Commission Regulation (EC) No 316/2003 of 19 February 2003 concerning the permanent authorisation of an additive in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (Text with EEA relevance)

# COMMISSION REGULATION (EC) No 316/2003

of 19 February 2003

concerning the permanent authorisation of an additive in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs

(Text with EEA relevance)

### THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs<sup>(1)</sup>, as last amended by Commission Directive 2003/7/EC<sup>(2)</sup>, and in particular Articles 3, 9d, and 9e thereof,

### Whereas:

- (1) Article 9d(1) of Directive 70/524/EEC provides that additives referred to in Part II of Annex C to that Directive may be authorised without a time limit if the conditions laid down in Article 3(a) are satisfied.
- (2) New data were submitted by the producing company in support of an application for authorisation without a time limit of the micro-organism preparation set out in this Regulation.
- (3) The assessment of the application for authorisation submitted in respect of that microorganism preparation, shows that all the conditions required for an authorisation, as provided for in Directive 70/524/EEC are satisfied.
- (4) That micro-organism preparation may therefore be authorised for an unlimited period.
- (5) Directive 70/524/EEC provides that a new use of an additive already authorised requires a Community authorisation.
- (6) Directive 70/524/EEC provides that provisional authorisation of a new additive for use in feedingstuffs or of a new use of an additive already authorised may be given if the conditions laid down in that Directive are satisfied, and if it is reasonable to assume, in view of the available results, that when used in animal nutrition it has one of the effects referred to in Article 2(a) of that Directive. Such provisional authorisation may be given for a period not exceeding four years in the case of additives referred to in Part II of Annex C to that Directive.

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- (7) New data were submitted by the producing company in support of an application to extend the authorisation of an enzyme preparation set out in this Regulation.
- (8) The assessment of the application for authorisation submitted in respect of the new use of the preparation of this enzyme, shows that the conditions provided for in Directive 70/524/EEC for provisional authorisation are satisfied.
- (9) This enzyme preparation should therefore be provisionally authorised for a period of four years.
- (10) The assessment of the application shows that certain procedures should be required to protect workers from exposure to the additives set out in the Annexes. Such protection should be assured by the application of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work<sup>(3)</sup>.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

### HAS ADOPTED THIS REGULATION:

#### Article 1

The preparation belonging to the group 'Micro-organisms' as set out in Annex I is authorised for use as additive in animal nutrition under the conditions laid down in that Annex.

### Article 2

The preparation belonging to the group 'Enzymes' as set out in Annex II is provisionally authorised for use as additive in animal nutrition under the conditions laid down in that Annex.

### Article 3

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

It shall apply from 1 March 2003.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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## ANNEX I

No (or Additive Chemic EC formula					mMinimu content	mMaximu content	End of nsperiod	
No)			on io <b>n</b> ategory	age	CFU/kg	L	provision	of
110)		ucscripti	of		complete			authorisation
			animal		feedings			
'Micro-o	rganisms		***********		iccumgs	tuii		<u></u>
		D (	C 41		0	E1 0	IT 41	XX7'.1
E 1702		n Procepsaratio	for	_	$4 \times 10^9$	$[^{\text{F1}}8 \times 10^9]$	in the directions	Without
	cerevisiae NCYC	Saccharoi					for use	limit'
	Sc 47	cerevisiae					of the	1111111
	SC +/	containing					additive	
		a	5				and the	
		minimum					premixtur	e
		of					indicate	-,
		$5 \times 10^9 \mathrm{C}$	FI I/				the	
		g	1 01				storage	
		additive					temperatu	re,
							storage	
							life and	
							stability	
							to	
							pelletting.	
							Indicate in the	
							in the instruction	<b>n</b> g
							for use:	118
							"the	
							quantity	
							of	
							Saccharon	nvces
							cerevisae	
							in the	
							daily	
							ration	
							must not	
							exceed	
							$2,5 \times 10^9$	CFU
							for	
							100 kg	
							of	1 .
							bodyweig	nt
							and	CDV.
							$0.5 \times 10^{10}$	CFU
							for each	
							additional	
							100 kg of	
							oi bodyweig	ht "
							bouyweig	111.

ANNEX II
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#### **Textual Amendments**

F1 Deleted by Commission Implementing Regulation (EU) No 1018/2012 of 5 November 2012 amending Regulations (EC) No 232/2009, (EC) No 188/2007, (EC) No 186/2007, (EC) No 209/2008, (EC) No 1447/2006, (EC) No 316/2003, (EC) No 1811/2005, (EC) No 1288/2004, (EC) No 2148/2004, (EC) No 1137/2007, (EC) No 1293/2008, (EC) No 226/2007, (EC) No 1444/2006, (EC) No 1876/2006, (EC) No 1847/2003, (EC) No 2036/2005, (EC) No 492/2006, (EC) No 1200/2005, and (EC) No 1520/2007 as regards the maximum content of certain micro-organisms in complete feedingstuffs (Text with EEA relevance).

### ANNEX II

No (or EC No)	Additive	Chemical Species formula, or descriptionategor of animal		age	nMinimumMaximu content content Units of activity/ kg of complete feedingstuff		mOther provision	End of nsperiod of authorisation
<b>Enzymes</b>	3							
	beta- xylanase EC 3.2.1.8 Endo-1,3( beta- glucanase	beta- xylanase A)nd endo-1,3(beta- Effucanase Bp2old6ced by Aspergilla niger (CNCM I-1517) having a minimum activity of:	for fattening 4)-		280 QXU 1 400 QGU	840 QXU 4 200 QGU	2.	28.2.2007 In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.  Recommended dose per kilogram

a 1 QXU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat xylan per minute at pH 5,1 and 50 °C.

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

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				complete feedingstuff: 560 QXU 2 800 QGU.
				For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 20 % wheat and/or barley.

a 1 QXU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat xylan per minute at pH 5,1 and 50 °C.

b 1 QGU is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley betaglucan per minute at pH 4,8 and 50 °C.'

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- (1) OJ L 270, 14.12.1970, p. 1.
- (2) OJ L 22, 25.1.2003, p. 28.
- (**3**) OJ L 183, 29.6.1989, p. 1.

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