

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2299**of 12 December 2017**

concerning the authorisation of a preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive 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, the authorisation of that feed additive for use in water for drinking and amending Regulations (EC) No 2036/2005, (EC) No 1200/2005 and Implementing Regulation (EU) No 413/2013 (holder of authorisation Danstar Ferment AG represented 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 such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The preparation of *Pediococcus acidilactici* CNCM MA 18/5M was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening by Commission Regulation (EC) No 1200/2005 ⁽³⁾, and as a feed additive for pigs for fattening by Commission Regulation (EC) No 2036/2005 ⁽⁴⁾. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003. That preparation was authorised for the use in water for drinking for weaned piglets, pigs for fattening, laying hens and chickens for fattening by Commission Implementing Regulation (EU) No 413/2013 ⁽⁵⁾.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for chickens for fattening and for pigs for fattening and, in accordance with Article 7 of that Regulation, for the authorisation for use for minor porcine species (weaned), minor porcine species for fattening, minor avian species for fattening and minor avian species reared for laying and for the use in water for drinking, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 20 April 2016 ⁽⁶⁾ that, under the proposed conditions of use, the preparation of *Pediococcus acidilactici* CNCM MA 18/5M does not have an adverse effect on animal health, human health or the environment. The Authority further concluded that the use of the preparation in feed and in water for drinking has the potential to improve the zootechnical performance of pigs for fattening and chickens for fattening. It considered that since the mechanism of action of the additive is presumed to be the same, the preparation has also the potential to improve the zootechnical performance of minor porcine species (weaned), minor porcine species for fattening, minor avian species for fattening and minor

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Commission Regulation (EC) No 1200/2005 of 26 July 2005 concerning the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (OJ L 195, 27.7.2005, p. 6).

⁽⁴⁾ Commission Regulation (EC) No 2036/2005 of 14 December 2005 concerning the permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of certain additives already authorised in feedingstuffs (OJ L 328, 15.12.2005, p. 13).

⁽⁵⁾ Commission Implementing Regulation (EU) No 413/2013 of 6 May 2013 concerning the authorisation of a preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for use in water for weaned piglets, pigs for fattening, laying hens and chickens for fattening (holder of authorisation Lallemand SAS) (OJ L 125, 7.5.2013, p. 1).

⁽⁶⁾ EFSA Journal 2016; 14(6):4483.

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 *Pediococcus acidilactici* CNCM MA 18/5M 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 Annex I to this Regulation.
- (6) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulations (EC) No 1200/2005, (EC) No 2036/2005 and Implementing Regulation (EU) No 413/2013 should be amended accordingly.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) 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

Authorisation

The preparation specified in Annex I, 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

Amendment to Regulation (EC) No 1200/2005

In Annex II to Regulation (EC) No 1200/2005, entry E1712 on *Pediococcus acidilactici* CNCM MA 18/5M is deleted.

Article 3

Amendment to Regulation (EC) No 2036/2005

In Annex I to Regulation (EC) No 2036/2005, entry E1712 on *Pediococcus acidilactici* CNCM MA 18/5M is deleted.

Article 4

Amendment to Implementing Regulation (EU) No 413/2013

The Annex to Implementing Regulation (EU) No 413/2013 is replaced by Annex II to this Regulation.

Article 5

Transitional measures

The preparation specified in the Annex I and feed containing that preparation, which are produced and labelled before 2 July 2018 in accordance with the rules applicable before 2 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

*Article 6***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, 12 December 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

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 by Lallemand SAS	<i>Pediococcus acidilactici</i> CNCM MA 18/5M	<p><i>Additive composition</i></p> <p>Preparation of <i>Pediococcus acidilactici</i> CNCM MA 18/5M containing a minimum of 1×10^{10} CFU/g</p> <p>Solid not-coated and coated forms</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Pediococcus acidilactici</i> CNCM MA 18/5M</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration of the active substance in feed additive, premixtures, feedingstuffs and water: spread plate method (EN 15786:2009).</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE) method.</p>	<p>Pigs for fattening</p> <p>Minor porcine species (weaned and for fattening)</p> <p>Chickens for fattening and minor avian species for fattening and for laying</p>	—	1×10^9	—	5×10^8	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive, premixture and compound feed, the storage conditions and stability to heat treatment and stability in drinking water shall be indicated. 2. For use of the additive in water for drinking the homogeneous dispersion of the additive shall be ensured. 3. The use is permitted in feed containing the following authorised coccidiostats: decoquinat, halofuginone, diclazuril, and nicarbazin. 	2.1.2028

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			
										<p>4. 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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.</p> <p>5. The additive may be used in water for drinking.</p>	

(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>

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/l of water for drinking			

Category of zootechnical additives. Functional group: gut flora stabilisers

4d1712	Lallemand SAS	<i>Pediococcus acidilactici</i> CNCM MA 18/5M	<p><i>Additive composition</i></p> <p>Preparation of <i>Pediococcus acidilactici</i> CNCM MA 18/5M containing a minimum of 1×10^{10} CFU/g additive</p> <p><i>Characterisation of active substance</i></p> <p>Viable cells of <i>Pediococcus acidilactici</i> CNCM MA 18/5 M</p> <p><i>Analytical methods</i> ⁽¹⁾</p> <p>Enumeration: spread plate method using MRS agar (EN 15786:2009)</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE)</p>	Piglets (weaned) Laying hens	—	5×10^8	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive, the storage conditions and stability heat treatment and stability in drinking water shall be indicated 2. For piglets (weaned) up to 35 kg. 3. For safety: breathing protection, glasses and gloves shall be used during handling. 4. The additive shall be mixed with other feed additives or feed materials in order to allow its complete homogeneous dispersion in water for drinking. 	27.5.2023
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⁽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>