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

(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, applications were submitted for 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). 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 *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, to be classified in the additive category 'technological additives'.

([1]) OJ L 268, 18.10.2003, p. 29.

(4) The European Food Safety Authority (the Authority) concluded in its opinions of 6 September 2011 on *Lactobacillus buchneri* (DSM 16774) ([2]), *Lactobacillus buchneri* (DSM 12856) ([3]) and on *Lactobacillus brevis* (DSM 12835) ([4]), that these micro-organisms do not have an adverse effect on animal health, human health or the environment, and that they have the potential to improve the production of silage from all forages by increasing acetic production resulting in an extended aerobic stability of the silage. 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 Authority concluded in its opinions of 6 September 2011 on *Lactobacillus paracasei* (DSM 16245) ([5]), on *Lactobacillus paracasei* (DSM 16773) ([6]), *Lactobacillus plantarum* (DSM 12836) ([7]) *Lactobacillus plantarum* (DSM 12837) ([8]), *Lactobacillus rhamnosus* (NCIMB 30121) ([9]) *Lactococcus lactis* (NCIMB 30160) ([10]) *Pediococcus acidilactici* (DSM 16243) ([11]) and on *Pediococcus pentosaceus* (DSM 12834) ([12]), and in its opinion of 8 September 2011 on *Lactococcus lactis* (DSM 11037) ([13]) that these micro-organisms do not have an adverse effect on animal health, human health or the environment, and that they have the potential to improve the production of silage from all forages by reducing the pH and increasing the preservation of the dry matter. 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.

(6) The assessment of *Lactobacillus buchneri* (DSM 16774), *Lactobacillus buchneri* (DSM 12856), *Lactobacillus paracasei* (DSM 16245), *Lactobacillus paracasei* (DSM 16773),

([2]) EFSA Journal 2011; 9(9):2359.
([3]) EFSA Journal 2011; 9(9):2361.
([4]) EFSA Journal 2011; 9(9):2368.
([5]) EFSA Journal 2011; 9(9):2363.
([6]) EFSA Journal 2011; 9(9):2370.
([7]) EFSA Journal 2011; 9(9):2367.
([8]) EFSA Journal 2011; 9(9):2362.
([9]) EFSA Journal 2011; 9(9):2365.
([10]) EFSA Journal 2011; 9(9):2366.
([11]) EFSA Journal 2011; 9(9):2364.
([12]) EFSA Journal 2011; 9(9):2369.
([13]) EFSA Journal 2011; 9(9):2374.

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) 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 micro-organisms should be authorised as specified in the Annex to this Regulation.

(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

The micro-organisms 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

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation is binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 December 2011.

For the Commission
The President
José Manuel BARROSO

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.									
1k2074	—	*Lactobacillus buchneri* (DSM 16774)	Additive composition: Preparation of *Lactobacillus buchneri* (DSM 16774) containing a minimum of 5×10^{11} CFU/g additive Characterisation of the active substance: *Lactobacillus buchneri* (DSM 16774) Analytical method (1) Enumeration: spread plate method using MSR agar (EN 15787) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021
1k2075	—	*Lactobacillus buchneri* (DSM 12856)	Additive composition: Preparation of *Lactobacillus buchneri* (DSM 12856) containing a minimum of 5×10^{11} CFU/g additive Characterisation of the active substance: *Lactobacillus buchneri* (DSM 12856) Analytical method (1) Enumeration: spread plate method using MSR agar (EN 15787) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021
1k2076	—	*Lactobacillus paracasei* (DSM 16245)	Additive composition: Preparation of *Lactobacillus paracasei* (DSM 16245) containing a minimum of 5×10^{11} CFU/g additive Characterisation of the active substance: *Lactobacillus paracasei* (DSM 16245) Analytical method (1) Enumeration: spread plate method using MSR agar (EN 15787) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021

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			
1k2077	—	*Lactobacillus paracasei* (DSM 16773)	Additive composition: Preparation of *Lactobacillus paracasei* (DSM 16773) containing a minimum of 4×10^{11} CFU/g additive Characterisation of the active substance: *Lactobacillus paracasei* (DSM 16773) Analytical method (1) Enumeration: spread plate method using MSR agar (EN 15787) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021
1k2078	—	*Lactobacillus plantarum* (DSM 12836)	Additive composition: Preparation of *Lactobacillus plantarum* (DSM 12836) containing a minimum of 5×10^{11} CFU/g additive Characterisation of the active substance: *Lactobacillus plantarum* (DSM 12836) Analytical method (1) Enumeration: spread plate method using MSR agar (EN 15787) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021
1k2079	—	*Lactobacillus plantarum* (DSM 12837)	Additive composition: Preparation of *Lactobacillus plantarum* (DSM 12837) containing a minimum of 5×10^{11} CFU/g additive Characterisation of the active substance: *Lactobacillus plantarum* (DSM 12837) Analytical method (1) Enumeration: spread plate method using MSR agar (EN 15787) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021

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			
1k20710	—	*Lactobacillus brevis* (DSM 12835)	Additive composition: Preparation of *Lactobacillus brevis* (DSM 12835) containing a minimum of 5×10^{11} CFU/g additive Characterisation of the active substance: *Lactobacillus brevis* (DSM 12835) Analytical method (1) Enumeration: spread plate method using MSR agar (EN 15787) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021
1k20711	—	*Lactobacillus rhamnosus* (NCIMB 30121)	Additive composition: Preparation of *Lactobacillus rhamnosus* (NCIMB 30121) containing a minimum of 4×10^{11} CFU/g additive Characterisation of the active substance: *Lactobacillus rhamnosus* (NCIMB 30121) Analytical method (1) Enumeration: spread plate method using MSR agar (EN 15787) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021
1k2081	—	*Lactococcus lactis* (DSM 11037)	Additive composition: Preparation of *Lactococcus lactis* (DSM 11037) containing a minimum of 5×10^{10} CFU/g additive Characterisation of the active substance: *Lactococcus lactis* (DSM 11037) Analytical method (1) Enumeration: pour plate method using MSR agar (ISO 15214) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021

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			
1k2082	—	*Lactococcus lactis* (NCIMB 30160)	Additive composition: Preparation of *Lactococcus lactis* (NCIMB 30160) containing a minimum of 4×10^{11} CFU/g additive Characterisation of the active substance: *Lactococcus lactis* (NCIMB 30160) Analytical method (1) Enumeration: pour plate method using MSR agar (ISO 15214) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021
1k2102	—	*Pediococcus acidilactici* (DSM 16243)	Additive composition: Preparation of *Pediococcus acidilactici* (DSM 16243) containing a minimum of 5×10^{11} CFU/g additive Characterisation of the active substance: *Pediococcus acidilactici* (DSM 16243) Analytical method (1) Enumeration: spread plate method using MSR agar (EN 15786) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021
1k2103	—	*Pediococcus pentosaceus* (DSM 12834)	Additive composition: Preparation of *Pediococcus pentosaceus* (DSM 12834) containing a minimum of 4×10^{11} CFU/g additive Characterisation of the active substance: *Pediococcus pentosaceus* (DSM 12834) Analytical method (1) Enumeration: spread plate method using MSR agar (EN 15786) Identification: Pulsed-Field Gel Electrophoresis (PFGE).	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. 3. For safety: it is recommended to use breathing protection and gloves during handling.	26.12.2021

(1) 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