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Safety and efficacy of Biacton® (*Lactobacillus farciminis* CNCM I-3740) as a feed additive for chickens for fattening, turkeys for fattening and laying hens

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Abstract

Following a request from the European Commission, the EFSA Panel on Additives and products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of Biacton® when used as a feed additive for chickens for fattening, turkeys for fattening and laying hens. Biacton® is a preparation of viable cells of *Lactobacillus farciminis* CNCM I-3740 intended for use in feed for chickens for fattening, turkeys for fattening and laying hens at a minimum recommended application level of 5×10^8 CFU/kg complete feedingstuffs. *L. farciminis* is a species considered by EFSA to be suitable for the Qualified Presumption of Safety (QPS) approach to safety assessment which requires the identity of the strain to be conclusively established and evidence that it does not show acquired resistance to antibiotics of human and veterinary importance. The strain was found to meet the criteria for the QPS approach to safety assessment, and since concerns are not expected from other components of the additive, the additive is presumed safe for all target species, consumers and the environment. In the absence of data, no conclusions can be drawn on the irritancy of Biacton® to skin and eyes or on its dermal sensitisation potential. The additive should be considered a respiratory sensitiser. Due to poor reporting and significant limitations in the data available, the FEEDAP Panel cannot conclude on the efficacy of the additive for chickens for fattening, turkeys for fattening and laying hens.

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

Requestor: European Commission

Question number: EFSA-Q-2016-00711

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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. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from ChemVet dk A/S[2] for authorisation of the product Biacton® (*Lactobacillus farciminis* CNCM I-3740[3]), when used as a feed additive for laying hens, chickens for fattening and turkeys for fattening (category: zootechnical additives; functional group: other zootechnical additives).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 18 October 2017.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product Biacton® (*Lactobacillus farciminis* CNCM I-3740), when used under the proposed conditions of use (see Section 3.1.4).

1.2. Additional information

Biacton® is a preparation of viable cells of *Lactobacillus farciminis* CNCM I-3740. EFSA adopted one opinion on the safety of Biacton for chickens for fattening, turkeys and laying hens (EFSA, 2006) and one for weaned piglets (EFSA FEEDAP Panel, 2020).

Biacton® is currently authorised for chickens for fattening, turkeys and laying hens.[4]

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[5] in support of the authorisation request for the use of Biacton® (*Lactobacillus farciminis* CNCM I-3740) as a feed additive.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active agent in animal feed. The Executive Summary of the EURL report can be found in Annex A.[6]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Biacton is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the relevant guidance documents: Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel,

[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] ChemVet dk A/S, A.C. Illums Vej 6, DK-8600, Denmark.
[3] Formerly identified as *Lactobacillus farciminis* CNCM MA 67/4R.
[4] 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. 16 plus amendments.
[5] FEED dossier reference: FAD-2010_0131.
[6] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep_fad-2010-0131_lactobac_farci.pdf
[7] 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.

2011), Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012a), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b) and Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive Biacton® is a preparation of viable cells of *L. farciminis* CNCM I-3740 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 to improve performance.

3.1. Characterisation

3.1.1. Characterisation of the active agent

The strain of *L. farciminis* was isolated from a healthy pig and is deposited [redacted] Identity was established by whole genome sequence (WGS) analysis. [redacted]

The susceptibility of the strain to the antibiotics recommended by the FEEDAP Panel (EFSA FEEDAP Panel, 2018) was tested [redacted] Exceedance of the cut-off value by one dilution is considered to be within the normal range of variation and thus, not a matter of concern.

[redacted] The analysis performed did not identify any hit of concern. [redacted] do not raise safety concerns.

3.1.2. Characterisation of the product

The active agent is produced by batch fermentation with a medium typical for the commercial production of lactic acid bacteria. [redacted]

Three batches of the additive were analysed for the presence of chemical and microbiological contaminants.[14] Values for lead were ≤ 0.1 mg/kg, for arsenic ≤ 0.01 mg/kg and for mercury and aflatoxin B1 were below the limit of detection (0.005 mg/kg and 0.001 m/kg, respectively). Coliforms, staphylococci, sulphite reducing anaerobes, *Salmonella* spp., yeast and filamentous fungi were below detection limits.[15]

[redacted]

[14] Technical dossier/Section II.

[15] Coliforms, *E. coli* and staphylococci < 1 CFU/g, sulfite-reducing anaerobes, < 2 CFU/g, *Salmonella* spp. absent in 25 g, yeast and filamentous fungi < 5 CFU/g.

The additive is in powder form.[16] [redacted]

3.1.3. Stability and homogeneity

The stability [redacted]

To investigate the capacity of the additive [redacted] to be homogeneously distribute into a feed [redacted]

3.1.4. Conditions of use

The additive is intended for use in compound feedstuffs for chickens for fattening, turkeys for fattening and laying hens at recommended application level of 5×10^8 CFU/kg complete feedingstuffs.

3.2. Safety

3.2.1. Safety for the target species, consumers and environment

The bacterial species *L. farciminis* is considered by EFSA to be potentially suitable for the qualified presumption of safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2020). This approach requires the identity of the strain to be conclusively established and evidence that it does not harbour acquired antimicrobial genes to clinically relevant antibiotics. In the view of the FEEDAP Panel, the antibiotic resistance qualification has been met and the identity of the strain established as *L. farciminis*. Therefore, *L. farciminis* CNCM I-3740 is considered by EFSA to be suitable for the QPS approach to safety assessment and, consequently, is presumed safe for the target species, consumers of products from animals fed the additive and the environment. Since no concerns arise from other components of the additive, Biacton® is also presumed safe for the target animals, consumers and the environment.

3.2.2. Safety for user

Despite the request, no studies to assess the safety for the user were submitted. Therefore, the FEEDAP Panel cannot conclude on the irritancy potential to skin and eyes or on the dermal sensitisation potential of Biacton®. Owing to the proteinaceous nature of the active agent, Biacton® should be considered a respiratory sensitiser.

[16] Technical dossier/Supplementary information July 2019/Annex II amendment, section II.6.

[redacted]

3.3. Efficacy

3.3.1. Efficacy for chickens for fattening

A total of six studies, including one dose-finding study and a digestibility trial, were provided to support the efficacy of Biacton® for chickens for fattening. [redacted] Since the applicant did not provide indications on the mortality, the FEEDAP Panel has reservations in accepting the validity of the data. In addition, in the statistical analysis of the last two studies the comparison of the mean values does not allow to correct for multiple comparisons. Therefore, no conclusions can be drawn from these studies.

3.3.2. Efficacy for turkeys for fattening

[redacted] due to poor reporting [redacted] no conclusions can be drawn from these studies.

[redacted]

3.3.3 Efficacy for laying hens

[redacted]

[redacted]

Rhodes Island	[redacted]							
Leghorn	[redacted]							

CFU: colony forming unit.

[redacted]

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.

3.3.3.1. Conclusions on efficacy

Due to poor reporting and significant limitations in the data available, the FEEDAP Panel cannot conclude on the efficacy of the additive Biacton® for chickens for fattening, turkeys for fattening and laying hens.

3.4. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation[35] and Good Manufacturing Practice.

4. Conclusions

The active agent fulfils the requirements of the QPS approach to the assessment of safety and no concerns are expected from other components of the additive. Consequently, Biacton® can be presumed safe for the target animals, consumers of products from animals receiving the additive and the environment.

[redacted]

[35] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

In the absence of data, no conclusions can be drawn on the skin/eye irritation or skin sensitisation potential of the additive, but Biacton® should be considered a respiratory sensitiser.

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
04/05/2017	Dossier received by EFSA. Biacton for poultry. Submitted by ChemVet dk A/S
06/06/2017	Reception mandate from the European Commission
18/07/2017	Application validated by EFSA – Start of the scientific assessment
13/09/2017	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: safety for the consumer*
29/09/2017	Reception of supplementary information from the applicant - Scientific assessment re-started
19/10/2017	Comments received from Member States
18/11/2017	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
13/03/2018	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*
13/11/2018	Reception of supplementary information from the applicant - Scientific assessment re-started
20/12/2018	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*
26/02/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
29/01/2020	Reception of spontaneous supplementary information from the applicant
19/03/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. https://doi.org/10.2903/j.efsa.2012.2539

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Abbreviations

AMR	antimicrobial resistance
BIOHAZ	EFSA Panel on Biological Hazards
CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
MIC	minimum inhibitory concentration
PFGE	pulsed field gel electrophoresis
QPS	Qualified Presumption of Safety
WGS	whole genome sequence

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Biacton

In the current application authorisation is sought under Article 10(2) for *Lactobacillus farciminis* (CNCM MA67/4R)[36] under the category/functional group 4(b) 'zootechnical additives'/'gut flora stabilisers', according to Annex I of Regulation (EC) No 1831/2003. Authorisation is sought for the use of the *feed additive* for chickens and turkeys for fattening and laying hens. This *feed additive* is currently authorised by Regulation (EC) No 1876/2006.

According to the Applicant, the *feed additive* contains as active substance *Lactobacillus farciminis* (CNCM MA67/4R. The *feed additive* is to be marketed with a minimum *Lactobacillus farciminis* (CNCM MA67/4R) content of 10^9 Colony Forming Unit (CFU)/g. It is intended to be incorporated through *premixtures* at a minimum content of 5×10^8 CFU/kg *feedingstuffs*.

For the identification of *Lactobacillus farciminis* (CNCM MA67/4R) the Applicant applied partial 16S rDNA gene sequence analysis. The EURL recommends instead for official control Pulsed Field Gel Electrophoresis (PFGE), a generally recognised methodology for genetic identification of bacterial strains.

For the enumeration of *Lactobacillus farciminis* (CNCM MA67/4R) in the *feed additive* and *feedingstuffs,* the Applicant applied an amended French Standard (NF V04-503, 1988). The EURL recommends instead for official control the ring-trial validated spread plate method EN 15787.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761) is not considered necessary.

[36] Now renamed as *Lactobacillus farciminis* CNCM I-3740.