COMMISSION REGULATION (EC) No 1332/2004

of 20 July 2004

concerning the permanent authorisation of certain 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], and in particular Articles 3 and 9d(1) thereof,

Whereas:

(1) Directive 70/524/EEC provides for the authorisation of additives to be used in the Community. The additives referred to in Part II of Annex C to that Directive may be authorised without a time limit subject to certain conditions being satisfied.

(2) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287) was provisionally authorised, for the first time, for chickens for fattening, turkeys for fattening and piglets by Regulation (EC) No 1436/98 [2].

(3) The use of the enzyme preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Humicola insolens* (DSM 10442) was provisionally authorised, for the first time, for chickens for fattening by Commission Regulation (EC) No 1436/98 [2].

(4) New data were submitted in support of the applications for authorisation without a time limit of each of these enzyme preparations. The assessment shows that the conditions laid down in Directive 70/524/EEC for such authorisations are satisfied in each case.

(5) Accordingly, the use of these enzyme preparations should be authorised without a time, under certain conditions.

(6) The assessment of these applications 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 [3].

(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', as set out in Annexes I and II, are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in those Annexes.

Article 2

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.

Done at Brussels, 20 July 2004.

For the Commission

David BYRNE

Member of the Commission

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[1] OJ L 270, 14.12.1970, p. 1. Regulation as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

[2] OJ L 191, 7.7.1998, p. 15.

[3] OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

ANNEX I

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								
E 1607	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287) having a minimum activity of: Coated form: 1 000 FXU [1]/g Liquid form: 650 FXU/ml	Chickens for fattening	—	100 FXU	400 FXU	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: 100-400 FXU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 50 % cereals (e.g. wheat, barley, rye or triticale)	Without a time limit
			Turkeys for fattening	—	100 FXU	400 FXU	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: 100-400 FXU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 50 % cereals (e.g. wheat, barley, rye or triticale).	Without a time limit
			Piglets	—	200 FXU	400 FXU	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: 200-400 FXU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 50 % cereals (e.g. wheat, barley, rye or triticale). 4. For use in weaned piglets until approx. 35 kg	Without a time limit

[1] 1 FXU is the amount of enzyme which liberates 7,8 micromoles of reducing sugars (xylose equivalents) from azo-wheat arabinoxylan per minute at pH 6,0 and 50 °C.

ANNEX II

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								
E 1608	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,4-beta-glucanase EC 3.2.1.4	Preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Humicola insolens* (DSM 10442) having minimum activities of: Coated form: Endo-1,4-beta-xylanase: 800 FXU (1)/g Endo-1,4-beta-glucanase: 75 FBG (2)/g Liquid form: Endo-1,4-beta-xylanase: 550 FXU/ml Endo-1,4-beta-glucanase: 50 FBG/ml	Chickens for fattening	—	400 FXU 36 FBG	1 000 FXU 94 FBG	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: 400-1 000 FXU 36-94 FBG. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabino-xylans and beta-glucans), e.g. containing more than 40% vegetable ingredients (barley, oats, wheat, rye, triticale, sorghum or lupin).	Without a time limit

(1) FXU is the amount of enzyme which liberates 3,1 micromoles of reducing sugars (xylose equivalents) from azo-wheat arabinoxylan per minute at pH 6,0 and 50 °C.
(2) FBG is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5,0 and 30 °C.