# COMMISSION REGULATION (EU) No 516/2010

## of 15 June 2010

## concerning the permanent authorisation of an additive in feedingstuffs

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs [1], and in particular Article 3 and Article 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 application for authorisation of the additive set out in the Annex to this Regulation was submitted before the date of application of Regulation (EC) No 1831/2003.

(4) Initial comments on that application, 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. This application is therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

(5) 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 laying hens by Commission Regulation (EC) No 1458/2005 [3]. It was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 358/2005 [4] and for turkeys for fattening by Commission Regulation (EC) No 1284/2006 [5].

(6) New data were submitted in support of an application for authorisation without a time limit of that enzyme preparation for laying hens.

(7) 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 the Annex to this Regulation, should be authorised without a time limit.

(8) 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 'Enzymes', as specified in the Annex, is authorised without a time limit as additive in animal nutrition under the conditions laid down in that Annex.

*Article 2*

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, 15 June 2010.

*For the Commission*

*The President*

José Manuel BARROSO

[1] OJ L 270, 14.12.1970, p. 1.
[2] OJ L 268, 18.10.2003, p. 29.
[3] OJ L 233, 9.9.2005, p. 3.
[4] OJ L 57, 3.3.2005, p. 3.
[5] OJ L 235, 30.8.2006, p. 3.

*ANNEX*

| 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 1621 | Endo-1,3(4)-beta-glucanase EC 3.2.1.6<br><br>Endo-1,4-beta-glucanase EC 3.2.1.4<br><br>Alpha-amylase EC 3.2.1.1<br><br>Endo-1,4-beta-xylanase EC 3.2.1.8 | Preparation of:<br>endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94),<br><br>endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94),<br><br>alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) and<br><br>endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP4842)<br>having a minimum activity of:<br>Endo-1,3(4)-beta-glucanase: 10 000 U (1)/g,<br>Endo-1,4-beta-glucanase: 120 000 U (2)/g,<br>alpha-amylase: 400 U (3)/g,<br>Endo-1,4-beta-xylanase: 210 000 U (4)/g. | Laying hens | — | endo-1,3(4)-beta-glucanase 500 U<br><br>endo-1,4-beta-glucanase 6 000 U<br><br>alpha-amylase 20 U<br><br>endo-1,4-beta-xylanase 10 500 U | | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.<br><br>2. Recommended dose per kg of complete feedingstuff:<br>endo-1,3(4)-beta-glucanase: 500-1 500 U<br>endo-1,4-beta-glucanase: 6 000-18 000 U<br>alpha-amylase: 20-60 U<br>endo-1,4-beta-xylanase: 10 500-31 500 U.<br><br>3. For use in compound feed rich in non-starch polysaccharides, (mainly betaglucans and arabinoxylans), e.g. containing 30-50 % wheat. | Without a time limit. |

(1) 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.
(2) 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.
(3) 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.
(4) 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.