

ADOPTED: 4 October 2019

doi: 10.2903/j.efsa.2019.5882

Efficacy of EB15 10 (*Bacillus subtilis* DSM 25841) as a feed additive for weaned piglets and weaned minor porcine species

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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 EB15 10 for weaned piglets and minor porcine species. The additive is a preparation containing viable spores of a strain of *Bacillus subtilis* (DSM 25841). This product is available in two forms, EB15 and EB15 10, which contain the bacterium in concentrations of 1.25×10^9 CFU/g additive and 1.25×10^{10} CFU/g additive, respectively. In a previous opinion, the FEEDAP Panel assessed the safety and the efficacy of the product when used in weaned piglets. The Panel concluded that the active agent fulfils the requirements of the qualified presumption of safety (QPS) approach to the assessment of safety. Consequently, the additive 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 potential respiratory sensitiser. The data provided in the previous assessment to support the efficacy of the additive was not sufficient to conclude on the efficacy of the additive in weaned piglets or minor weaned porcine species. The applicant provided supplementary information to complement the data, including a statistical analysis pooling data from different studies. Based on the newly submitted data, the Panel concluded that the additive has a potential to be efficacious as a zootechnical additive in weaned piglets at a level of 5×10^8 CFU/kg complete feed or in water for drinking at 1.7×10^8 CFU/L. This conclusion was extrapolated to minor porcine species at the same developmental stage.

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Keywords: Zootechnical additive, gut flora stabilisers, efficacy, piglets

Requestor: European Commission

Question Number: EFSA-Q-2019-00217

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Acknowledgements: The Panel wishes to acknowledge the contribution of Rosella Brozzi and Elisa Pettenati to this opinion.

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, Kouba M, Kos Durjava M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R and Anguita M, 2019. Scientific Opinion on the efficacy of EB15 10 (*Bacillus subtilis* DSM 25841) as a feed additive for weaned piglets and weaned minor porcine species. EFSA Journal 2019;17(11):5882, 7 pp. <https://doi.org/10.2903/j.efsa.2019.5882>

ISSN: 1831-4732

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1. Introduction

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

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

The applicant, Chr. Hansen A/S, is seeking a Community authorisation of *Bacillus subtilis* DSM 25841 as a feed additive to be used as a gut flora stabilisers for piglets (weaned) and weaned minor porcine species (Table 1).

Table 1: Description of the substances

Category of additive	Zootechnical additive
Functional group of additive	Gut flora stabilisers
Description	<i>Bacillus subtilis</i> DSM 25841
Target animal category	Piglets (weaned) and weaned minor porcine species
Applicant	Chr. Hansen A/S
Type of request	New opinion

On 20 February 2018, the Panel on Additives and Products or substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion of the product, could not conclude on the safety of *Bacillus subtilis* DSM 25841 in piglets (weaned) and weaned minor porcine species, under the condition of use as proposed by the applicant. After the discussion with the Member States on the Standing Committee, 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 in order to complete the assessment and to allow a revision of Authority's opinion. The new data were received on 24 July 2018.

In view of the above, the Commission asks the Authority to deliver a new opinion on *Bacillus subtilis* DSM 25841 as a feed additive for piglets (weaned) and weaned minor porcine species based on the additional data submitted by the applicant.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information¹ to a previous application on the same product.²

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess efficacy of EB15 10 is in line with the principles laid down in Regulation (EC) No 429/2008³ and the Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012) and the technical guidance on tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).

3. Assessment

The additive is a preparation containing viable spores of a strain of *B. subtilis* (DSM 25841). This product is available in two forms, EB15 and EB15 10, which contain the bacterium in concentrations of 1.25×10^9 CFU/g additive and 1.25×10^{10} CFU/g additive, respectively. In a previous opinion the FEEDAP Panel assessed the safety and the efficacy of the product when used in weaned piglets (EFSA FEEDAP Panel, 2018). The Panel concluded that the active agent fulfils the requirements of the qualified presumption of safety (QPS) approach to the assessment of safety. Consequently, the additive

¹ FEED dossier reference: FAD-2018-0047.

² FEED dossier reference: FAD-2016-0070.

³ 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.

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 potential respiratory sensitiser. The data provided to support the efficacy of the additive was not sufficient to conclude on the efficacy of the additive in weaned piglets or minor weaned porcine species.

The applicant has provided new data to complement the information available supporting the efficacy of the additive in weaned piglets and minor porcine species. The additive is intended to be used as a zootechanical additive in weaned piglets and minor porcine species (functional group: gut flora stabilisers) at a proposed dose of 5×10^8 CFU/kg complete feed or in water for drinking at 1.7×10^8 CFU/L.

3.1. Efficacy for weaned piglets

[REDACTED]

The applicant provided a new efficacy study.

[REDACTED]

[REDACTED]

The applicant provided a statistical analysis in which the data of all the studies were pooled

[REDACTED]

[REDACTED]

[REDACTED] the Panel concludes that the additive, in either form, has a potential to be efficacious as a zootechanical additive in weaned piglets at the recommended level of 5×10^8 CFU/kg complete feed. The conclusions are extended to the use of the additive in water for drinking at 1.7×10^8 CFU/L. These conclusions are extrapolated to minor porcine species in the same developmental stage.

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3.2. 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 Regulation¹² and Good Manufacturing Practice.

[Redacted]

¹² Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 268, 8.2.2005, p. 1.

4. Conclusions

The additive EB15 10 or EB15 (*Bacillus subtilis* DSM 25841) has a potential to be efficacious as a zootechnical additive in weaned piglets and minor porcine species at the recommended level of 5×10^8 CFU/kg complete feed (corresponding to 1.7×10^8 CFU/L drinking water).

Documentation as provided to EFSA/Chronology

Date	Event
23/07/2018	Dossier received by EFSA
12/02/2019	Reception mandate from the European Commission
12/02/2019	Application validated by EFSA – Start of the scientific assessment
30/04/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issue: efficacy</i>
11/06/2019	Clarification teleconference during risk assessment with the applicant according to the “EFSA’s Catalogue of support initiatives during the life-cycle of applications for regulated products”
13/08/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
04/10/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

CFU	colony forming unit
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
QPS	qualified presumption of safety