

ADOPTED: 4 October 2019

doi: 10.2903/j.efsa.2019.5881

## Efficacy of ZM16 10 (*Bacillus amyloliquefaciens* DSM 25840) as a feed additive for weaned piglets and minor porcine species

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Jaume Galobart, Orsolya Holczknecht, Paola Manini, Jordi Tarrés-Call, Fabiola Pizzo and Montserrat Anguita

### 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 ZM16 10 for weaned piglets and minor porcine species. The additive is a preparation containing viable spores of a strain of *Bacillus amyloliquefaciens* (DSM 25840). This product is available in two forms, ZM16 and ZM16 10, which contain the bacterium in concentrations of  $1.25 \times 10^9$  CFU/g additive and  $1.25 \times 10^{10}$  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  $5 \times 10^8$  CFU/kg complete feed or in water for drinking at  $1.7 \times 10^8$  CFU/L. This conclusion was extrapolated to minor porcine species at the same developmental stage.

© 2019 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

**Keywords:** Zootechnical additives, gut flora stabilisers, *Bacillus amyloliquefaciens*, efficacy, piglets

**Requestor:** European Commission

**Question number:** EFSA-Q-2019-00079

**Correspondence:** feedap@efsa.europa.eu

**Panel members:** Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

**Legal notice:** Relevant information or parts of this scientific output have been blackened in accordance with the confidentiality requests formulated by the applicant pending a decision thereon by the European Commission. The full output has been shared with the European Commission, EU Member States and the applicant. The blackening will be subject to review once the decision on the confidentiality requests is adopted by the European Commission.

**Acknowledgements:** The Panel wishes to thank the following for the support provided to this scientific output: Rosella Brozzi and Elisa Pettenati.

**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, Galobart J, Holczknecht O, Manini P, Tarrés-Call J, Pizzo F and Anguita M, 2019. Scientific Opinion on the efficacy of ZM16 10 (*Bacillus amyloliquefaciens* DSM 25840) as a feed additive for weaned piglets and minor porcine species. EFSA Journal 2019;17(11):5881, 7 pp. <https://doi.org/10.2903/j.efsa.2019.5881>

**ISSN:** 1831-4732

© 2019 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs](https://creativecommons.org/licenses/by-nd/4.0/) License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.



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



## Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference as provided by the requestor.....	4
1.2. Additional information.....	4
2. Data and methodologies.....	4
2.1. Data.....	4
2.2. Methodologies.....	4
3. Assessment.....	4
3.1. Efficacy for weaned piglets.....	5
3.2. Post-market monitoring.....	6
4. Conclusion.....	7
Chronology.....	7
References.....	7
Abbreviations.....	7

## 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 amyloliquefaciens* DSM 25840 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

<b>Category of additive</b>	Zootechnical additive
<b>Functional group of additive</b>	Gut flora stabilizer
<b>Description</b>	<i>Bacillus amyloliquefaciens</i> DSM 25840
<b>Target animal category</b>	Piglets (weaned) and weaned minor porcine species
<b>Applicant</b>	Chr. Hansen A/S
<b>Type of request</b>	New opinion

On 21 February 2018, the Panel on Additives and Products or Substances use in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the product, could not conclude on the efficacy of *Bacillus amyloliquefaciens* DSM 25840 in piglets (weaned) and weaned minor porcine species, under the condition of use as proposed by the applicant.

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 have been received on 24 July 2018.

In view of the above, the Commission asks the Authority to deliver a new opinion on *Bacillus amyloliquefaciens* DSM 25840 as a feed additive for piglets (weaned) and weaned minor porcine species based on the additional data submitted by the applicant.

### 1.2. Additional information

The FEEDAP Panel issued an opinion on the safety and efficacy of ZM16 10 (*Bacillus amyloliquefaciens* DSM 25840) as a feed additive for weaned piglets and minor porcine species (EFSA FEEDAP Panel, 2018). In that assessment, the Panel could not conclude on the efficacy of the additive due to insufficient data/information.

## 2. Data and methodologies

### 2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information<sup>1</sup> to a previous application on the same product.<sup>2</sup>

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess efficacy of ZM16 10 is in line with the principles laid down in Regulation (EC) No 429/2008<sup>3</sup> 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. amyloliquefaciens* (DSM 25840). This product is available in two forms, ZM16 and ZM16 10, which contain the bacterium in concentrations

<sup>1</sup> FEED dossier reference: FAD-2018-0046.

<sup>2</sup> FEED dossier reference: FAD-2016-0069.

<sup>3</sup> 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.

of  $1.25 \times 10^9$  CFU/g additive and  $1.25 \times 10^{10}$  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 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 zootechnical additive in weaned piglets and minor porcine species (functional group: gut flora stabilisers) at the proposed level of  $5 \times 10^8$  CFU/kg complete feed or in water for drinking at  $1.7 \times 10^8$  CFU/L.

### 3.1. Efficacy for weaned piglets

[REDACTED]

The applicant provided a new efficacy study.

[REDACTED]

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

[REDACTED]

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

[REDACTED]

[Redacted]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted]

### 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 Regulation<sup>12</sup> and Good Manufacturing Practice.

[Redacted]

<sup>12</sup> 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, 24.9.2003, p. 1.

## 4. Conclusion

The additive ZM16 or ZM16 10 (*Bacillus amyloliquefaciens* DSM 25840) has a potential to be efficacious as a zootechnical additive in weaned piglets and minor porcine species at the recommended level of  $5 \times 10^8$  CFU/kg complete feed or at  $1.7 \times 10^8$  CFU/L drinking water.

## Chronology

Date	Event
23/7/2018	Dossier received by EFSA. ZM16 ( <i>Bacillus amyloliquefaciens</i> DSM 25840) for weaned piglets and minor porcine species. Submitted by Chr. Hansen A/S.
12/2/2019	Reception mandate from the European Commission
12/2/2019	Application validated by EFSA – Start of the scientific assessment
11/3/2016	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>
11/6/2019	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'
13/8/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
4/10/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

## References

- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Technical guidance: Tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. <https://doi.org/10.2903/j.efsa.2011.2175>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance for the preparation of dossiers for zootechnical additives. EFSA Journal 2012;10(1):2536, 19 pp. <https://doi.org/10.2903/j.efsa.2012.2536>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rycken G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Villa RE, Wallace RJ, Wester P, Brozzi R and Saarela M, 2018. Scientific Opinion on the safety and efficacy of ZM16 10 (*Bacillus amyloliquefaciens* DSM 25840) as a feed additive for weaned piglets and minor porcine species. EFSA Journal 2018;16(4):5200, 9 pp. <https://doi.org/10.2903/j.efsa.2018.5200>

## Abbreviations

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