



2025/2502

12.12.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/2502

of 11 December 2025

concerning the authorisation of a preparation of protease produced with *Bacillus subtilis* CBS 148232 and viable spores of *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 as a feed additive for pigs for fattening of all Suidae species and weaned piglets of minor Suidae species (holder of authorisation: Genencor International B.V.)

(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 protease produced with *Bacillus subtilis* CBS 148232 and viable spores of *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510. 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 protease produced with *Bacillus subtilis* CBS 148232 and viable spores of *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 as a feed additive for pigs for fattening and other growing Suidae, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 January 2025 ⁽²⁾ that the preparation of protease produced with *Bacillus subtilis* CBS 148232 and viable spores of *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 is safe for the target species, consumers and the environment. The Authority also concluded that the preparation of protease produced with *Bacillus subtilis* CBS 148232 and viable spores of *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 is not irritant to eyes or skin but should be considered a skin and respiratory sensitiser and any exposure through skin and respiratory tract is considered a risk. The Authority further concluded that the preparation of protease produced with *Bacillus subtilis* CBS 148232 and viable spores of *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 has the potential to be efficacious in pigs for fattening and other minor porcine species at the same physiological stage at 5 000 U protease/kg and $1,5 \times 10^8$ CFU/kg of complete feed. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) Following a request from the Commission, the Authority, in its reply dated May 5, 2025, confirmed that in this specific case the phrase 'other minor porcine species at the same physiological stage' includes weaned piglets of minor porcine species or pigs for fattening of minor porcine species.

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

⁽²⁾ EFSA Journal. 2025;23:e9265, <https://doi.org/10.2903/j.efsa.2025.9265>.

- (6) On 27 June 2025, the applicant withdrew the application for use in suckling piglets of minor Suidae species.
- (7) In view of the above, the Commission considers that the preparation of protease produced with *Bacillus subtilis* CBS 148232 and viable spores of *Bacillus velezensis* NRRL B-50508, *Bacillus velezensis* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for pigs for fattening of all Suidae species and weaned piglets of minor Suidae species. 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.
- (8) 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 'digestibility enhancers', 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, 11 December 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Name of the holder of authorisation	Name of the 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 and CFU/kg of complete feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a63	Genencor International B.V.	Protease (EC 3.4.21.62), <i>Bacillus velezensis</i> NRRL B-50508, <i>Bacillus velezensis</i> NRRL B-50509 and <i>Bacillus subtilis</i> NRRL B-50510	<i>Additive composition</i> Preparation of: — protease (EC 3.4.21.62) produced with <i>Bacillus subtilis</i> CBS 148232 with a minimum activity of: 50 000 U (°)/g — <i>Bacillus velezensis</i> NRRL B-50508, <i>Bacillus velezensis</i> NRRL B-50509 and <i>Bacillus subtilis</i> NRRL B-50510 containing a minimum total of: <i>Bacillus</i> spp. 1,5 × 10 ⁹ CFU/g (ratio 1:1:1) — Food- grade mineral oil: ≤ 0,4 % — Food- grade polyvinyl alcohol: ≤ 3,5 % Solid form. <i>Characterisation of the active substance</i> Protease (EC 3.4.21.62) produced with <i>Bacillus subtilis</i> CBS 148232, and viable spores of <i>Bacillus velezensis</i> NRRL B-50508, <i>Bacillus velezensis</i> NRRL B-50509 and <i>Bacillus subtilis</i> NRRL B-50510	Pigs for fattening of all Suidae species Weaned piglets of minor Suidae species	—	5 000 U Protease And 1,5 × 10 ⁸ CFU <i>Bacillus</i> spp.	—	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 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 skin and breathing protective equipment.	1 January 2036

Identification number of the feed additive	Name of the holder of authorisation	Name of the 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 and CFU/kg of complete feed with a moisture content of 12 %			
			<i>Analytical method</i> ⁽²⁾ For the quantification of protease in the feed additive, premixtures and compound feed: Colorimetric method based on the enzymatic hydrolysis by protease of a dyed cross-linked casein substrate at pH 10,0 and 50 °C. For the identification of <i>Bacillus velezensis</i> NRRL B-50508, <i>Bacillus velezensis</i> NRRL B-50509 and <i>Bacillus subtilis</i> NRRL B-50510: Pulsed Field Gel Electrophoresis (PFGE) - CEN/TS 17697 or DNA sequencing methods. For the enumeration of the overall <i>Bacillus</i> spp. (NRRL B-50508, NRRL B-50509 and NRRL B-50510) in the feed additive, premixture and compound feed: Spread plate method on tryptone soya agar (EN 15784).						

⁽¹⁾ 1 unit of protease activity is defined as the amount of enzyme that liberates, under defined assay conditions, 2,3 µg of phenolic compounds (expressed as tyrosine equivalents) from a casein substrate per minute at pH 10,0 and 50 °C.

⁽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