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)

^{F1}Article 1

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.

F1ANNEX I

[^{F1}]

No(or EC No)	Additive	Chemica formula descripti	ll Species or o c ategory of animal	Maximu age	mMinimu content Units of kg of con feedings	mMaximu content activity/ mplete tuff	mOther provisio	Period nsof authorisation
16	Endo-1,4- beta- glucanase EC 3.2.1.4	Preparatio of endo-1,4- beta- glucanase produced by <i>Trichoder</i> <i>longibrac</i> (IMI SD 142) having a minimum activity of:	Mchickens for fattening ma hiatum Solid form: 2 000 CU/ g ^a Liquid form: 2 000 CU/ ml		250 CU		1. 2. 3.	30.9.2000 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Recommended dose per kg of complete feedingstuff: 500-1 000 CU. For

ANNEX II

				in compound feed rich in non- starch polysaccharides (mainly beta- glucans), e.g. containing more than 40 % barley.
	Laying hens	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: 500-1 000 CU.

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.

			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.

Pigs for fattening250 CU1.starch polysaccharide: (mainly beta- glucans), e.g. containing more than 40 % barley.Pigs for fattening250 CU1.1.In the additive and premixture, indicate the storage tife and stability to pelleting.2.Recommended dose per kg				3.	500-1 000 CU. For use in compound feed rich in non-
Pigs for fattening — 250 CU — 30.9.2000 In the directions for use of the additive and premixture, indicate the storage life and storage life and storage life and stability to pelleting. 2. Recommended dose per kg					polysaccharides (mainly beta- glucans), e.g. containing more than 40 % barley.
2. Recommended dose per kg		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

1 CI a beta-glucan per minute at pH 4,5 and 30 °C.

					3.	of complete feedingstuff: 500-1 000 CU. 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	Preparatio of endo-1,4- beta- xylanase produced by <i>Trichoder</i> <i>longibrac</i> (IMI SD 135) having a minimum activity of:	Chickens for fattening ma hiatum Solid form: 6 000 EPU/ g ^b	750 EPU	1.	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.

Liquid 2. Recommended form: dose D per **b**00 kg of EPU/ ml complete feedingstuff: 500-3 000 EPU. 3. For use in compound feed rich in nonstarch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat. 30.9.2000 In Laying 750 1. hens EPU 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.

				2.	and stability to pelleting. Recommended dose per kg of complete feedingstuff: 1 500-3 000
				3.	EPU. 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.

		2.	temperature, storage life and stability to pelleting. Recommended dose per kg of complete feedingstuff: 1 500-3 000 EPU. For
		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.

				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.

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.

ANNEX III

No.	Additive	Chemica	I Species	Maximu	mMinimu	mMaximu	mOther	Period
(or EC		formula,	or	age	content	content	provisio	nsof
No)		descripti	io c ategory	-				authorisation

			of animal		Units of kg of cor feedings	activity/ mplete tuff		
12	Endo-1,4- beta- glucanase EC 3.2.1.4 Endo-1,3(beta- glucanase EC 3.2.1.6 Endo-1,4- beta- xilanase EC 3.2.1.8	Preparation of endo-1,4- beta- glucanase endo-1,3 (4)-beta- glucanase and endo-1,4- beta- xylanase produced by <i>Trichoder</i> <i>viride</i> (FERM BP-4447) having a minimum activity	ma Endo-1,4- beta- glucanase: glucanase: boto U/ g ^a Endo-1,3(2 glucanase: 18 000 U/ g ^b Endo-1,4- beta- xylanase: 26 000 U/ g ^c	4)-	Endo-1,4- beta- glucanase 800 U Endo-1,3(beta- glucanase 1 800 U Endo-1,4- beta- xylanase: 2 600 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. 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- glucanase: 1 800-2 700 U Endo-1,4- beta- glucanase: 1 800-2 700 U Endo-1,4- beta- glucanase: 1 800-2 700 U

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

					3.	complete feedingstuff: 1 500-3 000 EPU. For use in compound feed rich in non- starch polysaccharides (mainly arabinoxylans), e.g. containing more than 35 % wheat.
42	Endo-1,4(betaxylan EC	(4) reparation as fe endo-1,4-	fattening	 4 000 U	 1.	30.9.2001 In the directions
	3.2.1.8	beta- xylanase produced				for use of
		by Trichoder	ma hiatum			the additive
		(IMI SD 135)	пшит			and premixture,
		having a				indicate the
		activity of:				storage temperature,
			Solid form:			storage life
			4 000			and stability
			U/ g ^e			to pelleting.
		Character of the	istic		2.	Recommended dose
		preparatio	a n:			per kg
		-	endo-1,4- beta-			of

		xylanase: 1,99 % wheat: 97,7 % calcium propionat 0,3 % lecithin: 0,01 %	e:			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 Er be gh EC 3 Er be xill EC 3 Al an EC 3 Pc C 3	ndo-1,3(4)repeta- of ucanase endo 2.1.6 gluc ndo-1,4 by <i>Tric</i> lanasa C (ATV 2.1.8 2100 lfa- mylase beta 2.1.1 proc acillolys <i>Fric</i> long 4.24.28 (IM olygalact Por alph 2.1.15 amy proc by <i>Bacu</i> amy (DS 9554	paratio Chickens for p-1,3(4f)attening canase ducted <i>hoderma</i> gibrachiatum CC 6), p-1,4- unase duced <i>hoderma</i> gibrachiatum I lase duced <i>illus</i> cloliquefaciens M 4)	s —	Endo-1,3(beta- glucanase 150 U Endo-1,4- beta- xylanase: 1 500 U Alfa- amylase: 500 U Bacillolys 800 U Polygalac 50 U	(4)- : 	1.	30.9.2001 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Recommended dose per kg of complete feedingstuffs:

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

1					h
		alpha-			indicate
		amylase:			the
		1 000 U			storage
					temperature,
		bacillolys	1 n:-		storage
		800 U			life
		nolvalac	turonase.		and
		50 II	unonase.		stability
		50 0			to
					pelleting.
					r
				2.	Recommended
					dose
					per
					kg
					of
					complete
					feedingstuffs:
					endo-1 3(4)-
					heta-
					alucanase.
					150
					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
					nolysaccharidas
					mainly
					maliny
					araomoxylans
					petaglucans),

						e.g. containing more than 30 % wheat.
50	6- phytase EC 3.1.3.26	Preparatic of 6- phytase produced by <i>Aspergilli</i> <i>oryzae</i> (DSM 11857) having a minimum activity of:	Chickens for fattening <i>is</i> coated form: 2 500 FYT/ g ^k Liquid form:	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.
			5 000 FYT/ g		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.

Laying	 250 FYT	 1	30.9.2001
hens		1.	In the
			directions
			for
			use
			of
			the
			and
			premixture,
			indicate
			the
			storage
			storage
			life
			and
			stability
			nelleting
		2.	Recommended
			per
			kg
			of
			complete
			500-1
			000
			FYT
		3.	For
			use
			in
			compound food
			containing
			more
			than
			0,25 %
			phytin
			phosphorus.
Turkeys	 250 FVT	 <u> </u>	30.9.2001
for	230111	 1.	In
fattening			the
			airections
			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.
Ι	Piglets	2 months	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 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

					3.	kg of complete feedingstuff: 500-1 000 FYT For use in compound feed containing more than 0,25 % phytin bound phosphorus.
51	Endo-1,4- betaxylan EC 3.2.1.8	Preparatic asf endo-1,4- beta- xylanase produced by <i>Bacillus</i> (LMG-S 15136) having a minimum activity of:	Chickens for fattening 100 IU/ g ^l	10 IU	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: 10- IU For
					٦.	use

							in compound feed rich in non- starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.
52	Endo-1,3(beta- glucanase EC 3.2.1.6 Endo-1,4- beta- glucanase EC 3.2.1.4 Alpha- amylase EC 3.2.2.1	Preparation of endo-1,3(beta- glucanasa produced by <i>Aspergilla</i> <i>aculeatus</i> (CBS 589.94), endo-1,4- beta- glucanase produced by <i>Trichoder</i> <i>longibrac</i> (CBS 592.94) and alpha- amylase produced by <i>Bacillus</i> <i>amyloliqua</i> (DSM 9553), having a minimum activity of:	Mchickens for Affattening us ma hiatum efaciens Liquid form:	Endo-1,30 beta- glucanase 1 000 U Endo-1,4- beta- glucanase 12 000 U Alpha- amylase: 40 U	(4) : :	1.	30.9.2001 In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Recommended dose per kg of complete feedingstuff: endo-1,3(4)- beta- glucanase: 1 000-2 000 U endo-1,4-

		Endo-1,3 (4)- beta- glucanase: 10 000 U/ m ^m Endo-1,4- beta- glucanase: 120 000 U/ m ⁿ Alpha- amylase: 400 U/ ml°	3.	beta- glucanase: 12 000-24 000 U For use 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.
a	1 U is the amount of enzyme which liberate 5.0 and 40 $^{\circ}$ C.	es 0,1 micromoles of glucose from	carboxymethylcellulose per mi	nute at pH
b	1 U is the amount of enzyme which liberate 40 °C.	es 0,1 micromoles of glucose from	barley beta-glucan per minute a	at pH 5.0 and
c	$1~{\rm U}$ is the amount of enzyme which liberate 40 °C.	es 0,1 micromoles of glucose from	oat spelt xylan per minute at pH	H 5.0 ande
d	1 EPU is the amount of enzyme which liber xylan per minute at pH 4,7 and 30 °C.	rates 0,0083 micromoles of reducin	ng sugars (xylose equivalents) f	rom oat spelt
e	1 U is the amount of enzyme which liberate per minute at pH 5,3 and 50 °C.	es 1 micromole of reducing sugars	(xylose equivalents) from oat s	pelt xylan
f	1 U is the amount of enzyme which liberate glucan per minute at pH 5,0 and 30 °C.	es 1 micromole of reducing sugars	(glucose equivalents) from barl	ey beta-
g	1 U is teh amount of enzyme which liberate per minute at pH 5,3 and 50 °C.	es 1 micromole of reducing sugars	(xylose equivalents) from oat s	pelt xylan
h	1 U is the amount of enzyme which liberate polymer per minute at pH 6,5 and 37 °C.	es 1 micromole of glucosidic linkag	ges from water insoluble cross-	linked starch
i	1 U is the amount of enzyme which liberate substrate per minute at pH 7,5 and 40 °C.	es 1 microgram of phenolic compo	und (tyrosine equivalents) from	casein

- j 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.
- k 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.
- 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.
- m 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 $^{\circ}$ C.
- **n** 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.
- 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.

No.	Additive	Chemica formula	l Species or	Maximu age	mMinimu content	mMaximu content	mOther provisio	Period nsof
		descript	io n ategory of animal		CFU/kg complete feedings	of e tuff	F	authorisation
19	Streptocod infantariu CNCM I-841 <i>Lactobacti</i> plantarum CNCM I-840	cMisxture sof: Streptocoo infantariu and Lactobact plantarum containing a minimum of: Streptocoo infantariu $0,5 \times$ 10^9 CFU/g and: Lactobact plantarum 2×10^9 CFU/g	Calves ccus s illus g ccus s illus	6 months	Streptocod infantariu 1 × 10 ⁹ Lactobact plantarum 0,5 × 10 ⁹	c Stus ptocod sinfantariu 1 × 10 ⁹ illusctobact aplantarun 0,5 × 10 ⁹	ctaxthe sdirections for use of the additive and premixtur indicate the storage temperatu storage life and stability to pelleting.	30.9.2001 e, re,

ANNEX IV

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EC) No 1353/2000.