COMMISSION IMPLEMENTING REGULATION (EU) 2023/256

of 6 February 2023

concerning the authorisation of a preparation of *Limosilactobacillus reuteri* DSM 32203 as a feed additive for dogs and a preparation of *Limosilactobacillus reuteri* DSM 32264 as a feed additive for cats (holder of authorisation: NBF Lanes s.r.l.)

(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, two applications were submitted, one for the authorisation of a preparation of *Limosilactobacillus reuteri* DSM 32203 and one for the authorisation of a preparation of *Limosilactobacillus reuteri* DSM 32264. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The applications concern the authorisation of the preparation of *Limosilactobacillus reuteri* DSM 32203 as a feed additive for dogs and the preparation of *Limosilactobacillus reuteri* DSM 32264 as a feed additive for cats, to be classified in the category 'zootechnical additives' and in the functional group 'gut flora stabilisers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 27 November 2018 ([2]), ([3]) and of 29 June 2022 ([4]), ([5]) that, under the proposed conditions of use, the preparations of *Limosilactobacillus reuteri* DSM 32203 and of *Limosilactobacillus reuteri* DSM 32264 do not have adverse effects on animal health, consumer safety or the environment. It also concluded that those preparations should be considered a potential respiratory sensitiser, and that in the absence of data, it could not conclude on the irritancy potential of the additives to skin and eyes or on its dermal sensitisation potential. The Authority also concluded that the preparations of *Limosilactobacillus reuteri* DSM 32203 and of *Limosilactobacillus reuteri* DSM 32264 have the potential to be efficacious in improving the faecal consistency. However, the Authority expressed some reservations on linear decrease in the moisture content of faeces, which if maintained over time, might cast doubts on the benefits on the long-term use of the additives since it could lead to constipation. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparations of *Limosilactobacillus reuteri* DSM 32203 and of *Limosilactobacillus reuteri* DSM 32264 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations should be authorised. It is appropriate to provide for post-market monitoring and for specific labelling of the additives and premixtures containing them as regards possible long-term adverse effects of the use of the additives. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additives.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2019;17(1):5524.
([3]) *EFSA Journal* 2019;17(1):5526.
([4]) *EFSA Journal* 2022;20(7):7436.
([5]) *EFSA Journal* 2022;20(8):7437.

(6) 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 preparations specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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, 6 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the 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.									
4b1850	NBF Lanes s.r.l.	*Limosilactobacillus reuteri* DSM 32203	*Additive composition* Preparation of *Limosilactobacillus reuteri* DSM 32203 containing a minimum of 1×10^{11} CFU/g Solid form *Characterisation of the active substance:* Viable cells of *Limosilactobacillus reuteri* DSM 32203 *Analytical method* (1) Identification: DNA sequencing methods or pulsed Field Gel Electrophoresis (PFGE) Enumeration in feed additive and compound feed: spread plate method on MRS agar (EN 15787)	Dogs	-	1×10^{10}	-	1. Post-market monitoring is required on the effects of the additive on constipation for a long-term use. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive and premixtures, the following shall be indicated: "The decision to supplement dogs with *Limosilactobacillus reuteri* DSM 32203 for a period longer than five weeks should take into account the characteristics of the supplemented feed and diet, the breed of dog and the availability of water, in order to avoid constipation." 4. 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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eyes, skin and breathing protection.	27 February 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

Identification number of the 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.									
4b1851	NBF Lanes s.r.l.	*Limosilactobacillus reuteri* DSM 32264	*Additive composition* Preparation of *Limosilactobacillus reuteri* DSM 32264 containing a minimum of 1×10^{11} CFU/g Solid form *Characterisation of the active substance:* Viable cells of *Limosilactobacillus reuteri* DSM 32264 *Analytical method* (1) Identification: DNA sequencing methods or pulsed Field Gel Electrophoresis (PFGE) Enumeration in feed additive and compound feed: spread plate method on MRS agar (EN 15787)	Cats	-	1×10^{10}	-	1. Post-market monitoring is required on the effects of the additive on constipation for a long-term use. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive and premixtures, the following shall be indicated: "The decision to supplement cats with *Limosilactobacillus reuteri* DSM 32264 for a period longer than five weeks should take into account the characteristics of the supplemented feed and diet, the breed of cat and the availability of water, in order to avoid constipation." 4. 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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eyes, skin and breathing protection.	27 February 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