

COMMISSION IMPLEMENTING REGULATION (EU) 2023/53

of 4 January 2023

concerning the authorisation of a preparation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive for all animal species

(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 an authorisation.
- (2) In accordance with Article 7(1) of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Pediococcus acidilactici* CNCM I-4622. 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 preparation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive for all animal species, to be classified in the additive category 'technological additives' and in the functional groups 'acidity regulators' and 'hygiene condition enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 June 2022 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Pediococcus acidilactici* CNCM I-4622 does not have adverse effects on animal health, consumer safety or the environment. It also concluded that it is considered a respiratory sensitiser, but not irritant to eyes/skin or a skin sensitiser. The Authority further concluded that the preparation showed a potential to reduce the pH and the growth of coliforms in liquid feeds. It also verified the report on the methods 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 I-4622 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. 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.
- (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

1. The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'acidity regulators', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.
2. The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'hygiene condition enhancers', 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⁾ EFSA Journal 2022;20(8):7424.

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, 4 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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 of additive/kg of complete feed with a moisture content of 12 %			
Category: technological additives. Functional group: acidity regulators.								
4d1712	<i>Pediococcus acidilactici</i> CNCM I-4622	<p><i>Additive composition</i></p> <p>Preparation of <i>Pediococcus acidilactici</i> CNCM I-4622 containing a minimum of 1×10^{10} CFU/g</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Pediococcus acidilactici</i> CNCM I-4622</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration: Spread plate method using MRS agar (EN 15786)</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods</p>	All animal species	-	1×10^9	-	<ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions shall be indicated. The additive shall be used only in mash compound feed intended for the preparation of liquid feed on the farm and/or in solid feed materials intended for the preparation of liquid feed on the farm. May be used in feed containing the following permitted coccidiostats: halofuginone, diclazuril, decoquinate and nicarbazin. 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 protection. 	24.1.2033

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identification number of the additive	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 of additive/kg of fresh material			

Category: technological additives. Functional group: hygiene condition enhancers (reduction of the growth of coliforms).

4d1712	<i>Pediococcus acidilactici</i> CNCM I-4622	<p><i>Additive composition</i></p> <p>Preparation of <i>Pediococcus acidilactici</i> CNCM I-4622 containing a minimum of 1×10^{10} CFU/g</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Pediococcus acidilactici</i> CNCM I-4622</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration: Spread plate method using MRS agar (EN 15786)</p> <p>Identification: Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods</p>	All animal species	-	1×10^9	-	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. The additive shall be used only in mash compound feeds intended for the preparation of liquid feed on the farm and/or in solid feed materials intended for the preparation of liquid feed on the farm. 3. May be used in feed containing the following permitted coccidiostats: halofuginone, diclazuril, decoquinate and nicarbazin. 4. 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 protection. 	24.1.2033
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