Commission Implementing Regulation (EU) 2020/151 of 4 February 2020 concerning the authorisation of Pediococcus acidilactici CNCM I-4622 as a feed additive for all porcine species for fattening and for breeding other than sows, all avian species, all fish species and all crustaceans and repealing Regulations (EC) No 911/2009, (EU) No 1120/2010 and (EU) No 212/2011 and Implementing Regulations (EU) No 95/2013, (EU) No 413/2013 and (EU) 2017/2299 (holder of authorisation Danstar Ferment AG represented in the Union by Lallemand SAS) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/151

of 4 February 2020

concerning the authorisation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive for all porcine species for fattening and for breeding other than sows, all avian species, all fish species and all crustaceans and repealing Regulations (EC) No 911/2009, (EU) No 1120/2010 and (EU) No 212/2011 and Implementing Regulations (EU) No 95/2013, (EU) No 413/2013 and (EU) 2017/2299 (holder of authorisation Danstar Ferment AG represented in the Union by Lallemand SAS)

(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) *Pediococcus acidilactici* CNCM I-4622 (former *Pediococcus acidilactici* CNCM MA 18/5M) was authorised for 10 years as a feed additive for salmonids and shrimps by Commission Regulation (EC) No 911/2009[(2)], for weaned piglets by Commission Regulation (EU) No 1120/2010[(3)], for laying hens by Commission Regulation (EU) No 212/2011[(4)], for all fish other than salmonids by Commission Implementing Regulation (EU) No 95/2013[(5)], for weaned piglets, pigs for fattening, laying hens and chickens for fattening by Commission Implementing Regulation (EU) No 413/2013[(6)], for pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, minor poultry species for fattening and minor poultry species for laying by Commission Implementing Regulation (EU) 2017/2299[(7)].

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted by the holder of the authorisation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive for the renewal of the

authorisation for chickens for fattening, minor avian species for fattening, laying hens, minor avian species for laying, weaned piglets, pigs for fattening, minor porcine species (weaned) and for fattening, all fish and shrimp, and for a new authorisation for chickens reared for laying and for breeding purposes, for ornamental birds and other non-food producing birds, for turkeys for fattening, for turkeys reared for breeding purposes, for turkeys for breeding purposes, for chickens for breeding purposes and related minor poultry species and other ornamental and non-food producing birds, for suckling piglets and related minor porcine species, for all crustaceans, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Articles 7(3) and 14(2) of that Regulation

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 2 April 2019[8] that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority confirmed its previous conclusions that *Pediococcus acidilactici* CNCM I-4622 is considered safe for the target species, consumers of products from animals fed with the additive and the environment. It also concluded that there is a potential for users to be exposed via inhalation and that no conclusion could be drawn on the potential for skin and eyes irritancy and dermal sensitisation. 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. It also concluded that the additive is efficacious for chickens reared for laying, chickens reared for breeding, chickens for breeding, turkeys and minor avian species reared for laying/breeding and for breeding, and for suckling piglets and minor porcine species for breeding and for fattening and all crustaceans.

(5) The assessment of *Pediococcus acidilactici* CNCM I-4622 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 911/2009, (EU) No 1120/2010 and (EU) No 212/2011 and Implementing Regulations (EU) No 95/2013, (EU) No 413/2013 and (EU) 2017/2299 should be repealed.

(7) 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 authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' for all porcine species for fattening and for breeding other than sows, all birds, and to the functional group 'other zootechnical additives' for all fish and all crustaceans is renewed subject to the conditions laid down in that Annex.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/151. (See end of Document for details)*

Article 2

Regulations (EC) No 911/2009, (EU) No 1120/2010 and (EU) No 212/2011, as well as Implementing Regulations (EU) No 95/2013, (EU) No 413/2013 and (EU) 2017/2299 are repealed.

Article 3

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, 4 February 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/151. (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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			
Category of zootechnical additives. Functional group: gut flora stabilisers											
4d1712	Danstar Ferment AG represented in the Union by Lallemand SAS	*Pediococcus acidilactici* CNCM I-4622	**Additive composition** Preparation of *Pediococcus acidilactici* CNCM I-4622 containing a minimum of 1×10^{10} CFU/g Solid not-coated and coated forms	All porcine species for fattening and for breeding, other than sows		1×10^{9}		5×10^{8}		1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.	25 February 2030
			Characterisation of the active substance Viable cells of *Pediococcus acidilactici* CNCM I-4622	All avian species						2. For use of the additive in water for drinking the homogenous dispersion of the additive shall	
			Analytical method[a] Enumeration of the								

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