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EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of *Enterococcus lactis* DSM 7134 as a feed additive for sows (holder of authorisation: Lactosan GmbH&Co.KG) and repealing Implementing Regulation (EU) No 1083/2014

(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[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* (originally assigned to the *Enterococcus faecium* species) DSM 7134, was authorised for a period of 10 years as a feed additive for sows by Commission Implementing Regulation (EU) No 1083/2014[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 for sows, requesting the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'gut flora stabilisers'. 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 19 March 2025[3] that the preparation of *Enterococcus lactis* DSM 7134 remains safe for sows, as well as for the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of *Enterococcus lactis* DSM 7134 in its powder form is not irritant to skin and eyes but no such conclusion is possible for the granulated form of the additive. Both forms of the additive should be considered skin and respiratory sensitisers and any exposure through skin and respiratory tract is considered a risk. The Authority also indicated that there is no need for assessing the efficacy of the preparation of *Enterococcus lactis* DSM 7134, as the application for renewal of the authorisation does not include a proposal for amending

[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 1083/2014 of 15 October 2014 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive for sows (OJ L 298, 16.10.2014, pp. 5, ELI: http://data.europa.eu/eli/reg_impl/2014/1083/oj).

[3] *EFSA Journal*. 2025;23:e9353. https://doi.org/10.2903/j.efsa.2025.9353.

or supplementing the conditions of the original authorisations which would have an impact on the efficacy of the additive. 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.

(6) In view of the above, the Commission considers that the preparation of *Enterococcus lactis* DSM 7134 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive 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 additive. Those protective measures should be without prejudice to other workers' safety requirements under Union law.

(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 1083/2014 should be repealed.

(8) 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 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

Implementing Regulation (EU) No 1083/2014 is repealed.

Article 3
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.

[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 059 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN