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

of **XXX**

concerning the renewal of the authorisation of the preparations of *Lactiplantibacillus plantarum* DSM 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944, *Lentilactobacillus buchneri* ATCC PTA-2494 and *Lentilactobacillus buchneri* ATCC PTA-6138 as feed additives for all animal species, amending Implementing Regulation (EU) No 1065/2012 and repealing Implementing Regulation (EU) No 1113/2013

(Text with EEA relevance)

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concerning the renewal of the authorisation of the preparations of *Lactiplantibacillus plantarum* DSM 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944, *Lentilactobacillus buchneri* ATCC PTA-2494 and *Lentilactobacillus buchneri* ATCC PTA-6138 as feed additives for all animal species, amending Implementing Regulation (EU) No 1065/2012 and repealing Implementing Regulation (EU) No 1113/2013

(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) The preparations of *Lactiplantibacillus plantarum* DSM 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944 (previously taxonomically identified as *Lactobacillus plantarum* DSM 18112, *Lactobacillus plantarum* DSM 18113, *Lactobacillus plantarum* DSM 18114, *Lactobacillus plantarum* ATCC 55943, *Lactobacillus plantarum* ATCC 55944) were authorised for a period of 10 years as feed additives for all animal species by Commission Implementing Regulation (EU) No 1065/2012².
- (3) The preparations of *Lentilactobacillus buchneri* ATCC PTA-2494 (previously identified as *Lactobacillus buchneri* LN 4637/ATCC PTA-2494) and *Lentilactobacillus buchneri* ATCC PTA-6138 (previously identified as *Lactobacillus buchneri* LN 40177/ATCC PTA-6138) were authorised for a period of 10 years as

¹ 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).

feed additives for all animal species by Commission Implementing Regulation (EU) No 1113/2013³.

- (4) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, seven applications were submitted for the renewal of the authorisation of the preparations of *Lactiplantibacillus plantarum* DSM 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944, *Lentilactobacillus buchneri* ATCC PTA-2494 and *Lentilactobacillus buchneri* ATCC PTA-6138 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 Regulation (EC) No 1831/2003.
- (5) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 15 April 2024^{4,5} and 17 April 2024^{6,7,8,9,10} that the preparations of *Lactiplantibacillus plantarum* DSM 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944, *Lentilactobacillus buchneri* ATCC PTA-2494 and *Lentilactobacillus buchneri* ATCC PTA-6138 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 as 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 authorisation 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 the preparations of *Lactiplantibacillus plantarum* DSM 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944, *Lentilactobacillus buchneri* ATCC PTA-2494 and *Lentilactobacillus buchneri* ATCC PTA-6138. In the subsequent opinion of 24 June 2025¹¹ the Authority reported that the applicant provided new data and concluded that the additives are characterised regarding the microbiological contamination (except for the *Enterobacteriaceae*) and chemical purity, and no safety concerns were identified.

³ Commission Implementing Regulation (EU) No 1113/2013 of 7 November 2013 concerning the authorisation of preparations of *Lactobacillus plantarum* NCIMB 40027, *Lactobacillus buchneri* DSM 22501, *Lactobacillus buchneri* NCIMB 40788/CNCM I-4323, *Lactobacillus buchneri* LN 40177/ATCC PTA-6138, and *Lactobacillus buchneri* LN 4637/ATCC PTA-2494 as feed additives for all animal species (OJ L 298, 8.11.2013, pp. 29–33, ELI: http://data.europa.eu/eli/reg_impl/2013/1113/oj).

⁴ EFSA Journal, 22(5), e8767. <https://doi.org/10.2903/j.efsa.2024.8767>.

⁵ EFSA Journal, 22(5), e8768. <https://doi.org/10.2903/j.efsa.2024.8768>.

⁶ EFSA Journal, 22(5), e8782. <https://doi.org/10.2903/j.efsa.2024.8782>.

⁷ EFSA Journal, 22(5), e8783. <https://doi.org/10.2903/j.efsa.2024.8783>.

⁸ EFSA Journal, 22(5), e8784. <https://doi.org/10.2903/j.efsa.2024.8784>.

⁹ EFSA Journal, 22(5), e8786. <https://doi.org/10.2903/j.efsa.2024.8786>.

¹⁰ EFSA Journal, 22(5), e8787. <https://doi.org/10.2903/j.efsa.2024.8787>.

¹¹ EFSA Journal, 23(7), e9591. <https://doi.org/10.2903/j.efsa.2025.9591>.

- (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 the preparations of *Lactiplantibacillus plantarum* DSM 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944, *Lentilactobacillus buchneri* ATCC PTA-2494 and *Lentilactobacillus buchneri* ATCC PTA-6138 as feed additives in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005¹², an evaluation report of the Reference Laboratory is therefore not required.
- (7) In view of the above, the Commission considers that the preparations of *Lactiplantibacillus plantarum* DSM 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944, *Lentilactobacillus buchneri* ATCC PTA-2494 and *Lentilactobacillus buchneri* ATCC PTA-6138 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 the preparations of *Lactiplantibacillus plantarum* DSM 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944, *Lentilactobacillus buchneri* ATCC PTA-2494 and *Lentilactobacillus buchneri* ATCC PTA-6138 as feed additives, Implementing Regulation (EU) No 1065/2012 should be amended and Implementing Regulation (EU) No 1113/2013 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 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944, *Lentilactobacillus buchneri* ATCC PTA-2494 and *Lentilactobacillus buchneri* ATCC PTA-6138, 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,

¹² 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>).

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

Amendment to Implementing Regulation (EU) No 1065/2012

Implementing Regulation (EU) 1065/2012 is amended as follows:

- (1) In the title the deposition numbers ‘DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944’ are deleted.
- (2) In the Annex, the following entries are deleted:
 - 1k20726 on *Lactobacillus plantarum* (DSM 18112)
 - 1k20727 on *Lactobacillus plantarum* (DSM 18113)
 - 1k20728 on *Lactobacillus plantarum* (DSM 18114)
 - 1k20729 on *Lactobacillus plantarum* (ATCC 55943)
 - 1k20730 on *Lactobacillus plantarum* (ATCC 55944).

Article 3

Repeal of Implementing Regulation (EU) No 1113/2013

Implementing Regulation (EU) 1113/2013 is repealed.

Article 4

Transitional measures

The preparations of *Lactiplantibacillus plantarum* DSM 18112, *Lactiplantibacillus plantarum* DSM 18113, *Lactiplantibacillus plantarum* DSM 18114, *Lactiplantibacillus plantarum* ATCC 55943, *Lactiplantibacillus plantarum* ATCC 55944, *Lentilactobacillus buchneri* ATCC PTA-2494 and *Lentilactobacillus buchneri* ATCC PTA-6138 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