



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/3882887/2024 CIS
(POOL/G5/2024/3882887/3882887-EN
CIS.docx)
[...](2026) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the renewal of the authorisation of a preparation of *Lactiplantibacillus plantarum* ATCC PTA-6139 and a preparation of *Lacticaseibacillus paracasei* ATCC PTA-6135 as feed additives for all animal species, repealing Implementing Regulations (EU) No 1065/2012 and No 96/2013

(Text with EEA relevance)

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(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 nutrition¹, 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) A preparation of *Lactiplantibacillus plantarum* ATCC PTA-6139, previously identified as *Lactobacillus plantarum* (ATCC PTSA-6139), was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 1065/2012².
- (3) A preparation of *Lacticaseibacillus paracasei* ATCC PTA-6135, previously identified as *Lactobacillus casei* ATCC PTA 6135, was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 96/2013³.
- (4) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, two applications were submitted for the renewal of the authorisation of a preparation of *Lactiplantibacillus plantarum* ATCC PTA-6139 and a preparation of *Lacticaseibacillus paracasei* ATCC PTA-6135 as feed additives for all animal species,

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: <https://eur-lex.europa.eu/eli/reg/2003/1831/oj>).

² 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 (OJ L 314, 14.11.2012, pp. 15–22, ELI: http://data.europa.eu/eli/reg_impl/2012/1065/oj).

³ Commission Implementing Regulation (EU) No 96/2013 of 1 February 2013 concerning the authorisation of a preparation of *Lactobacillus buchneri* NCIMB 30139 and of a preparation of *Lactobacillus casei* ATCC PTA 6135 as feed additives for all animal species (OJ L 33, 2.2.2013, pp. 21–23, ELI: http://data.europa.eu/eli/reg_impl/2013/96/oj).

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 Regulation (EC) No 1831/2003.

- (5) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 17 April 2024^{4,5} that a preparation of *Lactiplantibacillus plantarum* ATCC PTA-6139 and a preparation of *Lacticaseibacillus paracasei* ATCC PTA-6135 remain safe for all animal species, consumers and the environment, under the conditions of use currently authorised. It also concluded that the additives should be considered a potential skin and respiratory sensitizers, and that any dermal and respiratory exposure is considered a risk. In the absence of data, the Authority could not conclude on their eye irritation potential. The Authority further concluded that there is no need for assessing the efficacy of the additives as the applications for renewal of their authorisations do not include a proposal for amending or supplementing the conditions of the original authorisation which would have an impact on the efficacy of the additives. Due to the absence of data regarding the microbiological contamination and impurities, the Authority could not conclude on the full characterisation of a preparation of *Lactiplantibacillus plantarum* ATCC PTA-6139 and a preparation of *Lacticaseibacillus paracasei* ATCC PTA-6135. In the subsequent opinion of 10 March 2026⁶ the Authority reported that the applicant provided new data and concluded that the additives are characterised regarding the microbiological contamination and chemical purity, and no safety concerns were identified.
- (6) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of a preparation of *Lactiplantibacillus plantarum* ATCC PTA-6139 and a preparation of *Lacticaseibacillus paracasei* ATCC PTA-6135 as feed additives in the context of the previous authorisations are valid and applicable for the current applications. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005⁷, an evaluation report of the Reference Laboratory is therefore not required.
- (7) In view of the above, the Commission considers that a preparation of *Lactiplantibacillus plantarum* ATCC PTA-6139 and a preparation of *Lacticaseibacillus paracasei* ATCC PTA-6135 satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of those additives should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additives. Those protective measures should be without prejudice to other workers’ safety requirements under Union law.
- (8) As a consequence of the renewal of the authorisation of a preparation of *Lactiplantibacillus plantarum* ATCC PTA-6139 and a preparation of

⁴ EFSA Journal, 22(5), e8785. <https://doi.org/10.2903/j.efsa.2024.8785>.

⁵ EFSA Journal, 22(5), e8792. <https://doi.org/10.2903/j.efsa.2024.8792>.

⁶ EFSA Journal, 24(4), e10042. <https://doi.org/10.2903/j.efsa.2026.10042>.

⁷ 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, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

Lacticaseibacillus paracasei ATCC PTA-6135 as feed additives, Implementing Regulations (EU) No 1065/2012 and No 96/2013 should be repealed.

- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of a preparation of *Lactiplantibacillus plantarum* ATCC PTA-6139 and a preparation of *Lacticaseibacillus paracasei* ATCC PTA-6135, 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 the authorisation

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

Repeal of Implementing Regulation (EU) No 1065/2012

Implementing Regulation (EU) No 1065/2012 is repealed.

Article 3

Repeal of Implementing Regulation (EU) No 96/2013

Implementing Regulation (EU) No 96/2013 is repealed.

Article 4

Transitional measures

The preparation of *Lactiplantibacillus plantarum* ATCC PTA-6139 and the preparation of *Lacticaseibacillus paracasei* ATCC PTA-6135, as authorised by Commission Implementing Regulation (EU) No 1065/2012 and Commission Implementing Regulation (EU) No 96/2013, respectively, and feed containing them, which are produced and labelled before [**12 months after the date of entry into force of the Regulation – Date to be inserted by the Service responsible for the publication**] in accordance with the rules applicable before [*the date of entry into force of the Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the stocks concerned are exhausted.

Article 5

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,

For the Commission
The President
Ursula VON DER LEYEN