COMMISSION REGULATION (EC) No 2036/2005
of 14 December 2005

concerning the permanent authorisations of certain additives in feedingstuffs and the provisional
authorisation of a new use of certain additives 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, 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:


(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 micro-organism preparation of Saccharomyces cerevisiae (CNMC I-1079) was provisionally authorised, for the first time, for sows by Commission Regulation (EC) No 1436/98 (3). New data were submitted in support of an application for authorisation without a 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 I, should be authorised without a time limit.

(6) The use of the micro-organism preparation of Pediococcus acidilactici (CNMC MA 18/5M) was provisionally authorised, for the first time, for pigs for fattening by Commission Regulation (EC) No 866/1999 (4). New data were submitted in support of an application for authorisation without a 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 I, should be authorised without a time limit.

(7) The use of the micro-organism preparation of Enterococcus faecium (CECT 4515) was provisionally authorised, for the first time, for piglets by Commission Regulation (EC) No 654/2000 (5). New data were submitted in support of an application for authorisation without a 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 I, should be authorised without a time limit.

The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by \textit{Trichoderma reesei} (CBS 526.94) was provisionally authorised for the first time for chickens for fattening by Commission Regulation (EC) No 2374/98 (\textsuperscript{1}). New data were submitted in support of an application for authorisation without a time limit of that enzyme 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 enzyme preparation, as specified in Annex II, should be authorised without a time limit.

The use of the enzyme preparation of endo-1,4-beta-xylanase produced by \textit{Trichoderma longibrachiatum} (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by \textit{Bacillus amyloliquefaciens} (DSM 9553), subtilisin produced by \textit{Bacillus subtilis} (ATCC 2107) and polygalacturonase produced by \textit{Aspergillus aculeatus} (CBS 589.94) was provisionally authorised for the first time for chickens for fattening by Commission Regulation (EC) No 418/2001 (\textsuperscript{2}). New data were submitted in support of an application for authorisation without a time limit of that enzyme 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 enzyme preparation, as specified in Annex II, should be authorised without a time limit.

The use of the enzyme preparation of endo-1,4-beta-xylanase produced by \textit{Aspergillus oryzae} (DSM 10287) was authorised without a time limit for chickens for fattening, turkeys for fattening and piglets by Commission Regulation (EC) No 1332/2004 (\textsuperscript{3}). New data were submitted in support of an application to extend the authorisation of that enzyme preparation to ducks and pigs for fattening. The European Food Safety Authority (EFSA) has delivered an opinion on the use of this preparation to ducks. The EFSA has concluded that it does not present a risk for ducks and laying hens. The EFSA has extended the authorisation of the use of this enzyme preparation to ducks and laying hens. The EFSA has concluded that it does not present a risk for ducks and laying hens, as specified in Annex III, should be authorised for four years.

The use of the enzyme preparation of endo-1,4-beta-xylanase produced by \textit{Trichoderma longibrachiatum} (ATCC 2107) and subtilisin produced by \textit{Bacillus subtilis} (ATCC 2107) was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 943/2005 (\textsuperscript{4}). New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to ducks. The EFSA has delivered an opinion on the use of this preparation which concludes that it does not present a risk for this additional animal category. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for an authorisation of that preparation for that use are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex III, should be authorised for four years.

The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, according to the opinion of the Standing Committee on the Food Chain and Animal Health, and of the European Parliament and of the Council.
HAS ADOPTED THIS REGULATION:

Article 1

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

Article 3

The preparations belonging to the group ‘Enzymes’, as specified in Annex III, are authorised for use for four years as additives in animal nutrition under the conditions laid down in that Annex.

Article 4

This Regulation shall enter into force on the 20th 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, 14 December 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission
<table>
<thead>
<tr>
<th>EC No</th>
<th>Additive</th>
<th>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>E 1703</td>
<td>Saccharomyces cerevisiae CNCM I-1079</td>
<td>Preparation of Saccharomyces cerevisiae containing a minimum of: 2 × 10^9 CFU/g additive</td>
<td>Sows</td>
<td>—</td>
<td>1 × 10^9</td>
<td>6 × 10^9</td>
<td>In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</td>
<td>Without a time limit</td>
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<tr>
<td>E 1712</td>
<td>Pediococcus acidilactici CNCM MA 18/5M</td>
<td>Preparation of Pediococcus acidilactici containing a minimum of: 1 × 10^10 CFU/g additive</td>
<td>Pigs for fattening</td>
<td>—</td>
<td>1 × 10^9</td>
<td>1 × 10^9</td>
<td>In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</td>
<td>Without a time limit</td>
</tr>
</tbody>
</table>
| E 1713 | Enterococcus faecium CECT 4515 | Preparation of Enterococcus faecium containing a minimum of: 1 × 10^9 CFU/g additive | Piglets (weaned) | — | 1 × 10^9 | 1 × 10^9 | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 
2. For use in weaned piglets until approximately 35 kg. | Without a time limit |
### Enzymes

<table>
<thead>
<tr>
<th>EC No</th>
<th>Additive</th>
<th>Chemical formula, description</th>
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<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>
</table>
| E 1636 | Endo-1,3(4)-beta-glucanase EC 3.2.1.6 | Preparation of endo-1,3(4)-beta-glucanase produced by Trichoderma reesei (CBS 526.94) having a minimum activity of:  
Solid form: 700 000 BU/g  
Liquid form: 300 000 BU/g | Chickens for fattening | — | 17 500 BU | — | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.  
2. Recommended dose per kg of complete feedingstuff: 17 500-50 000 BU.  
3. For use in compound feed rich in non-starch polysaccharides (mainly glucans), e.g. containing more than 20% barley or 30% rye. | Without a time limit |
| E 1637 | Endo-1,4-beta-xylanase EC 3.2.1.8  
Endo-1,3(4)-beta-glucanase EC 3.2.1.6  
Subtilisin EC 3.4.21.62  
Alpha-amylase EC 3.2.1.1  
Polygalacturonase EC 3.2.1.15 | Preparation of endo-1,4-beta-xylanase produced by Trichoderma longibrachiatum (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by Bacillus amyloliquefaciens (DSM 9553), subtilisin produced by Bacillus subtilis (ATCC 2107), polygalacturonase produced by Aspergillus aculeatus (CBS 589.94) having a minimum activity of:  
Endo-1,4-beta-xylanase: 300 U/g  
Endo-1,3(4)-beta-glucanase: 150 U/g  
Subtilisin: 4 000 U/g  
Alpha-amylase: 400 U/g  
Polygalacturonase: 25 U/g | Chickens for fattening | — | endo-1,4-beta-xylanase: 300 U  
endo-1,3(4)-beta-glucanase: 150 U  
subtilisin: 4 000 U  
alpha-amylase: 400 U  
polygalacturonase: 25 U | — | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.  
2. Recommended dose per kg of complete feedingstuff: endo-1,4-beta-xylanase: 300 U  
endo-1,3(4)-beta-glucanase: 150 U  
subtilisin: 4 000 U  
alpha-amylase: 400 U  
polygalacturonase: 25 U.  
3. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoylans and beta-glucans), e.g. containing more than 40% maize or 60% wheat. | Without a time limit |

(1) 1 BU is the amount of enzyme which liberates 0.06 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4.8 and 50 °C.  
(2) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 5.3 and 50 °C.  
(3) 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5.0 and 30 °C.  
(4) 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 6.5 and 37 °C.  
(5) 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 7.5 and 40 °C.  
(6) 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 6.5 and 37 °C.  
(7) 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 7.5 and 40 °C.  
(8) 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 6.5 and 37 °C.
<table>
<thead>
<tr>
<th>EC No or No</th>
<th>Additive</th>
<th>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>
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<tbody>
<tr>
<td>5</td>
<td>Endo-1,4-beta-xylanase EC 3.2.1.8</td>
<td>Preparation of endo-1,4-beta-xylanase produced by Aspergillus oryzae (DSM 10287) having a minimum activity of: Coated form: 1 000 FXU ((l)/g Liquid form: 650 FXU/ml</td>
<td>Pigs for fattening</td>
<td>—</td>
<td>200 FXU</td>
<td>—</td>
<td>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dose per kg of complete feedingstuff: 200-400 FXU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 50 % cereals (e.g. wheat, barley, rye or triticale).</td>
<td>4.1.2010</td>
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<td></td>
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<td>Ducks</td>
<td>—</td>
<td>100 FXU</td>
<td>—</td>
<td>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dose per kg of complete feedingstuff: 100-200 FXU. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 50 % cereals (e.g. wheat, barley, rye or triticale).</td>
<td>4.1.2010</td>
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<tr>
<td>EC No or No</td>
<td>Additive</td>
<td>Chemical formula, description</td>
<td>Species or category of animal</td>
<td>Minimum age</td>
<td>Minimum content</td>
<td>Maximum content</td>
<td>Other provisions</td>
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<td>37</td>
<td>Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62</td>
<td>Preparation of endo-1,4-beta-xylanase produced by Trichoderma longibrachiatum (ATCC 2105) and subtilisin produced by Bacillus subtilis (ATCC 2107) having a minimum activity of: Endo-1,4-beta-xylanase: 5 000 U ((\times))g Subtilisin: 1 600 U ((\times))g</td>
<td>Ducks</td>
<td>—</td>
<td>endo-1,4-beta-xylanase: 2 500 U subtilisin: 800 U</td>
<td>—</td>
<td>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended dose per kg of complete feedingstuf: endo-1,4-beta-xylanase: 2 500 U subtilisin: 800 U. 3. For use in compound feed e.g. containing more than 65 % wheat.</td>
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<tr>
<td>59</td>
<td>Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Subtilisin EC 3.4.21.62 Alpha-amylase EC 3.2.1.1 Polygalacturonase EC 3.2.1.15</td>
<td>Preparation of endo-1,4-beta-xylanase produced by Trichoderma longibrachiatum (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by Bacillus amyloliquefaciens (DSM 9533), subtilisin produced by Bacillus subtilis (ATCC 2107), polygalacturonase produced by Aspergillus aculeatus (CBS 589.94) having a minimum activity of: Endo-1,4-beta-xylanase: 300 U ((\times))g Endo-1,3(4)-beta-glucanase: 150 U ((\times))g Subtilisin: 4 000 U ((\times))g Alpha-amylase: 400 U ((\times))g Polygalacturonase: 25 U ((\times))g</td>
<td>Ducks</td>
<td>—</td>
<td>endo-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalacturonase: 25 U</td>
<td>—</td>
<td>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended dose per kg of complete feedingstuf: endo-1,4-beta-xylanase: 300 U endo-1,3(4)-beta-glucanase: 150 U subtilisin: 4 000 U alpha-amylase: 400 U polygalacturonase: 25 U. 3. For use in compound feed rich in starch and non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 40 % maize.</td>
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<tr>
<td>EC No or 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>
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<td>Laying hens</td>
<td>—</td>
<td>endo-1,4-beta-xylanase: 225 U</td>
<td>—</td>
<td>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</td>
<td>4.1.2010</td>
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<td>endo-1,3(4)-beta-glucanase: 112 U</td>
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<td>2. Recommended dose per kg of complete feedingstuff:</td>
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<td>subtilisin: 3 000 U</td>
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<td>endo-1,4-beta-xylanase: 225 U</td>
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<td>alpha-amylase: 300 U</td>
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<td>endo-1,3(4)-beta-glucanase: 112 U</td>
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<td>polygalacturonase: 18 U</td>
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<td>subtilisin: 3 000 U</td>
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<td></td>
<td>alpha-amylase: 300 U</td>
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<td>alpha-amylase: 300 U</td>
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<td></td>
<td></td>
<td>polygalacturonase: 18 U</td>
<td>—</td>
<td>polygalacturonase: 18 U</td>
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</tbody>
</table>

1. FXU is the amount of enzyme which liberates 7.8 micromoles of reducing sugars (xylose equivalents) from azo-wheat arabinobiose per minute at pH 6.0 and 50 °C.
2. U is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 5.3 and 50 °C.
3. U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7.5 and 40 °C.
4. U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5.0 and 30 °C.
5. U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from a water insoluble cross-linked starch polymer substrate per minute at pH 6.5 and 37 °C.
6. U is the amount of enzyme which liberates 1 micromole of reducing material (galacturonic acid equivalents) from a poly-D-galacturonic substrate per minute at pH 5.0 and 40 °C.