

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 212/2011

of 3 March 2011

concerning the authorisation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for laying hens (holder of authorisation Lallemand SAS)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Regulation (EC) No 911/2009⁽⁴⁾ and for weaned piglets by Commission Regulation (EU) No 1120/2010⁽⁵⁾.

Having regard to the Treaty on the Functioning of the European Union,

- (5) New data were submitted in support of the application for the authorisation of *Pediococcus acidilactici* CNCM MA 18/5M for laying hens. The European Food Safety Authority ('the Authority') concluded in its opinion of 5 October 2010⁽⁶⁾ that *Pediococcus acidilactici* CNCM MA 18/5M, under the proposed conditions of use, does not have an adverse effect on animal health, human health or the environment, and that its use significantly increased the laying intensity of the target species. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

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,

- (6) The assessment 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 this preparation should be authorised as specified in the Annex to this Regulation.

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 *Pediococcus acidilactici* CNCM MA 18/5M. 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 a new use of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for laying hens, to be classified in the additive category 'zootechnical additives'.
- (4) The use of *Pediococcus acidilactici* CNCM MA 18/5M was authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 1200/2005⁽²⁾, without a time limit for pigs for fattening by Commission Regulation (EC) No 2036/2005⁽³⁾ and for 10 years for salmonids and shrimps by Commission

- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 195, 27.7.2005, p. 6.

⁽³⁾ OJ L 328, 15.12.2005, p. 13.

⁽⁴⁾ OJ L 257, 30.9.2009, p. 10.

⁽⁵⁾ OJ L 317, 3.12.2010, p. 12.

⁽⁶⁾ EFSA Journal 2010; 8(10):1865.

Article 2

This Regulation shall enter into force on the 20th day following 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, 3 March 2011.

For the Commission
The President
José Manuel BARROSO

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									
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</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 MSR agar (EN 15786:2009)</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE)</p>	Laying hens	—	1×10^9	—	<p>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>2. For safety: breathing protection, glasses and gloves shall be used during handling.</p>	24 March 2021

⁽¹⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives