

**COMMISSION REGULATION (EC) No 2785/98**  
**of 22 December 1998**  
**concerning the modification of the period of authorisations of additives referred**  
**to in Article 9e(3) of Council Directive 70/524/EEC**

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<sup>(1)</sup>, as last amended by Commission Directive 98/19/EC<sup>(2)</sup>, and in particular Articles 9j and 3 thereof,

Whereas Directive 70/524/EEC provides that new additives or uses of additives may be authorised, taking account of advances in scientific and technical knowledge;

Whereas a provisional authorisation of new additives or uses of additives may be given for a period of five years, if, at the level permitted in feedingstuffs, it does not adversely affect human or animal health or the environment, nor harm the consumer by altering the characteristics of livestock product, if its presence in feedingstuffs can be controlled, and it is reasonable to assume, in view of the available results, that it has a favourable effect on the characteristics of those feedingstuffs or on livestock production when incorporated in such feedingstuffs;

Whereas research into various additives referred to in Article 9e(3) of Directive 70/524/EEC which can be authorised provisionally at national level until 30 November 1998 has not yet been completed; whereas, therefore, the period of authorisation of these substances should be extended taking into account that the period of

provisional authorisation of these additives can not exceed five years;

Whereas the Commission has consulted the Scientific Committee for animal nutrition concerning the authorisation of the micro-organisms included in the Annex to the present Regulation; whereas this Committee delivered an opinion in particular with regard to the safety of these additives;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Feedingstuffs,

HAS ADOPTED THIS REGULATION:

*Article 1*

Additives referred to in the Annex to this Regulation may be authorised in accordance with Directive 70/524/EEC under the conditions laid down in this Annex.

*Article 2*

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

It shall apply with effect from 1 December 1998.

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

Done at Brussels, 22 December 1998.

*For the Commission*  
Franz FISCHLER  
*Member of the Commission*

<sup>(1)</sup> OJ L 270, 14. 12. 1970, p. 1.

<sup>(2)</sup> OJ L 96, 28. 3. 1998, p. 39.

## ANNEX

## Binders, anti-caking agents and coagulants

Registration number	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
					mg/kg of complete feedingstuff			
2	Natrolite-phonolite	Natural mixture of aluminium silicates, alkalines and alkaline-earth and aluminium hydrosilicates, natrolite (43 to 46,5 %) and feldspar	All animal species and categories	—	—	25 000	All feedingstuffs	21.4.1999 <sup>(1)</sup>

## Micro-organisms

Registration number	Additive	Chemical formula, description	Species or category of animal	Maximum age	CFU/kg of complete feedingstuffs		Other provisions	Duration of authorisation
					Minimum	Maximum		
1	<i>Bacillus cereus</i> var. <i>toyoi</i> (CNCM I-1012/NCIB 40112)	Preparations of <i>Bacillus cereus</i> var. <i>toyoi</i> containing a minimum 10 <sup>10</sup> CFU/g additive	Piglets	2 months	10 <sup>9</sup>	10 <sup>9</sup>	—	21.4.1999 <sup>(1)</sup>
				4 months	0,5 × 10 <sup>9</sup>	10 <sup>9</sup>	—	21.4.1999 <sup>(1)</sup>
			Pigs	6 months	0,2 × 10 <sup>9</sup>	10 <sup>9</sup>	—	21.4.1999 <sup>(1)</sup>
			Sows	—	0,5 × 10 <sup>9</sup>	2 × 10 <sup>9</sup>	—	21.4.1999 <sup>(1)</sup>
2	<i>Bacillus licheniformis</i> (DSM 5749)/ <i>Bacillus subtilis</i> (DSM 5750) (in a 1/1 ratio)	Mixture of <i>Bacillus licheniformis</i> and <i>Bacillus subtilis</i> containing a minimum 3,2 × 10 <sup>9</sup> CFU/g additive (1,6 × 10 <sup>9</sup> CFU/g of each bacteria)	Piglets	4 months	1,28 × 10 <sup>9</sup>	3,2 × 10 <sup>9</sup>	—	17.7.1999 <sup>(2)</sup>
3	<i>Saccharomyces cerevisiae</i> (NCYC Sc 47)	Preparation of <i>Saccharomyces cerevisiae</i> containing a minimum 5 × 10 <sup>9</sup> CFU/g additive	Cattle for fattening	—	4 × 10 <sup>9</sup>	8 × 10 <sup>9</sup>	Indicate in the instructions for use: 'The quantity of <i>Saccharomyces cerevisiae</i> in the daily ration must not exceed 2,5 × 10 <sup>10</sup> CFU for 100 kg of bodyweight; 0,5 × 10 <sup>10</sup> CFU for each additional 100 kg of bodyweight'	20.2.2001 <sup>(3)</sup>

Registration number	Additive	Chemical formula, description	Species or category of animal	Maximum age	CFU/kg of complete feedingstuffs		Other provisions	Duration of authorisation
					Minimum	Maximum		
4	<i>Bacillus cereus</i> (ATCC 14893/CIP 5832)	Preparation of <i>Bacillus cereus</i> containing a minimum 10 <sup>10</sup> CFU/g additive	Rabbits for fattening	—	0,5 × 10 <sup>9</sup>	2 × 10 <sup>9</sup>	—	20.2.2001 <sup>(2)</sup>
			Breeding rabbits	—	0,5 × 10 <sup>9</sup>	2 × 10 <sup>9</sup>	—	20.2.2001 <sup>(2)</sup>

<sup>(1)</sup> First authorisation 22 April 1994, Commission Directive 94/17/EC (OJ L 105, 26. 4. 1994, p. 19).

<sup>(2)</sup> First authorisation 18 July 1994, Commission Directive 94/41/EC (OJ L 209, 12. 8. 1994, p. 18).

<sup>(3)</sup> First authorisation 21 February 1996, Commission Directive 96/7/EC (OJ L 51, 1. 3. 1996, p. 45).

### Radionuclide binders

#### 1. Radioactive caesium binders (<sup>137</sup>Cs and <sup>134</sup>Cs):

Registration number	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
					mg/kg of complete feedingstuff			
1.1	Ferric (III) ammonium hexacyanoferrate (II)	NH <sub>4</sub> Fe(III)[(Fe(II)(CN) <sub>6</sub> ]]	Ruminants (domestic and wild)	—	50	500	Indicate in the instructions for use: 'The quantity of Ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 and 150 mg for 10 kg of body weight'	13.10.2001 <sup>(1)</sup>
			Calves prior to the start of rumination	—	50	500	Indicate in the instructions for use: 'The quantity of Ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 and 150 mg for 10 kg of body weight'	13.10.2001 <sup>(1)</sup>
			Lambs prior to the start of rumination	—	50	500	Indicate in the instructions for use: 'The quantity of Ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 and 150 mg for 10 kg of body weight'	13.10.2001 <sup>(1)</sup>

Registration number	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Duration of authorisation
					mg/kg of complete feedingstuff			
			Kids prior to the start of rumination	—	50	500	Indicate in the instructions for use: 'The quantity of Ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 and 150 mg for 10 kg of body weight'	13.10.2001 <sup>(1)</sup>
			Pigs (domestic and wild)	—	50	500	Indicate in the instructions for use: 'The quantity of Ferric (III) ammonium hexacyanoferrate (II) in the daily ration must be between 10 and 150 mg for 10 kg of body weight'	13.10.2001 <sup>(1)</sup>

<sup>(1)</sup> First authorisation 14 October 1996, Commission Directive 96/66/EC (OJ L 272, 25. 10. 1996, p. 32).