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)

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:


(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 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 (5). 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.

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.

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.

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 (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.

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 (2).

(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.

Done at Brussels, 26 July 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission


### ANNEX I

<table>
<thead>
<tr>
<th>Registration number of additive</th>
<th>Name and registration number of person responsible for putting the additive into circulation</th>
<th>Additive (trade name)</th>
<th>Composition, chemical formula, description</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BASF Aktiengesellschaft</td>
<td>Potassium diformate (Formi LHS)</td>
<td><strong>Additive composition:</strong> Potassium diformate, solid min. 98 %, Silicate max. 1,5 %, Water max. 0,5 %</td>
<td>Sows</td>
<td>—</td>
<td>8 000</td>
<td>12 000</td>
<td>—</td>
<td>30 July 2009</td>
</tr>
</tbody>
</table>

#### Growth promoters

- **Active substance:** Potassium diformate, solid. 
  - CAS No: 20642-05-1
### ANNEX II

<table>
<thead>
<tr>
<th>EC No</th>
<th>Additive</th>
<th>Chemical formula, description</th>
<th>Species or category of animal</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rabbits for fattening</td>
<td>0.1 × 10⁹</td>
<td>5 × 10⁹</td>
<td>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.</td>
<td>Without a time-limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Chickens for fattening</td>
<td>0.2 × 10⁹</td>
<td>1 × 10⁹</td>
<td>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.</td>
<td>Without a time-limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prep. of Bacillus cereus var. toyoi containing a minimum of: 1 × 10¹⁰ CFU/g additive</td>
<td>Sows</td>
<td>0.7 × 10⁹</td>
<td>1.25 × 10⁹</td>
<td>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.</td>
<td>Without time-limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prep. of Enterococcus faecium containing a minimum of: Microencapsulated form: 1.0 × 10¹⁰ CFU/g additive Granulated form: 3.5 × 10¹⁰ CFU/g additive</td>
<td>Piglets</td>
<td>1 × 10⁹</td>
<td>1 × 10¹⁰</td>
<td>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.</td>
<td>Without a time-limit</td>
</tr>
<tr>
<td>EC No</td>
<td>Additive</td>
<td>Chemical formula, description</td>
<td>Species or category of animal</td>
<td>Maximum age</td>
<td>Minimum content</td>
<td>Maximum content</td>
<td>Other provisions</td>
</tr>
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<tr>
<td>E 1710</td>
<td><em>Saccharomyces cerevisiae</em> MUCL 39885</td>
<td>Preparation of <em>Saccharomyces cerevisiae</em> containing a minimum of: Powder, spheric and oval granulated forms: $1 \times 10^9$ CFU/g additive</td>
<td>Piglets (weaned)</td>
<td>—</td>
<td>$3 \times 10^8$</td>
<td>$3 \times 10^9$</td>
<td>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.</td>
</tr>
<tr>
<td>E 1711</td>
<td><em>Saccharomyces cerevisiae</em> CNCM I-1077</td>
<td>Preparation of <em>Saccharomyces cerevisiae</em> containing a minimum of: Granulated powder form: $2 \times 10^{10}$ CFU/g additive Coated form: $1 \times 10^{10}$ CFU/g additive</td>
<td>Dairy cows</td>
<td>—</td>
<td>$4 \times 10^8$</td>
<td>$2 \times 10^9$</td>
<td>In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. The quantity of <em>Saccharomyces cerevisiae</em> 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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cattle for fattening</td>
<td>—</td>
<td>$5 \times 10^8$</td>
<td>$1.6 \times 10^9$</td>
<td>In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. The quantity of <em>Saccharomyces cerevisiae</em> in the daily ration must not exceed $4.6 \times 10^9$ CFU for 100 kg body weight. Add $2 \times 10^9$ CFU for each additional 100 kg body weight.</td>
</tr>
<tr>
<td>E 1712</td>
<td><em>Pediococcus acidilactici</em> CNCM MA 18/5M</td>
<td>Preparation of <em>Pediococcus acidilactici</em> containing a minimum of $1 \times 10^{10}$ CFU/g additive</td>
<td>Chickens for fattening</td>
<td>—</td>
<td>$1 \times 10^8$</td>
<td>$1 \times 10^{10}$</td>
<td>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.</td>
</tr>
</tbody>
</table>