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[...](2019) **XXX** draft

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

**of **XXX****

**authorising a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for sows  
(holder of authorisation Lactosan Starterkulturen GmbH & Co)**

(Text with EEA relevance)

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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<sup>1</sup>, 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 an application was submitted for the authorisation of a preparation of *Enterococcus faecium* DSM 7134. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for sows to be used in water for drinking, to be classified in the additive category 'zootechnical additives'.
- (4) The preparation of *Enterococcus faecium* DSM 7134, belonging to the additive category of 'zootechnical additives', was authorised for ten years as a feed additive for sows by Commission Implementing Regulation (EU) 2014/1083<sup>2</sup>.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 January 2019<sup>3</sup> that, under the proposed conditions of use, the preparation of *Enterococcus faecium* DSM 7134 does not have an adverse effect on animal health or the environment. It also concluded that the additive is considered as a potential 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. The Authority also concluded that the additive has a potential to be efficacious to improve zootechnical parameters in water for drinking, for sows. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

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<sup>1</sup> OJ L 268, 18.10.2003, p. 29.

<sup>2</sup> Commission Implementing Regulation (EU) 2014/1083 of 15 October 2014 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for sows (OJ L 298, 16.10.2014, p. 5).

<sup>3</sup> EFSA Journal 2019;17(2):5612.

- (6) The assessment of the preparation 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 use of that preparation 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 Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

Authorisation

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*

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*  
*Jean-Claude JUNCKER*