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Efficacy of a feed additive consisting of *Companilactobacillus farciminis* CNCM I-3740 (Biacton®) for chickens and turkeys for fattening (ChemVet dk A/S)

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the efficacy of the additive consisting of *Companilactobacillus farciminis* (formerly *Lactobacillus farciminis*) CNCM I-3740 (tradename: Biacton®) for chickens for fattening, turkeys for fattening and laying hens. The additive is a preparation containing viable cells of *C. farciminis* CNCM I-3740 at the minimum concentration of 1×10^9 CFU/g additive. It is intended to be used as a zootechnical additive in feed for chickens for fattening, turkeys for fattening and laying hens at the recommended application level of 5×10^8 CFU/kg complete feed. In the context of previous opinions, no conclusions could be drawn on the efficacy of the additive in any of the target species based on the data provided. As regards chickens for fattening, in the former opinions the supplementation of the additive at the recommended level showed a significantly greater weight or weight gain compared to birds in the control group only in two studies. New statistical analysis data of one efficacy trial were submitted. The results showed that Biacton® supplemented at 8.5×10^8 CFU/kg feed or at higher levels significantly improved the feed to gain ratio of chickens for fattening compared to control birds or to birds receiving the additive at the recommended level. Therefore, the Panel concluded that Biacton® has the potential to be efficacious in chickens for fattening at the concentration of 8.5×10^8 CFU/kg complete feed. This conclusion was extrapolated to turkeys for fattening.

Keywords: zootechnical additive, other zootechnical additives, Biacton®, *Companilactobacillus farciminis* CNCM I-3740, efficacy, chickens for fattening, turkeys for fattening

Requestor: European Commission

Question number: EFSA-Q-2023-00044

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003 establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, ChemVet dk A/S, is seeking a Community authorisation of *Companilactobacillus farciminis*[1] CNCM MA67/4R (now CNCM I-3740) as a feed additive to be used as "other zootechnical additive" for chickens for fattening, laying hens and turkeys for fattening. (Table 1).

Table 1: Description of the additive

Category of additive	Zootechnical additives
Functional group of additive	Other zootechnical additives
Description	*Companilactobacillus farciminis* CNCM MA67/4R (now CNCM I-3740)
Target animal category	chickens for fattening and turkeys for fattening
Applicant	ChemVet dk A/S
Type of request	New opinion

On 19 March 2020, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the safety and efficacy of the product, could not conclude on the efficacy of *Companilactobacillus farciminis* CNCM MA67/4R (now CNCM I-3740).

After the discussion with the Member States during a meeting of the Standing Committee on Plants, Animals, Food and Feed (Animal Nutrition section), it was suggested to check for the possibility to demonstrate the efficacy of the additive.

The Commission gave the possibility to the applicant to submit complementary information and data in order to complete the assessment and to allow a revision of the Authority's opinion. The new data have been received and were submitted to the Authority by the applicant.

In view of the above, the Commission asks the Authority to deliver an opinion on *Companilactobacillus farciminis* CNCM MA67/4R (now CNCM I-3740) as a feed additive for chickens for fattening and turkeys for fattening based on the additional data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

1.2. Additional information

The FEEDAP Panel issued two opinions on the safety and efficacy of Biacton® (*Companilactobacillus farciminis* (formerly *Lactobacillus farciminis*) CNCM I-3740, EFSA FEEDAP Panel, 2020, 2021) in which no conclusions could be drawn on the efficacy of the additive for chickens for fattening, turkeys for fattening and laying hens due to poor reporting and significant limitations in the available data. The applicant has now provided new data to address the issues previously identified regarding the efficacy of the additive for chickens for fattening and turkeys for fattening.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[2] to previous applications on the same product.[3]

In accordance with Article 38 of the Regulation (EC) No 178/2002[4] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements

[1] Formerly known as *Lactobacillus farciminis*.
[2] Dossier references: EFSA-Q-2023-00044.
[3] Dossier reference: FAD-2020-0071 and FAD-2010-0131.
[4] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, pp.1–48.

concerning transparency and confidentiality,[5] a non-confidential version of the supplementary information (for Art 29) has been published on Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00044.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of Biacton® (*C. farciminis* CNCM MA67/4R) is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive under assessment is a preparation containing viable cells of *C. farciminis* (formerly *L. farciminis*) CNCM I-3740 (tradename: Biacton®) at the minimum concentration of 1×10^9 colony forming units (CFU)/g additive. The additive is intended to be used as a zootechnical additive (functional group: other zootechnical additives) in feed for chickens for fattening, turkeys for fattening and laying hens at the recommended application level of 5×10^8 CFU/kg complete feed, to improve performance. It will be hereafter referred to as Biacton®.

In previous opinions, the FEEDAP Panel assessed the safety and the efficacy of the product when used in feed for chickens for fattening, turkeys for fattening and laying hens (EFSA FEEDAP Panel, 2020, 2021). The Panel concluded that the active agent fulfils the requirements of the QPS approach to the assessment of safety. Consequently, the additive Biacton® is presumed safe for the target animals, consumers and the environment. Regarding the safety for the user, the FEEDAP Panel could not conclude on the potential of the additive to be irritant to skin and eyes or a dermal sensitiser due to the lack of data. However, it was concluded that the additive should be considered a respiratory sensitiser. The data provided to support the efficacy of the additive were not sufficient to conclude on the efficacy of the additive for any of the three target species.

The applicant has provided additional data to complement the information available supporting the efficacy of the additive in chickens and turkeys for fattening.

3.1. Efficacy

3.1.1. Efficacy for chickens for fattening

In the first opinion, the FEEDAP Panel assessed six trials, three of which were not considered further due to several shortcomings: too short duration in one case, too high mortality observed in a second case and inappropriate endpoints measured in the third case (EFSA FEEDAP Panel, 2020). The remaining three studies were fully assessed. However, no conclusions could be drawn since no information on the mortality was provided for any of the trials and the statistical analysis conducted in two of the studies (2 and 3) was not appropriate.

In the second opinion (EFSA FEEDAP Panel, 2021), the Panel reassessed the same studies considered in the 2020 opinion, with some additional information provided by the applicant. Consequently, the Panel concluded that the administration of Biacton® at the proposed conditions of use (5×10^8 CFU/kg complete feed) positively affected the performance of the chickens in two studies (1 and 2). However, in the absence of a third positive study, the Panel could not conclude on the efficacy of Biacton® for chickens for fattening.

To address the flaws identified in the previous opinions in one of the studies originally submitted (study 3), the applicant has provided the statistical analysis of the data that is described below.[7]

A total of 180 one-day-old male Ross chickens for fattening were distributed in 180 individual cages and allocated to five dietary treatments (36 replicates per treatment). Two basal diets (starter: 1–19 days of age; grower: 20–40 days of age) based on maize, wheat and soyabean meal were either not supplemented (control) or supplemented with Biacton® to provide 4.45×10^8; 8.5×10^8; 12.75×10^8 and 1.7×10^9 CFU of *C. farciminis* CNCM I-3740 per kg of complete feed (confirmed by

[5] Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.
[6] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.
[7] Biacton study_4.1.5_new statistics_2022 and Biacton Study_4.1.5_new additional statistics_2023.

analysis). The diets in mash form and water were offered ad libitum for a total of 40 days. Mortality and health status were checked daily. Chickens were individually weighed on days 20 and 40. Cumulative feed intake was measured and feed to gain ratio (F:G) calculated for the overall duration. Data were statistically analysed by one-way analysis of variance with the cage as the statistical unit and the treatment as a fixed effect. Tukey test was used for the multiple comparison of means. Significance level was set at $p < 0.05$.

Table 2: Effects of Biacton® on the zootechnical performance of chickens for fattening

Biacton® (CFU/kg feed)	Total feed intake (g)	Final bodyweight (g)	Feed to gain ratio
Control	3,824	2,029	1.92[a]
4.45×10^8	3,831	2,056	1.90[a]
8.5×10^8	3,838	2,093	1.87[b]
12.75×10^8	3,839	2,085	1.88[b]
1.7×10^9	3,810	2,070	1.88[b]

CFU: colony forming unit.
[a,b]: Mean values within a column with a different superscript are significantly different $p < 0.05$.

No mortality or culling occurred in the trial. At the end of the experimental period, the feed to gain ratio of birds supplemented with Biacton® at the inclusion level of 8.5×10^8 CFU/kg complete feed or higher was significantly lower than that of the control group (Table 2). Total feed intake and final bodyweight of birds in the Biacton® groups were not influenced by treatment.

3.1.1.1. Conclusions on efficacy for chickens for fattening

Based on the overall results, Biacton® has the potential to be efficacious for chickens for fattening at 8.5×10^8 CFU/kg complete feed.

3.1.2. Efficacy for turkeys for fattening

The efficacy of the additive for chickens for fattening has been established at 8.5×10^8 CFU/kg feed and these conclusions can be extrapolated to turkeys for fattening.

4. Conclusions

Biacton® has the potential to be efficacious in chickens for fattening and turkeys for fattening at the minimum inclusion level of 8.5×10^8 CFU/kg complete feed.

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Abbreviations

CFU	colony forming unit
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in AnimalFeed
F:G	feed to gain ratio