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Efficacy of the feed additive containing *Companilactobacillus farciminis* (formerly *Lactobacillus farciminis*) CNCM I-3740 (Biacton®) for chickens for fattening, turkeys for fattening and laying hens (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. In a previous opinion, the FEEDAP Panel assessed the safety and the efficacy of the product when used in these target species. The Panel concluded that based on the qualified presumption of safety of the active agent, and the lack of concerns deriving from other components of the additive, Biacton® was 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 its dermal sensitisation due to the lack of data. However, it concluded that the additive should be considered a respiratory sensitiser. The data provided in the previous assessment to support the efficacy of the additive did not allow drawing conclusions on the efficacy of the additive in any of the target species. The additional information submitted with chickens for fattening and laying hens did not provide sufficient evidence to conclude on the efficacy of Biacton® for these target species. No new information was provided that would lead the Panel to reconsider the conclusions already reached on the use of the additive with turkeys for fattening. The FEEDAP Panel, based on the available data, cannot conclude on the efficacy of Biacton® in chickens for fattening, turkeys for fattening and laying hens.

Keywords: zootechnical additive, other zootechnical additives, Biacton®, *Companilactobacillus farciminis* CNCM I-3740, safety, efficacy

Requestor: European Commission

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1. Introduction

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

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition and in particular, Article 9 defined the terms of authorisation by the Commission.

The applicant ChemVet dk A/S, is seeking a Community authorisation of *Companilactobacillus farciminis*[2] CNCM MA67/4R (now CNCM I-3740) as a feed additive to be used as "other zootechnical additive" for chickens for fattening, turkeys for fattening and laying hens (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, turkeys for fattening and laying hens
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 on 06 October 2020 and were already transmitted to the Authority by the applicant.

In view of the above, the Commission asks the Authority to deliver a new opinion on *Companilactobacillus farciminis* CNCM MA67/4R (now CNCM I-3740) as a feed additive for chickens for fattening, turkeys for fattening and laying hens based on the additional data submitted by the applicant, in accordance with Article 20(1)(a) of regulation (EC) No 178/2002.

1.2. Additional information

The FEEDAP Panel issued an opinion on the safety and efficacy of Biacton® (*Companilactobacillus farciminis* (formerly *Lactobacillus farciminis*) CNCM I-3740, EFSA FEEDAP Panel, 2020) 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.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[3] to a previous application on the same product.[4]

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Formerly *Lactobacillus farciminis.*
[3] FEED dossier reference: FAD-2020-0071.
[4] FEED dossier reference: FAD-2010-0131.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of the feed additive is in line with the principles laid down in Regulation (EC) No 429/2008[5] 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 a previous opinion, 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). The Panel concluded that the active agent fulfils the requirements of the qualified presumption of safety (QPS) approach to the assessment of safety (EFSA, 2007; EFSA BIOHAZ Panel, 2020). Consequently, the additive Biacton® is presumed safe for the target animals, consumers of products from animals fed with the additive 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 its dermal sensitisation due to the lack of data. However, it concluded that the additive should be considered a respiratory sensitiser. The data provided to support the efficacy of the additive was not sufficient to conclude on the efficacy of the additive for any of the three target species.

The applicant has provided new data to complement the information available supporting the efficacy of the additive in feed for chickens for fattening, turkeys for fattening and laying hens.

3.1. Efficacy for chickens for fattening

In the previous 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 end-points 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 since the statistical analysis conducted in two of the studies (2 and 3) was not appropriate.

The applicant has resubmitted the three study reports considered in the previous opinion. However, that for study 2[6] did not include any new information. As regards study 3,[6] the applicant declares that no mortality occurred in the trial. However, no new statistical analysis of the data has been submitted. Consequently, the Panel reiterates its previous conclusion that no conclusion can be drawn from these two studies. Regarding study 1,[7] the applicant declared that no mortality occurred in this trial.[6] The description of the study design and results are presented below.

[redacted]

At the end of the experimental period, birds in the Biacton® group showed a significantly greater weight compared to birds in the control group (1,869 g vs 1,827 g) and a significantly better feed to gain ratio (1.94 vs 1.98). Total feed intake was not different among groups (control: 3,610 g, Biacton®: 3,617 g).

[5] 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.
[6] Technical dossier/re. request supp info-Ares(2020)3426874.pdf and Annex 1.
[7] Study conducted in 2001 and originally submitted to EFSA in 2010.

The applicant also resubmitted the report of the study discarded in the first assessment due to high mortality.[8] The reanalysis of the study identified an error in the interpretation of mortality values in the first assessment. The Panel considers this study acceptable and is described below.

[redacted]

Mortality and culling were 3.3% and 2.3% for the Biacton® group and 1.8% and 1.3% for the control group, respectively. At the end of the experimental period the BW and average daily weight gain (ADG) of animals in the Biacton® group were significantly greater than those of the control group (BW: 2.33 vs 2.27 kg; ADG: 65.2 vs 63.7 g; FI and feed to gain ratio (F:G) were not influenced by treatment (FI: control = 100.8 g, Biacton® = 101.1 g; F:G: control = 1.56, Biacton® = 1.55).

3.1.1. Conclusions on efficacy for chickens for fattening

In the absence of three positive studies, there is insufficient evidence to conclude on the efficacy of Biacton® for chickens for fattening.

3.2. Efficacy for turkeys for fattening

In the previous opinion, the FEEDAP Panel assessed four trials, however, none could be considered further due to several shortcomings: too short duration, poor reporting, wrong statistical unit and inappropriate endpoints measured (EFSA FEEDAP Panel, 2020).

No new information has been provided that would lead the Panel to reconsider the conclusions already reached.[9] Therefore, the Panel reiterated its previous conclusions that no conclusions can be drawn on the efficacy of Biacton® for turkeys for fattening.

3.3. Efficacy for laying hens

In the previous opinion the FEEDAP Panel assessed three trials, however, one could not be considered further due to poor reporting and data missing (EFSA FEEDAP Panel, 2020). Regarding the two remaining studies the Panel concluded *'The results of the individual studies did not show any significant effect on any performance parameter with the supplementation of diets with Biacton®. In addition, as the studies were done in the same place and overlapped in time, and the only difference between these two studies is the breed of the animals with similar production rates, the studies are not considered to be independent. These studies should be analysed considering the pooled data in order to allow reaching conclusions. Therefore, no conclusions can be drawn on the efficacy of Biacton® in laying hens'*.

The applicant has resubmitted the report of the study involving [redacted] hens (study 2 in the former opinion), an updated report of the study with [redacted] hens[10] (study 1 in the former opinion) and a new statistical analysis pooling the data on mortality, laying rate, cumulative egg number per hen, average egg weight, cumulative egg mass, daily feed intake, cumulative feed intake and feed conversion ratio of these two studies.[11]

In the revised report of the study involving [redacted][13] Consequently, in the absence of the scientific rational for the exclusion of the data from some hens from the study, the FEEDAP Panel has reservations on the validity of the study and therefore cannot draw conclusions from it.

[8] Technical dossier/re. request supp info-Ares(2020)3426874.pdf and Annex 2.
[9] Technical dossier/re. request supp info-Ares(2020)3426874.pdf and Annex 3.
[10] Technical dossier/re. request supp info-Ares(2020)3426874.pdf and Annex 6.
[11] Technical dossier/re. request supp info-Ares(2020)3426874.pdf and Annex 8.
[12] Technical dossier/re. request supp info-Ares(2020)3426874.pdf, Annex 4 and Annex 6.
[13] Technical dossier/Supplementary information December 2020/Annex I_reply to the question EFSA-Q-2020_00699.pdf.

4. Conclusions

The FEEDAP Panel, based on the available data, cannot conclude on the efficacy of Biacton® in chickens for fattening, turkeys for fattening and laying hens.

5. Documentation as provided to EFSA/Chronology

Date	Event
05/10/2020	Dossier received by EFSA. Lactobacillus farciminis CNCM MA67/4R (now CNCM I-3740). Submitted by ChemVet dk A/S
13/10/2020	Reception mandate from the European Commission
07/12/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: efficacy*
21/12/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
05/05/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

ADG	average daily weight gain
ANOVA	analysis of variance
BW	body weight
CFU	colony forming unit
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
F:G	feed to gain ratio
FI	feed intake
LSD	Least Significant Difference
QPS	qualified presumption of safety