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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

amending Implementing Regulation (EU) No 237/2012 as regards the authorisation of a new form 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) (holder of authorisation Kerry Ingredients and Flavours)

(Text with EEA relevance)

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(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 nutrition¹, 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 ten years for chickens for fattening by Commission Implementing Regulation (EC) No 237/2012², and for minor poultry species for fattening and for chickens reared for laying by Commission Implementing Regulation (EU) No 1365/2013³.
- (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 2014⁴ 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*

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 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).

⁴ EFSA Journal 2014; 12(11):3897.

(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, Annex to Regulation (EC) 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,

HAS ADOPTED THIS REGULATION:

Article 1

Annex to Regulation (EC) 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,

For the Commission
The President
Jean-Claude JUNCKER