



2024/220

15.1.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/220

of 12 January 2024

concerning the renewal of the authorisation of a preparation of *Pediococcus pentosaceus* NCIMB 30168 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* NCIMB 30168 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* NCIMB 30168 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 11 May 2023 ⁽³⁾ that the preparation of *Pediococcus pentosaceus* NCIMB 30168 remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised, including the proposed use of a new cryoprotectant in the formulation of the preparation. It also concluded that the additive should be considered a respiratory sensitiser but no conclusions could be drawn on the skin sensitisation and on the skin and eye irritancy potential of the additive. The Authority 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* NCIMB 30168 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(6):8046.

⁽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* NCIMB 30168 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* NCIMB 30168 as a feed additive, Implementing Regulation (EU) No 1119/2012 should be amended.
- (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 1k2107 on '*Pediococcus pentosaceus* NCIMB 30168' 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, 12 January 2024.

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								
1k2107	<i>Pediococcus pentosaceus</i> NCIMB 30168	Additive composition Preparation of <i>Pediococcus pentosaceus</i> NCIMB 30168 containing a minimum of 5×10^{10} CFU/g additive Solid form Characterisation of the active substance Viable cells of <i>Pediococcus pentosaceus</i> NCIMB 30168 Analytical method ⁽¹⁾ Enumeration in the feed additive of <i>Pediococcus pentosaceus</i> NCIMB 30168: — Spread plate method using MRS Agar (EN 15786) Identification of <i>Pediococcus pentosaceus</i> NCIMB 30168: — Pulsed Field Gel Electrophoresis (PFGE) CEN/TS 17697 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-organism as silage additive: 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 their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	4 February 2034

(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