

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1341

of 30 June 2023

concerning the renewal of the authorisation of the preparations of *Lactiplantibacillus plantarum* DSM 12836, *Lactiplantibacillus plantarum* DSM 12837, *Lentilactobacillus buchneri* DSM 16774, *Pediococcus acidilactici* DSM 16243, *Pediococcus pentosaceus* DSM 12834, *Lacticaseibacillus paracasei* DSM 16245, *Levilactobacillus brevis* DSM 12835, *Lacticaseibacillus rhamnosus* NCIMB 30121, *Lactococcus lactis* NCIMB 30160, *Lentilactobacillus buchneri* DSM 12856 and *Lactococcus lactis* DSM 11037 as feed additives for all animal species, and repealing Implementing Regulation (EU) No 1263/2011

(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 an authorisation.
- (2) The preparations of *Lactiplantibacillus plantarum* DSM 12836 (previously taxonomically identified as *Lactobacillus plantarum* DSM 12836), *Lactiplantibacillus plantarum* DSM 12837 (previously taxonomically identified as *Lactobacillus plantarum* DSM 12837), *Lentilactobacillus buchneri* DSM 16774 (previously taxonomically identified as *Lactobacillus buchneri* DSM 16774), *Pediococcus acidilactici* DSM 16243, *Pediococcus pentosaceus* DSM 12834, *Lacticaseibacillus paracasei* DSM 16245 (previously taxonomically identified as *Lactobacillus paracasei* DSM 16245), *Levilactobacillus brevis* DSM 12835 (previously taxonomically identified as *Lactobacillus brevis* DSM 12835), *Lacticaseibacillus rhamnosus* NCIMB 30121 (previously taxonomically identified as *Lactobacillus rhamnosus* NCIMB 30121), *Lactococcus lactis* NCIMB 30160, *Lentilactobacillus buchneri* DSM 12856 (previously taxonomically identified as *Lactobacillus buchneri* DSM 12856) and *Lactococcus lactis* DSM 11037 were authorised for a period of 10 years as feed additives for all animal species by Commission Implementing Regulation (EU) No 1263/2011 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, applications were submitted for the renewal of the authorisation of the preparations of *Lactiplantibacillus plantarum* DSM 12836, *Lactiplantibacillus plantarum* DSM 12837, *Lentilactobacillus buchneri* DSM 16774, *Pediococcus acidilactici* DSM 16243, *Pediococcus pentosaceus* DSM 12834, *Lacticaseibacillus paracasei* DSM 16245, *Levilactobacillus brevis* DSM 12835, *Lacticaseibacillus rhamnosus* NCIMB 30121, *Lactococcus lactis* NCIMB 30160, *Lentilactobacillus buchneri* DSM 12856 and *Lactococcus lactis* DSM 11037 as feed additives for all animal species, requesting the additives to be classified in the additive category 'technological additives' and in the functional group 'silage additives'. Those applications were accompanied by the particulars and documents required under Article 14(2) of that Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Commission Implementing Regulation (EU) No 1263/2011 of 5 December 2011 concerning the authorisation of *Lactobacillus buchneri* (DSM 16774), *Lactobacillus buchneri* (DSM 12856), *Lactobacillus paracasei* (DSM 16245), *Lactobacillus paracasei* (DSM 16773), *Lactobacillus plantarum* (DSM 12836), *Lactobacillus plantarum* (DSM 12837), *Lactobacillus brevis* (DSM 12835), *Lactobacillus rhamnosus* (NCIMB 30121), *Lactococcus lactis* (DSM 11037), *Lactococcus lactis* (NCIMB 30160), *Pediococcus acidilactici* (DSM 16243) and *Pediococcus pentosaceus* (DSM 12834) as feed additives for all animal species (OJ L 322, 6.12.2011, p. 3).

- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 5 May 2021 ⁽³⁾ ⁽⁴⁾, 23 June 2021 ⁽⁵⁾ ⁽⁶⁾ ⁽⁷⁾, 29 September 2021 ⁽⁸⁾ ⁽⁹⁾ ⁽¹⁰⁾, 10 November 2021 ⁽¹¹⁾, 26 January 2022 ⁽¹²⁾ and 23 March 2022 ⁽¹³⁾ that the applicants have provided evidence that the additives remain safe for all animal species, the consumers and the environment under the authorised conditions of use. It also concluded that the preparations are not irritant to skin and eyes, but that they should be considered potential skin and respiratory sensitisers.
- (5) In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ⁽¹⁴⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessments are valid and applicable for the current applications.
- (6) The assessment of the preparations 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.
- (7) The Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (8) As a consequence of the renewal of the authorisation of those preparations as feed additives as well as the expiry of another authorisation concerned by Implementing Regulation (EU) No 1263/2011, that Regulation should be repealed.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparations of *Lactiplantibacillus plantarum* DSM 12836, *Lactiplantibacillus plantarum* DSM 12837, *Lentilactobacillus buchneri* DSM 16774, *Lacticaseibacillus paracasei* DSM 16245, *Levilactobacillus brevis* DSM 12835, *Lacticaseibacillus rhamnosus* NCIMB 30121 and *Lentilactobacillus buchneri* DSM 12856, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (10) 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 authorisation

The authorisation of the preparations specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', are renewed subject to the conditions laid down in that Annex.

⁽³⁾ EFSA Journal 2021;19(6):6626.

⁽⁴⁾ EFSA Journal 2021;19(6):6614.

⁽⁵⁾ EFSA Journal 2021;19(7):6696.

⁽⁶⁾ EFSA Journal 2021;19(7):6697.

⁽⁷⁾ EFSA Journal 2021;19(7):6713.

⁽⁸⁾ EFSA Journal 2021;19(11):6902.

⁽⁹⁾ EFSA Journal 2021;19(11):6900.

⁽¹⁰⁾ EFSA Journal 2021;19(11):6901.

⁽¹¹⁾ EFSA Journal 2022;20(1):6975.

⁽¹²⁾ EFSA Journal 2022;20(2):7148.

⁽¹³⁾ EFSA Journal 2022;20(4):7241.

⁽¹⁴⁾ 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).

*Article 2***Repeal**

Implementing Regulation (EU) No 1263/2011 is repealed.

*Article 3***Transitional measures**

The preparations of *Lactiplantibacillus plantarum* DSM 12836, *Lactiplantibacillus plantarum* DSM 12837, *Lentilactobacillus buchneri* DSM 16774, *Lacticaseibacillus paracasei* DSM 16245, *Levilactobacillus brevis* DSM 12835, *Lacticaseibacillus rhamnosus* NCIMB 30121 and *Lentilactobacillus buchneri* DSM 12856 specified in the Annex and feed containing them, which are produced and labelled before 23 July 2024 in accordance with the rules applicable before 23 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

*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, 30 June 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: technological additives. Functional group: silage additives

1k2078	<i>Lactiplantibacillus plantarum</i> DSM 12836	Additive composition: Preparation of <i>Lactiplantibacillus plantarum</i> DSM 12836 containing a minimum of 5×10^{11} CFU/g additive Characterisation of the active substance: Viable cells of <i>Lactiplantibacillus plantarum</i> DSM 12836 Analytical method ⁽¹⁾ Enumeration in the feed additive of <i>Lactiplantibacillus plantarum</i> DSM 12836: — Spread plate method using MRS agar (EN 15787) Identification of <i>Lactiplantibacillus plantarum</i> DSM 12836: — Pulsed-Field Gel Electrophoresis (PFGE) 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 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 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.	23.7.2033
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⁽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/kg of fresh material			
Category: technological additives. Functional group: silage additives								
1k2079	<i>Lactiplantibacillus plantarum</i> DSM 12837	<i>Additive composition:</i> Preparation of <i>Lactiplantibacillus plantarum</i> DSM 12837 containing a minimum of 5 × 10¹¹ CFU/g additive <i>Characterisation of the active substance:</i> Viable cells of <i>Lactiplantibacillus plantarum</i> DSM 12837 <i>Analytical method ⁽¹⁾</i> Enumeration in the feed additive of <i>Lactiplantibacillus plantarum</i> DSM 12837: — Spread plate method using MRS agar (EN 15787) Identification of <i>Lactiplantibacillus plantarum</i> DSM 12837: — Pulsed-Field Gel Electrophoresis (PFGE) 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 content of the additive when used without combination with other micro-organisms as silage additives: 1×10⁸ 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 and breathing protective equipment.	23.7.2033

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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								
1k2074	<i>Lentilactobacillus buchneri</i> DSM 16774	<i>Additive composition:</i> Preparation of <i>Lentilactobacillus buchneri</i> DSM 16774 containing a minimum of 5 × 10¹¹ CFU/g additive <i>Characterisation of the active substance:</i> Viable cells of <i>Lentilactobacillus buchneri</i> DSM 16774 <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive of <i>Lentilactobacillus buchneri</i> DSM 16774: — Spread plate method using MRS agar (EN 15787) Identification of <i>Lentilactobacillus buchneri</i> DSM 16774: — Pulsed-Field Gel Electrophoresis (PFGE) 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 content of the additive when used without combination with other micro-organisms as silage additives: 1×10⁸ 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 and breathing protective equipment.	23.7.2033

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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

1k2102	<i>Pediococcus acidilactici</i> DSM 16243	<i>Additive composition:</i> Preparation of <i>Pediococcus acidilactici</i> DSM 16243 containing a minimum of 5×10^{11} CFU/g additive <i>Characterisation of the active substance:</i> Viable cells of <i>Pediococcus acidilactici</i> DSM 16243 <i>Analytical method ⁽¹⁾</i> Enumeration in the feed additive of <i>Pediococcus acidilactici</i> DSM 16243: — Spread plate method using MRS agar (EN 15786) Identification of <i>Pediococcus acidilactici</i> DSM 16243: — Pulsed-Field Gel Electrophoresis (PFGE) 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 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 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.	23.7.2033
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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

1k2103	<i>Pediococcus pentosaceus</i> DSM 12834	<i>Additive composition:</i> Preparation of <i>Pediococcus pentosaceus</i> DSM 12834 containing a minimum of 4×10^{11} CFU/g additive <i>Characterisation of the active substance:</i> Viable cells of <i>Pediococcus pentosaceus</i> DSM 12834 <i>Analytical method ⁽¹⁾</i> Enumeration in the feed additive of <i>Pediococcus pentosaceus</i> DSM 12834: — Spread plate method using MRS agar (EN 15786) — Identification of <i>Pediococcus pentosaceus</i> DSM 12834: Pulsed-Field Gel Electrophoresis (PFGE) 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 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 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.	23.7.2033
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					CFU/kg of fresh material			
Category: technological additives. Functional group: silage additives								
1k2076	<i>Lactacaseibacillus paracasei</i> DSM 16245	<i>Additive composition:</i> Preparation of <i>Lactacaseibacillus paracasei</i> DSM 16245 containing a minimum of 5 × 10¹¹ CFU/g additive <i>Characterisation of the active substance:</i> Viable cells of <i>Lactacaseibacillus paracasei</i> DSM 16245 <i>Analytical method ⁽¹⁾</i> Enumeration in the feed additive of <i>Lactacaseibacillus paracasei</i> DSM 16245: — Spread plate method using MRS agar (EN 15787) Identification of <i>Lactacaseibacillus paracasei</i> DSM 16245: — Pulsed-Field Gel Electrophoresis (PFGE) 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 content of the additive when used without combination with other micro-organisms as silage additives: 1×10⁸ 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 and breathing protective equipment.	23.7.2033

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					CFU/kg of fresh material			

Category: technological additives. Functional group: silage additives

1k20710	<i>Levilactobacillus brevis</i> DSM 12835	<i>Additive composition:</i> Preparation of <i>Levilactobacillus brevis</i> DSM 12835 containing a minimum of 5×10^{11} CFU/g additive <i>Characterisation of the active substance:</i> Viable cells of <i>Levilactobacillus brevis</i> DSM 12835 <i>Analytical method ⁽¹⁾</i> Enumeration in the feed additive of <i>Levilactobacillus brevis</i> DSM 12835: — Spread plate method using MRS agar (EN 15787) Identification of <i>Levilactobacillus brevis</i> DSM 12835: — Pulsed-Field Gel Electrophoresis (PFGE) 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 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 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.	23.7.2033
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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								
1k20711	<i>Lacticaseibacillus rhamnosus</i> NCIMB 30121	<i>Additive composition:</i> Preparation of <i>Lacticaseibacillus rhamnosus</i> NCIMB 30121 containing a minimum of 4 × 10¹¹ CFU/g additive <i>Characterisation of the active substance:</i> Viable cells of <i>Lacticaseibacillus rhamnosus</i> NCIMB 30121. <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive of <i>Lacticaseibacillus rhamnosus</i> NCIMB 30121: — Spread plate method using MRS agar (EN 15787) Identification of <i>Lacticaseibacillus rhamnosus</i> NCIMB 30121: — Pulsed-Field Gel Electrophoresis (PFGE) 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 content of the additive when used without combination with other micro-organisms as silage additives: 1×10⁸ 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 and breathing protective equipment.	23.7.2033

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					CFU/kg of fresh material			

Category: technological additives. Functional group: silage additives

1k2082	<i>Lactococcus lactis</i> NCIMB 30160	<i>Additive composition:</i> Preparation of <i>Lactococcus lactis</i> NCIMB 30160 containing a minimum of 4×10^{11} CFU/g additive <i>Characterisation of the active substance:</i> Viable cells of <i>Lactococcus lactis</i> NCIMB 30160 <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive of <i>Lactococcus lactis</i> NCIMB 30160: — Pour plate method using MRS agar (ISO 15214) Identification of <i>Lactococcus lactis</i> NCIMB 30160: — Pulsed-Field Gel Electrophoresis (PFGE) 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 content of the additive when used without combination with other micro-organisms as silage additives: 1×10^8 CFU/kg fresh material. 3. If polyethylene glycol (PEG 4000) is used as a cryoprotectant, it shall be used up to a maximum concentration of 0,025 mg/kg silage. 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 by such procedures and measures, the additive and premixtures shall be used with personal skin and breathing protective equipment.	23.7.2033
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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								
1k2075	<i>Lentilactobacillus buchneri</i> DSM 12856	<i>Additive composition:</i> Preparation of <i>Lentilactobacillus buchneri</i> DSM 12856 containing a minimum of 5 × 10¹¹ CFU/g additive <i>Characterisation of the active substance:</i> Viable cells of <i>Lentilactobacillus buchneri</i> DSM 12856 <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive of <i>Lentilactobacillus buchneri</i> DSM 12856: — Spread plate method using MRS agar (EN 15787) Identification of <i>Lentilactobacillus buchneri</i> DSM 12856: — Pulsed-Field Gel Electrophoresis (PFGE) 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 content of the additive when used without combination with other micro-organisms as silage additives: 1×10⁸ 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 and breathing protective equipment.	23.7.2033

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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

1k2081	<i>Lactococcus lactis</i> DSM 11037	<i>Additive composition:</i> Preparation of <i>Lactococcus lactis</i> DSM 11037 containing a minimum of 5×10^{10} CFU/g additive <i>Characterisation of the active substance:</i> Viable cells of <i>Lactococcus lactis</i> DSM 11037 <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive of <i>Lactococcus lactis</i> DSM 11037: — Pour plate method using MRS agar (ISO 15214) Identification of <i>Lactococcus lactis</i> DSM 11037: — Pulsed-Field Gel Electrophoresis (PFGE) 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 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 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.	23.7.2033
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