

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/1426****of 31 August 2021****concerning the authorisation of serine protease produced by *Bacillus licheniformis* DSM 19670 as a feed additive for chickens for fattening (holder of the authorisation: DSM Nutritional Products Ltd., represented in the Union 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 <sup>(1)</sup>, 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 serine protease produced by *Bacillus licheniformis* (DSM 19670). The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of serine protease produced by *Bacillus licheniformis* (DSM 19670) as a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2021 <sup>(2)</sup> that, under the proposed conditions of use, serine protease produced by *Bacillus licheniformis* DSM 19670 does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that that additive should be considered a skin irritant, potential skin sensitiser and a respiratory sensitiser. 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 that additive. The Authority concluded that the additive has the potential to be efficacious for 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 serine protease produced by *Bacillus licheniformis* DSM 19670 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 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> EFSA Journal 2021;19(3):6448.

*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, 31 August 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## 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 feed with a moisture content of 12 %			

**Category of zootechnical additives****Functional group: digestibility enhancers**

4a13	DSM Nutritional Products Ltd., represented in the Union by DSM Nutritional Products Sp. z o. o.	Serine protease (EC 3.4.21.-)	<i>Additive composition:</i> Solid and liquid preparation of serine protease (EC 3.4.21.-) produced by <i>Bacillus licheniformis</i> DSM 19670 having a minimum activity of 75 000 PROT <sup>(1)</sup> /g	Chickens for fattening	-	15 000 PROT		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 by inhalation, dermal contact or eyes contact. 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 eyes, skin and breathing protection.	21 September 2031
			<i>Characterisation of the active substance:</i> Serine protease (EC 3.4.21.-) produced by <i>Bacillus licheniformis</i> DSM 19670						
			<i>Analytical method <sup>(2)</sup></i> For the quantification of the serine protease activity in the feed additive, premixtures, compound feed and feed materials: — colourimetric method based on the enzymatic reaction of serine protease on the Suc-Ala-Ala-Pro-Phe-pNA substrate.						

<sup>(1)</sup> One PROT is the amount of enzyme that releases 1 µmol of p-nitroaniline from 1mM substrate (Suc-Ala-Ala-Pro-Phe-pNA) per minute at pH 9,0 and temperature 37 °C.

<sup>(2)</sup> 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>