Commission Implementing Regulation (EU) 2017/440 of 13 March 2017 concerning the authorisation of the preparation of Bacillus amyloliquefaciens (PTA-6507), Bacillus amyloliquefaciens (NRRL B-50013) and Bacillus amyloliquefaciens (NRRL B-50104) as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species for fattening and minor poultry species reared for laying (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/440

of 13 March 2017

concerning the authorisation of the preparation of *Bacillus amyloliquefaciens* (PTA-6507), *Bacillus amyloliquefaciens* (NRRL B-50013) and *Bacillus amyloliquefaciens* (NRRL B-50104) as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species for fattening and minor poultry species reared for laying (holder of authorisation **[**F1Danisco (UK) Ltd, trading as Danisco Animal Nutrition and 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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of the preparation of *Bacillus amyloliquefaciens* (PTA-6507), *Bacillus amyloliquefaciens* (NRRL B-50013) and *Bacillus amyloliquefaciens* (NRRL B-50104). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of the preparation of *Bacillus amyloliquefaciens* (PTA-6507), *Bacillus amyloliquefaciens* (NRRL B-50013) and *Bacillus amyloliquefaciens* (NRRL B-50104) as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species for fattening and minor poultry species reared for laying, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 24 May 2016(2) that, under the proposed conditions of use, the preparation of

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/440. (See end of Document for details)*

Bacillus amyloliquefaciens (PTA-6507), *Bacillus amyloliquefaciens* (NRRL B-50013) and *Bacillus amyloliquefaciens* (NRRL B-50104) does not have an adverse effect on animal health, human health or the environment, and that it has a potential to improve performance in chickens for fattening. This conclusion can be extended to the additive when used for chickens reared for laying and can be extrapolated to minor avian species for fattening and minor avian species reared for laying. 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.

(5) The assessment of the preparation of *Bacillus amyloliquefaciens* (PTA-6507), *Bacillus amyloliquefaciens* (NRRL B-50013) and *Bacillus amyloliquefaciens* (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 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:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/221 of 6 February 2019 amending Regulations (EC) No 785/2007, (EC) No 379/2009, (EC) No 1087/2009, (EU) No 9/2010, (EU) No 337/2011 and Implementing Regulations (EU) No 389/2011, (EU) No 528/2011, (EU) No 840/2012, (EU) No 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 as regards the name of the holder of the authorisation and the representative of the holder of the authorisation for certain feed additives (Text with EEA relevance).

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/440. (See end of Document for details)*

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									
4b1827	[F1Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.],	*Bacillus amyloliquefaciens* DSM 32324, *Bacillus amyloliquefaciens* NRRL B-50013 and *Bacillus amyloliquefaciens* NRRL B-50104	*Additive composition* Preparation of *Bacillus amyloliquefaciens* DSM 32324, *Bacillus amyloliquefaciens* NRRL B-50013 and *Bacillus amyloliquefaciens* NRRL B-50104 containing a minimum of $2,5 \times 10^9$ CFU/g (total) with a minimum of bacterial concentration of $8,3 \times 10^8$ of each strain/g additive. Solid form *Characterisation of the*	Chickens for fattening Chickens reared for laying Minor poultry species for fattening and reared for laying	—	$7,5 \times 10^7$	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. The use is compatible in feed containing the following authorised coccidiostats: narasin/ nicarbazin, maduramicin ammonium, lasalocid A sodium, salinomycin sodium, monensin sodium,	3 April 2027

a 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