

Commission Regulation (EC) No 1353/2000 of 26 June 2000 concerning the permanent authorisation of an additive and the provisional authorisation of new additives, new additive uses and new preparations in feedingstuffs (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1353/2000

of 26 June 2000

concerning the permanent authorisation of an additive and the provisional authorisation of new additives, new additive uses and new preparations in feedingstuffs

(Text with EEA relevance)

*<sup>F1</sup>Article 1*

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**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 2*

The conditions for the authorisation of the preparations No 16 and No 17 belonging to the group ‘Enzymes’ listed in Annex II to the present Regulation are hereby replaced by those set out in the said Annex according to Directive 70/524/EEC.

*Article 3*

The preparations belonging to the group ‘Enzymes’ listed in Annex III to the present Regulation shall be authorised according to Directive 70/524/EEC as additives in animal nutrition under the conditions laid down in the said Annex.

*Article 4*

The preparation belonging to the group ‘Micro-organisms’ listed in Annex IV to the present Regulation shall be authorised according to Directive 70/524/EEC as additives in animal nutrition under the conditions laid down in the said Annex.

*Article 5*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

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 1353/2000. (See end of Document for details)

<sup>F1</sup>ANNEX I

[<sup>F1</sup>]

ANNEX II

No(or EC No)	Additive	Chemical formula, or description	Species or category of animal	Maximum age	Minimum	Maximum	Other provisions	Period of authorisation
					content	content		
					Units of activity/ kg of complete feedingstuff			
16	Endo-1,4- beta- glucanase EC 3.2.1.4	Preparation of endo-1,4- beta- glucanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 142) having a minimum activity of:	Chickens for fattening	—	250 CU	—	1.	30.9.2000 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
			Solid form: 2 000 CU/ g <sup>a</sup> Liquid form: 2 000 CU/ ml				2.	Recommended dose per kg of complete feedingstuff: 500-1 000 CU.
							3.	For use

**a** 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.

**b** 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.

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							in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley.
			Laying hens	—	250 CU	—	<p>1. 30.9.2000 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>2. Recommended dose per kg of complete feedingstuff: 500-1 000 CU.</p>

**a** 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.

**b** 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.

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							3.	For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley.
			Piglets	4 months	250 CU	—	1.	30.9.2000 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:

**a** 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.

**b** 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.

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							500-1000 CU.
						3.	For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley.
		Pigs for fattening	—	250 CU	—	1.	30.9.2000 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

**a** 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.

**b** 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.

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							of complete feedingstuff: 500-1000 CU.
						3.	For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 40 % barley.
17	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135) having a minimum activity of:	Chickens for fattening	—	750 EPU	—	30.9.2000 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.

**a** 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.

**b** 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.

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			Liquid form: 2 000 EPU/ ml				2.	Recommended dose per kg of complete feedingstuff: 1 500-3 000 EPU.
							3.	For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.
		Laying hens	—	750 EPU	—		1.	30.9.2000 In the directions for use of the additive and premixture, indicate the storage temperature, storage life

**a** 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.

**b** 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.

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							and stability to pelleting.
							2. Recommended dose per kg of complete feedingstuff: 1 500-3 000 EPU.
							3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.
		Piglets	4 months	750 EPU	—	1.	30.9.2000 In the directions for use of the additive and premixture, indicate the storage

**a** 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.

**b** 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.



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							temperature, storage life and stability to pelleting.
							2. Recommended dose per kg of complete feedingstuff: 1 500-3 000 EPU.
							3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.
		Pigs for fattening	—	750 EPU	—	1.	30.9.2000 In the directions for use of the additive and premixture,

**a** 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.

**b** 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.

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								indicate the storage temperature, storage life and stability to pelleting.
								2. Recommended dose per kg of complete feedingstuff: 1 500-3 000 EPU.
								3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.
<p><b>a</b> 1 CU is the amount of enzyme which liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,5 and 30 °C.</p>								
<p><b>b</b> 1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.</p>								

ANNEX III

No. (or EC No)	Additive	Chemical formula, or description	Species category	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
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**Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 1353/2000. (See end of Document for details)

			of animal		Units of activity/ kg of complete feedingstuff		
12	Endo-1,4-beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by <i>Trichoderma viride</i> (FERM BP-4447) having a minimum activity	Turkeys for fattening	—	Endo-1,4-beta-glucanase 800 U	1.	30.9.2001 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Endo-1,3(4)-beta-glucanase: 1 800 U						
Endo-1,4-beta-xylanase EC 3.2.1.8	Endo-1,4-beta-xylanase: 2 600 U						
				Endo-1,4-beta-glucanase: 8 000 U/ g <sup>a</sup>		2.	Recommended dose per kg of complete feedingstuff: Endo-1,4-beta-glucanase: 800-1 200 U Endo-1,3(4)-beta-glucanase: 1 800-2 700 U Endo-1,4-beta-xylanase: 2 600-3 900 U.

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							3.	For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 20 % wheat and 20 % barley.
17	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135) having a minimum activity of:	Turkeys for fattening	—	750 EPU	—	1.	30.9.2001 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
			Solid form: 6 000 EPU/g <sup>d</sup> Liquid form: 6 000 EPU/ml				2.	Recommended dose per kg of

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							complete feedingstuff: 1 500-3 000 EPU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 35 % wheat.
42	Endo-1,4-beta-xylanase EC 3.2.1.8	(Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135) having a minimum activity of:	Pigs for fattening	—	4 000 U	—	1. 30.9.2001 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
		Solid form: 4 000 U/ g <sup>e</sup> Characteristic of the authorised preparation: endo-1,4-beta-					

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			xylanase: 1,99 % wheat: 97,7 % calcium propionate: 0,3 % lecithin: 0,01 %			3.	complete feedingstuff: 4 000 U  For use in compound feed rich in non- starch polysaccharides (mainly arabinoxylans), e.g. containing more than 60 % wheat.
49	Endo-1,3(4)- beta- glucanase EC 3.2.1.6	Preparation of endo-1,3(4)- beta- glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106),	Chickens for fattening	—	Endo-1,3(4)- beta- glucanase: 150 U	1.	30.9.2001 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
	Endo-1,4- beta- xylanasa EC 3.2.1.8	endo-1,4- beta- xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135)			Endo-1,4- beta- xylanase: 1 500 U		
	Alfa- amylase EC 3.2.1.1	endo-1,4- beta- xylanase produced by <i>Trichoderma longibrachiatum</i> (IMI SD 135)			Alfa- amylase: 500 U		
	Bacillolysin EC 3.4.24.28	<i>Trichoderma longibrachiatum</i> (IMI SD 135)			Bacillolysin 800 U		
	Polygalacturonase C 3.2.1.15	alpha- amylase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9554) and			Polygalacturonase 50 U	2.	Recommended dose per kg of complete feedingstuffs:

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	<p>polygalacturonase produced by <i>Aspergillus aculeatus</i> (CBS 589.94) having a minimum activity of:</p>	<p>endo-1,3(4)-beta-glucanase: 150 U/ g<sup>f</sup></p> <p>endo-1,4-beta-xylanase: 1 500 U/ g<sup>g</sup></p> <p>alfa-amylase: 500 U/ g<sup>h</sup></p> <p>bacillolysin: 800 U/ g<sup>i</sup></p> <p>polygalacturonase: 50 U/ g<sup>j</sup></p>				<p>3.</p>	<p>endo-1,3(4)-beta-glucanase: 150 U</p> <p>endo-1,4-beta-xylanase: 1 500 U</p> <p>alpha-amylase: 800 U.</p> <p>bacillolysin: 800 U</p> <p>polygalacturonase: 50 U</p> <p>For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and betaglucans), e.g. containing more than 30 % wheat.</p>
	Layinghens			<p>endo-1,3(4)-beta-glucanase: 150 U</p>	1.	<p>30.9.2001</p> <p>In the directions for use of the additive and premixture,</p>	
				<p>endo-1,4-beta-xylanase: 1 500 U</p>			

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				alpha-amylase: 1 000 U	—	indicate the storage temperature, storage life and stability to pelleting.
				bacillolysine: 800 U		
				polygalacturonase: 50 U		
						2. Recommended dose per kg of complete feedingstuffs: endo-1,3(4)-beta-glucanase: 150 U endo-1,4-beta-xylanase: 1 500 U alpha-amylase: 1 000 U polygalacturonase: 25 U.
						3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and betaglucans),



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							e.g. containing more than 30 % wheat.
50	6-phytase EC 3.1.3.26	Preparation of 6-phytase produced by <i>Aspergillus oryzae</i> (DSM 11857) having a minimum activity of:	Chickens for fattening	—	250 FYT	—	<p>1. 30.9.2001 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>2. Recommended dose per kg of complete feedingstuff: 500-1 000 FYT</p> <p>3. For use in compound feed containing more than 0,25 % phytin bound phosphorus.</p>
		Coated form: 2 500 FYT/g <sup>k</sup> Liquid form: 5 000 FYT/g					

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		Laying hens	—	250 FYT	—	1.	30.9.2001 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: 500-1 000 FYT
						3.	For use in compound feed containing more than 0,25 % phytin bound phosphorus.
		Turkeys for fattening	—	250 FYT	—	1.	30.9.2001 In the directions for use of the

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							additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
						2.	Recommended dose per kg of complete feedingstuff: 500-1 000 FYT
						3.	For use in compound feed containing more than 0,25 % phytin bound phosphorus.
		Piglets	2 months	500 FYT	—	1.	30.9.2001 In the directions for use of the additive and premixture, indicate the storage temperature, storage

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							life and stability to pelleting.
						2.	Recommended dose per kg of complete feedingstuff: 500-1 000 FYT
						3.	For use in compound feed containing more than 0,25 % phytin bound phosphorus.
		Pigs for fattening	—	500 FYT	—	1.	30.9.2001 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
						2.	Recommended dose per



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							in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.
52	Endo-1,3(4)-beta-glucanase: EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Aspergillus aculeatus</i> (CBS 589.94),	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 1 000 U	1.	30.9.2001 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
	Endo-1,4-beta-glucanase: EC 3.2.1.4	by <i>Aspergillus aculeatus</i> (CBS 589.94),			Endo-1,4-beta-glucanase: 12 000 U		
	Alpha-amylase EC 3.2.2.1	endo-1,4-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (CBS 592.94) and alpha-amylase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9553), having a minimum activity of:			Alpha-amylase: 40 U	2.	Recommended dose per kg of complete feedingstuff: endo-1,3(4)-beta-glucanase: 1 000-2 000 U endo-1,4-
			Liquid form:				

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			Endo-1,3 (4)- beta- glucanase: 10 000 U/ m <sup>m</sup> Endo-1,4- beta- glucanase: 120 000 U/ m <sup>n</sup> Alpha- amylase: 400 U/ ml <sup>o</sup>			3.	beta- glucanase: 12 000-24 000 U For use in in compound feed rich in non starch polysaccharides (mainly arabinoxylans and betaglucans) e.g. containing more than 20 % wheat and 15 % sorghum and 5 % maize.
<b>a</b>	1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from carboxymethylcellulose per minute at pH 5.0 and 40 °C.						
<b>b</b>	1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from barley beta-glucan per minute at pH 5.0 and 40 °C.						
<b>c</b>	1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from oat spelt xylan per minute at pH 5.0 and 40 °C.						
<b>d</b>	1 EPU is the amount of enzyme which liberates 0,0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4,7 and 30 °C.						
<b>e</b>	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.						
<b>f</b>	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.						
<b>g</b>	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.						
<b>h</b>	1 U is the amount of enzyme which liberates 1 micromole of glucosidic linkages from water insoluble cross-linked starch polymer per minute at pH 6,5 and 37 °C.						
<b>i</b>	1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from casein substrate per minute at pH 7,5 and 40 °C.						

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<b>j</b>	1 U is the amount of enzyme which liberates 1 micromole of reducing material (galacturonic acid equivalents) from poly D-galacturonic substrate per minute at pH 5,0 and 40 °C.
<b>k</b>	1 FYT is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5.5 and 37 °C.
<b>l</b>	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.
<b>m</b>	1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from barley-glucan per minute at pH 7.5 and 30 °C.
<b>n</b>	1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from carboxymethylcellulose per minute at pH 7.5 and 30 °C.
<b>o</b>	1 U is the amount of enzyme which liberates 1 micromole of glucose from a cross-linked starch polymer per minute at pH 7.4 and 37 °C.

## ANNEX IV

No.	Additive	Chemical formula, or description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
					CFU/kg of complete feedingstuff			
19	Mixture of: <i>Streptococcus infantarius</i> CNCM I-841 and <i>Lactobacillus plantarum</i> CNCM I-840	<i>Streptococcus infantarius</i> and <i>Lactobacillus plantarum</i> containing a minimum of: <i>Streptococcus infantarius</i> $0,5 \times 10^9$ CFU/g and: <i>Lactobacillus plantarum</i> $2 \times 10^9$ CFU/g	Calves	6 months	<i>Streptococcus infantarius</i> $1 \times 10^9$	<i>Streptococcus infantarius</i> $1 \times 10^9$  <i>Lactobacillus plantarum</i> $0,5 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	30.9.2001



**Changes to legislation:**

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