

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1711**of 7 September 2023****concerning the renewal of the authorisation of a preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 as a feed additive for dairy cows and repealing Regulation (EC) No 537/2007 (holder of authorisation: Biozyme Incorporated)****(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 authorisation.
- (2) A preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 was authorised for 10 years as a feed additive for dairy cows by Commission Regulation (EC) No 537/2007 ⁽²⁾.
- (3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of that preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 as a feed additive for dairy cows in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. The application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 10 November 2021 ⁽³⁾, with reference to its opinion of 28 January 2020 ⁽⁴⁾, that the applicant had provided evidence that the preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 remains safe for the target species, the consumers and the environment under the conditions of use currently authorised. The Authority stated that the preparation should be considered a potential respiratory sensitiser, and indicated that there was no need for assessing its efficacy in the context of the renewal of the authorisation. It also verified the report on the methods of analysis used for the control of the active substances of the preparation submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003, including a modified method for the quantification of endo-1,4-beta-glucanase activity in the feed additive. The Reference Laboratory recommended to change the specification and description of the endo-1,4-beta-glucanase enzyme accordingly in the authorisation act.
- (5) The assessment of the preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that preparation should be renewed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 537/2007 of 15 May 2007 concerning the authorisation of the fermentation product of *Aspergillus oryzae* (NRRL 458) (Amaferm) as a feed additive (OJ L 128, 16.5.2007, p. 13).

⁽³⁾ EFSA Journal 2022;20(2):6983.

⁽⁴⁾ EFSA Journal 2020;18(2):6011.

- (6) The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. Those protective measures should be without prejudice to other worker safety requirements under Union law.
- (7) As a consequence of the renewal of the authorisation of the preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 as a feed additive, Regulation (EC) No 537/2007 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation concerned, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from 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 the authorisation

The authorisation of the preparation of the fermentation product of *Aspergillus oryzae* NRRL 458, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers' is renewed subject to the conditions laid down in the Annex.

Article 2

Repeal of Regulation (EC) No 537/2007

Regulation (EC) No 537/2007 is repealed.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 28 March 2024 in accordance with the rules applicable before 28 September 2023 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 28 September 2024 in accordance with the rules applicable before 28 September 2023 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, 7 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

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
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers

4a2i	Biozyme Incorporated	Fermentation product of <i>Aspergillus oryzae</i> NRRL 458	<i>Additive composition</i> Preparation of: Fermentation product of <i>Aspergillus oryzae</i> NRRL 458: 4 to 5 % Wheat bran: 94 to 95 % Solid form. <i>Characterisation of the active substance</i> Endo-1,4-beta-glucanase (EC 3.2.1.4) and alpha-amylase (EC 3.2.1.1) having respectively a minimum activity of 14,5 mU ⁽¹⁾/g and 20 mIU ⁽²⁾/g. <i>Analytical method ⁽³⁾</i> For the quantification of endo-1,4-beta-glucanase in the feed additive: colorimetric method based on the enzymatic reaction by endo-1,4-beta-glucanase on a CellG5 substrate. For the quantification of alpha-amylase in the feed additive: colorimetric (DNS) method based on the enzymatic reaction by alpha-amylase on a potato starch substrate.	Dairy cows	—	85	300	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Recommended dose: the quantity of the additive in daily ration should be 3 to 5 g/cow/day. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address 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 protective equipment.	28 September 2033
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⁽¹⁾ One CellG5 Unit (U) is the amount of enzyme in the presence of excess thermostable beta-glucosidase, required to release one micromole of 4-nitrophenol from CellG5 in one minute under the defined assay conditions.

⁽²⁾ One unit of alpha-amylase activity (IU) refers to the amylase that liberates 1 micromole of glucose per minute from potato starch at pH 6,9 and at 38 °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.