

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1704**of 7 September 2023****concerning the renewal of the authorisation of a preparation of *Pediococcus pentosaceus* DSM 23376 as a feed additive for all animal species and amending Implementing Regulation (EU) No 1119/2012****(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) The preparation of *Pediococcus pentosaceus* DSM 23376 was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 1119/2012 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Pediococcus pentosaceus* DSM 23376 as a feed additive for all animal species, requesting the additive to be classified in the additive category 'technological additives' and in the functional group 'silage additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 1 February 2023 ⁽³⁾ that the preparation of *Pediococcus pentosaceus* DSM 23376 remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additive is not irritant to skin or eyes but that, owing to its proteinaceous nature, it should be considered a respiratory sensitiser. The Authority could not conclude, in the absence of data, on the skin sensitisation potential of the additive. It also indicated that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of the preparation of *Pediococcus pentosaceus* DSM 23376 as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c) of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, an evaluation report of the Reference Laboratory is therefore not required.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 1119/2012 of 29 November 2012 concerning the authorisation of preparations of *Pediococcus acidilactici* CNCM MA 18/5M DSM 11673, *Pediococcus pentosaceus* DSM 23376, NCIMB 12455 and NCIMB 30168, *Lactobacillus plantarum* DSM 3676 and DSM 3677 and *Lactobacillus buchneri* DSM 13573 as feed additives for all animal species (OJ L 330, 30.11.2012, p. 14).

⁽³⁾ EFSA Journal 2023;21(3):7872.

⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

- (6) In view of the above, the Commission considers that the preparation of *Pediococcus pentosaceus* DSM 23376 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) As a consequence of the renewal of the authorisation of the preparation of *Pediococcus pentosaceus* DSM 23376 as a feed additive, Implementing Regulation (EU) No 1119/2012 should be amended accordingly.
- (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

Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', is renewed subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) No 1119/2012

In the Annex to Implementing Regulation (EU) No 1119/2012, entry 1k2105 on '*Pediococcus pentosaceus* DSM 23376' is deleted.

Article 3

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, 7 September 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/kg of fresh material			
Category: technological additives. Functional group: silage additives								
1k2105	<i>Pediococcus pentosaceus</i> DSM 23376	<i>Additive composition</i> Preparation of <i>Pediococcus pentosaceus</i> DSM 23376 containing a minimum of 1 × 10 ¹¹ CFU/g additive Solid form <i>Characterisation of the active substance</i> Viable cells of <i>Pediococcus pentosaceus</i> DSM 23376 <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive of <i>Pediococcus pentosaceus</i> DSM 23376: — Spread plate method using MRS Agar (EN 15786) Identification of <i>Pediococcus pentosaceus</i> DSM 23376: — Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods	All animal species	-		-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum dose of the additive when used without combination with other micro-organisms as silage additives: 1 × 10⁸ CFU/kg fresh material. 3. 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 by such procedures and measures, the additive and premixtures shall be used with personal skin and breathing protective equipment.	28 September 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.