent) from oat xylan per minute at pH 4,8 and 50 °C.