Commission Implementing Regulation (EU) No 1065/2012 of 13 November 2012 concerning the authorisation of preparations of Lactobacillus plantarum (DSM 23375, CNCM I-3235, DSM 19457, DSM 16565, DSM 16568, LMG 21295, CNCM MA 18/5U, NCIMB 30094, VTT E-78076, ATCC PTSA-6139, DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944) as feed additives for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1065/2012

of 13 November 2012

concerning the authorisation of preparations of *Lactobacillus plantarum* (DSM 23375, CNCM I-3235, DSM 19457, DSM 16565, DSM 16568, LMG 21295, CNCM MA 18/5U, NCIMB 30094, VTT E-78076, ATCC PTSA-6139, DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944) 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[(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 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, the preparations of *Lactobacillus plantarum* DSM 23375, CNCM I-3235, DSM 19457, DSM 16565, DSM 16568, LMG 21295, CNCM MA 18/5U, NCIMB 30094, VTT E-78076, ATCC PTSA-6139, DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944 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 the preparations of *Lactobacillus plantarum* DSM 23375, CNCM I-3235, DSM 19457, DSM 16565, DSM 16568, LMG 21295, CNCM MA 18/5U, NCIMB 30094, VTT E-78076, ATCC PTSA-6139, DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944 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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1065/2012. (See end of Document for details)*

applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 May 2012[(2)] that, under the proposed conditions of use, the preparations of *Lactobacillus plantarum* DSM 23375, CNCM I-3235, DSM 19457, DSM 16565, DSM 16568, LMG 21295, CNCM MA 18/5U, NCIMB 30094, VTT E-78076, ATCC PTSA-6139, DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944 do not have an adverse effect on animal health, human health or the environment. The preparations of *Lactobacillus plantarum* DSM 23375, CNCM I-3235, DSM 19457, DSM 16565, DSM 16568, LMG 21295, CNCM MA 18/5U and NCIMB 30094 have the potential to improve the production of silage from all forages by increasing the preservation of dry matter and reducing the pH. The preparation of *Lactobacillus plantarum* VTT E-78076 has the potential to improve the production of silage from easy and moderately difficult to ensile material by reducing the pH and ammonia nitrogen. The preparations of *Lactobacillus plantarum* ATCC PTSA-6139, DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944 have the potential to improve the production of silage from easy ensile material by reducing the pH and dry matter loss. 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 of *Lactobacillus plantarum* DSM 23375, CNCM I-3235, DSM 19457, DSM 16565, DSM 16568, LMG 21295, CNCM MA 18/5U, NCIMB 30094, VTT E-78076, ATCC PTSA-6139, DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944 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 reasons 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1065/2012. (See end of Document for details)*

Article 2

Transitional measures

The preparations specified in the Annex and feed containing them, which are produced and labelled before 4 June 2013 in accordance with the rules applicable before 4 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, 13 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 1065/2012. (See end of Document for details)*

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 fresh material			
Category of technological additives. Functional group: silage additives									
1k20716	—	*Lactobacillus plantarum* (DSM 23375)	*Additive composition* Preparation of *Lactobacillus plantarum* (DSM 23375) containing a minimum of 2×10^{10} CFU/g additive *Characterisation of the active substance* *Lactobacillus plantarum* (DSM 23375) *Analytical method*[a] Enumeration in the feed additive: spread plate method	All animal species.	—		—	1. In the directions for use of the additive and premixture, indicate the storage temperature and storage life. 2. Minimum dose of the additive when used without combination with other micro-organisms as silage additives: 1×10^8 CFU/kg fresh material.	4 December 2022

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 (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp). Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material (e.g. meadow grass, fescue or wilted alfalfa). Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

c Easy to ensile forage: > 3 % soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp). Regulation (EC) No 429/2008.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1065/2012. (See end of Document for details)*

				using MRS agar (EN 15787) Identification in the feed additive: pulsed-field gel electrophoresis (PFGE).				3. For safety: it is recommended to use breathing protection and gloves during handling.	
1k20717	—	*Lactobacillus plantarum* (CNCM I-3235)		*Additive composition* Preparation of *Lactobacillus plantarum* (CNCM I-3235) containing a minimum of 5×10^{10} CFU/g additive *Characterisation of the active substance* *Lactobacillus plantarum* (CNCM I-3235) *Analytical method*[a] Enumeration in	All animal species	—	—	1. In the directions for use of the additive and premixture, indicate the storage temperature and storage life. 2. Minimum dose of the additive when used without combination with other micro-organisms as silage	4 December 2022

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 (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp). Moderately difficult to ensile forages: 1,5-3,0 % soluble carbohydrate in fresh material (e.g. meadow grass, fescue or wilted alfalfa). Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

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