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

of **XXX**

concerning the renewal of the authorisation of a preparation of *Enterococcus lactis* DSM 10663 as a feed additive for calves for rearing, suckling and weaned piglets, chickens for fattening, turkeys for fattening, cats and dogs (holder of authorisation: Chevita Tierarzneimittel GmbH) and repealing Implementing Regulation (EU) 2015/1053

(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 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 an authorisation.
- (2) A preparation of *Enterococcus faecium* DSM 10663/NCIMB 10415, was authorised for a period of 10 years as a feed additive for calves for rearing, piglets, chickens for fattening, turkeys for fattening, cats and dogs by Commission Implementing Regulation (EU) 2015/1053².
- (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 faecium* DSM 10663/ NCIMB 10415 as a feed additive for calves for rearing, suckling and weaned piglets, chickens for fattening, turkeys for fattening, cats and dogs, 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’) stated in its opinion of 27 January 2026³ that the active agent, originally assigned to the *Enterococcus faecium* species, was identified as *Enterococcus lactis* based on bioinformatic analysis of the whole genome sequence (‘WGS’) data. In its opinion, the Authority concluded that the

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² Commission Implementing Regulation (EU) 2015/1053 of 1 July 2015 concerning the authorisation of the preparation of *Enterococcus faecium* DSM 10663/NCIMB 10415 as a feed additive for calves for rearing, piglets, chickens for fattening, turkeys for fattening, cats and dogs and amending Regulations (EC) No 1259/2004, (EC) No 255/2005, (EC) No 1200/2005 and (EC) No 1520/2007 (holder of authorisation Chevita Tierarzneimittel-GmbH) (OJ L 171, 2.7.2015, pp. 8, ELI: http://data.europa.eu/eli/reg_impl/2015/1053/oj).

³ EFSA Journal. 2026;24:e9921. <https://doi.org/10.2903/j.efsa.2026.9921>.

preparation of *Enterococcus lactis* DSM 10663 (no proof of deposit in the British National Collection of Industrial and Marine Bacteria ('NCIMB') having been provided, the deposit number DSM 10663 is retained) remains safe for the target species, the consumers and the environment under the conditions of use currently authorised. It also considered that the amounts of the detected impurities in the additive do not raise safety concerns, except for nickel in the liquid form of the preparation of *Enterococcus lactis* DSM 10663. The Authority therefore concluded that the preparation of *Enterococcus lactis* DSM 10663 should be considered as a skin and respiratory sensitiser. Exposure by dermal and respiratory routes is considered a risk and should be minimised. The powder, granulated and liquid preparations of the additive are not irritant to eyes, but no conclusion can be reached for the coated form. The Authority also stated that 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 additives. Therefore, it concluded that there is no need for assessing the efficacy of the preparation in the context of the renewal of the authorisation. 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 a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinions of 4 March 2014⁴ and 21 May 2014⁵ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁶, an evaluation report of the Reference Laboratory was therefore not required.
- (6) In view of the above, the Commission considers that the preparation of *Enterococcus lactis* DSM 10663, previously taxonomically identified as *Enterococcus faecium* DSM 10663/NCIMB 10415, satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. Due to the presence of nickel as an impurity detected in the liquid form of the additive, specifications concerning the composition of the additive should include the upper level of nickel reflecting the characteristics of the additive. 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. Finally, as regards the use of the additive for weaned piglets, the Commission considers that it is no longer necessary to provide explicitly for the approximate maximum weight of 35 kg, as such characteristic is mentioned on a general basis for that animal category in Annex IV to Commission Regulation (EC) No 429/2008⁷.

⁴ EFSA Journal 2014;12(3):3602. <https://doi.org/10.2903/j.efsa.2014.3602>.

⁵ EFSA Journal 2014;12(6):3727. <https://doi.org/10.2903/j.efsa.2014.3727>.

⁶ 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>).

⁷ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/429/oj>).

- (7) As a consequence of the renewal of the authorisation of the preparation of *Enterococcus lactis* DSM 10663 as a feed additive, Implementing Regulation (EU) 2015/1053 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation *Enterococcus faecium* DSM 10663/NCIMB 10415 for calves for rearing, piglets, chickens for fattening, turkeys for fattening, cats and dogs, 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

Implementing Regulation (EU) 2015/1053 is repealed.

Article 3

Transitional measures

1. The feed additive *Enterococcus faecium* DSM 10663/NCIMB 10415, as authorised by Implementing Regulation (EU) 2015/1053, and premixtures containing that additive, which are intended for calves for rearing, piglets, chickens for fattening, turkeys for fattening, cats and dogs, and which are produced and labelled before ...[OJ please insert the date falling 6 months from the date of entry into force of this Regulation] in accordance with the rules applicable before ...[OJ please insert the date of entry into force of this Regulation] may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for calves for rearing, piglets, chickens for fattening and turkeys for fattening and which are produced and labelled before [OJ please insert the date falling 12 months from the date of entry into force of this Regulation] in accordance with the rules applicable before [OJ please insert the date of entry into force of this Regulation] may continue to be placed on the market and used until the stocks concerned are exhausted.
3. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for cats and dogs and which are produced and labelled before [OJ please insert the date falling 24 months from the date of entry into force of this Regulation] in accordance with the rules applicable before [OJ please insert the date of entry into force of this Regulation] may continue to be placed on the market and used until the stocks concerned 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