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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 and *Lacticaseibacillus rhamnosus* DSM 7133 as a feed additive for calves for rearing (holder of authorisation: Lactosan GmbH & Co.KG) and repealing Implementing Regulation (EU) No 1101/2013

(Text with EEA relevance)

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(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 and *Lacticaseibacillus rhamnosus* DSM 7133 (previously taxonomically identified as *Enterococcus faecium* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133 respectively) was authorised for 10 years as a feed additive for calves for rearing by Commission Implementing Regulation (EU) No 1101/2013[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 and *Lacticaseibacillus rhamnosus* DSM 7133 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 and *Lacticaseibacillus rhamnosus* DSM 7133 remains safe for calves for rearing, the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of *Enterococcus lactis* DSM 7134 and *Lacticaseibacillus rhamnosus* DSM 7133 is non-irritant to skin and eyes but should be considered a respiratory sensitiser. The Authority could not

[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 1101/2013 of 6 November 2013 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133 as a feed additive for calves for rearing and amending Regulation (EC) No 1288/2004 (holder of authorisation Lactosan GmbH & CoKG) (OJ L 296, 7.11.2013, p. 1; ELI: http://data.europa.eu/eli/reg_impl/2013/1101/oj).

[3] EFSA Journal 2023;21(10):8350.

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 and *Lacticaseibacillus rhamnosus* DSM 7133 as the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that 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 and *Lacticaseibacillus rhamnosus* DSM 7133 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 and *Lacticaseibacillus rhamnosus* DSM 7133 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 and *Lacticaseibacillus rhamnosus* DSM 7133 as a feed additive, Implementing Regulation (EU) No 1101/2013 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 and *Lacticaseibacillus rhamnosus* DSM 7133, 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 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 of Implementing Regulation (EU) No 1101/2013

[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).

Implementing Regulation (EU) No 1101/2013 is repealed.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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 [*12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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,

For the Commission
The President
Ursula VON DER LEYEN