# COMMISSION IMPLEMENTING REGULATION (EU) No 1365/2013

## of 18 December 2013

## concerning the authorisation of a preparation of alpha-galactosidase produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 120604) as a feed additive for minor poultry species for fattening and for chickens reared for laying (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 a new use of a preparation of alpha-galactosidase produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase 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) That application concerns the authorisation of a new use of a preparation of alpha-galactosidase produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 120604) as a feed additive for minor poultry species for fattening and for chickens reared for laying, to be classified in the additive category 'zootechnical additives'.

(4) The use of that preparation was authorised for 10 years for chickens for fattening by Commission Implementing Regulation (EU) No 237/2012 [2].

(5) The European Food Safety Authority ('the Authority') concludes in its opinion of 18 June 2013 [3] that, under the proposed conditions of use, the preparation of alpha-galactosidase produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 120604) does not have an adverse effect on animal health, human health or the environment and it has the potential to be efficacious on chickens reared for laying and that can be extrapolated to minor poultry species 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.

(6) The assessment of the preparation of alpha-galactosidase produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase 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 that preparation should be authorised as specified in the Annex to this Regulation.

(7) 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] 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) (OJ L 80, 20.3.2012, p. 1).

[3] *EFSA Journal* 2013; 11(7):3286.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of 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, 18 December 2013.

*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<br>Endo-1,4-beta-glucanase EC 3.2.1.4 | *Additive composition*<br>Preparation of alpha-galactosidase produced by *Saccharomyces cerevisiae* (CBS 615.94) and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 120604) having a minimum activity of:<br>— 1 000 U (1) alpha-galactosidase/g,<br>— 5 700 U (2) endo-1,4-beta-glucanase/g.<br>Solid form<br>*Characterisation of the active substance*<br>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).<br>*Analytical method* (3)<br>For the determination of:<br>— alpha-galactosidase: colorimetric method measuring p-nitrophenol released by action of alpha-galactosidase from p-nitrophenyl-alpha-galactopyranoside substrate,<br>— endo-1,4-beta-glucanase: colorimetric method measuring water soluble dye released by action of endo-1,4-beta-glucanase from azurine-crosslinked barley glucan substrate. | Minor poultry species for fattening.<br>Chickens reared for laying. | — | alpha-galactosidase 50 U<br>endo-1,4-beta-glucanase 285 U | — | 1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.<br>2. Maximum recommended dose:<br>— 100 U alpha-galactosidase/kg of complete feed,<br>— 570 U endo-1,4-beta-glucanase/kg of complete feed.<br>3. For safety: breathing protection, glasses and gloves shall be used during handling. | 8 January 2024 |

(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