



2024/2394

10.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2394

of 9 September 2024

**concerning the renewal of the authorisation of a preparation of *Enterococcus lactis* NCIMB 10415 as a feed additive for cats and dogs (holder of authorisation: DSM Nutritional Products Ltd.) and repealing
Implementing Regulation (EU) No 1061/2013**

(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) A preparation of *Enterococcus lactis* NCIMB 10415 (previously taxonomically identified as *Enterococcus faecium* NCIMB 10415) was authorised for 10 years as a feed additive for cats and dogs by Commission Implementing Regulation (EU) No 1061/2013 ⁽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 *Enterococcus lactis* NCIMB 10415 for use in feed for cats and dogs, requesting the additive to be classified in the category 'zootechnical additives' and in the functional groups 'gut flora stabilisers' for cats, and 'other zootechnical additives' for dogs. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 January 2024 ⁽³⁾ that the applicant has provided evidence that the preparation of *Enterococcus lactis* NCIMB 10415 remains safe for cats and dogs under the conditions of use currently authorised. It also concluded that the additive was not shown to be skin and eye irritant, but that it should be considered a respiratory sensitiser, while no conclusions could be drawn on the skin sensitisation. The Authority further indicated that there was no need for assessing the efficacy of the preparation of *Enterococcus lactis* NCIMB 10415 in the context of the renewal of the authorisation as the application for renewal does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. It did not consider that there is a need for specific requirements of post-market monitoring.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same additive as regards the method of analysis are valid and applicable for the current application. In accordance with Article 5(4), point (a), 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, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ Commission Implementing Regulation (EU) No 1061/2013 of 29 October 2013 concerning the authorisation of a preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for calves, kids, cats and dogs and amending Regulation (EC) No 1288/2004 (holder of the authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o) (OJ L 289, 31.10.2013, p. 38, ELI: http://data.europa.eu/eli/reg_impl/2013/1061/oj).

⁽³⁾ EFSA Journal, 2024;22:e8622.

⁽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, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

- (6) In view of the above, the Commission considers that the preparation of *Enterococcus lactis* NCIMB 10415 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. It is appropriate, for control reasons, to allocate a specific identification number to that preparation for cats and dogs to allow differentiating from the other forms of that preparation authorised by Commission Implementing Regulation (EU) 2024/1161 ⁽⁵⁾ for other species. 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. Those protective measures should be without prejudice to other workers' safety requirements under Union law.
- (7) As a consequence of the renewal of the authorisation of the preparation of *Enterococcus lactis* NCIMB 10415 as a feed additive for cats and dogs, Implementing Regulation (EU) No 1061/2013 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Enterococcus lactis* NCIMB 10415 as a feed additive for cats and dogs, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (9) 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 'zootechnical additives' and to the functional group 'gut flora stabilisers' for cats and 'other zootechnical additives' for dogs, is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal

Implementing Regulation (EU) No 1061/2013 is repealed.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 30 March 2025 in accordance with the rules applicable before 30 September 2024 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 30 September 2026 in accordance with the rules applicable before 30 September 2024 may continue to be placed on the market and used until the existing stocks are exhausted.

⁽⁵⁾ Commission Implementing Regulation (EU) 2024/1161 of 22 April 2024 concerning the renewal of the authorisation of a preparation of *Enterococcus lactis* NCIMB 10415 as a feed additive for certain animal species, the authorisation of that preparation as a feed additive for certain other animal species (holder of authorisation: DSM Nutritional Products Ltd.), amending Implementing Regulation (EU) No 1061/2013 and repealing Implementing Regulations (EU) No 361/2011, (EU) 2015/518 and (EU) 2019/11 (OJ L, 2024/1161, 23.4.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/1161/oj).

*Article 4***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, 9 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the feed 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: zootechnical additives. Functional group: gut flora stabilisers									
4b1705ii	DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.	<i>Enterococcus lactis</i> NCIMB 10415	<p><i>Additive composition</i> Preparation of <i>Enterococcus lactis</i> NCIMB 10415 containing a minimum of:</p> <ul style="list-style-type: none"> — micro-encapsulated form with shellac: 5×10^9 CFU/g additive. <p>Solid form.</p> <p><i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus lactis</i> NCIMB 10415</p> <p><i>Analytical method</i> ⁽¹⁾ Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697.</p> <p>Enumeration in the feed additive, premixtures and compound feed: spread plate method using bile esculin azide agar (EN 15788)</p>	Cats	-	7×10^9	-	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. 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 breathing and skin protective equipment. 	30 September 2034

Identification number of the feed 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: zootechnical additives. Functional group: other zootechnical additives (improvement of gut conditions)									
4b1705ii	DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.	<i>Enterococcus lactis</i> NCIMB 10415	<p><i>Additive composition</i> Preparation of <i>Enterococcus lactis</i> NCIMB 10415 containing a minimum of: — micro-encapsulated form with shellac: 5 × 10⁹ CFU/g additive. Solid form.</p> <p><i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus lactis</i> NCIMB 10415</p> <p><i>Analytical method</i> ⁽¹⁾ Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697.</p> <p>Enumeration in the feed additive, premixtures and compound feed: spread plate method using bile esculin azide agar (EN 15788)</p>	Dogs	-	2,5 × 10 ⁹	-	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. 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 breathing and skin protective equipment.</p>	30 September 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.