Commission Implementing Regulation (EU) 2015/2382 of 17 December 2015 concerning the authorisation 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) as a feed additive for laying hens and minor poultry species for laying (holder of the authorisation Kerry Ingredients and Flavours) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/2382

of 17 December 2015

concerning the authorisation 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) as a feed additive for laying hens and minor poultry species for laying (holder of the authorisation Kerry Ingredients and Flavours)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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 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). 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 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) as a feed additive for laying hens and minor poultry species for laying, to be classified in the additive category ‘zootechnical additives’.

(4) The use of 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) was authorised for 10 years for chickens for fattening by Commission Implementing Regulation (EU) No 237/2012[(2)] and for chickens reared for laying and minor poultry species for fattening Commission Implementing Regulation (EU) No 1365/2013[(3)].

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 April 2015[4] 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 it has a potential to improve the egg weight in laying hens. Since the mode of action can be considered to be the same, this conclusion can be extrapolated to minor poultry species for laying. 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 (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 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 Plants, Animals, Food and Feed,

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.

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, 17 December 2015.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/2382. (See end of Document for details)*

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** **Units of activity/kg of complete feedingstuff with a moisture content of 12 %**	**Maximum content**	**Other provisions**	**End of period of authorisation**
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: —	Laying hens Minor poultry species for laying	—	100 U alpha-galactosidase 570 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: — — 1 000	7 January 2026 100 U alpha-galactosidase/kg 570 U endo-1,4-beta-glucanase/kg.

a 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.

b 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.

c Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports.