Commission Implementing Regulation (EU) No 1119/2012 of 29 November 2012 concerning the authorisation of preparations of Pediococcus acidilactici CNCM MA 18/5M DSM 11673, Pediococcus pentosaceus DSM 23376, NCIMB 12455 and NCIMB 30168, Lactobacillus plantarum DSM 3676 and DSM 3677 and Lactobacillus buchneri DSM 13573 as feed additives for all animal species (Text with EEA relevance)

# COMMISSION IMPLEMENTING REGULATION (EU) No 1119/2012

#### of 29 November 2012

concerning the authorisation of preparations of *Pediococcus acidilactici* CNCM MA 18/5M DSM 11673, *Pediococcus pentosaceus* DSM 23376, NCIMB 12455 and NCIMB 30168, *Lactobacillus plantarum* DSM 3676 and DSM 3677 and *Lactobacillus buchneri* DSM 13573 as feed additives for all animal species

(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<sup>(1)</sup>, 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 authorisation. Article 10(7) of Regulation (EC) No 1831/2003 in conjunction with Article 10(1) to (4) thereof sets out specific provisions for the evaluation of products used in the Union as silage additives at the date that Regulation became applicable.
- (2) In accordance with Article 10(1) of Regulation (EC) No 1831/2003, preparations of Pediococcus acidilactici CNCM MA 18/5M DSM 11673, Pediococcus pentosaceus DSM 23376, Pediococcus pentosaceus NCIMB 12455, Pediococcus pentosaceus NCIMB 30168, Lactobacillus plantarum DSM 3676, Lactobacillus plantarum DSM 3677 and Lactobacillus buchneri DSM 13573 were entered in the Community Register of Feed Additives as existing products belonging to the functional group of silage additives, for all animal species.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the authorisation of those preparations as feed additives for all animal species, requesting those additives to be classified in the category 'technological additives' and in the functional group 'silage additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

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- The European Food Safety Authority ('the Authority') concluded in its opinions of (4)23 May 2012<sup>(2)</sup> and 14 June 2012<sup>(3)</sup> that, under the proposed conditions of use, the preparations concerned do not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the preparations of *Pediococcus* acidilactici CNCM MA 18/5M DSM 11673, Pediococcus pentosaceus DSM 23376, Pediococcus pentosaceus NCIMB 12455, Pediococcus pentosaceus NCIMB 30168 concerned have the potential to improve the production of silage from all forages by reducing the pH and increasing the preservation of dry matter and/or protein. It also concluded that the preparations of Lactobacillus plantarum DSM 3676 and Lactobacillus plantarum DSM 3677 concerned have the potential to improve the production of silage from easy and moderately difficult to ensile material by increasing the lactic acid content and the preservation of dry matter, by reducing the pH and moderately the loss of protein. It also concluded that the preparation of *Lactobacillus* buchneri DSM 13573 concerned has the potential to increase acetic acid concentration for a wide range of forages. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparations concerned 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 as specified in the Annex to this Regulation.
- (6) Since safety considerations do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

# Article 1

# Authorisation

The preparations specified in the Annex belonging to the additive category 'technological additives' and to the functional group 'silage additives', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

# Article 2

# **Transitional measures**

The preparations specified in the Annex and feed containing them, which are produced and labelled before 20 June 2013 in accordance with the rules applicable before 20

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December 2012 may continue to be placed on the market and used until the existing stocks are exhausted.

#### Article 3

# **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, 29 November 2012.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1119/2012. (See end of Document for details)

#### **ANNEX**

Identifi	ca <b>tiom</b> e	Additiv	e Compo	si <b>lipa</b> çies	Maxim	umMinim	ııMaxim	u <b>10</b> ther	End
number	of the		chemic		age			provisio	nsf
of the	holder		formula	a, categor		CFU/kg	of	_	period
additive	e of		descrip	ti <b>of</b> i,		fresh m			of
	authori	sation		ca <b>a</b> nimal					authorisation
			method						
Categor	y of techr	nological	additives.	Functiona	al group:	silage ado	ditives		
1k2104		Pedioco	ccus	<b>Add</b> ditive					<del>2</del> 0
		acidilact	ici	animpadsit	ion			1.	December
		CNCM		<b>Prepies</b> ati					<b>999</b> 2
		MA		of					directions
		18/5M		Pediococ	ccus				for
		DSM		acidilact					use
		11673		CNCM					of
				MA					the
				18/5M					additive
				DSM					and
				11673					premixture,
				containir	ıσ				indicate
				a	-8				the
				minimun	า				storage
				of	.1				temperature
				$\begin{vmatrix} 3 \\ 3 \\ \end{vmatrix}$					and
				$10^9$					storage
				CFU/					life.
									3.41. 1
				g additive				2.	Minimum
				l I					dose
				Characte	erisation				of
				of					the
				the					additive
				active					when
				substanc					used
				Pediococ					without
				acidilact	lCl				combination
				CNCM					with
				MA					other
				18/5M					micro-
				DSM 11672					organisms
				11673	1				as
				Analytic	ıı				silage
				methoda	,.				additives:
				Enumera	tion				3 ×
				in					$10^{7}$
				the					CFU/
				feed					Kg
				additive:					

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL\_feed\_additives/Pages/index.aspx

**b** Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material. Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

		spread plate method (EN 15786) Identific pulsed field gel electropl (PFGE)	horesis		3.	fresh material.  For safety: it is recommended to use breathing protection and gloves during handling.
1k2105	Pediococ pentosac DSM 23376	Additive animpds: Prepinsat of Pediococ pentosac DSM 23376 containing a minimum of 1 × 10 <sup>11</sup> CFU/ g additive Character of the active substance Pediococ pentosac DSM 23376 Analytic method <sup>a</sup> Enumeratin the feed	tion ion ccus eeus ng m erisation eecus eeus		<ol> <li>2.</li> </ol>	December 2022 directions for use of the additive and premixture, indicate the storage temperature and storage life.  Minimum dose of the additive when used without combination with other microorganisms as

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL\_feed\_additives/Pages/index.aspx

**b** Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material. Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

		additive: spread plate method (EN 15786) Identification: pulsed field gel electrophoresis (PFGE)	3.	silage additives:  1 ×  10 <sup>8</sup> CFU/ Kg fresh material.  For safety: it is recommended to use breathing protection and gloves during handling.
1k2106 —	Pediococcus pentosaceus NCIMB 12455	Additive — animalsition Speciesation of Pediococcus pentosaceus NCIMB 12455 containing a minimum of 3 × 109 CFU/ g additive Characterisation of the active substance Pediococcus pentosaceus NCIMB 12455	2.	20 December 2022 directions for use of the additive and premixture, indicate the storage temperature and storage life.  Minimum dose of the additive when used without

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL\_feed\_additives/Pages/index.aspx

**b** Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material. Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

breathing protection and gloves during handling.  1k2107 — Pediococcus pentosaceus NCIMB 30168  Pediococcus pentosaceus NCIMB  NCIMB Sprepiasation of Pediococcus pentosaceus NCIMB  NCIMB NCIMB Pediococcus pentosaceus NCIMB				Analytic method <sup>a</sup> Enumera in the feed additive spread plate method (EN 15786) Identific pulsed field gel electropi (PFGE)	ation:			3.	combination with other microorganisms as silage additives: $3 \times 10^7$ CFU/ Kg fresh material. For safety: it is recommended to use
1k2107 — Pediococcus pentosaceus NCIMB 30168  Pediococcus pentosaceus pentosaceus pentosaceus pentosaceus pentosaceus pentosaceus nCIMB									protection
pentosaceus NCIMB 30168  repieration of Pediococcus pentosaceus NCIMB  1. Becember 2022 directions for use of									gloves during
30168 containing a minimum of 5 × 10 <sup>10</sup> CFU/ g additive characterisation of  2. Minimum	1k2107	pentosac NCIMB		animpdsi Prepiasat of Pediocol pentosaa NCIMB 30168 containin a minimum of 5 × 10 <sup>10</sup> CFU/ g additive Characte	tion ion ccus eeus ng				December 2022 directions for use of the additive and premixture, indicate the storage temperature and storage life.
a Details of the analytical methods are available at the following address of the Reference Laboratory: http://			.,	the		64 7 6	Y .		

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL\_feed\_additives/Pages/index.aspx

**b** Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material. Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

		active substance Pediococcus pentosaceus NCIMB 30168 Analytical methoda Enumeration in the feed additive: spread plate method (EN 15786) Identification: pulsed field gel electrophoresis (PFGE)	3.	of the additive when used without combination with other micro- organisms as silage additives: 1 × 10 <sup>8</sup> CFU/ Kg fresh material.  For safety: it is recommended to use breathing protection and gloves during handling.
1k20731 —	Lactobacillus plantarum DSM 3676	Additive — animposition Speciesation of Lactobacillus plantarum DSM 3676 containing a minimum of 6 × 10 <sup>11</sup>		20 December 20 Dec

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL\_feed\_additives/Pages/index.aspx

**b** Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material. Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

ANNEX

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		CFU/				and
		g				storage
		additive				life.
		Characte	erisation		_	3.4° '
		of			2.	Minimum
		the				dose
		active				of
		substanc	e			the
		Lactoba				additive
		plantaru				when
		DSM				used
		3676				without
		Analytic	al			combination
		methoda				with
		Enumera	tion			other
		in	111011			micro-
		the				organisms
						as
		feed				silage
		additive:				additives:
		spread				1 ×
		plate				$10^{8}$
		method				CFU/
		(EN				Kg
		15787)				fresh
		Identific	ation:			material.
		pulsed				materiai.
		field			3.	The
		gel				additive
		electropl	noresis			shall
		(PFGE)				be
						used
						in
						easy
						and
						moderately
						difficult
						to
						ensile
						material <sup>b</sup> .
					4.	For
					r.	safety:
						it
						is
						recommended
						to
						use
						breathing

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL\_feed\_additives/Pages/index.aspx

**b** Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material. Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

Lactobacillus plantarum   DSM   3677   Containing a minimum of 4 × 10 <sup>11</sup>   CFU/ g additive substance   Lactobacillus plantarum   DSM   3677   Containing a minimum of 4 × 10 <sup>11</sup>   CFU/ g additive   Characterisation of the active substance   Lactobacillus plantarum   DSM   3677   Analytical method*   Enumeration in the additive spleat method (EN   15787)   Identification: pulsed field gel   3.   The additive material.					protection and gloves during handling.
	1k20732 —	plantarum DSM	animpdsition species tion of Lactobacillus plantarum DSM 3677 containing a minimum of 4 × 10 <sup>11</sup> CFU/ g additive Characterisation of the active substance Lactobacillus plantarum DSM 3677 Analytical method Enumeration in the feed additive: spread plate method (EN 15787) Identification: pulsed field	2.	directions for use of the additive and premixture, indicate the storage temperature and storage life.  Minimum dose of the additive when used without combination with other microorganisms as silage additives: 1 × 108 CFU/Kg fresh material.

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL\_feed\_additives/Pages/index.aspx

**b** Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material. Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

		electrophoresis (PFGE)	4.	shall be used in easy and moderately difficult to ensile material <sup>b</sup> .  For safety: it is recommended to use breathing protection and gloves during handling.
1k20733 —	Lactobacillus buchneri DSM 13573	Additive — animalsition Speciesation of Lactobacillus buchneri DSM 13573 containing a minimum of 2 × 10 <sup>11</sup> CFU/ g additive Characterisation of the active substance	2.	20 December 2022 directions for use of the additive and premixture, indicate the storage temperature and storage life. Minimum dose of the additive

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL\_feed\_additives/Pages/index.aspx

**b** Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material. Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

	Lactobacillus buchneri DSM 13573 Analytical methoda Enumeration in the feed additive: spread plate method (EN 15787) Identification: pulsed field gel electrophoresis (PFGE)	3.	when used without combination with other micro-organisms as silage additives: 1 × 10 <sup>8</sup> CFU/ Kg fresh material. For safety: it is recommended to use breathing protection and gloves during handling.
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a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL\_feed\_additives/Pages/index.aspx

**b** Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material. Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

- (1) OJ L 268, 18.10.2003, p. 29.
- (2) EFSA Journal 2012; 10(6):2733.
- (**3**) EFSA Journal 2012; 10(7):2780.

# **Changes to legislation:**

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1119/2012.