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**COMMISSION REGULATION (EC) No 1847/2003**

**of 20 October 2003**

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

(Text with EEA relevance)

(OJ L 269, 21.10.2003, p. 3)

Amended by:

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**COMMISSION REGULATION (EC) No 1847/2003****of 20 October 2003****concerning the provisional authorisation of a new use of an additive and the permanent authorisation 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 Article 3, Article 9d(1) and Article 9e(1) thereof,

Whereas:

- (1) Directive 70/524/EEC provides that a new use of an additive already authorised requires a Community authorisation.
- (2) In the case of additives referred to in Part II of Annex C to Directive 70/524/EEC, which include enzymes, provisional authorisation of a new use of an additive in feedingstuffs 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.
- (3) The enzyme referred to in Annex I to this Regulation (the enzyme) was provisionally authorised for chickens for fattening for the first time by Commission Regulation (EC) No 1436/98 <sup>(3)</sup>, following a favourable opinion of the Scientific Committee for Animal Nutrition (SCAN), in particular with regard to the safety of the product. The provisional authorisation of that additive was extended until 30 June 2004 by Commission Regulation (EC) No 2200/2001 <sup>(4)</sup>.
- (4) New data were submitted by the producing company in support of the application to extend the authorisation of the use of the enzyme to turkeys for fattening.
- (5) The assessment of the application for authorisation submitted in respect of the new use of the enzyme shows that the conditions provided for in Directive 70/524/EEC for provisional authorisation are satisfied.

<sup>(1)</sup> OJ L 270, 14.12.1970, p. 1.

<sup>(2)</sup> OJ L 22, 25.1.2003, p. 28.

<sup>(3)</sup> OJ L 191, 7.7.1998, p. 15.

<sup>(4)</sup> OJ L 299, 15.11.2001, p. 1.

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- (6) On 27 March 2003, the SCAN delivered a favourable opinion on the safety of the enzyme for turkeys for fattening under the conditions laid down in this Regulation.
- (7) 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.
- (8) The micro-organism referred to in Annex II to this Regulation (the micro-organism) was provisionally authorised for the first time by Commission Regulation (EC) No 1436/98, following a favourable opinion of the SCAN, in particular with regard to the safety of the product. The provisional authorisation of the micro-organism was extended until 30 June 2004 by Regulation (EC) No 2200/2001.
- (9) New data were submitted by the producing company in support of the application for authorisation without a time limit of the micro-organism.
- (10) The assessment of the application for authorisation submitted in respect of the micro-organism, shows that all the conditions required for an authorisation without a time limit as provided for in Directive 70/524/EEC are satisfied.
- (11) On 2 December 2002, the SCAN delivered a favourable opinion on the efficacy of the micro-organism under certain conditions laid down in this Regulation.
- (12) Accordingly, it is appropriate that the use of the enzyme for turkeys for fattening should be authorised for a period of four years, and the use of the micro-organism for piglets up to 35 kg should be authorised without a time limit.
- (13) The assessments of the two applications shows that certain procedures are required to protect workers from exposure to the enzyme and the micro-organism. However, such protection is 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>(1)</sup>.
- (14) 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 additive belonging to the group ‘enzymes’ referred to in Annex I is authorised for use as an additive in feedingstuffs under the conditions laid down in that Annex.

*Article 2*

The additive belonging to the group ‘micro-organisms’ referred to in Annex II is authorised for use as additive in feedingstuffs under the conditions laid down in that Annex.

<sup>(1)</sup> OJ L 183, 29.6.1989, p. 1.

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*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*.

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

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## ANNEX I

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			
<b>Enzymes</b>								
14	Endo-1,4-beta-xylanase EC 3.2.1.8.	Preparation of endo-1,4-beta-xylanase produced by <i>Aspergillus niger</i> (CBS 520.94) having a minimum activity of:  Solid form: 600 U/g <sup>(1)</sup>  Liquid form: 300 U/ml	Turkeys for fattening	—	300 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:  300 — 1 200 U  3. For use in compound feed rich in non-starch polysaccharides, (mainly arabin-oxylans) e.g. containing more than 40 % wheat.	24.10.2007

<sup>(1)</sup> One U is the amount of enzyme which liberates 1 micromole of xylose from birchwood xylan per minute at pH 5,3 and 50 °C.\*

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## ANNEX II

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			
<b>Micro-organisms</b>								
E 1703	<i>Saccharomyces cerevisiae</i> CNCM I-1079	Preparation of <i>Saccharomyces cerevisiae</i> containing a minimum of:  $2 \times 10^{10}$ CFU/g additive	Piglets	—	$2 \times 10^9$	► <b>M1</b> ◀	For piglets until approximately 35 kg.  In the direction for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.	Without a time limit?