



Brussels, **XXX**
SANTE/2946920/2025 CIS
(POOL/G5/2025/2946920/2946920-EN
CIS.docx)
[...](2025) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

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)

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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 nutrition¹, 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 2025² 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

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>.

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 5000 U protease/kg and 1.5×10^8 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.
- (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,

For the Commission
The President
Ursula VON DER LEYEN