COMMISSION IMPLEMENTING REGULATION (EU) 2019/805

of 17 May 2019

concerning the authorisation of a preparation of muramidase produced by *Trichoderma reesei* DSM 32338 as a feed additive for chickens for fattening and minor poultry species for fattening (holder of authorisation DSM Nutritional Products Ltd, represented in EU 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 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 by *Trichoderma reesei* DSM 32338. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) That application concerns the authorisation of a preparation of muramidase produced by *Trichoderma reesei* DSM 32338 as a feed additive for chickens for fattening and minor poultry species for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 14 June 2018 ([2]) that, under the proposed conditions of use, the preparation of muramidase produced by *Trichoderma reesei* DSM 32338 does not have an adverse effect on animal health, consumer safety or the environment. It was also concluded that the additive may have a skin/eyes irritancy potential and skin sensitisation potential. Therefore, 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. The Authority also concluded that the additive showed improvements of the feed to gain ratio in chickens for fattening. The Authority considered that this conclusion can be extrapolated to minor poultry species 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 muramidase produced by *Trichoderma reesei* DSM 32338 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) 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

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 the Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2018;16(7):5342.

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, 17 May 2019.

For the Commission

The President

Jean-Claude JUNCKER

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: other zootechnical additives (improvement of the feed to gain ratio)									
4d16	DSM Nutritional Products Ltd represented in the EU by DSM Nutritional Products Sp. Z o.o	Muramidase (EC 3.2.1.17)	*Additive composition* Preparation of muramidase (EC 3.2.1.17) (lysozyme) produced by *Trichoderma reesei* (DSM 32338) having a minimum activity of 60 000 LSU(F)/g (1) Solid and liquid forms *Characterisation of the active substance* Muramidase (EC 3.2.1.17) (lysozyme) produced by *Trichoderma reesei* (DSM 32338) *Method of analysis* (2) For the quantification of muramidase: fluorescence-based enzyme assay method that determines the enzyme-catalysed depolymerisation of a fluorescein-labelled peptidoglycan preparation at pH 6,0 and 30 °C.	Chickens for fattening Minor poultry species for fattening	—	25 000 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 from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment including skin and breathing protections.	9 June 2029

(1) One LSU(F) unit 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 I.

(2) 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