

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2118**of 16 December 2020****concerning the renewal of the authorisation of *Pediococcus pentosaceus* DSM 16244 as a feed additive for all animal species and repealing Regulation (EU) No 514/2010****(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 pentosaceus* DSM 16244 was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EU) No 514/2010 ⁽²⁾.
- (3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of *Pediococcus pentosaceus* DSM 16244 as a feed additive for all animal species, requesting the additive to be classified in the additive category 'technological 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 25 May 2020 ⁽³⁾ that the applicant has provided evidence that the additive complies with the existing conditions of authorisation. The Authority concluded that *Pediococcus pentosaceus* DSM 16244 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that it is not irritant to skin and eyes but considered a skin and respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards to users of the additive.
- (5) The assessment of *Pediococcus pentosaceus* DSM 16244 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 pentosaceus* DSM 16244 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EU) No 514/2010 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 'technological additives' and to the functional group 'silage additives', is renewed subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EU) No 514/2010 of 15 June 2010 concerning the authorisation of *Pediococcus pentosaceus* (DSM 16244) as a feed additive for all animal species (OJ L 150, 16.6.2010, p. 42).

⁽³⁾ EFSA Journal 2020;18(6):6166.

Article 2

Regulation (EU) No 514/2010 is 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, 16 December 2020.

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 of technological additives. Functional group: silage additives								
1k2101	<i>Pediococcus pentosaceus</i> DSM 16244	<p><i>Additive composition</i></p> <p>Preparation of <i>Pediococcus pentosaceus</i> DSM 16244 containing a minimum of 4×10^{11} CFU/g additive.</p> <p><i>Characterisation of the active substance</i></p> <p><i>Pediococcus pentosaceus</i> DSM 16244.</p> <p><i>Analytical method</i> ⁽¹⁾</p> <ul style="list-style-type: none"> — Enumeration: spread plate method on MSR agar (EN 15786). — Identification: pulsed-field gel electrophoresis (PFGE) method. 	All animal species	-	-	-	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1×10^8 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 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 gloves and breathing protection. 	6.1.2031

⁽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>