

COMMISSION REGULATION (EC) No 261/2003
of 12 February 2003
concerning the provisional authorisation of new uses of additives 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 ⁽¹⁾, as last amended by Regulation (EC) No 1756/2002 ⁽²⁾, and in particular Articles 3 and 9e thereof,

Whereas:

- (1) Directive 70/524/EEC provides that a new use of an additive already authorised requires a Community authorisation in accordance with Article 4 of the Directive.
- (2) Directive 70/524/EEC provides that provisional authorisation of a new additive for use in feedingstuffs or 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.
- (3) New data were submitted by the producing companies in support of application to extend the authorisation of the two preparations of the enzymes set out in Annex I and II to this Regulation, and which are listed under Numbers 50 and 51 in the Annexes to Directive 70/524/EEC, to new animal categories.
- (4) The assessments of the applications for authorisation submitted in respect of the new use of the preparations of the enzymes set out in Annex I and II, show that the

conditions referred to in Article 9e(1) of Directive 70/524/EEC are satisfied, and the extensions of use should therefore be authorised on a provisional basis for a period of four years.

- (5) The assessments of the applications also show that certain procedures may be required to protect workers from exposure to the additives set out in Annexes I and II. Such protections should however 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 ⁽³⁾.
- (6) The Scientific Committee for Animal Nutrition has delivered favourable opinions with regard to the safety of those preparations, under the conditions set out in the Annexes to this Regulation.
- (7) 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 preparations belonging to the group 'Enzymes' listed in Annex I and II are authorised for use as additives in animal nutrition under the conditions laid down in these Annexes.

Article 2

This Regulation shall enter into force on the 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.

Done at Brussels, 12 February 2003.

For the Commission
David BYRNE
Member of the Commission

⁽¹⁾ OJ L 270, 14.12.1970, p. 1.
⁽²⁾ OJ L 265, 3.10.2002, p. 1.

⁽³⁾ OJ L 183, 29.6.1989, p. 1.

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			
Enzymes								
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: Coated form: 2 500 FYT/g ⁽¹⁾ Liquid form: 5 000 FYT/g	Sows	—	750 FYT	— — —	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: 750-1 000 FYT 3. For use in compound feed containing more than 0,25 % phytin bound phosphorus	1.2.2007

⁽¹⁾ 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.

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
					Units of activity/kg of complete feedingstuff			
Enzymes								
51	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by <i>Bacillus subtilis</i> (LMG S-15136) having a minimum activity of: Endo-1,4-beta-xylanase: 100 IU/g ⁽¹⁾	Pigs for fattening		10 IU		<ol style="list-style-type: none"> 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 kilogram of complete feedingstuff: Endo-1,4-beta-xylanase: 10 IU/kg 3. For use in compound feed rich in arabinoxylans e.g. minimum 40 % wheat or barley 	1.1.2007

⁽¹⁾ 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.