



2025/2576

19.12.2025

**COMMISSION IMPLEMENTING REGULATION (EU) 2025/2576**

**of 18 December 2025**

**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)

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 <sup>(1)</sup>, 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) 2020/1762 <sup>(2)</sup>.
- (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'.
- (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  $3,2 \times 10^9$  to  $3,2 \times 10^{10}$  colony forming units (CFU)/g additive).

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

<sup>(2)</sup> 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/oj](http://data.europa.eu/eli/reg_impl/2020/1762/oj)).

- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 20 March 2025 <sup>(3)</sup> 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  $1,6 \times 10^9$  CFU/kg feed and  $5,4 \times 10^8$  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 2020 <sup>(4)</sup> are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 <sup>(5)</sup>, 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 the active agents in the additive (from  $3,2 \times 10^9$  to  $3,2 \times 10^{10}$  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.

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

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

<sup>(5)</sup> 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>).

*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 8 July 2026 in accordance with the rules applicable before 8 January 2026 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 8 January 2027 in accordance with the rules applicable before 8 January 2026 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, 18 December 2025.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX I

| Identification number of the feed additive                                 | Name of the holder of authorisation | Name of the additive                                                                                                   | Composition, chemical formula, description, analytical method                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Species or category of animal                  | Maximum age | Minimum content                                         | Maximum content | Minimum content             | Maximum content | Other provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | End of period of authorisation |
|----------------------------------------------------------------------------|-------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------|---------------------------------------------------------|-----------------|-----------------------------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
|                                                                            |                                     |                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                |             | CFU/kg of complete feed with a moisture content of 12 % |                 | CFU/l of water for drinking |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                |
| Category: zootechnical additives. Functional group: gut flora stabilisers. |                                     |                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                |             |                                                         |                 |                             |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                |
| 4b1894                                                                     | Chr. Hansen A/S                     | <i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840 | <p><i>Additive composition</i></p> <p>Preparation of <i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840 containing a minimum of <math>3,2 \times 10^9</math> CFU/g additive (<math>1,6 \times 10^9</math> CFU <i>B. subtilis</i> DSM 32324/g; <math>1,0 \times 10^9</math> CFU <i>B. subtilis</i> DSM 32325/g and <math>0,6 \times 10^9</math> CFU <i>B. amyloliquefaciens</i> DSM 25840/g) (ratio 1.6:1.0:0.6)</p> <p>Solid forms</p> <p><i>Characterisation of the active substance</i></p> <p>Viable spores of <i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840.</p> | All poultry species for laying or for breeding | -           | $1,6 \times 10^9$                                       | -               | $5,4 \times 10^8$           | -               | <p>1. The additive may be used via water for drinking.</p> <p>2. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated.</p> <p>3. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: diclazuril, decoquinate, halofuginone, monensin, salinomycin, narasin, a combination of nicarbazin and narasin or lasalocid.</p> | 8 January 2036                 |

| Identification number of the feed additive | Name of the holder of authorisation | Name of the additive | Composition, chemical formula, description, analytical method                                                                                                                                                                                                                         | Species or category of animal | Maximum age | Minimum content                                         | Maximum content | Minimum content             | Maximum content | Other provisions                                                                                                                                                                                                                                                                                                                                                        | End of period of authorisation |
|--------------------------------------------|-------------------------------------|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------|---------------------------------------------------------|-----------------|-----------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
|                                            |                                     |                      |                                                                                                                                                                                                                                                                                       |                               |             | CFU/kg of complete feed with a moisture content of 12 % |                 | CFU/l of water for drinking |                 |                                                                                                                                                                                                                                                                                                                                                                         |                                |
|                                            |                                     |                      | Analytical method <sup>(1)</sup><br><br>Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) (CEN/TS 17697)<br>Enumeration in the feed additive, premixtures, compound feed and water for drinking: Spread plate method on tryptone soya agar (EN 15784) |                               |             |                                                         |                 |                             |                 | 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment. |                                |

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: [https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\\_en](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en)

## ANNEX II

| Identification number of the feed additive                                 | Name of the holder of authorisation | Name of the additive                                                                                                   | Composition, chemical formula, description, analytical method                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Species or category of animal                                                 | Maximum age | Minimum content                                         | Maximum content | Minimum content             | Maximum content | Other provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | End of period of authorisation |
|----------------------------------------------------------------------------|-------------------------------------|------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|-------------|---------------------------------------------------------|-----------------|-----------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
|                                                                            |                                     |                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                               |             | CFU/kg of complete feed with a moisture content of 12 % |                 | CFU/l of water for drinking |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                |
| Category: zootechnical additives. Functional group: gut flora stabilisers. |                                     |                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                               |             |                                                         |                 |                             |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                |
| 4b1894                                                                     | Chr. Hansen A/S                     | <i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840 | <p><i>Additive composition</i></p> <p>Preparation of <i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840 containing a minimum of <math>3,2 \times 10^9</math> CFU/g additive (<math>1,6 \times 10^9</math> CFU <i>B. subtilis</i> DSM 32324/g; <math>1,0 \times 10^9</math> CFU <i>B. subtilis</i> DSM 32325/g and <math>0,6 \times 10^9</math> CFU <i>B. amyloliquefaciens</i> DSM 25840/g) (ratio 1.6:1.0:0.6)</p> <p>Solid forms</p> <p><i>Characterisation of the active substance</i></p> <p>Viable spores of cells of <i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840.</p> | All poultry species for fattening or reared for laying or reared for breeding | -           | $1,6 \times 10^9$                                       | -               | $5,4 \times 10^8$           | -               | <p>1. The additive may be used via water for drinking.</p> <p>2. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated.</p> <p>3. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: diclazuril, decoquinate, halofuginone, monensin, salinomycin, narasin, a combination of nicarbazin and narasin, or lasalocid.</p> | 16.12.2030                     |

| Identification number of the feed additive | Name of the holder of authorisation | Name of the additive | Composition, chemical formula, description, analytical method                                                                                                                                                                                                                             | Species or category of animal | Maximum age | Minimum content                                         | Maximum content | Minimum content             | Maximum content | Other provisions                                                                                                                                                                                                                                                                                                                                                                                                               | End of period of authorisation |
|--------------------------------------------|-------------------------------------|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------|---------------------------------------------------------|-----------------|-----------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
|                                            |                                     |                      |                                                                                                                                                                                                                                                                                           |                               |             | CFU/kg of complete feed with a moisture content of 12 % |                 | CFU/l of water for drinking |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                |
|                                            |                                     |                      | <i>Analytical method</i> <sup>(1)</sup><br>Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) (CEN/TS 17697)<br>Enumeration in the feed additive, premixtures, compound feed and water for drinking: Spread plate method on tryptone soya agar (EN 15784). |                               |             |                                                         |                 |                             |                 | 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, glasses and gloves. |                                |

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: [https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\\_en](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en)