



2024/1190

25.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1190

of 24 April 2024

concerning the renewal of the authorisation of a preparation of *Enterococcus lactis* DSM 7134 as a feed additive for chickens reared for laying and minor poultry species for fattening, reared for laying and reared for breeding (holder of authorisation: Lactosan GmbH & Co.KG) and repealing Implementing Regulation (EU) No 775/2013

(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 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 and renewing such an authorisation.
- (2) A preparation of *Enterococcus lactis* DSM 7134 (previously taxonomically identified as *Enterococcus faecium* DSM 7134), was authorised for 10 years as a feed additive for chickens reared for laying and minor poultry species other than those used for laying by Commission Implementing Regulation (EU) No 775/2013 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Enterococcus lactis* DSM 7134 as a feed additive. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 26 September 2023 ⁽³⁾ that the applicant has provided evidence that the preparation of *Enterococcus lactis* DSM 7134 remains safe for chickens reared for laying and minor poultry species other than those used for laying, the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of *Enterococcus lactis* DSM 7134 was found to be non-irritant to skin and eyes, but a potential respiratory sensitiser. The Authority could not conclude on the skin sensitisation potential of that preparation. It also indicated that there is no need for assessing the efficacy of the preparation of *Enterococcus lactis* DSM 7134 in the context of the renewal of the authorisation. The Authority did not consider that there is a need for specific requirements of post-market monitoring.
- (5) 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 preparation of *Enterococcus lactis* DSM 7134 as a feed additive 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 378/2005 ⁽⁴⁾, an evaluation report of the Reference Laboratory is therefore not required.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ Commission Implementing Regulation (EU) No 775/2013 of 12 August 2013 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens reared for laying and minor poultry species other than those used for laying (holder of authorisation Lactosan GmbH & Co KG) (OJ L 217, 13.8.2013, p. 32, ELI: http://data.europa.eu/eli/reg_impl/2013/775/oj).

⁽³⁾ EFSA Journal 2023;21(10):8351.

⁽⁴⁾ 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>).

- (6) In view of the above, the Commission considers that the preparation of *Enterococcus lactis* DSM 7134 satisfies the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. For reasons of clarity, the reference to 'minor poultry species (other than those used for laying)' in the column 'Species or category of animal' of the Annex should be replaced by 'minor poultry species for fattening, reared for laying and reared for breeding'. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) As a consequence of the renewal of the authorisation of the preparation of *Enterococcus lactis* DSM 7134 as a feed additive, Implementing Regulation (EU) No 775/2013 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Enterococcus lactis* DSM 7134, 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.
- (9) 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 authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulation (EU) No 775/2013

Implementing Regulation (EU) No 775/2013 is repealed.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 15 November 2024 in accordance with the rules applicable before 15 May 2024 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 15 May 2025 in accordance with the rules applicable before 15 May 2024 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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, 24 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the feed 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 complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: gut flora stabilisers									
4b1841	Lactosan GmbH & Co.KG	<i>Enterococcus lactis</i> DSM 7134	<p><i>Additive composition</i> Preparation of <i>Enterococcus lactis</i> DSM 7134 containing a minimum of:</p> <ul style="list-style-type: none"> — powder form: 1×10^{10} CFU/g of additive, or — granulated (micro-encapsulated) form: 1×10^{10} CFU/g of additive. <p>Solid forms</p> <p><i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus lactis</i> DSM 7134</p> <p><i>Analytical method</i> ⁽¹⁾ Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697. Enumeration in the feed additive, premixtures and compound feed: spread plate method using bile esculin azide agar (EN 15788)</p>	Chickens reared for laying Minor poultry species for fattening, reared for laying and reared for breeding	—	5×10^8	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used simultaneously with the following cocci-diostats, in accordance with their respective conditions of authorisation as feed additives: diclazuril, halofuginone hydrobromide, robenidine hydrochloride, decoquinate, lasalocid A sodium, maduramicin ammonium, monensin sodium. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment. 	15 May 2034

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en