SCIENTIFIC OPINION

efsa JOURNAL

ADOPTED: 22 November 2022

doi: 10.2903/j.efsa.2023.7712

Efficacy of the feed additive consisting of *Bacillus velezensis* NRRL B-67257 (Correlink™ ABS747) as a feed additive for all growing poultry species (Elanco GmbH)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the efficacy of a product consisting of viable spores of *Bacillus velezensis* NRRL B-67257 as a zootechnical additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species. The additive has the tradename Correlink™ ABS747 *Bacillus subtilis* and is not currently authorised in the European Union. It is intended for use in complete feed for the target species at a minimum inclusion level of 1.5×10^8 CFU/kg complete feed. In a previous opinion the FEEDAP Panel could not conclude on the efficacy of the additive for the poultry species due to the potential cross-contamination of the control diets in two of the three studies provided. The applicant has provided supplementary information to exclude this possibility. The new data showed that the gene used as marker in the previous analyses is non-specific of the NRRL B-67257 strain, which precluded the adequate quantification of the active agent in the feeds used in the studies. Moreover, in a second analysis, the active agent could not be isolated from the field excreta samples collected from either from the treated or the control group of one of the formerly submitted efficacy studies. The Panel concluded that the methodology was not able to discriminate between the strain under assessment and the background. Therefore, the FEEDAP Panel was not in the position to conclude on the efficacy of Correlink™ ABS747 for all growing poultry species based on the data newly provided.

Keywords: zootechnical additives, gut flora stabilisers, Correlink™ ABS747, *Bacillus velezensis* NRRL B-67257, poultry species, efficacy

Requestor: European Commission

Question number: EFSA-Q-2022-0233

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Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Acknowledgements: The Panel wishes to thank the following for the support provided to this scientific output: Microbiology WG.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Fašmon Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Prieto M, Anguita M, Pettenati E, Rossi B and Brozzi R, 2023. Scientific Opinion on the efficacy of the feed additive consisting of *Bacillus velezensis* NRRL B-67257 (Correlink™ ABS747) as a feed additive for all growing poultry species (Elanco GmbH). EFSA Journal 2023;21 (1):7712, 7 pp. https://doi.org/10.2903/j.efsa.2023.7712

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

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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 defines the terms of the authorisation by the Commission.

The applicant, Elanco GmbH, is seeking a Community authorisation of *Bacillus subtilis* ABS747 (*Bacillus velezensis* NRRL B-67257) as a feed additive to be used as a gut flora stabilisers for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species. (Table 1).

Table 1: Description of the additive

Category of additive	**Zootechnical additives**
Functional group of additive	Gut flora stabilisers
Description	*Bacillus subtilis* ABS747 (*Bacillus velezensis* NRRL B-67257)
Target animal category	Chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species
Applicant	Elanco GmbH
Type of request	New opinion

On 30 September 2020, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA), in its opinion on the safety and efficacy of the product, could not conclude on the efficacy of *Bacillus subtilis* ABS747 (*Bacillus velezensis* NRRL B-67257) for the target species and regarding the compatibility with monensin, lasalocid salinomycin, narasin, robenidine and maduramycin, due to lack of data.

The Commission gave the possibility to the applicant to submit supplementary information and data in order to complete the assessment and to allow a revision of the EFSA's opinion. The new data have been received on 15 November 2021.

In view of the above, the Commission asks the Authority to deliver a new opinion on *Bacillus subtilis* ABS747 (*Bacillus velezensis* NRRL B-67257) as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species.

1.2. Additional information

The additive under assessment is a preparation containing viable spores of *Bacillus velezensis* NRRL B-67257. It has not been previously authorised in the EU.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a supplementary information[2] to a previous application 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 39 e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] FEED dossier reference: EFSA-Q-2022-00233.
[3] FEED dossier reference: FAD-2019-0074.
[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.

arrangements concerning transparency and confidentiality,[5] a non-confidential version of the supplementary information has been published on Open.EFSA.[6]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *Bacillus velezensis* NRRL B-67257 (Correlink™ ABS747 *Bacillus subtilis*) is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a). Guidance on the characterisation of 3 microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b).

3. Assessment

Correlink™ ABS747 *Bacillus subtilis* (hereafter Correlink™ ABS747) is a preparation of viable spores of *B. velezensis* NRRL B-67257 intended for use as a zootechnical additive (functional group: gut flora stabilisers) in feed for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor growing poultry species at the minimum concentration of 1.5×10^8 CFU/kg complete feed.

In its previous opinion (EFSA FEEDAP Panel, 2020), the FEEDAP concluded that the additive is safe for the target species, consumers and the environment, that it is not irritant to skin and eyes, or a skin sensitiser, but is a respiratory sensitiser. However, the data provided were not sufficient to conclude on the efficacy of the additive for any poultry species. Moreover, the compatibility of *B. velezensis* NRRL B-67257 with diclazuril, decoquinate and halofuginone was established, but not with monensin, salinomycin, narasin, robenidine, maduramicin and lasalocid.

The applicant has provided new information to address the gaps identified in the assessment of the efficacy of the additive which are the subject of this assessment.

3.1. Efficacy

In the former opinion, three field trials conducted in chickens for fattening were submitted to support the efficacy of the additive. However, two of them could not be further considered due to the contamination of the control diets with the additive under assessment. In one study, the total bacilli count in the diets of the control and treated groups were equivalent (i.e. control: 0.7/0.4/0.9 $\times 10^8$ CFU/kg feedingstuffs versus Correlink™ ABS747: 1.2/1.0/0.8 $\times 10^8$ CFU/kg feedingstuffs, in the starter, grower and finisher diets, respectively). The presence of the active agent in all diets was confirmed by analysis using a polymerase chain reaction (PCR) targeting a functional gene of *B. velezensis* NRRL B-67257 [redacted], which the applicant declared to be strain-specific. Therefore, it was inferred that the control diets were contaminated with the additive. Similarly, equivalent total bacilli count in the control and treated diets were found in the second study (i.e., control: 0.8/1.6/1.0 $\times 10^8$ CFU/kg feedingstuffs versus Correlink™ ABS747: 2.8/4.5/1.9 $\times 10^8$ CFU/kg feedingstuffs in the starter, grower and finisher diets, respectively), but the presence of *B. velezensis* NRRL B-67257 could not be confirmed due to the lack of samples. However, considering the similarities between the studies (i.e. both ran in the same trial site and with the same experimental design), and since *B. velezensis* NRRL B-67257 was identified in excreta samples collected from both treatment groups using the same PCR method, the possibility that the control diets of this study were also contaminated with the additive could not be excluded. Therefore, the Panel considered there were insufficient data to allow reaching conclusions on the efficacy of Correlink™ ABS747 for chickens for fattening.

In the current application, the applicant declared that the [redacted] is present not only in the NRRL B-67257 strain, but can also be found in other bacilli and provided some data to support it.[8] To determine the prevalence of the [redacted] among bacilli, [redacted]

[5] Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.
[6] Available at: https://open.efsa.europa.eu/questions/EFSA-Q-2021-00233.
[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.
[8] SIn_Reply_Oct_2021 Correlink ABS747 and Annex IV.3.5.

[redacted]. Therefore, it can be concluded that the [redacted] is non-specific of the NRRL B-67257, and this precludes the adequate quantification of the additive strain in the feeds used in the studies.

Furthermore in the current application, an additional experiment was conducted with excreta samples from one of the above cited trials (study 3) to determine whether *B. velezensis* NRRL B-67257 could be detected after the gastrointestinal (GI) tract transit and to assess the genetic relatedness of strains recovered from the excreta samples, with the final aim of excluding the cross-contamination of control diets.[9] Samples for study 2 were not available, but the applicant declared that the same results would be expected, considering the similarities between the two studies (see above).

[redacted]

The Panel has some doubts on the methodology applied [redacted]

The Correlink™ ABS747 active agent could not be isolated from the field excreta samples collected from the treated (inoculated with the active agent) or control birds. These findings would suggest that either the Correlink™ ABS747 strain was not included in the correct way in the treated feeds, or the strain was not able to survive the chickens' GI tract transit, and/or the analysis was not able to discriminate between the strain under assessment and the background.

3.1.1. Conclusions on efficacy

The data provided do not allow to conclude on the efficacy of Correlink™ ABS747 for all growing poultry species.

4. Conclusions

The FEEDAP Panel is not in the position to conclude on the efficacy of Correlink™ ABS747 for all growing poultry species.

5. Documentation provided to EFSA/Chronology

Date	Event
28/10/2021	Dossier received by EFSA. Correlink™ (*Bacillus subtilis* ABS747) for chickens for fattening, turkeys for fattening, chickens reared for laying, turkeys reared for breeding, minor poultry species. Submitted by Elanco GmbH
24/03/2022	Reception mandate from the European Commission
01/04/2022	Acceptance mandate from the European Commission by EFSA – Start of the scientific assessment

[9] IV.3.3.3 and Supplementary information August 2022/SIn_Reply_July 2022_747, Annex IV.3.3.3.Updated.CONF and Annex_IV_3_3_3_ELA1900342_Fecal PCR_747_Updated_Aug22_CONF.

Date	Event
21/07/2022	Request of supplementary information to the applicant in line with Article 7(3) of Commission Regulation (EC) No 1304/2003 – Scientific assessment suspended. *Issues: efficacy*
08/08/2022	Reception of supplementary information from the applicant – Scientific assessment re-started
22/11/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

CFU	colony-forming unit
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed