

COMMISSION REGULATION (EC) No 2188/2002
of 9 December 2002
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 Commission 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 in the case of an already authorised additive requires a Community authorisation in accordance with Article 4 of the Directive.
- (2) Article 9e(1) of 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 of Article 3a(b) to (e) of 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 of up to four years in the case of additives referred to in Part II of Annex C to Directive 70/524/EEC.
- (3) New data were submitted by the producing companies to extend the authorisation of the two preparations of enzymes described in Annex I and II to this Regulation, and which are listed respectively under No 11 and 51 in the Annexes to Directive 70/524/EEC, to new animal categories.
- (4) The assessment of the dossiers submitted in respect of the new use of the preparations of enzymes described in Annex I and II shows that the conditions referred to in Article 9e(1) are satisfied, and the extensions of use may therefore be authorised on a provisional basis for a period of four years.
- (5) New data were submitted by the producing company to extend the authorisation of an enzyme preparation described in Annex III to this Regulation, and which is listed under No 51 in the Annexes to Directive 70/524/EEC, to a new physical form as regards one animal category.
- (6) The assessment of the dossier submitted in respect of the new use of the preparation of enzyme described in Annex III shows that the conditions referred to in Article 9e(1) are satisfied, and the extension of use may therefore be authorised on a provisional basis for a period of four years.
- (7) The assessment of the dossier also shows that certain procedures may be required to protect workers from exposure to the additives listed in the Annexes. Such protection 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⁾.
- (8) On 18 April and 19 June 2002 the Scientific Committee for Animal Nutrition has delivered favourable opinions with regard to the safety of the abovementioned enzymes preparations, under the conditions described in the Annexes to this Regulation.
- (9) 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 Annexes I and II to this Regulation are authorised for use as additives in animal nutrition under the conditions laid down in these Annexes.

Article 2

The preparation belonging to the group 'Enzymes' listed in Annex III to this Regulation is authorised for use as additive in animal nutrition under the conditions laid down in this Annex.

Article 3

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

⁽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.

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

Done at Brussels, 9 December 2002.

For the Commission
David BYRNE
Member of the Commission

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								
11	Endo-1,4-beta-glucanase EC 3.2.1.4 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase 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>Trichoderma longibrachiatum</i> (ATCC 74252) having a minimum activity of: Granular and liquid form: Endo-1,4-beta-glucanase: 8 000 U ⁽¹⁾ /g or ml Endo-1,3(4)-beta-glucanase: 18 000 U ⁽²⁾ /g or ml Endo-1,4-beta-xylanase: 26 000 U ⁽³⁾ /g or ml	Laying hens	—	Endo-1,4-beta-glucanase: 400 U Endo-1,3(4)-beta-glucanase: 900 U Endo-1,4-beta-xylanase: 1 300 U	— — —	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dosages per kilogram of complete feedingstuff: endo-1,4-beta-glucanase: 400-1 280 U endo-1,3(4)-beta-glucanase: 900-2 880 U endo-1,4-beta-xylanase: 1 300-4 160 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % wheat, triticale or barley.	1.1.2007

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			
			Piglets	—	Endo-1,4-beta-glucanase: 400 U	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dosages per kilogram of complete feedingstuff: endo-1,4-beta-glucanase: 400-1 600 U endo-1,3(4)-beta-glucanase: 900-3 600 U endo-1, 4-beta-xylanase: 1 300-5 200 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % wheat, triticale or maize or wheat and 20 % rye.	1.1.2007
				Endo-1,3(4)-beta-glucanase: 900 U	—			
				Endo-1,4-beta-xylanase: 1 300 U	—			

(¹) 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.

(²) 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.

(³) 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.

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 produced by <i>Bacillus subtilis</i> (LMG S-15136) having a minimum activity of: Endo-1,4-beta-xylanase: Solid and liquid: 100 IU ⁽¹⁾ /g or ml	Turkeys 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 dosages per kilogram of complete feedingstuff: 10 IU. 3. For use in compound feed rich in arabinoxylan, e.g. containing 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.

ANNEX III

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 produced by <i>Bacillus subtilis</i> (LMG S-15136) having a minimum activity of: Endo-1,4-beta-xylanase: Liquid: 100 IU ⁽¹⁾ /ml	Chickens 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 dosages per kilogram of complete feedingstuff: 10 IU. 3. For use in compound feed rich in arabinoxylan, e.g. containing 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 3 °C.