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

of **XXX**

concerning the authorisation of a preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 as a feed additive for all poultry species for laying or for breeding (holder of authorisation: Chr. Hansen A/S) and amending Implementing Regulation (EU) 2020/1762 as regards the terms of the authorisation of a preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 as a feed additive for all poultry species for fattening or reared for laying or reared for breeding

(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) and Article 13(3) 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) A preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 was authorised for a period of 10 years as a feed additive for all poultry species for fattening or reared for laying or reared for breeding by Commission Implementing Regulation (EU) 2020/1762².
- (3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The application concerns the authorisation of the preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 as a feed additive for all poultry species for laying or for breeding, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘gut flora stabilisers’.

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

² Commission Implementing Regulation (EU) 2020/1762 of 25 November 2020 concerning the authorisation of a preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 as a feed additive for all poultry species for fattening or reared for laying or reared for breeding (holder of authorisation Chr. Hansen A/S) (OJ L 397 26.11.2020, p. 14, ELI: http://data.europa.eu/eli/reg_impl/2020/1762/2024-03-21).

- (5) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted for the modification of the terms of the authorisation of the preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 as laid down in Implementing Regulation (EU) 2020/1762 as regards the use for all poultry species for fattening or reared for laying or reared for breeding. That application concerned the modification of the terms of the existing authorisation by introducing a new formulation with a 10-fold increased concentration of the active agents in the additive (from 3.2×10^9 to 3.2×10^{10} colony forming units (CFU)/g additive).
- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 20 March 2025³ that, under the proposed conditions of use, the preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 is safe for the target species, including poultry species for laying and breeding, as well as for consumers and the environment. The Authority also concluded that the preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840, in both forms of the additive are non-irritant to the eyes but are considered skin and respiratory sensitisers, and any exposure through skin and respiratory tract is considered a risk. The Authority further concluded that the preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 has the potential to be efficacious in all poultry at 1.6×10^9 CFU/kg feed and 5.4×10^8 CFU/L water for drinking. It did not consider that there is a need for specific requirements of post-market monitoring.
- (7) 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 opinion of 20 March 2020⁴ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁵, an evaluation report of the Reference Laboratory was therefore not required.
- (8) In view of the above, the Commission considers that the preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for all poultry species for laying or for breeding. 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.
- (9) In addition, the Commission considers that the authorisation of the preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 still meets the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 when the terms of that authorisation are modified as regards the use for all poultry species for fattening or reared for laying or reared for breeding, by introducing a new formulation with a 10-fold increased concentration of

³ EFSA Journal. 2025;23:e9361. <https://doi.org/10.2903/j.efsa.2025.9361>

⁴ EFSA Journal 2020;18(4):6094. <https://doi.org/10.2903/j.efsa.2020.6094>

⁵ 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>).

the active agents in the additive (from 3.2×10^9 to 3.2×10^{10} colony forming units (CFU)/g additive). Implementing Regulation (EU) 2020/1762 should therefore be amended accordingly.

- (10) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 for all poultry species for fattening or reared for laying or reared for breeding, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the modification of the authorisation.
- (11) 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 Annex I, 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 **Amendment to Implementing Regulation (EU) 2020/1762**

The Annex to Implementing Regulation (EU) 2020/1762 is replaced by the Annex II to this Regulation.

Article 3 **Transitional measures**

1. The feed additive *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840, as authorised by Implementing Regulation (EU) 2020/1762 and premixtures containing that additive, which are intended for all poultry species for fattening or reared for laying or reared for breeding, and which are produced and labelled before [6 months from 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 stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for all poultry species for fattening or reared for laying or reared for breeding, and which are produced and labelled before [12 months from 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 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