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COMMISSION REGULATION (EC) No 1200/2005

of 26 July 2005

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

(Text with EEA relevance)

(OJ L 195, 27.7.2005, p. 6)

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COMMISSION REGULATION (EC) No 1200/2005

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([2]), and in particular Article 25 thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.

(2) Article 25 of Regulation (EC) No 1831/2003 lays down transitional measures for applications for the authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of Regulation (EC) No 1831/2003.

(3) The applications for the authorisation of the additives listed in the Annexes to this Regulation were submitted before the date of application of Regulation (EC) No 1831/2003.

(4) Initial comments on those applications, as provided for in Article 4(4) of Directive 70/524/EEC, were forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. Those applications are therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

(5) The use of the growth promoter Formi LHS (potassium diformate) was provisionally authorised, for the first time, for piglets and pigs for fattening by Commission Regulation (EC) No 1334/2001 ([3]). The person responsible for putting into circulation Formi LHS (potassium diformate) submitted an application to obtain a provisional authorisation for extension of use for four years, as a growth promoter for sows, according to Article 4 of that Directive. The European Food Safety Authority (EFSA) has delivered an opinion on the safety of the use of this preparation for humans, animals and environment, under the conditions set out in Annex I to this Regulation. The assessment shows that the conditions laid down in Article 9a(1) of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of this preparation, as specified in Annex I, should be authorised for four years.

(6) The use of the micro-organism *Bacillus cereus* var. *toyoi* NCIMB 40112/CNCM I-1012 was provisionally authorised, for the first time, for chickens for fattening and for rabbits for fattening by Commission Regulation (EC) No 1411/1999 ([4]). New data were submitted in support of an application for authorisation without time-limit of that micro-organism. The assessment shows that the

([1]) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1800/2004 (OJ L 317, 16.10.2004, p. 37).
([2]) OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).
([3]) OJ L 180, 3.7.2001, p. 18. Regulation as amended by Regulation (EC) No 676/2003 (OJ L 97, 15.4.2003, p. 29).
([4]) OJ L 164, 30.6.1999, p. 56.

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conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex II, should be authorised without a time-limit.

(7) The use of the micro-organism *Enterococcus faecium* NCIMB 10415 was provisionally authorised, for the first time, for sows by Commission Regulation (EC) No 866/1999 ([1]). New data were submitted in support of an application for authorisation without time-limit of that micro-organism. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex II, should be authorised without a time-limit.

(8) The use of the micro-organism *Enterococcus faecium* DSM 10663/NCIMB 10415 was provisionally authorised, for the first time, for piglets by Regulation (EC) No 1411/1999. New data were submitted in support of an application for authorisation without time-limit of that micro-organism. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex II, should be authorised without a time-limit.

(9) The use of the micro-organism *Saccharomyces cerevisiae* MUCL 39885 was provisionally authorised, for the first time, for piglets by Regulation (EC) No 1411/1999. New data were submitted in support of an application for authorisation without time-limit of that micro-organism. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex II, should be authorised without a time-limit.

(10) The use of the micro-organism *Saccharomyces cerevisiae* CNCM I-1077 was provisionally authorised, for the first time, for dairy cows and cattle for fattening by the Commission Regulation (EC) No 1436/98 ([2]). New data were submitted in support of an application for authorisation without time-limit of that micro-organism. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex II, should be authorised without a time-limit.

(11) The use of the micro-organism *Pediococcus acidilactici* CNCM MA 18/5M was provisionally authorised, for the first time, for chickens for fattening by Regulation (EC) No 866/1999. New data were submitted in support of an application for authorisation without time-limit of that micro-organism. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex II, should be authorised without a time-limit.

(12) 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]).

([1]) OJ L 108, 27.4.1999, p. 21.
([2]) OJ L 191, 7.7.1998, p. 15.
([3]) OJ L 183, 29.6.1989, p. 1. Directive as last 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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(13) 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 preparation belonging to the group 'Growth promoters', as specified in Annex I, is authorised provisionally for four years for use as an additive in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparations belonging to the group 'Micro-organisms', as specified in Annex II, are authorised without a time-limit for use as additives in animal nutrition under the conditions laid down in that Annex.

Article 3

This Regulation shall enter into force on the third day following 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

Registration number of additive	Name and registration number of person responsible for putting the additive into circulation	Additive (trade name)	Composition, chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff			
Growth promoters									
1	BASF Aktiengesellschaft	Potassium diformate (Formi LHS)	**Additive composition**: Potassium diformate, solid min. 98 %, Silicate max. 1,5 %, Water max. 0,5 % **Active substance:** Potassium diformate, solid $KH(COOH)_2$ CAS No 20642-05-1	Sows	—	8 000	12 000	—	30 July 2009

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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
					CFU/kg of complete feedingstuff			
Micro-organisms								
▼M1								
E 1701	*Bacillus cereus* var. *toyoi* NCIMB 40112/CNCM I-1012	Preparation of *Bacillus cereus* var. *toyoi* containing a minimum of: 1×10^{10} CFU/g additive	Rabbits for fattening	—	$0{,}1 \times 10^{9}$	5×10^{9}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. May be used in compound feed containing the permitted coccidiostats: robenidine, salinomycin sodium.	Without a time-limit
			Chickens for fattening	—	$0{,}2 \times 10^{9}$	1×10^{9}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. May be used in compound feed containing the permitted coccidiostats: monensin sodium, lasalocid sodium, salinomycin sodium, decoquinate, robenidine, narasin, halofuginone, diclazuril, narasin/nicarbazin, maduramicin ammonium.	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			
E 1705	*Enterococcus faecium* NCIMB 10415	Preparation of *Enterococcus faecium* containing a minimum of: Microencapsulated form: $1,0 \times 10^{10}$ CFU/g additive Granulated form: $3,5 \times 10^{10}$ CFU/g additive	Sows	—	$0,7 \times 10^{9}$	$1,25 \times 10^{9}$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. Sows 2 weeks before farrowing and during lactation.	Without time-limit
E 1707	*Enterococcus faecium* DSM 10663/NCIMB 10415	Preparation of *Enterococcus faecium* containing a minimum of: Powder and granulated forms: $3,5 \times 10^{10}$ CFU/g additive Coated form: $2,0 \times 10^{10}$ CFU/g additive Liquid form: 1×10^{10} CFU/ml additive	Piglets	—	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. For use in piglets until approximately 35 kg.	Without a time-limit
E 1710	*Saccharomyces cerevisiae* MUCL 39885	Preparation of *Saccharomyces cerevisiae* containing a minimum of: Powder, spheric and oval granulated forms: 1×10^{9} CFU/g additive	Piglets (weaned)	—	3×10^{9}	3×10^{9}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. For use in weaned piglets until approximately 35 kg.	Without a time-limit

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			
E 1711	*Saccharomyces cerevisiae* CNCM I-1077	Preparation of *Saccharomyces cerevisiae* containing a minimum of: Granulated powder form: 2×10^{10} CFU/g additive Coated form: 1×10^{10} CFU/g additive	Dairy cows	—	4×10^{8}	2×10^{9}	In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. The quantity of *Saccharomyces cerevisiae* in the daily ration must not exceed $8{,}4 \times 10^{9}$ CFU for 100 kg body weight. Add $1{,}8 \times 10^{9}$ CFU for each additional 100 kg body weight.	Without a time-limit
			Cattle for fattening	—	5×10^{8}	$1{,}6 \times 10^{9}$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. The quantity of *Saccharomyces cerevisiae* in the daily ration must not exceed $4{,}6 \times 10^{9}$ CFU for 100 kg body weight. Add 2×10^{9} CFU for each additional 100 kg body weight.	Without a time-limit
E 1712	*Pediococcus acidilactici* CNCM MA 18/5M	Preparation of *Pediococcus acidilactici* containing a minimum of 1×10^{10} CFU/g additive	Chickens for fattening	—	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. May be used in compound feed containing the permitted coccidiostats:decoquinate, halofuginone, narasin, salinomycin sodium, maduramicin ammonium, diclazuril.	Without a time-limit