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COMMISSION IMPLEMENTING REGULATION (EU) 2025/2500

of 11 December 2025

concerning the authorisation of a preparation of *Bacillus velezensis* NRRL B-67647, *Bacillus pumilus* NRRL B-67648 and *Bacillus licheniformis* NRRL B-67649 as a feed additive for poultry for fattening and ornamental birds (holder of authorisation: S.I.Lesaffre)

(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 *Bacillus velezensis* NRRL B-67647, *Bacillus pumilus* NRRL B-67648 and *Bacillus licheniformis* NRRL B-67649. 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 *Bacillus velezensis* NRRL B-67647, *Bacillus pumilus* NRRL B-67648 and *Bacillus licheniformis* NRRL B-67649 as a feed additive for chickens for fattening, other poultry for fattening and ornamental birds, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'gut flora stabilisers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 May 2025 ([2]) that, under the proposed conditions of use, the preparation of *Bacillus velezensis* NRRL B-67647, *Bacillus pumilus* NRRL B-67648 and *Bacillus licheniformis* NRRL B-67649 is safe for the target species, consumers and the environment. The Authority also concluded that the preparation of *Bacillus velezensis* NRRL B-67647, *Bacillus pumilus* NRRL B-67648 and *Bacillus licheniformis* NRRL B-67649, in concentrated form is not irritant to the skin or eyes. Considering the similarity in composition, this conclusion can be extended to diluted form provided it is formulated with only calcium carbonate. Both forms of the additive are considered skin and respiratory sensitisers, and any exposure via skin or respiratory tract is considered a risk. The Authority further concluded that the preparation of *Bacillus velezensis* NRRL B-67647, *Bacillus pumilus* NRRL B-67648 and *Bacillus licheniformis* NRRL B-67649 has the potential to be efficacious in chickens for fattening, other poultry for fattening and ornamental birds at a proposed minimum inclusion level of 3×10^7 total CFU/kg of complete feedingstuffs. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) In view of the above, the Commission considers that the preparation of *Bacillus velezensis* NRRL B-67647, *Bacillus pumilus* NRRL B-67648 and *Bacillus licheniformis* NRRL B-67649 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for poultry for fattening and ornamental birds. 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.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) *EFSA Journal*. 2025;23:e9465. https://doi.org/10.2903/j.efsa.2025.9465.

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 'gut flora stabilisers', 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

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
						CFU/kg of complete feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: gut flora stabilisers.									
4b1898	S.I.Lesaffre	Preparation of *Bacillus velezensis* NRRL B-67647, *Bacillus pumilus* NRRL B-67648 and *Bacillus licheniformis* NRRL B-67649	*Additive composition* Preparation of *Bacillus velezensis* NRRL B-67647, *Bacillus pumilus* NRRL B-67648 and *Bacillus licheniformis* NRRL B-67649 containing a minimum total of *Bacillus* spp. (ratio 1:1:1): 2×10^8 CFU/g additive. Solid forms *Characterisation of the active substance* Viable cells of *Bacillus velezensis* NRRL B-67647, *Bacillus pumilus* NRRL B-67648 and *Bacillus licheniformis* NRRL B-67649.	Poultry for fattening Ornamental birds	-	3×10^7	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: diclazuril, narasin, maduramicin ammonium, salinomycin sodium, monensin sodium, robenidine hydrochloride, the combination narasin with nicarbazin, lasalocid or halofuginone.	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
						CFU/kg of complete feed with a moisture content of 12 %			
			Analytical method (1) — Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) (CEN/TS 17697) — Enumeration in the feed additive, premixtures, compound feed: Spread-plate method on tryptone soya agar (EN 15784)					3. 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 breathing, and skin protective equipment.	

(1) 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

ELI: http://data.europa.eu/eli/reg_impl/2025/2500/oj