COMMISSION REGULATION (EC) No 666/2003

of 11 April 2003

provisionally authorising the use of certain micro-organisms 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(1) thereof,

Whereas:

- (1) Directive 70/524/EEC requires that no additive may be put into circulation unless a Community authorisation has been granted.
- (2) In the case of additives referred to in Part II of Annex C to Directive. 70/524/EEC, which include micro-organisms, provisional authorisation of a new additive for use in feedingstuffs may be given if the conditions laid down 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 assessment of the application for authorisation submitted, in respect of the micro-organism preparation, specified in the Annex to this Regulation, shows that the conditions referred to in Article 9e(1) of Directive 70/ 524/EEC are satisfied.
- (4) The micro-organism preparation should therefore be authorised on a provisional basis for a period of four years.

- (5) The Scientific Committee for Animal Nutrition has delivered a favourable opinion on the safety of the preparation, which belongs to the group 'Micro-organisms', under the conditions set out in the Annex to this Regulation for piglets and pigs for fattening.
- (6) The assessment of the application shows that certain procedures are required to protect workers from exposure to the additives set out in the Annexe. 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 (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 additive belonging to the group 'Microorganisms' referred to in the Annex is authorised for use as an additive in feedingstuffs under the conditions laid down in the Annex.

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, 11 April 2003.

For the Commission David BYRNE Member of the Commission

^{(&}lt;sup>1</sup>) OJ L 270, 14.12.1970, p. 1. (²) OJ L 265, 3.10.2002, p. 1.

 0.2×10^{9}

No (or EC No)

22

'Microorganisms

Additive

Enterococcus faecium DSM 7134

Granules (micro-encapsulated): 1×10^{10} CFU/g of additive

Pigs for fattening

		AN	NNEX			
Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of
			CFU/kg of complete feedingstuff		other provisions	authorisation
	0		0,5 ×109	4 × 10 ⁹	The directions for use must indicate storage temperature, shelf life and pelleting stability of the additive and the premixture	15.4.2007
	Preparation of Enterococcus faecium containing a minimum of:	Preparation of Enterococcus faecium containing a minimum of:	Chemical formula, descriptionSpecies or category of animalMaximum agePreparationofEnterococcus faecium containing a minimum of:Piglets	Chemical formula, description Species or category of animal Maximum age Preparation of Enterococcus faecium containing a minimum of:	Chemical formula, description Species or category of animal Maximum age Minimum content Maximum content Preparation of Enterococcus faecium containing a minimum of: Piglets 0,5 × 10 ⁹ 4 × 10 ⁹	Chemical formula, description Species or category of animal Maximum age Minimum content Maximum content CFU/kg of complete feedingstuff CFU/kg of complete feedingstuff Other provisions Preparation of Enterococcus faecium containing a minimum of: Piglets 0,5 × 10° 4 × 10° The directions for use must indicate storage temperature, shelf life and

 $1 \times 10^{9'}$