



2024/764

1.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/764

of 29 February 2024

concerning the authorisation of a preparation of *Bacillus subtilis* CNCM I-4606, CNCM I-5043 and CNCM I-4607 and *Lactococcus lactis* CNCM I-4609 as a feed additive for all animal species

(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 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 subtilis* CNCM I-4606, CNCM I-5043 and CNCM I-4607 and *Lactococcus lactis* CNCM I-4609. 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 subtilis* CNCM I-4606, CNCM I-5043 and CNCM I-4607 and *Lactococcus lactis* CNCM I-4609 as a feed additive for all animal species, requesting that additive to be classified in the category 'technological additives' and in the functional group 'hygiene condition enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 30 September 2021 ⁽²⁾ and of 1 February 2023 ⁽³⁾ that, under the proposed conditions of use, which exclude the use of the additive in commercial premixtures containing trace elements or preservatives, the preparation of *Bacillus subtilis* CNCM I-4606, CNCM I-5043 and CNCM I-4607 and *Lactococcus lactis* CNCM I-4609 is safe for the target species, consumers and the environment. It also concluded that the preparation is not irritant to skin or eyes or a skin sensitiser but that, given the proteinaceous nature of the active agent, it should be considered a respiratory sensitiser. The Authority further concluded that the additive at the minimum proposed inclusion level showed potential to reduce *Salmonella* Typhimurium growth in feed with high moisture content (60–90 % moisture) and noted that the use of this additive cannot be considered as a replacement for the standard hygiene farming conditions. The Authority also verified the report on the method 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 subtilis* CNCM I-4606, CNCM I-5043 and CNCM I-4607 and *Lactococcus lactis* CNCM I-4609 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of that 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,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2021;19(11):6907.

⁽³⁾ EFSA Journal 2023;21(3):7871.

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'hygiene condition enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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, 29 February 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU/L of complete feedingstuff			
Category: technological additives. Functional group: hygiene condition enhancers (reduction of the contamination by <i>Salmonella</i> Typhimurium)								
1n01	<i>Bacillus subtilis</i> CNCM I-4606, CNCM I-5043 and CNCM I-4607 and <i>Lactococcus lactis</i> CNCM I-4609	<i>Additive composition</i> Preparation of <i>Bacillus subtilis</i> CNCM I-4606, CNCM I-5043 and CNCM I-4607 and <i>Lactococcus lactis</i> CNCM I-4609 containing a minimum of: — 2 × 10⁹ CFU/g in total for the three <i>Bacillus subtilis</i> strains (in ratio 1:1:1); — 2 × 10⁹ CFU/g for the <i>Lactococcus lactis</i>. <i>Characterisation of the active substance</i> Viable spores of <i>Bacillus subtilis</i> strains CNCM I-4606, CNCM I-5043 and CNCM I-4607 and live cells of <i>Lactococcus lactis</i> CNCM I-4609 <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive, premixtures and compound feeds of the total <i>Bacillus subtilis</i> CNCM I-4606, CNCM I-5043 and CNCM I-4607: — Spread plate method on tryptone soya agar (EN 15784); Enumeration in the feed additive, premixtures and compound feeds of the <i>Lactococcus lactis</i> CNCM I-4609: — Poured plate method on MRS agar (EN 15214).	All animal species	-	1 × 10 ⁹ of <i>Bacillus subtilis</i> CNCM I-4606, 4607, and 5043 (in ratio 1:1:1) 1 × 10 ⁹ of <i>Lactococcus lactis</i> CNCM I-4609	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall only be used in mash compound feed or in solid feed materials, intended for the preparation of feed with a moisture content of 60-90 %. 3. The additive shall not be used in premixtures containing trace elements or preservatives. 4. On the label of the additive and premixtures, the following shall be indicated: ‘The additive 1n01 is intended for the reduction of the contamination by <i>Salmonella</i> Typhimurium. It cannot be considered as a replacement for the standard hygiene farming conditions.’	21 March 2034

		Identification of <i>Bacillus subtilis</i> CNCM I-4606, CNCM I-5043 and CNCM I-4607 and of the <i>Lactococcus lactis</i> CNCM I-4609: Pulsed Field Gel Electrophoresis (PFGE) CEN/TS 17697 or DNA sequencing methods					5. 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 protective equipment.	
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(¹) 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