



2024/228

15.1.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/228

of 12 January 2024

concerning the authorisation of a preparation of *Companilactobacillus farciminis* CNCM I-3740 as a feed additive for chickens for fattening and turkeys for fattening (holder of authorisation: ChemVet dk A/S) and amending Regulation (EC) No 1876/2006

(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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The preparation of *Companilactobacillus farciminis* CNCM I-3740 (previously taxonomically identified as *Lactobacillus farciminis* CNCM MA 67/4R) was authorised for four years in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening, turkeys for fattening and laying hens by Commission Regulation (EC) No 1876/2006 ⁽³⁾. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of the preparation of *Companilactobacillus farciminis* CNCM I-3740 as a feed additive for chickens for fattening, turkeys for fattening and laying hens. The applicant requested the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'other zootechnical additives'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 19 March 2020 ⁽⁴⁾, 5 May 2021 ⁽⁵⁾ and 11 May 2023 ⁽⁶⁾ that, under the proposed conditions of use, the preparation of *Companilactobacillus farciminis* CNCM I-3740 is presumed safe for chickens for fattening, turkeys for fattening and laying hens, consumers and the environment. Regarding the safety for the user, the Authority could not conclude on the potential of the preparation of *Companilactobacillus farciminis* CNCM I-3740 to be irritant to skin and eyes or its dermal sensitisation potential due to the lack of data, but concluded that that additive should be considered a respiratory sensitiser. The Authority concluded that the preparation of *Companilactobacillus farciminis* CNCM I-3740 is efficacious as a zootechnical additive in chickens for fattening and turkeys for fattening at the concentration of $8,5 \times 10^8$ CFU/kg complete feed. 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Commission Regulation (EC) No 1876/2006 of 18 December 2006 concerning the provisional and permanent authorisation of certain additives in feedingstuffs (OJ L 360, 19.12.2006, p. 126).

⁽⁴⁾ EFSA Journal 2020;18(4):6083.

⁽⁵⁾ EFSA Journal 2021;19(5):6627.

⁽⁶⁾ EFSA Journal 2023;21(6):8049.

- (5) The applicant committed on 23 June 2023 to submit supplementary information with a view to demonstrate the efficacy of *Companilactobacillus farciminis* CNCM I-3740 for laying hens. In addition, the applicant accepted by a letter of 8 August 2023 that the additive be classified in the functional group 'gut flora stabilisers' instead of 'other zootechnical additives'.
- (6) In view of the above, the Commission considers that the preparation of *Companilactobacillus farciminis* CNCM I-3740 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 for use in chickens for fattening and turkeys for fattening. Accordingly, the use of that preparation should be authorised for chickens for fattening and turkeys for fattening. 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.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Companilactobacillus farciminis* CNCM I-3740, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) As a consequence of the authorisation of the preparation of *Companilactobacillus farciminis* CNCM I-3740 as a feed additive for chickens for fattening and turkeys for fattening, Regulation (EC) No 1876/2006 should be amended.
- (9) 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 the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition for chickens for fattening and turkeys for fattening, subject to the conditions laid down in that Annex.

Article 2

Amendment of Regulation (EC) No 1876/2006

The text in the column 'Species or category of animal' of Annex I to Regulation (EC) No 1876/2006 is replaced by the following:

'Laying hens'.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 4 August 2024 in accordance with the rules applicable before 4 February 2024 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 4 February 2025 in accordance with the rules applicable before 4 February 2024 may continue to be placed on the market and used until the existing stocks 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, 12 January 2024.

For the Commission
The President
Ursula VON DER LEYEN

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	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1852	ChemVet dk A/S	<i>Companilactobacillus farciminis</i> CNCM I-3740	<p><i>Additive composition</i></p> <p>Preparation of <i>Companilactobacillus farciminis</i> CNCM I-3740 with a minimum concentration of 1×10^9 CFU/g of additive.</p> <p>Solid form.</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Companilactobacillus farciminis</i> CNCM I-3740.</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Identification:</p> <ul style="list-style-type: none"> — Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or — DNA sequencing methods. <p>Enumeration in feed additive and compound feed: spread plate method on MRS agar (EN 15787).</p>	Chickens for fattening Turkeys for fattening	—	$8,5 \times 10^8$	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. 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. 	4 February 2034

⁽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