Commission Implementing Regulation (EU) 2020/159 of 5 February 2020 concerning the renewal of the authorisation of Enterococcus faecium DSM 7134 as a feed additive for weaned piglets and pigs for fattening and repealing Regulation (EC) No 538/2007 (holder of authorisation Lactosan Starterkulturen GmbH & Co) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/159

of 5 February 2020

concerning the renewal of the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive for weaned piglets and pigs for fattening and repealing Regulation (EC) No 538/2007 (holder of authorisation Lactosan Starterkulturen GmbH & Co)

(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 authorisation.

(2) *Enterococcus faecium* DSM 7134 was authorised for 10 years as a feed additive for weaned piglets and pigs for fattening by Commission Regulation (EC) No 538/2007[(2)].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive for weaned piglets and pigs for fattening, requesting that additive to be classified in the additive category ‘zootechnical additives’. 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 27 February 2019[(3)] that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority concluded that *Enterococcus faecium* DSM 7134 remains safe under the authorised conditions of use for the target animals, consumers, users and the environment. The Authority also concluded that the additive is considered a potential skin and respiratory sensitiser. Therefore the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

(5) The assessment of *Enterococcus faecium* DSM 7134 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 538/2007 should be repealed.

(7) 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

The authorisation of the additive 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

Regulation (EC) No 538/2007 is repealed.

Article 3

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, 5 February 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/159. (See end of Document for details)*

ANNEX

Identification number of the additive	**Name of the holder of authorisation**	**Additive (Trade name)**	**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 of zootechnical additives. Functional group: gut flora stabilisers.									
4b1841	Lactosan Starterkulturen GmbH & Co	*Enterococcus faecium* DSM 7134	**Additive composition:** Preparation of *Enterococcus faecium* DSM 7134 containing a minimum of: Powder: $1x10^{10}$ CFU/g of additive Granules (microencapsulated): $1x10^{10}$ CFU/g of additive **Characterisation of the active substance:** Viable cells of *Enterococcus faecium* DSM 7134 **Analytical method**[a] For enumeration: spread	Piglets (weaned)	—	$0,5 \times 10^9$	4×10^9	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures	26 February 2030

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports