

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1104****of 8 July 2015****amending Implementing Regulation (EU) No 237/2012 as regards a new form 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) (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 <sup>(1)</sup>, 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) The use 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 <sup>(2)</sup>, and for minor poultry species for fattening and for chickens reared for laying by Commission Implementing Regulation (EU) No 1365/2013 <sup>(3)</sup>.
- (3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation to include a liquid form of alpha-galactosidase and endo-1,4-beta-glucanase to be used as a feed additive for chickens for fattening. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority ('the Authority').
- (4) The Authority concluded in its opinion of 28 October 2014 <sup>(4)</sup> that the liquid form 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 favourably affect animal performance 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 existing authorisation should be modified in order to include the new form.
- (6) Therefore, the Annex to Implementing Regulation (EU) No 237/2012 should be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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) (OJ L 343, 19.12.2013, p. 31).

<sup>(4)</sup> EFSA Journal 2014; 12(11):3897.

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Implementing Regulation (EU) No 237/2012 is replaced by the text set out in the Annex to this Regulation.

*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, 8 July 2015.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX

## ‘ANNEX

| Identi-<br>fication<br>number of<br>the addi-<br>tive | Name of the<br>holder of<br>authorisation | Additive | Composition, chemical formula, description, analy-<br>tical method | Species or<br>category of<br>animal | Maximum<br>age | Minimum<br>content   | Maximum<br>content | Other provisions | End of period<br>of authorisa-<br>tion |
|---|---|----------|--|-------------------------------------|----------------|--|--------------------|------------------|--|
|   |   |          |  |                                     |                | Units of activity/kg of<br>complete feedingstuff<br>with a moisture content<br>of 12 % |                    |                  |  |

**Category of zootechnical additives. Functional group: digestibility enhancers**

|      |                               |   |   |                        |   |   |   |   |              |
|------|-------------------------------|---|---|------------------------|---|---|---|---|--------------|
| 4a17 | Kerry ingredients and flavors | Alpha-galactosidase<br>EC 3.2.1.22<br>Endo-1,4-beta-glucanase<br>EC 3.2.1.4 | <p><i>Additive composition</i></p> <p>Preparation of alpha-galactosidase (EC 3.2.1.22) produced by <i>Saccharomyces cerevisiae</i> (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by <i>Aspergillus niger</i> (CBS 120604) with a minimum activity of:</p> <p>Solid form:</p> <ul style="list-style-type: none"> <li>— 1 000 U <sup>(1)</sup> alpha-galactosidase/g</li> <li>— 5 700 U <sup>(2)</sup> endo-1,4- beta-glucanase/g</li> </ul> <p>Liquid form:</p> <ul style="list-style-type: none"> <li>— 500 U alpha-galactosidase/g</li> <li>— 2 850 U endo-1,4- beta-glucanase/g.</li> </ul> <p><i>Characterisation of the active substance</i></p> <p>Alpha-galactosidase produced by <i>Saccharomyces cerevisiae</i> (CBS 615.94) Endo-1,4-beta-glucanase produced by <i>Aspergillus niger</i> (CBS 120604).</p> <p><i>Method of Analysis</i> <sup>(3)</sup></p> <p>Determination:</p> <ul style="list-style-type: none"> <li>— Alpha-galactosidase: colorimetric method measuring p-nitrophenol released by action of alpha-galactosidase from p-nitrophenyl-alpha-galactopyranoside substrate,</li> </ul> | Chickens for fattening | — | 50 U alpha-galactosidase<br>285 U endo-1,4-beta-glucanase | — | <ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.</li> <li>2. Maximum recommended dose: <ul style="list-style-type: none"> <li>— 100 U alpha-galactosidase/kg;</li> <li>— 570 U endo-1,4-beta-glucanase/kg.</li> </ul> </li> <li>3. For safety: breathing protection glasses and gloves shall be used during handling.</li> </ol> | 9 April 2022 |
|------|-------------------------------|---|---|------------------------|---|---|---|---|--------------|

| Identi-<br>fication<br>number of<br>the addi-<br>tive | Name of the<br>holder of<br>authorisation | Additive | Composition, chemical formula, description, analy-<br>tical method   | Species or<br>category of<br>animal | Maximum<br>age | Minimum<br>content   | Maximum<br>content | Other provisions | End of period<br>of authorisa-<br>tion |
|---|---|----------|--|-------------------------------------|----------------|--|--------------------|------------------|--|
|   |   |          |  |                                     |                | Units of activity/kg of<br>complete feedingstuff<br>with a moisture content<br>of 12 % |                    |                  |  |
|   |   |          | — endo-1,4-beta-glucanase: colorimetric<br>method measuring water soluble dye re-<br>leased by action of endo-1,4-beta-gluca-<br>nase from azurine-crosslinked barley glu-<br>can substrate. |                                     |                |  |                    |                  |  |

(<sup>1</sup>) 1 U is the amount of the enzyme which liberates 1 µmol of p-nitrophenol per minute from p-nitrophenyl-alpha-galactopyranoside (pNPG) at pH 5,0 and 37 °C.

(<sup>2</sup>) 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.

(<sup>3</sup>) 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>