COMMISSION IMPLEMENTING REGULATION (EU) 2021/2051

of 24 November 2021

concerning the authorisation of a preparation of *Bacillus velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104 as a feed additive for turkeys for fattening (holder of authorisation: Danisco Animal Nutrition represented by 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 and renewing 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 *Bacillus velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104. 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* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104, previously identified as *Bacillus amyloliquefaciens* PTA-6507, *Bacillus amyloliquefaciens* NRRL B-50013 and *Bacillus amyloliquefaciens* NRRL B-50104 as a feed additive for turkeys for fattening, to be classified in the category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021 ([2]) that under the proposed conditions of use, the preparation of *Bacillus velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that this preparation is not irritant to skin and eyes and is not a dermal sensitiser but given the proteinaceous nature of the active agents, the preparation should be considered 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 the additive. The Authority also concluded that the preparation has the potential to be efficacious as zootechnical additive in feedingstuffs. The Authority does not consider that there is a need for specific requirements of postmarket monitoring. It 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) The assessment of the preparation of *Bacillus velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of the product 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,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2021;19(4):6535.

HAS ADOPTED THIS REGULATION:

Article 1

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

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, 24 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives									
Functional group: gut flora stabilisers									
4b1827i	Danisco Animal Nutrition represented by Genencor International B.V.	*Bacillus velezensis* PTA-6507, *Bacillus. velezensis* NRRL B-50013 and *Bacillus. velezensis* NRRL B-50104	*Additive composition* Preparation of *Bacillus velezensis* PTA-6507, *Bacillus. velezensis* NRRL B-50013 and *Bacillus. velezensis* NRRL B-50104 containing a minimum $2,5 \times 10^9$ CFU/g additive (total) with a minimum of bacterial concentration of $8,3 \times 10^8$ of each strain/g additive. Solid form *Characterisation of the active substance* Viable spores of *Bacillus velezensis* PTA-6507, *Bacillus. velezensis* NRRL B-50013 and *Bacillus. velezensis* NRRL B-50104 *Analytical method* (1) Identification and enumeration of *Bacillus velezensis* PTA-6507, *Bacillus. velezensis* NRRL B-50013 and *Bacillus. velezensis* NRRL B-50104 in the feed additive, premixtures and feedingstuffs	Turkeys for fattening	-	$7,5 \times 10^7$	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. May be used in feed containing the following permitted coccidiostats: lasalocid A sodium, monensin sodium and diclazuril. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot	15 December 2031

			— Identification: Pulsed Field Gel Electrophoresis (PFGE) — Enumeration: Spread plate method following heat treatment – EN 15784					be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	

([1]) 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