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# COMMISSION REGULATION (EC) No 600/2005

**of 18 April 2005**

**concerning a new authorisation for 10 years of a coccidiostat as an additive in feedingstuffs, the provisional authorisation of an additive and the permanent authorisation of certain additives in feedingstuffs**

**(Text with EEA relevance)**

(OJ L 99, 19.4.2005, p. 5)

Amended by:

| | | Official Journal | | |
|---|---|---|---|---|
| | | No | page | date |
| ►M1 | Commission Regulation (EC) No 2028/2006 of 18 December 2006 | L 414 | 26 | 30.12.2006 |
| ►M2 | Commission Regulation (EC) No 496/2007 of 4 May 2007 | L 117 | 9 | 5.5.2007 |
| ►M3 | Commission Regulation (EC) No 202/2009 of 16 March 2009 | L 71 | 8 | 17.3.2009 |
| ►M4 | Commission Implementing Regulation (EU) No 516/2011 of 25 May 2011 | L 138 | 43 | 26.5.2011 |
| ►M5 | Commission Implementing Regulation (EU) No 118/2012 of 10 February 2012 | L 38 | 36 | 11.2.2012 |
| ►M6 | Commission Implementing Regulation (EU) No 334/2012 of 19 April 2012 | L 108 | 6 | 20.4.2012 |

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# COMMISSION REGULATION (EC) No 600/2005

## of 18 April 2005

## concerning a new authorisation for 10 years of a coccidiostat as an additive in feedingstuffs, the provisional authorisation of an additive and the permanent authorisation of certain additives 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, 9d(1) and 9e(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 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 person responsible for putting into circulation Salinomax 120G submitted an application for authorisation for 10 years, as a coccidiostat for chickens for fattening, 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 the environment, under the conditions set out in Annex I to this Regulation. 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 this preparation, as specified in Annex I, should be authorised for 10 years.

([1]) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission 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).

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(6) Data were submitted in support of an application of the new additive *Lactobacillus acidophilus* DSM 13241 for dogs and cats. The EFSA delivered favourable opinions on 15 April 2004 and 27 October 2004 on the safety for the target animals, the user and the environment. The assessment shows that the conditions laid down in Article 9e(1) 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 provisionally authorised.

(7) The use of the micro-organism preparation *Enterococcus faecium* ATCC 53519 and *Enterococcus faecium* ATCC 55593 was provisionally authorised, for the first time, for chickens for fattening by Commission Regulation (EC) No 1436/98 ([1]). New data were submitted in support of an application for authorisation without time limit of that micro-organism preparation. 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 III, should be authorised without a time limit.

(8) The use of the micro-organism preparation *Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750 was provisionally authorised, for the first time, for turkeys for fattening by Commission Regulation (EC) No 2437/2000 ([2]) and for calves by Commission Regulation (EC) No 418/2001 ([3]). New data were submitted in support of an application for authorisation without time limit of that micro-organism preparation. 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 III, should be authorised without a time limit.

(9) The use of the micro-organism preparation *Saccharomyces cerevisiae* NCYC Sc 47 was provisionally authorised, for the first time, for rabbits by the Regulation (EC) No 1436/98. New data were submitted in support of an application for authorisation without time limit of that micro-organism preparation. 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 III, should be authorised without a time limit.

(10) The assessment of this application shows that certain procedures should be required to protect workers from exposure to the additive set out in the Annex. 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 ([4]).

([1]) OJ L 191, 7.7.1998, p. 15.
([2]) OJ L 280, 4.11.2000, p. 28.
([3]) OJ L 62, 2.3.2001, p. 3.
([4]) 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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(11) 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 'Coccidiostats and other medicinal substances', as specified in Annex I, is authorised for use for 10 years as additive in animal nutrition under the conditions laid down in that Annex.

*Article 2*

The preparation belonging to the group 'Micro-organisms', as specified in Annex II, is authorised provisionally for four years as an additive in animal nutrition under the conditions laid down in that Annex.

*Article 3*

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

*Article 4*

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.

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*ANNEX I*

| Registration number of additive | Name and registration number of person responsible for putting 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 | Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | mg of active substance/kg of complete feedingstuff | | | | |
| **Coccidiostats and other medicinal substances** | | | | | | | | | | |
| 'E 766 | ►**M5** Pfizer Ltd ◄ | Salinomycin sodium 120 g/kg (Salinomax 120G) | **Additive composition**:<br>Salinomycin sodium 120 g/kg<br>Calcium lignosulfonate: 40 g/kg<br>Calcium sulphate dihydrate to 1 000 g/kg<br>**Active substance**:<br>Salinomycin sodium, $C_{42}H_{69}O_{11}Na$,<br>Sodium salt of a polyether monocarboxylic acid produced by fermentation of *Streptomyces albus* (ATCC 21838/US 9401-06), CAS No: 55 721-31-8<br>Related impurities:<br>< 42 mg elaiophylin/kg salinomycin sodium.<br>< 40 g 17-epi-20 desoxysalinomycin/kg salinomycin sodium | Chickens for fattening | — | 50 | 70 | Use prohibited at least one day before slaughter.<br>Indicate in the instructions for use:<br>"Dangerous for equines and turkeys";<br>"This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g.tiamulin) can be contraindicated" | 22.4.2015 | 5 µg of Salinomycin/kg for all wet tissues' |

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*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 |
|---|---|---|---|---|---|---|---|---|
| | | | | | CFU/kg of complete feedingstuff | | | |
| **Micro-organisms** | | | | | | | | |
| '25 | *Lactobacillus acidophilus* DSM 13241 | Preparation of *Lactobacillus acidophilus* containing a minimum of:<br>$1 \times 10^{11}$ CFU/g additive | Dogs | — | $6 \times 10^{9}$ | $2 \times 10^{10}$ | In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>For use in dry feed with a water content at or below 2 %. | 22.4.2009 |
| | | | Cats | — | $3 \times 10^{9}$ | $2 \times 10^{10}$ | In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>For use in dry feed with a water content at or below 2 %. | 22.4.2009' |

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*ANNEX III*

| 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 1709 | *Enterococcus faecium* ATCC 53519<br>*Enterococcus faecium* ATCC 55593<br>(In a 1/1 ratio) | Mixture of encapsulated *Enterococcus faecium* and *Enterococcus faecium* containing a minimum of $2 \times 10^8$ CFU/g additive.<br>(i.e. a minimum of $1 \times 10^8$ CFU/g of each bacterium) | Chickens for fattening | — | $1 \times 10^8$ | $1 \times 10^8$ | In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>May be used in compounded feed containing coccidiostats: decoquinate, halofuginone, lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, narasin/nicarbazin, and salinomycin sodium. | Without a time limit |
| ▼M4<br>E 1700 | *Bacillus licheniformis* DSM 5749<br>*Bacillus subtilis* DSM 5750<br>(In a 1/1 ratio) | Mixture of *Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750 containing a minimum of $3,2 \times 10^9$ CFU/g additive ($1,6 \times 10^9$ of each bacterium) | Turkeys for fattening | — | $1,28 \times 10^9$ | $1,28 \times 10^9$ | In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>May be used in compound feed containing one of the following coccidiostats: diclazuril, halofuginone, monensin sodium, robenidine, maduramicin ammonium, lasalocid sodium and the preservative formic acid. | Without a time limit |
| | | | Calves | 3 months | $1,28 \times 10^9$ | $1,28 \times 10^9$ | In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. | Without a time limit |
| ▼M6<br>_____ | | | | | | | | |