

COMMISSION REGULATION (EC) No 2013/2001
of 12 October 2001
concerning the provisional authorisation of a new additive use and the permanent authorisation of
an additive 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 Directive 2001/46/EC of the European Parliament and of the Council ⁽²⁾, and in particular Article 3 thereof,

Whereas:

- (1) Directive 70/524/EEC provides that new uses of additives may be authorised following the review of an application made in accordance with Article 4 of the Directive.
- (2) Article 9e(1) of Directive 70/524/EEC provides that provisional authorisation of a new use of an additive may be given if the conditions of Article 3a(b) to (e) 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). Such provisional authorisations may be given for a period up to four years in the case of additives referred to in Part II of Annex C to Directive 70/524/EEC.
- (3) The assessment of the dossier submitted in respect of the new use of the enzyme preparation described in Annex I shows that it satisfies those conditions and may therefore be authorised on a provisional basis for a four-year period.
- (4) The assessment of this dossier also shown that certain precautions should be taken in order to avoid exposure of workers to these additives. Such protection should be assured by the application of Community legislation on the safety and health of workers at work.
- (5) The Scientific Committee for Animal Nutrition has delivered a favourable opinion with regard to the safety of this enzyme preparation.
- (6) The Chernobyl accident caused radioactive caesium fallout, which contaminated forage in certain regions of northern Europe. Due to the long physical half-life of radiocaesium, this fallout still affects animal production.

This emergency situation still continues in particular in Norway. The substance listed in Annex II to this Regulation may be used to decontaminate affected forage. The competent authorities of Norway therefore supported a dossier, seeking an extension of the period of authorisation of this substance.

- (7) This additive is intended to be used only in contaminated areas for a limited period of time. Under normal conditions there is no need for the use of this additive, however, it should be kept available in case of similar future accidents in the Community.
- (8) As no adverse effects were detected during its national use at Member State level nor since the provisional authorisation which was given at Community level in 1996, all conditions in Article 3a of Directive 70/524/EEC are met. Therefore a permanent authorisation of this additive belonging to the group of radionuclide binders listed in Annex II should be given.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Feedingstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

The additive belonging to the group 'Radionuclide binders', listed in Annex II is authorised for use as additive in animal nutrition under the conditions laid down in Annex II.

Article 3

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

It shall apply from 14 October 2001.

⁽¹⁾ OJ L 270, 14.12.1970, p. 1.

⁽²⁾ OJ L 234, 1.9.2001, p. 55.

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

Done at Brussels, 12 October 2001.

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			
54	Endo-1,3(4)-beta-glucanase: EC 3.2.1.6 Endo-1,4-beta-glucanase: EC 3.2.1.4 Alpha-amylase: EC 3.2.1.1 Endo-1,4-beta-xylanase: EC 3.2.1.8	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Aspergillus aculeatus</i> (CBS 589.94), endo-1,4-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (CBS 592.94), alpha-amylase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9553) and endo-1,4-beta-xylanase produced by <i>Trichoderma viride</i> (NIBH FERM BP 4842) having a minimum activity of: Endo-1,3(4)-beta-glucanase: 10 000 U ⁽¹⁾ /g Endo-1,4-beta-glucanase: 120 000 U ⁽²⁾ /g Alpha-amylase: 400 U ⁽³⁾ /g Endo-1,4-beta-xylanase: 210 000 U ⁽⁴⁾ /g	Turkeys for fattening	—	Endo-1,3(4)- beta-glucanase: 500 U Endo-1,4-beta- glucanase: 6 000 U Alpha- amylase: 20 U Endo-1,4-beta- xylanase: 10 500 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 kilo-gram of complete feedingstuff: endo-1,3(4)-beta-glucanase: 500 to 1 500 U endo-1,4-beta-glucanase: 6 000 to 18 000 U alpha-amylase: 20 to 60 U endo-1,4-beta-xylanase: 10 500 to 31 500 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 30 % wheat.	13.10.2005

⁽¹⁾ 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 7,5 and 30 °C.

⁽²⁾ 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from carboxymethylcellulose per minute at pH 4,8 and 50 °C.

⁽³⁾ 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from water insoluble cross-linked starch polymer per minute at pH 7,5 and 37 °C.

⁽⁴⁾ 1 U is the amount of enzyme which liberates 0,0067 micromoles of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 5,3 and 50 °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
					mg/kg of complete feedingstuff			
Radionuclide binders								
1. Radioactive caesium binders (¹³⁷ Cs and ¹³⁴ Cs)								
1.1	Ferric (III) ammonium hexacyanoferrate (II)	NH ₄ Fe(III)[Fe(II)(CN) ₆]	Ruminants (domestic and wild)	—	50	500	Indicate in the instructions for use: 'Only for limited geographical areas in case of contamination with radionuclides' 'The quantity of ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 mg and 150 mg for 10 kg of body weight'	Without time limit
			Calves prior to the start of rumination	—	50	500	Indicate in the instructions for use: 'Only for limited geographical areas in case of contamination with radionuclides' 'The quantity of ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 mg and 150 mg for 10 kg of body weight'	Without time limit
			Lambs prior to the start of rumination	—	50	500	Indicate in the instructions for use: 'Only for limited geographical areas in case of contamination with radionuclides' 'The quantity of ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 mg and 150 mg for 10 kg of body weight'	Without time limit
			Kids prior to the start of rumination	—	50	500	Indicate in the instructions for use: 'Only for limited geographical areas in case of contamination with radionuclides' 'The quantity of ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 mg and 150 mg for 10 kg of body weight'	Without time limit

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
					mg/kg of complete feedingstuff			
			Pigs (domestic and wild)	—	50	500	Indicate in the instructions for use: 'Only for limited geographical areas in case of contamination with radionuclides' 'The quantity of ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 mg and 150 mg for 10 kg of body weight'	Without time limit