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# COMMISSION REGULATION (EC) No 358/2005

**of 2 March 2005**

**concerning the authorisations without a time limit of certain additives and the authorisation of new uses of additives already authorised in feedingstuffs**

**(Text with EEA relevance)**

(OJ L 57, 3.3.2005, p. 3)

Amended by:

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# COMMISSION REGULATION (EC) No 358/2005

## of 2 March 2005

## concerning the authorisations without a time limit of certain additives and the authorisation of new uses of 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 and 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 in the European Union.

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

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

(4) Initial comments by Member States on these applications were issued under Article 4(4) of Directive 70/524/EEC and have been forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. Such applications therefore shall continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

([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.

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(5) The use of the enzyme preparation of alpha-amylase and endo-1,3(4)-beta-glucanase produced by *Bacillus amyloliquefaciens* (DSM 9553) was provisionally authorised, for the first time, for chickens for fattening, by Commission Regulation (EC) No 654/2000 ([1]).

(6) New data were submitted in support of the application for authorisation without a time limit of this enzyme preparation.

(7) The European Food Safety Authority (EFSA) delivered a favourable opinion on the toxin producing potential of the micro-organism producing this enzyme preparation dated 15 September 2004.

(8) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(9) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) was provisionally authorised, for chickens for fattening, by Commission Regulation (EC) No 2437/2000 ([2]).

(10) New data were submitted in support of the application for authorisation without a time limit of this enzyme preparation.

(11) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(12) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) was provisionally authorised, for chickens for fattening, by Commission Regulation (EC) No 2437/2000.

(13) New data were submitted in support of the application for authorisation without a time limit of this enzyme preparation.

([1]) OJ L 79, 30.3.2000, p. 26.
([2]) OJ L 280, 4.11.2000, p. 28.

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(14) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(15) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CBS 357.94) was provisionally authorised for the first time for chickens for fattening, by Commission Regulation (EC) No 1436/98 ([1]).

(16) New data were submitted in support of the application for authorisation without a time limit of this enzyme preparation.

(17) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(18) Accordingly, the use of those four enzyme preparations as specified in Annex I, should be authorised without a time limit.

(19) The use of the substance 'tartrazine' was provisionally authorised, as colourant for grain-eating ornamental birds and small rodents, by Commission Regulation (EC) No 2697/2000 ([2]).

(20) New data were submitted in support of the application for authorisation without a time limit of this colourant.

(21) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(22) The use of the substance 'sunset yellow FCF', was provisionally authorised, as colourant, for grain-eating ornamental birds and small rodents, by Regulation (EC) No 2697/2000.

(23) New data were submitted in support of the application for authorisation without a time limit of this colourant.

([1]) OJ L 191, 7.7.1998, p. 15.
([2]) OJ L 319, 16.12.2000, p. 1.

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(24) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(25) The use of the substance ‘patent blue V’, was provisionally authorised, as colourant, for grain-eating ornamental birds and small rodents, by Regulation (EC) No 2697/2000.

(26) New data were submitted in support of the application for authorisation without a time limit of this colourant.

(27) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(28) The use of the substance chlorophyll copper complex was provisionally authorised as coulourant, for grain-eating ornamental birds and small rodents, by Regulation (EC) No 2697/2000.

(29) New data were submitted in support of the application for authorisation without a time limit of this colourant.

(30) The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied.

(31) Accordingly, the use of those four colourants as specified in Annex II, should be authorised without a time limit.

(32) The use of the enzyme preparation of endo-1(4)-beta- xylanase produced by *Bacillus subtilis* (LMG-15136) is authorised for chickens for fattening without a time limit by Commission Regulation (EC) No 1259/2004 ([1]), and provisionally for piglets by Commission Regulation (EC) No 937/2001 ([2]), for turkeys for fattening by Commission Regulation (EC) No 2188/2002 ([3]), and for pigs for fattening by Commission Regulation (EC) No 261/2003 ([4]).

(33) New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to laying hens.

([1]) OJ L 239, 9.7.2004, p. 8.
([2]) OJ L 130, 12.5.2001, p. 25.
([3]) OJ L 333, 10.12.2002, p. 5.
([4]) OJ L 37, 13.2.2003, p. 12.

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(34) The European Food Safety Authority (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, under the conditions set out in Annex III to this Regulation.

(35) The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for an authorisation of such preparation for that use have been satisfied.

(36) The use of the enzyme preparation of 3-phytase produced by *Trichoderma reesei* (CBS 528.94) is authorised for chickens for fattening by Commission Regulation (EC) No 418/2001 ([1]).

(37) New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to turkeys for fattening and sows.

(38) The European Food Safety Authority (EFSA) has delivered an opinion on the use of this preparation which concludes that it do not present a risk for these additional animal categories, under the conditions set out in Annex III to this Regulation.

(39) Accordingly, the use of these two enzyme preparations as specified in Annex III, should be provisionally authorised for four years.

(40) The use of the micro-organism preparation of *Enterococcus faecium* is authorised for calves without a time limit by Commission Regulation (EC) No 1288/2004 ([2]) and provisionally until 30 June 2004, for chickens for fattening, piglets, pigs for fattening, sows, and cattle for fattening by Commission Regulation (EC) No 866/1999 ([3]).

(41) New data were submitted in support of an application to extend the authorisation of the use of this micro-organism preparation to dogs and cats.

([1]) OJ L 62, 2.3.2001, p. 3.
([2]) OJ L 243, 15.7.2004, p. 10.
([3]) OJ L 108, 27.4.1999, p. 21.

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(42) The European Food Safety Authority (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, under the conditions set out in Annex IV to this Regulation.

(43) The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for an authorisation of such preparation for that use have been satisfied.

(44) Accordingly, the use of this micro-organism preparation as specified in Annex IV, should be provisionally authorised for four years.

(45) 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 ([1]).

(46) 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 ‘Enzymes’ 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 substances belonging to the group ‘Colourants, including pigments, other colourants’ as set out in Annex II are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in that Annex.

([1]) OJ L 183, 29.6.1989, p. 1.

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*Article 3*

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

*Article 4*

The preparation belonging to the group ‘Micro-organisms’, as set out in Annex IV is authorised provisionally for four years as additive in animal nutrition under the conditions laid down in that Annex.

*Article 5*

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*

| EC No | Additive | Chemical formula, description | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|
| | | | | | Units of activity/kg of complete feedingstuff | | | |
| **Enzymes** | | | | | | | | |
| E 1619 | Alpha-amylase EC 3.2.1.1<br>Endo-1,3(4)-beta-glucanase EC 3.2.1.6 | Preparation of alpha-amylase and endo-1,3(4)-beta-glucanase produced by *Bacillus amyloliquefaciens* (DSM 9553) having minimum activities of:<br>Coated form:<br>Alpha-amylase: 200 KNU ([1])/g<br>Endo-1,3(4)-beta-glucanase: 350 FBG ([2])/g<br>Liquid form:<br>Alpha-amylase: 130 KNU/ml<br>Endo-1,3(4)-beta-glucanase: 225 FBG/ml | Chickens for fattening | — | alpha-amylase: 10 KNU | — | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.<br>2. Recommended dose per kg of complete feedingstuff:<br>alpha-amylase: 20–40 KNU<br>endo-1,3(4)-beta-glucanase: 35–70 FBG<br>3. For use in compound feed rich in starch and beta glucans, e.g. containing more than 40 % cereals (e.g. barley, oats, wheat, rye, triticale, or maize). | Without a time limit |
| | | | | | endo-1,3(4)-beta –gluc-anase: 17 FBG | — | | |
| E 1620 | Endo-1,3(4)-beta-glucanase EC 3.2.1.6<br>Endo-1,4-beta-glucanase EC 3.2.1.4<br>Alpha-amylase EC 3.2.1.1<br>Bacillolysin EC 3.4.24.28<br>Endo-1,4-beta-xylanase EC 3.2.1.8 | Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) having a minimum activity of:<br>Endo-1,3(4)-beta-glucanase: 2 350 U ([3])/g<br>Endo-1,4-beta-glucanase: 4 000 U ([4])/g<br>Alpha-amylase: 400 U ([5])/g<br>Bacillolysin: 450 U ([6])/g<br>Endo-1,4-beta-xylanase: 20 000 U ([7])/g | Chickens for fattening | — | Endo-1,3(4)-beta-gluc-anase: 587 U | — | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.<br>2. Recommended dose per kg of complete feedingstuff:<br>endo-1,3(4)-beta-glucanase: 1 175–2 350 U<br>endo-1,4-beta-glucanase: 2 000–4 000 U<br>alpha-amylase: 200–400 U<br>bacillolysin: 225–450 U<br>endo-1,4-beta-xylanase: 10 000–20 000 U<br>3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 45 % wheat. | Without a time limit |
| | | | | | Endo-1,4-beta-gluc-anase: 1 000 U | — | | |
| | | | | | Alpha-amylase: 100 U | — | | |
| | | | | | Bacillolysin: 112 U | — | | |
| | | | | | Endo-1,4-beta-xylanase: 5 000 U | — | | |

| EC No | Additive | Chemical formula, description | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|
| | | | | | Units of activity/kg of complete feedingstuff | | | |
| E 1621 | Endo-1,3(4)-beta-glucanase EC 3.2.1.6<br>Endo-1,4-beta-glucanase EC 3.2.1.4<br>Alpha-amylase EC 3.2.1.1<br>Endo-1,4-beta-xylanase EC 3.2.1.8 | Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94) , alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) having a minimum activity of :<br>Endo-1,3(4)-beta-glucanase: 10 000 U ([3])/g<br>Endo-1,4-beta-glucanase: 120 000 U ([4])/g<br>Alpha-amylase: 400 U ([5])/g<br>Endo-1,4-beta-xylanase: 210 000 U ([7])/g | Chickens for fattening | — | Endo-1,3(4)-beta-glucanase: 500 U | — | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.<br>2. Recommended dose per kg of complete feedingstuff:<br>endo-1,3(4)-beta-glucanase: 1 000–2 000 U<br>endo-1,4-beta-glucanase: 12 000–24 000 U<br>alpha-amylase: 40–80 U<br>endo-1,4-beta-xylanase: 21 000–42 000 U<br>3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 45 % wheat. | Without a time limit |
| | | | | | Endo-1,4-beta-glucanase: 6 000 U | — | | |
| | | | | | Alpha-amylase: 20 U | — | | |
| | | | | | Endo-1,4-beta-xylanase: 10 500 U | — | | |
| E 1622 | Endo-1,3(4)-beta-glucanase EC 3.2.1.6<br>Endo-1,4-beta-xylanase EC 3.2.1.8 | Preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CBS 357.94) having a minimum activity of:<br>Granulated form:<br>6 000 BGU ([8])/g<br>8 250 EXU ([9])/g<br>Liquid form:<br>2 000 BGU/ml<br>2 750 EXU/ml | Chickens for fattening | — | endo-1,3(4)-beta-glucanase: 500 BGU | — | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.<br>2. Recommended dose per kg of complete feedingstuff:<br>endo-1,3(4)-beta-glucanase: 500 BGU<br>endo-1,4-beta-xylanase: 680 EXU<br>3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 30 % wheat and 30 % barley, or 20 % rye. | Without a time limit |
| | | | | | endo-1,4-beta-xylanase: 680 EXU | — | | |

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(1) 1 KNU is the amount of enzyme which liberates 672 micromoles of reducing sugars (glucose equivalent) from soluble starch per minute at pH 5,6 and 37 °C.
(2) 1 FBG 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.
(3) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 7,5 and 30 °C.
(4) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from carboxymethylcellulose per minute at pH 4,8 and 50 °C.
(5) 1 U is the amount of enzyme which hydrolyses 1 micromole of glucosidic linkages from water insoluble cross-linked starch polymer per minute at pH 7,5 and 37 °C.
(6) 1 U is the amount of enzyme which makes 1 microgram of azo-casein soluble in trichloracetic acid per minute at pH 7,5 and 37 °C.
(7) 1 U is the amount of enzyme which liberates 0,0067 micromoles of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 5,3 and 50 °C.
(8) 1 BGU is the amount of enzyme which liberates 0,278 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 3,5 and 40 °C.
(9) 1 EXU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH 3,5 and 55 °C.

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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 |
|---|---|---|---|---|---|---|---|---|
| | | | | | mg/kg of complete feedingstuff | | | |
| **Colourants, including pigments** | | | | | | | | |
| 2. **Other colourants** | | | | | | | | |
| E 102 | Tartrazine | $C_{16}H_9N_4O_9S_2Na_3$ | Grain-eating ornamental birds | — | — | 150 | — | Without a time limit |
| | | | Small rodents | — | — | 150 | — | Without a time limit |
| E 110 | Sunset yellow FCF | $C_{16}H_{10}N_2O_7S_2Na_2$ | Grain-eating ornamental birds | — | — | 150 | — | Without a time limit |
| | | | Small rodents | — | — | 150 | — | Without a time limit |
| ▼M1 _____ | | | | | | | | |
| ▼B E 141 | Chlorophyll copper complex | — | Grain-eating ornamental birds | — | — | 150 | — | Without a time limit |
| | | | Small rodents | — | — | 150 | — | Without a time limit |

*ANNEX III*

| EC No or No | Additive | Chemical formula, description | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|
| | | | | | Units of activity/kg of complete feedingstuff | | | |
| **Enzymes** | | | | | | | | |
| 51 | Endo-1,4-beta-xylanase EC 3.2.1.8 | Preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) having a minimum activity of:<br>Solid and liquid form:<br>100 IU (1)/g or ml | Laying hens | — | 10 IU | — | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.<br>2. Recommended dose per kg of complete feedingstuff: 10 IU<br>3. For use in compound feed rich in arabinoxylan, e.g. containing minimum 40 % wheat or barley. | 6 March 2009 |
| 28 | 3-Phytase EC 3.1.3.8 | Preparation of 3-phytase produced by *Trichoderma reesei* (CBS 528.94) having a minimum activity of:<br>Solid form: 5 000 PPU (2)/g<br>Liquid form: 1 000 PPU/g | Turkeys for fattening | — | 250 PPU | — | 1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting.<br>2. Recommended dose per kg of complete feedingstuff: 250-1 000 PPU<br>3. For use in compound feed containing more than 0,22 % phytin bound phosphorus. | 6 March 2009 |
| | | | Sows | — | 250 PPU | — | 1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting.<br>2. Recommended dose per kg of complete feedingstuff: 500-1 000 PPU<br>3. For use in compound feed containing more than 0,22 % phytin bound phosphorus. | 6 March 2009 |

(1) 1 IU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 4,5 and 30 °C.
(2) 1 PPU is the amount of enzyme which liberates 1 micromole of inorganic phosphate from sodium phytate per minute at pH 5 and 37 °C.

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*ANNEX IV*

| 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** | | | | | | | | |
| 10 | *Enterococcus faecium* NCIMB 10415 | Preparation of *Enterococcus faecium* containing a minimum of microencapsulated form: $5 \times 10^9$ CFU/g | Dogs | — | $4{,}5 \times 10^6$ | $2 \times 10^9$ | In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting | 6 March 2009 |
| | | | Cats | — | $5 \times 10^6$ | $8 \times 10^9$ | In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting | 6 March 2009 |