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EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of *Bacillus paralicheniformis* DSM 33902 and *Bacillus subtilis* DSM 33903 as a feed additive for ruminants for milk production/ reproduction (holder of authorisation: Chr. Hansen A/S)

(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 such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Bacillus paralicheniformis* DSM 33902 and *Bacillus subtilis* DSM 33903. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation of *Bacillus paralicheniformis* DSM 33902 and *Bacillus subtilis* DSM 33903 as a feed additive for dairy cows and other dairy ruminants, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘gut flora stabilisers’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 9 April 2025[2] that, under the proposed conditions of use, the preparation of *Bacillus paralicheniformis* DSM 33902 and *Bacillus subtilis* DSM 33903 is safe for the target species, consumers and the environment. The Authority also concluded that the preparation of *Bacillus paralicheniformis* DSM 33902 and *Bacillus subtilis* DSM 33903 in its both forms is considered non-irritant to the skin and eyes, but skin and respiratory sensitiser, and any exposure through the skin and respiratory tract are considered a risk. The Authority further concluded that the preparation of *Bacillus paralicheniformis* DSM 33902 and *Bacillus subtilis* DSM 33903 has the potential to be efficacious as a zootechnical additive in dairy cows and other dairy ruminants when used in feed and water. It also concluded that the minimum use level of the preparation in feed can be established at 3.8×10^8 CFU/kg complete feed while the minimum use level in water can be established based on the daily dose per animal (9.6×10^9 CFU per head) and the daily water intake. The Authority did not consider that there is a

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

[2] *EFSA Journal*. 2025;23:e9426. https://doi.org/10.2903/j.efsa.2025.9426

need for specific requirements of post-market monitoring. It 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.

(5) In view of the above, the Commission considers that the preparation of *Bacillus paralicheniformis* DSM 33902 and *Bacillus subtilis* DSM 33903 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for ruminants for milk production/reproduction. 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.

(6) 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
Ursula VON DER LEYEN