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COMMISSION REGULATION (EC) No 1288/2004

of 14 July 2004

concerning the permanent authorisation of certain additives and the provisional authorisation of a new use of an additive already authorised in feedingstuffs

(Text with EEA relevance)

(OJ L 243, 15.7.2004, p. 10)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 1812/2005 of 4 November 2005	L 291	18	5.11.2005
►M2	Commission Implementing Regulation (EU) No 1018/2012 of 5 November 2012	L 307	56	7.11.2012
►M3	Commission Implementing Regulation (EU) No 1061/2013 of 29 October 2013	L 289	38	31.10.2013
►M4	Commission Implementing Regulation (EU) No 1101/2013 of 6 November 2013	L 296	1	7.11.2013
►M5	Commission Implementing Regulation (EU) No 1109/2014 of 20 October 2014	L 301	19	21.10.2014

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concerning the permanent authorisation of certain additives and the provisional authorisation of a new use of an additive already authorised 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 Article 3, and Articles 9d(1) and 9e(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 astaxanthin-rich *Phaffia rhodozyma* (ATCC 74219) as a colourant for salmon and trout has been provisionally authorised by Commission Regulation (EC) No 2316/98 ([3]).

(3) New data were submitted in support of an application for an authorisation without a time limit for that colourant. The assessment shows that the conditions laid down in Directive 70/524/EEC for such an authorisation have been satisfied.

(4) The Scientific Panel on Additives and Products or Substances Used in Animal Feed of the European Food Safety Authority (EFSA) delivered a favourable opinion on 22 January 2003 on the efficacy of that additive when used in the animal category salmon and trout. In a second opinion adopted on 1 April 2004, the EFSA concluded that the yeast in that product is not a living organism and it is not expected to have any consequence on the environment, under the conditions of use set out in Annex I to this Regulation.

(5) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (NCYC Sc 47) has been provisionally authorised, for the first time, for sows by Commission Regulation (EC) No 1436/98 ([4]).

([1]) OJ L 270, 14.12.1970, p. 1.
([2]) OJ L 265, 3.10.2002, p. 1.
([3]) OJ L 289, 28.10.1998, p. 4.
([4]) OJ L 191, 7.7.1998, p. 15.

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(6) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (CBS 493.94) has been provisionally authorised, for the first time, for calves by Commission Regulation (EC) No 1436/98 and for cattle for fattening by Commission Regulation (EC) No 866/1999 ([1]).

(7) The use of the micro-organism preparation of *Enterococcus faecium* (NCIMB 10415) has been provisionally authorised, for the first time, for calves by Commission Regulation (EC) No 866/1999.

(8) The use of the micro-organism preparation of *Enterococcus faecium* (DSM 7134) and *Lactobacillus rhamnosus* (DSM 7133) has been provisionally authorised, for the first time, for calves by Commission Regulation (EC) No 2690/1999 ([2]).

(9) New data were submitted in support of applications for authorisation without a time limit for those micro-organisms. The assessment of those applications shows that the conditions laid down in Directive 70/524/EEC for such authorisations have been satisfied.

(10) Accordingly, the use of those additives without a time limit should be authorised.

(11) In addition, Directive 70/524/EEC provides for the authorisation on a provisional basis of a new use of an additive already authorised to be granted for a period not exceeding four years, subject to certain conditions.

(12) The use of the micro-organism preparation of *Enterococcus faecium* (DSM 10663/NCIMB 10415) has been provisionally authorised, for the first time, for piglets by Commission Regulation (EC) No 1411/1999 ([3]), for calves and chickens for fattening by Commission Regulation (EC) No 1636/1999 ([4]) and for turkeys for fattening by Commission Regulation (EC) No 1801/2003 ([5]).

(13) New data were submitted in support of an application to extend the authorisation of the use of that additive to dogs. The assessment shows that the conditions laid down in Directive 70/524/EEC for such an authorisation have been satisfied.

(14) The EFSA delivered a favourable opinion on 15 April 2004 on the safety of that additive when used in the animal category dogs, under the conditions of use set out in Annex II to this Regulation.

(15) Accordingly, the use of the *Enterococcus faecium*, as specified in Annex II, should be authorised for a period not exceeding four years.

(16) The assessment of the applications shows that certain procedures should be required to protect workers from exposure to the additives set out in Annexes I and II to this Regulation. 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 ([6]).

([1]) OJ L 108, 27.4.1999, p. 21.
([2]) OJ L 326, 18.12.1999, p. 33.
([3]) OJ L 164, 30.6.1999, p. 56.
([4]) OJ L 194, 27.7.1999, p. 17.
([5]) OJ L 264, 15.10.2003, p. 16.
([6]) 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).

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(17) 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 'Colourants, including pigments' and 'Micro-organisms', as set out in Annex I, are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparation belonging to the group 'micro-organisms', as set out in Annex II, is provisionally authorised for use as an additive in animal nutrition under the conditions laid down in that Annex.

Article 3

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

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
					mg/kg of complete feedingstuff			
Colourants, including pigments								
1. *Carotenoids and xanthophylls*								
E 161(z)	Astaxanthin-rich *Phaffia Rhodozyma* (ATCC 74219)	Concentrated biomass of the yeast *Phaffia rhodozyma* (ATCC 74219), killed, containing at least 4,0 g astaxanthin per kilogram of additive and having a maximum ethoxyquin content of 2 000 mg/kg	Salmon	—	—	100	The maximum content is expressed as astaxanthin Use permitted only from the age of six months onwards The mixture of the additive with canthaxanthin is allowed provided that the total concentration of astaxanthin and canthaxanthin does not exceed 100 mg/kg in the complete feedingstuff Ethoxyquin content to be declared	Without a time limit
			Trout	—	—	100	The maximum content is expressed as astaxanthin Use permitted only from the age of six months onwards The mixture of the additive with canthaxanthin is allowed provided that the total concentration of astaxanthin and canthaxanthin does not exceed 100 mg/kg in the complete feedingstuff Ethoxyquin content to be declared	Without a time limit

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EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU/kg of complete feedingstuff			
Micro-organisms								
E 1702	*Saccharomyces cerevisiae* NCYC Sc 47	Preparation of *Saccharomyces cerevisiae* containing a minimum of 5×10^9 CFU/g additive	Sows	—	5×10^9	►M2 — ◄	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting	Without a time limit
▼M5 —								
▼B E 1705	►M3 — ◄	Preparation of *Enterococcus faecium* containing a minimum of Microencapsulated form: 1×10^{10} CFU/g additive Granulated form: $3{,}5 \times 10^{10}$ CFU/g additive	Calves	6 months	1×10^9	$6{,}6 \times 10^9$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting Granulated form to be used exclusively in milk replacers	Without a time limit
E 1706	►M4 — ◄ ►M4 — ◄	Mixture of: *Enterococcus faecium* containing a minimum of: 7×10^9 CFU/g and of *Lactobacillus rhamnosus* containing a minimum of: 3×10^9 CFU/g	Calves	4 months	1×10^9	5×10^9	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting	Without a time limit

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ANNEX II

No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU/kg of complete feedingstuff			
Micro-organisms								
13	*Enterococcus faecium* DSM10663/ NCIMB 10415	Preparation of *Enterococcus faecium* containing a minimum of: Powder and granulated form: $3{,}5 \times 10^{10}$ CFU/g of additive Coated form: $2{,}2 \times 10^{10}$ CFU/g of additive Liquid form: 1×10^{10} CFU/ml of additive	Dogs	—	1×10^{9}	1×10^{10}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting	17 July 2008