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

of **XXX**

concerning the renewal of the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens for fattening, and repealing Regulation (EU) No 998/2010 (holder of authorisation: Lactosan GmbH & Co KG)

(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 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 preparation of *Enterococcus faecium* DSM 7134 was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EU) No 998/2010².
- (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 the preparation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens for fattening, requesting the 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 that Regulation.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 27 January 2021³ that the applicant had provided evidence that the additive complies with the existing conditions of authorisation. The Authority further concluded that the preparation of *Enterococcus faecium* DSM 7134 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the preparation is not irritant to skin and eyes, but it should be considered a potential skin sensitiser and a 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 verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

¹ OJ L 268, 18.10.2003, p. 29.

² Commission Regulation (EU) No 998/2010 of 5 November 2010 concerning the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens for fattening (holder of the authorisation Lactosan GmbH & Co KG) (OJ L 290, 6.11.2010, p. 22).

³ EFSA Journal 2021;19(3):6451.

- (5) 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 authorisation of that additive should be renewed.
- (6) As a consequence of the renewal of the authorisation of the preparation of *Enterococcus faecium* DSM 7134 as a feed additive, Regulation (EU) No 998/2010 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 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

Regulation (EU) No 998/2010 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,

For the Commission
The President
Ursula VON DER LEYEN