



2024/781

6.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/781

of 5 March 2024

concerning the renewal of 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 chickens for fattening, minor poultry species for fattening and chickens reared for laying (holder of authorisation: Kerry Ingredients & Flavours Ltd.) and repealing Implementing Regulations (EU) No 237/2012 and (EU) No 1365/2013

(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 and renewing such an authorisation.
- (2) A preparation of alpha-galactosidase produced by *Saccharomyces cerevisiae* CBS 615.94 and endo-1,4-beta-glucanase produced by *Aspergillus niger* CBS 120604, was authorised for 10 years as a feed additive for chickens for fattening by Commission Implementing Regulation (EU) No 237/2012 ⁽²⁾, and for minor poultry species for fattening and chickens reared for laying by Commission Implementing Regulation (EU) No 1365/2013 ⁽³⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation 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, as a feed additive for chickens for fattening, minor poultry species for fattening and chickens reared for laying, requesting the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 July 2023 ⁽⁴⁾ that the preparation of alpha-galactosidase produced by *Saccharomyces cerevisiae* CBS 615.94 and endo-1,4-beta-glucanase produced by *Aspergillus niger* CBS 120604 remains safe for chickens for fattening, minor poultry species for fattening and chickens reared for laying, the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of alpha-galactosidase produced by *Saccharomyces cerevisiae* CBS 615.94 and endo-1,4-beta-glucanase produced by *Aspergillus niger* CBS 120604, is a skin and eye irritant and a dermal sensitiser, and that it should be considered a respiratory sensitiser. It also indicated that there is no need for assessing the efficacy 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 as the application for renewal of the

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽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, ELI: http://data.europa.eu/eli/reg_impl/2012/237/oj).

⁽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, ELI: http://data.europa.eu/eli/reg_impl/2013/1365/oj).

⁽⁴⁾ EFSA Journal 2023;21(8):8175.

authorisation does not include a proposal for amending or supplementing the conditions of the original authorisations which would have an impact on the efficacy of the additive. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis 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 as a feed additive in the context of the previous authorisations are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ⁽³⁾, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the preparation of alpha-galactosidase produced by *Saccharomyces cerevisiae* CBS 615.94 and endo-1,4-beta-glucanase produced by *Aspergillus niger* CBS 120604, satisfies the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive. Those protective measures should be without prejudice to other workers' safety requirements under Union law.
- (7) As a consequence of the renewal of the authorisation 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, as a feed additive, Implementing Regulations (EU) No 237/2012 and (EU) No 1365/2013 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation 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, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (9) 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

Renewal of authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeals

Implementing Regulations (EU) No 237/2012 and (EU) No 1365/2013 are repealed.

⁽³⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

*Article 3***Transitional measures**

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 26 September 2024 in accordance with the rules applicable before 26 March 2024 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 26 March 2025 in accordance with the rules applicable before 26 March 2024 may continue to be placed on the market and used until the existing stocks are exhausted.

*Article 4***Entry into force**

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, 5 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

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 Ltd.	Alpha-galactosidase (EC 3.2.1.22) Endo-1,4-beta-glucanase (EC 3.2.1.4)	<i>Additive composition</i> Preparation of alpha-galactosidase produced by <i>Saccharomyces cerevisiae</i> CBS 615.94 and endo-1,4-beta-glucanase produced by <i>Aspergillus niger</i> CBS 120604 having a minimum activity of: — 1 000 U ⁽¹⁾ alpha-galactosidase/g, — 5 700 U ⁽²⁾ endo-1,4-beta-glucanase/g. Solid form. <i>Characterisation of the active substance</i> 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. <i>Analytical method</i> ⁽³⁾ For the determination of alpha-galactosidase: in the feed additive, premixtures and compound feed: colorimetric method measuring p-nitrophenol released by action	Chickens for fattening Minor poultry species for fattening Chickens reared for laying	—	50 U alpha-galactosidase 285 U endo-1,4-beta-glucanase	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Indicate in the directions for use: 'Maximum recommended dose: — 100 U alpha-galactosidase/kg complete feed — 570 U endo-1,4-beta-glucanase/kg complete feed' 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	26 March 2034

			of alpha-galactosidase from p-nitrophenyl-alpha-galactopyranoside substrate. For the determination of endo-1,4-beta-glucanase in the feed additive, premixtures and compound feed: colorimetric method measuring water soluble dye released by action of endo-1,4-beta-glucanase from azurine-crosslinked barley glucan substrate.						
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Category of zootechnical additives. Functional group: digestibility enhancers

4a17	Kerry Ingredients and Flavours Ltd.	Alpha-galactosidase (EC 3.2.1.22) Endo-1,4-beta-glucanase (EC 3.2.1.4)	<i>Additive composition</i> Preparation of alpha-galactosidase produced by <i>Saccharomyces cerevisiae</i> CBS 615.94 and endo-1,4-beta-glucanase produced by <i>Aspergillus niger</i> CBS 120604 having a minimum activity of: — 500 U alpha-galactosidase/g, — 2 850 U endo-1,4-beta-glucanase/g. Liquid form. <i>Characterisation of the active substance</i> 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.	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, the storage conditions and stability to heat treatment shall be indicated. 2. Indicate in the directions for use: 'Maximum recommended dose: — 100 U alpha-galactosidase/kg complete feed — 570 U endo-1,4-beta-glucanase/kg complete feed' 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be	26 March 2034
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			<i>Analytical method</i> For the determination of alpha-galactosidase: in the feed additive, premixtures and compound feed: colorimetric method measuring p-nitrophenol released by action of alpha- galactosidase from p-nitrophenyl-alpha-galactopyranoside substrate. For the determination of endo-1,4-beta-glucanase in the feed additive, premixtures and compound feed: colorimetric method measuring water soluble dye released by action of endo-1,4-beta-glucanase from azurine-crosslinked barley glucan substrate.					eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	
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(¹) One alpha-galactosidase unit (U) is the amount of enzyme that will produce one micromole of para-nitrophenol per minute from p-nitrophenyl-alpha-galactopyranoside (pNPG) under the specified conditions (pH = 5,0; temperature 37 °C).

(²) One endo-1,4-beta-glucanase unit (U) is the amount of enzyme that will produce one milligram of reducing sugar (glucose equivalent) per minute from hydrolyses of beta-D-glucans under the specified conditions (pH = 5,0; temperature 50 °C).

(³) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en