

COMMISSION IMPLEMENTING REGULATION (EU) 2023/8

of 3 January 2023

concerning the renewal of the authorisation of preparations of *Lactiplantibacillus plantarum* DSM 21762, of *Lactiplantibacillus plantarum* NCIMB 30236 and of *Lactococcus lactis* NCIMB 30117 as feed additives for all animal species and repealing Implementing Regulations (EU) No 868/2011, (EU) No 1111/2011 and (EU) No 227/2012

(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 preparations of *Lactiplantibacillus plantarum* DSM 21762, previously taxonomically identified as *Lactobacillus plantarum* (DSM 21762), *Lactiplantibacillus plantarum* NCIMB 30236, previously taxonomically identified as *Lactobacillus plantarum* (NCIMB 30236) and *Lactococcus lactis* NCIMB 30117 were authorised for a period of 10 years as feed additives for all animal species by Commission Implementing Regulations (EU) No 868/2011 ⁽²⁾, (EU) No 1111/2011 ⁽³⁾ and (EU) No 227/2012 ⁽⁴⁾, respectively.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, applications were submitted for the renewal of the authorisation of the preparation of *Lactiplantibacillus plantarum* DSM 21762, *Lactiplantibacillus plantarum* NCIMB 30236 and *Lactococcus lactis* NCIMB 30117 as feed additives for all animal species, requesting the additives to be classified in the additive category 'technological additives'. Those applications were 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 opinions of 5 May 2021 ⁽⁵⁾, 26 January 2022 ⁽⁶⁾ and 23 March 2022 ⁽⁷⁾ that the applicants have provided evidence that the additives comply with the existing conditions of authorisation. The Authority concluded that the preparations of *Lactiplantibacillus plantarum* DSM 21762, *Lactiplantibacillus plantarum* NCIMB 30236 and *Lactococcus lactis* NCIMB 30117 do not have an adverse effect on animal health, consumer safety or the environment. It also concluded that *Lactococcus lactis* NCIMB 30117 should be considered a respiratory sensitiser, but no conclusions can be drawn on the skin sensitisation and its potential to be irritant to eyes and skin, whereas *Lactiplantibacillus plantarum* NCIMB 30236 should be considered a skin and respiratory sensitiser, but no conclusions can be drawn on its potential to be irritant to skin and eyes. The Authority also concluded that *Lactiplantibacillus plantarum* DSM 21762 is not irritant to skin and eyes but is considered a skin and respiratory sensitiser. The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods of analysis used for the control of the agents in animal feed are valid and applicable for the current applications.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EU) No 868/2011 of 31 August 2011 concerning the authorisation of a preparation of *Lactobacillus plantarum* (DSM 21762) and of a preparation of *Lactobacillus buchneri* (DSM 22963) as feed additives for all animal species (OJ L 226, 1.9.2011, p. 2).

⁽³⁾ Commission Implementing Regulation (EU) No 1111/2011 of 3 November 2011 concerning the authorisation of *Lactobacillus plantarum* (NCIMB 30236) as a feed additive for all animal species (OJ L 287, 4.11.2011, p. 30).

⁽⁴⁾ Commission Implementing Regulation (EU) No 227/2012 of 15 March 2012 concerning the authorisation of *Lactococcus lactis* (NCIMB 30117) as a feed additive for all animal species (OJ L 77, 16.3.2012, p. 8).

⁽⁵⁾ EFSA Journal 2021;19(5):6613.

⁽⁶⁾ EFSA Journal 2022;20(3):7149.

⁽⁷⁾ EFSA Journal 2022;20(4):7243.

- (5) The assessment of the preparations of *Lactiplantibacillus plantarum* DSM 21762, *Lactiplantibacillus plantarum* NCIMB 30236 and *Lactococcus lactis* NCIMB 30117 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of those additives should be renewed.
- (6) 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 additives. Those protective measures should comply with Union legislation on worker safety requirements.
- (7) As a consequence of the renewal of the authorisation of preparations of *Lactiplantibacillus plantarum* DSM 21762, *Lactiplantibacillus plantarum* NCIMB 30236 and *Lactococcus lactis* NCIMB 30117 as feed additives for all animal species, Implementing Regulations (EU) No 868/2011, (EU) No 1111/2011 and (EU) No 227/2012 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparations of *Lactiplantibacillus plantarum* DSM 21762, *Lactiplantibacillus plantarum* NCIMB 30236 and *Lactococcus lactis* NCIMB 30117, it is appropriate to allow a transitional period for 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

The authorisation of the preparations 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

1. The preparations of *Lactiplantibacillus plantarum* DSM 21762, *Lactiplantibacillus plantarum* NCIMB 30236 and *Lactococcus lactis* NCIMB 30117 as specified in the Annex and premixtures containing them, which are produced and labelled before 24 July 2023 in accordance with the rules applicable before 24 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the preparations of *Lactiplantibacillus plantarum* DSM 21762, *Lactiplantibacillus plantarum* NCIMB 30236 and *Lactococcus lactis* NCIMB 30117 as specified in the Annex which are produced and labelled before 24 January 2024 in accordance with the rules applicable before 24 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the preparations of *Lactiplantibacillus plantarum* DSM 21762, *Lactiplantibacillus plantarum* NCIMB 30236 and *Lactococcus lactis* NCIMB 30117 as specified in the Annex which are produced and labelled before 24 January 2025 in accordance with the rules applicable before 24 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

Implementing Regulations (EU) No 868/2011, (EU) No 1111/2011 and (EU) No 227/2012 are repealed.

Article 4

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, 3 January 2023.

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								
1k2071	<i>Lactiplantibacillus plantarum</i> DSM 21762	<p><i>Additive composition:</i></p> <p>Preparation of <i>Lactiplantibacillus plantarum</i> DSM 21762 containing a minimum of 5×10^{11} CFU/g additive.</p> <p>Solid form</p> <p><i>Characterisation of the active substance:</i></p> <p>Viable cells of <i>Lactiplantibacillus plantarum</i> DSM 21762.</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>— Enumeration: Pour plate method: EN 15787</p> <p>— Identification: Pulsed- Field Gel Electrophoresis (PFGE) or DNA sequencing methods</p>	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 skin and breathing protection. 	24 January 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	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 of additive/kg of fresh material			
Category: technological additives. Functional group: silage additives								
1k2073	<i>Lactiplantibacillus plantarum</i> NCIMB 30236	<p><i>Additive composition:</i></p> <p>Preparation of <i>Lactiplantibacillus plantarum</i> NCIMB 30236 containing a minimum of $1,2 \times 10^{11}$ CFU/g additive</p> <p>Solid form</p> <hr/> <p><i>Characterisation of the active substance:</i></p> <p>Viable cells of <i>Lactiplantibacillus plantarum</i> NCIMB 30236</p> <hr/> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration of <i>Lactiplantibacillus plantarum</i> NCIMB 30236 in the feed additive:</p> <ul style="list-style-type: none"> — spread plate method (EN 15787) <p>Identification of <i>Lactiplantibacillus plantarum</i> NCIMB 30236:</p> <ul style="list-style-type: none"> — Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods 	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: $2,4 \times 10^8$ 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 eyes, skin and breathing protection. 	24 January 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	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 of additive/kg of fresh material			
Category: technological additives. Functional group: silage additives								
1k2083	<i>Lactococcus lactis</i> NCIMB 30117	<p><i>Additive composition:</i></p> <p>Preparation of <i>Lactococcus lactis</i> NCIMB 30117 containing a minimum of 5×10^{10} CFU/g additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance:</i></p> <p>Viable cells of <i>Lactococcus lactis</i> NCIMB 30117</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration in the feed additive: — pour plate method using MSR agar (ISO 15214)</p> <p>Identification: — Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods</p>	All animal species	-	-	-	<ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions shall be indicated. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1×10^8 CFU/kg fresh material. 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 eyes, skin and breathing protection. 	24 January 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