



2023/2736

8.12.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2736

of 7 December 2023

concerning the authorisation of a preparation of *Bacillus velezensis* NITE BP-01844 as a feed additive for all poultry species for fattening, chickens reared for laying, turkeys reared for breeding, minor poultry species reared for laying or for breeding and ornamental birds (holder of authorisation: Toa Biopharma Co., Ltd)

(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 velezensis* NITE BP-01844 as a feed additive. 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 a preparation of *Bacillus velezensis* NITE BP-01844 as a feed additive for chickens for fattening, turkeys for fattening, chickens reared for laying, turkeys reared for breeding and all minor avian species (including also sporting, ornamental and exotic birds) to slaughter or point of lay ('the target species'), 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 opinions of 26 January 2022 ⁽²⁾ and of 12 May 2023 ⁽³⁾ that, under the proposed conditions of use, the preparation of *Bacillus velezensis* NITE BP-01844 is safe for the target species, consumers and the environment. It also concluded that the preparation of *Bacillus velezensis* NITE BP-01844 is not irritant to skin but potentially irritant to eyes, and that it should be considered a respiratory sensitiser. Since no test of skin sensitisation was provided, the Authority could not draw conclusions on the skin sensitisation potential of that preparation. The Authority further concluded that the preparation of *Bacillus velezensis* NITE BP-01844, has the potential to be efficacious for the target species when supplemented at $2,0 \times 10^8$ CFU/kg complete feed, and is compatible with the coccidiostats diclazuril, decoquinat, halofuginone, monensin, salinomycin, narasin, robenidone and maduramicin. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority 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 velezensis* NITE BP-01844 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Furthermore, in accordance with the Authority's guidance on the assessment of the efficacy of feed additives ⁽⁴⁾, it should be considered that that preparation has the potential to be efficacious for the target species when supplemented at $1,0 \times 10^8$ CFU/l drinking water. Accordingly, the use of the preparation of *Bacillus velezensis* NITE BP-01844 should be authorised for all poultry species for fattening, chickens reared for laying, turkeys reared for breeding, minor poultry species reared for laying or for breeding and ornamental birds, including when supplemented in the drinking water. 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2022;20(2):7152.

⁽³⁾ EFSA Journal 2023;21(6):8053.

⁽⁴⁾ EFSA Journal 2018;16(5):5274.

- (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, 7 December 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	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 feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			

Category of zootechnical additives. Functional groups: gut flora stabilisers

4b1903	Toa Biopharma Co., Ltd., Japan, represented by Toa Biopharma Co., Ltd., Europe Representative Office	<i>Bacillus velezensis</i> NITE BP-01844	<p><i>Additive composition:</i> Preparation of viable spores of <i>Bacillus velezensis</i> NITE BP-01844 with a minimum concentration of 1×10^8 CFU/g of additive Solid form</p> <p><i>Characterisation of the active substance:</i> Viable spores of <i>Bacillus velezensis</i> NITE BP-01844</p> <p><i>Analytical method</i> (1): Identification: — Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697, or — DNA sequencing methods. Enumeration in the feed additive, premixtures, compound feed and water: spread-plate method on tryptone soya agar (EN 15784).</p>	<p>All poultry species for fattening</p> <p>Chickens reared for laying</p> <p>Turkeys reared for breeding</p> <p>Minor poultry species reared for laying or for breeding</p> <p>Ornamental birds</p>	—	2×10^8	—	1×10^8	—	<p>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. The additive may be used in compound feed containing the following coccidiostats, where authorised as feed additives for the same animal species and categories: diclazuril, decoquinate, halofuginone, monensin, salinomycin, narasin, robenidine and maduramicin.</p>	28 December 2033
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										<p>3. 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, eye and skin protective equipment.</p>
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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