II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 237/2012

of 19 March 2012

concerning the authorisation of alpha-galactosidase (EC 3.2.1.22) produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* (CBS 120604) as a feed additive for chickens for fattening (holder of authorisation Kerry Ingredients and Flavours)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 [1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of alpha-galactosidase (EC 3.2.1.22) produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* (CBS 120604). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of alpha-galactosidase (EC 3.2.1.22) produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* (CBS 120604) as a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 November 2011 [2] that, under the proposed conditions of use, the preparation of alpha-galactosidase (EC 3.2.1.22) produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* (CBS 120604) does not have an adverse effect on animal health, human health or the environment, and that its use can improve the final body weight in chickens for fattening. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of alpha-galactosidase (EC 3.2.1.22) produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* (CBS 120604) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(6) 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 specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

[1] OJ L 268, 18.10.2003, p. 29.

[2] *EFSA Journal* 2011; 9(12):2451.

Article 2

This Regulation shall enter into force on the twentieth 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, 19 March 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	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 with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a17	Kerry Ingredients and Flavours	Alpha-galactosidase (EC 3.2.1.22) Endo-1,4-beta-glucanase (EC 3.2.1.4)	*Additive composition* Preparation of alpha-galactosidase (EC 3.2.1.22) produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* (CBS 120604), solid form, with a minimum activity of: — 1 000 U (1) alpha-galactosidase/g — 5 700 U (2) endo-1,4-beta-glucanase/g *Characterisation of the active substance* Alpha-galactosidase produced by *Saccharomyces cerevisiae* (CBS 615.94) Endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 120604) *Method of Analysis* (3) Determination: — colorimetric method measuring p-nitrophenol released by action of alpha-galactosidase from p-nitrophenyl-alpha-galactopyranoside substrate, — colorimetric method measuring water soluble dye released by action of endo-1,4-beta-glucanase from azurine-crosslinked barley glucan substrate.	Chickens for fattening	—	50 U alpha-galactosidase 285 U endo-1,4-beta-glucanase	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Maximum recommended dose: — 100 U alpha-galactosidase/kg — 570 U endo-1,4-beta-glucanase/kg. 3. For safety: breathing protection, glasses and gloves shall be used during handling.	9 April 2022

(1) 1 U is the amount of the enzyme which liberates 1 μmol of p-nitrolphenol per minute from p-nitrophenyl-alpha-galactopyranoside (pNPG) at pH 5,0 and 37 °C.
(2) 1 U is the amount of the enzyme which liberates 1 mg of reducing sugar (glucose equivalent) per minute from beta-glucan at pH 5,0 and 50 °C.
(3) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx