



2024/1104

18.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1104

of 17 April 2024

concerning the authorisation of a preparation of *Lactiplantibacillus plantarum* DSM 11520 as a feed additive for horses, dogs, cats and rabbits

(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 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Lactiplantibacillus plantarum* DSM 11520. 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 the preparation of *Lactiplantibacillus plantarum* DSM 11520 as a feed additive for horses, dogs, cats and rabbits, requesting that additive to be classified in the category 'technological additives' and in the functional group 'acidity regulators'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 March 2023 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Lactiplantibacillus plantarum* DSM 11520 is safe for the target species, consumers of horse meat and the environment. The Authority also concluded that the additive is not a skin or an eye irritant, but, given the proteinaceous nature of the active agent, it should be considered a respiratory sensitiser. No conclusion could be drawn on the skin sensitisation potential of the additive. The Authority further concluded that incorporation of *Lactiplantibacillus plantarum* DSM 11520 at a minimum concentration of $8,0 \times 10^{10}$ CFU/kg into oat-derived products (ca. 55 % moisture content), carrot root-derived products (≥ 90 % moisture) and coconut flesh-derived products (≥ 90 % moisture) has the potential to reduce the pH of these feedingstuffs. The Authority also verified the report on the method 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 *Lactiplantibacillus plantarum* DSM 11520 should take into account the fact that rabbits are considered as food-producing animals in accordance with Article 1(1) of Commission Regulation (EC) No 429/2008 ⁽³⁾. In the 169th Plenary meeting of the Scientific Panel on Additives and Products or Substances used in Animal Feed ⁽⁴⁾, the Panel stated that as the Authority concluded in the opinion of 23 March 2023 that *Lactiplantibacillus plantarum* DSM 11520 qualified for the Qualified Presumption of Safety ('QPS') approach, the additive is considered safe for the consumers of rabbits fed with the additive.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal 2023;21(4):7974.

⁽³⁾ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/429/2021-03-27>).

⁽⁴⁾ Minutes of the meeting can be accessed at the following address: <https://www.efsa.europa.eu/en/events/169th-plenary-meeting-feedap-panel>.

- (6) In view of the above, the Commission considers that the preparation of *Lactiplantibacillus plantarum* DSM 11520 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. 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) 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

Authorisation

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.

Article 2

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, 17 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed 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 feed material			
Category: technological additives. Functional group: acidity regulators								
1j002	<i>Lactiplantibacillus plantarum</i> DSM 11520	<p><i>Additive composition</i> Preparation of <i>Lactiplantibacillus plantarum</i> DSM 11520 containing a minimum of $1,3 \times 10^{10}$ CFU/g additive Solid form</p> <p><i>Characterisation of the active substance</i> Viable cells of <i>Lactiplantibacillus plantarum</i> DSM 11520</p> <p><i>Analytical method</i> (*) Enumeration in the feed additive of <i>Lactiplantibacillus plantarum</i> DSM 11520:</p> <ul style="list-style-type: none"> — Spread plate (or pour plate) method on MRS Agar (EN 15787) <p>Identification of <i>Lactiplantibacillus plantarum</i> DSM 11520:</p> <ul style="list-style-type: none"> — DNA sequencing methods or Pulsed-Field Gel Electrophoresis (PFGE) – CEN/TS 17697 	Horses Dogs Cats Rabbits	—	$8,0 \times 10^{10}$	—	<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. In the directions for use of the additive and premixtures, the following should be indicated: 'Shall be used exclusively in: <ul style="list-style-type: none"> — oat-derived products (≥ 55 % moisture content) — carrot root-derived products (≥ 90 % moisture content) — coconut flesh-derived products (≥ 90 % moisture content).' 	8 May 2034

Identification number of the feed 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 feed material			
Category: technological additives. Functional group: acidity regulators								
							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.	

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