II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1313

of 2 August 2019

concerning the authorisation of a preparation of *Bacillus amyloliquefaciens* NRRL B-50508, *Bacillus amyloliquefaciens* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 as a feed additive for pigs for fattening and minor porcine species for fattening (holder of authorisation Cargill Incorporated, represented by Provimi Holding BV)

(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 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 amyloliquefaciens* NRRL B-50508, *Bacillus amyloliquefaciens* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) That application concerns the authorisation of a preparation of *Bacillus amyloliquefaciens* NRRL B-50508, *Bacillus amyloliquefaciens* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 as a feed additive for pigs for fattening and minor porcine species for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 February 2019 ([2]) that, under the proposed conditions of use, the preparation *Bacillus amyloliquefaciens* NRRL B-50508, *Bacillus amyloliquefaciens* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 does not have an adverse effect on animal health or the environment. It also concluded that the additive is considered as a potential respiratory sensitiser, even if with a low dusting potential, and that no conclusion could be drawn on skin or eyes sensitisation or irritation by the additive. 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 additive has a potential to be efficacious in feed to gain ratio in pigs for fattening at the recommended dose and that this conclusion can be extended to minor porcine species 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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2019;17(3):5647.

(5) The assessment of the preparation of *Bacillus amyloliquefaciens* NRRL B-50508, *Bacillus amyloliquefaciens* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 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 'gut flora stabilisers', is authorised as an additive in animal nutrition as set out 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, 2 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

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 of zootechnical additives. Functional group: gut flora stabilisers									
4b1893	Cargill Incorporated, represented by Provimi Holding BV	*Bacillus amyloliquefaciens* NRRL B-50508, *Bacillus amyloliquefaciens* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510	*Additive composition:* Preparation of *Bacillus amyloliquefaciens* NRRL B-50508, *Bacillus amyloliquefaciens* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 containing a minimum of: *Bacillus* spp. $2,5 \times 10^9$ CFU/g (ratio 1:1:1) Powder form *Characterisation of the active substance:* Viable spore of *Bacillus amyloliquefaciens* NRRL B-50508, *Bacillus amyloliquefaciens* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510 *Analytical method* (1) For the identification: Pulsed Field Gel Electrophoresis (PFGE) For enumeration in the feed additive, premixtures and feedingstuffs: Spread plate method on tryptone soya agar (EN 15784)	Pigs for fattening Minor porcine species for fattening	—	$1,5 \times 10^8$	—	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 resulting from its use. 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 breathing and skin protection.	25 August 2029

(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