Official Journal
of the European Union

EN
L series

2025/161

30.1.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/161

of 29 January 2025

concerning the authorisation of a preparation of muramidase produced with *Trichoderma reesei* DSM 32338 as a feed additive for laying hens (holder of authorisation: DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.)

(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 such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of muramidase produced with *Trichoderma reesei* DSM 32338 as a feed additive. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation of muramidase produced with *Trichoderma reesei* DSM 32338 as a feed additive for laying hens, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'other zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 April 2024 ([2]) that, under the proposed conditions of use, the preparation of muramidase produced with *Trichoderma reesei* DSM 32338 is safe for the target species, consumers and the environment. It also concluded that the liquid formulation of the preparation is considered not irritant to the skin or eyes, that its solid formulation is considered not irritant to the skin, and that due to the proteinaceous nature of the preparation both formulations should be considered respiratory sensitisers. However, the Authority could not conclude on the potential of the preparation (both formulations) to be a dermal sensitiser or the potential of its solid formulation to be irritant to the eyes. The Authority further concluded that the preparation has the potential to be efficacious as a zootechnical additive for laying hens at 30 000 LSU(F)/kg feed. It 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 previous assessment regarding the methods used for the control of muramidase in animal feed are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ([3]), an evaluation report of the Reference Laboratory is therefore not required.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) *EFSA Journal*. 2024;22:e8788.
([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).

(6) In view of the above, the Commission considers that the preparation of muramidase produced with *Trichoderma reesei* DSM 32338 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. 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.

(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

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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, 29 January 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed 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
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: other zootechnical additives (improvement of laying performance)									
4d16	DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.	Muramidase (EC 3.2.1.17)	*Additive composition* Preparation of muramidase (EC 3.2.1.17) produced with *Trichoderma reesei* DSM 32338 having a minimum activity of 60 000 LSU(F) ([1])/g. Solid and liquid forms. *Characterisation of the active substance* Muramidase (EC 3.2.1.17, also known as 'lysozyme') produced with *Trichoderma reesei* DSM 32338 *Analytical method* ([2]) For the quantification of muramidase: fluorescence-based enzyme assay method that determines the enzyme-catalyzed depolymerisation of a fluorescein-labelled peptidoglycan preparation at pH 6,0 and 30 °C.	Laying hens	—	30 000 LSU(F)	60 000 LSU(F)	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. 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 skin and breathing protective equipment, as well as personal eye protective equipment for the solid form of the additive.	19 February 2035

([1]) One LSU(F) is defined as the amount of enzyme that increases the fluorescence of 12,5 µg/ml fluorescein-labelled peptidoglycan per minute at pH 6,0 and 30 °C by a value that corresponds to the fluorescence of approximately 0,06 nmol fluorescein isothiocyanate isomer.

([2]) 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