SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 23 January 2019

doi: 10.2903/j.efsa.2019.5612

Safety and efficacy of Bonvital (*Enterococcus faecium*, DSM 7134) as an additive in water for drinking for sows

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Abstract

The additive Bonvital is a preparation of *Enterococcus faecium* authorised in feed for piglets and pigs for fattening, sows, chickens for fattening, chickens reared for laying and minor poultry species. The current authorisation in sows does not include the use of the additive in water for drinking. The additive is intended for use in water for drinking for sows at a minimum level of 2.5×10^8 colony forming unit (CFU)/L. This level is half of that minimum authorised in complete feed (5×10^8 CFU/kg), for the same target animals and would provide essentially the same exposure assuming that water consumption is approximately two- to three fold greater than feed consumption. Consequently, the conclusions on safety and efficacy of the additive when used in feedingstuffs also apply to its use in water for drinking for sows.

Keywords: Bonvital, *Enterococcus faecium*, gut flora stabiliser, use in water, safety, efficacy, exposure

Requestor: European Commission

Question number: EFSA-Q-2018-00647

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Acknowledgements: The Panel wishes to thank the following for the support provided to this scientific output: Rosella Brozzi and Lucilla Gregoretti. The Panel wishes to acknowledge all European competent institutions, Member State bodies and other organisations that provided data for this scientific output.

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, Anguita M, Galobart J, Holczknecht O, Manini P, Tarres-Call J, Pettenati E and Pizzo F, 2019. Scientific Opinion on the safety and efficacy of Bonvital (*Enterococcus faecium*, DSM 7134) as an additive in water for drinking for sows. EFSA Journal 2019;17(2):5612, 7 pp. https://doi.org/10.2903/j.efsa.2019.5612

ISSN: 1831-4732

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

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Lactosan GmbH & Co. KG[2] for authorisation of the product Bonvital (*Enterococcus faecium* DSM 7134), when used as an additive for sows (category: zootechnical additive; functional group: gut flora stabiliser) in water for drinking.

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 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 13 November 2018.

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 Bonvital (*Enterococcus faecium* DSM 7134), when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The additive Bonvital is a preparation of *Enterococcus faecium* (DSM 7134), currently authorised for use in feed for piglets and pigs for fattening, sows, chickens for fattening, chickens reared for laying and minor poultry species. The current authorisation in sows does not include the use of the additive in water for drinking.

The safety and efficacy of Bonvital when used as a feed additive for piglets, pigs for fattening, sows, chickens for fattening, chickens reared for lying and minor avian species was previously assessed by EFSA (EFSA, 2004, 2007a,b, 2009a,b; EFSA FEEDAP Panel, 2013, 2014).

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[3] in support of the authorisation request for the use of Bonvital (*Enterococcus faecium* DSM 7134) as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the active agent in animal feed are valid and applicable for the current application.[4]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Bonvital (*Enterococcus faecium* DSM 7134) is in line with the principles laid down in Regulation (EC) No 429/2008[5] and the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012a) and Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017).

[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] Lactosan GmbH & Co. KG, Industriestrasse West 5, Kapfenberg (Austria).
[3] FEED dossier reference: FAD-2018-0058.
[4] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2008-0007.pdf
[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.

3. Assessment

Bonvital is a preparation of *Enterococcus faecium* (DSM 7134) and is currently authorised for use in complete feed for sows at 5×10^8 colony forming unit (CFU)/kg. The applicant now seeks the authorisation for Bonvital as a zootechnical feed additive (functional group: gut microflora stabiliser), to be used in water for drinking for sows.

3.1. Characterisation

The characterisation of the additive and the active agent, the manufacturing process and the technological properties of the additive have been reviewed by the FEEDAP Panel in the previous assessment (EFSA FEEDAP Panel, 2013). For the purpose of the present assessment, updated data have been submitted on composition, possible presence of impurities, stability and homogeneity of the additive when used in water.

3.1.1. Characterisation of *Enterococcus faecium* DSM 7134/Bonvital

Bonvital is a preparation of *Enterococcus faecium* DSM 7134. It is produced by fermentation in a culture medium containing dextrose, whey powder, yeast extract and mineral salts.

The additive is present on the market in two formulations: powder and granules (micro-encapsulated). The current application covers the powder formulation only.

Bonvital powder is a mixture of *Enterococcus faecium* DSM 7134 (3%) with sweet whey powder (96%), lactose, sodium glutamate, sodium ascorbate, sodium lactate and mannose as excipients with a minimum guaranteed concentration of 1×10^{10} CFU/g product. Bonvital powder had a mean particle diameter of 80.1 μm, with approximately 10% of particles of 10 μm diameter or less, and a dusting potential of 1.15 g/m^3 as determined by the Stauber–Heubach method (EFSA FEEDAP Panel, 2013).

The applicant provided results on ten samples of a single production batch of Bonvital powder. The range of the finished product varies between 1.15×10^{10} and 1.36×10^{10} CFU/g.[6]

The results demonstrate that the product is manufactured in accordance with the current specifications.

Additionally, the applicant provided results on possible presence of impurities of six batches of the product. Results were provided for Enterobacteriaceae (< 1,000 CFU/g), yeast and moulds (< 1,000 CFU/g) and *Salmonella* (absence in 25 g),[7] aflatoxin (< LOD), deoxynivalenol (< LOD), zearalenone (< LOD),[8] arsenic (< LOD), lead (< LOD), cadmium (< LOD) and mercury (< LOD).[9]

3.1.2. Stability and homogeneity

Analytical data on the stability in water of three batches of Bonvital have been tested. A total of 0.05 g of Bonvital was suspended in 1 L of drinking water at 20°C and stored at a constant temperature (20°C). After a short stirring time, bacterial counts were measured in 10 subsamples after 0, 24 and 48 h. No losses (< 0.5 log) were observed in bacterial count after 48 h at 20°C.[10]

The capacity of the additive to distribute homogeneously in water for drinking was evaluated in the stability study (described above) and the coefficient of variation (CV) was approximately 7%.

3.1.3. Conditions of use

The additive is intended to be used as a powder at a minimum level of 2.5×10^8 CFU/L water for sows. This level is half of that minimum authorised in complete feed (5×10^8 CFU/kg) for the same target animals and would provide essentially the same exposure assuming that water consumption is approximately two- to three-fold greater than feed consumption.

3.1.4. Safety and efficacy

The applicant did not provide data in support of the safety nor of the efficacy of the additive when used in water for drinking for sows.

[6] Technical dossier/Section II/Annex II.1-7.
[7] Technical dossier/Section II/Annex II.1-9.
[8] Technical dossier/Section II/Annex II.1-10.
[9] Technical dossier/Section II/Annex II.1-11.
[10] Technical dossier/Section II/Annex II.4-9.

The safety for the target species, consumers of products derived from animals fed the additive, users, the environment and the efficacy of the additive have been considered in the context of the previous opinions (EFSA, 2007a,b, 2009a,b; EFSA FEEDAP Panel, 2012b, 2013, 2014). In these assessments, it was concluded that the use of Bonvital under the conditions proposed is considered safe for the target species, the consumer and the environment and should be considered to have the potential to be a skin/respiratory sensitiser and treated accordingly.

Three efficacy studies, each performed over two complete reproductive cycles, demonstrated significant effects of Bonvital at the minimum recommended level (5×10^8 CFU/kg feed) in sows: weight gain of the litter, body weight of sows and piglet number and live weight at weaning (EFSA FEEDAP Panel, 2014).

The level proposed for use in water for drinking would provide essentially the same exposure as the level currently authorised for use in feedingstuffs. Consequently, the conclusions on safety and efficacy of the additive when used in feedingstuffs also apply to use in water for drinking for sows.

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[11] and Good Manufacturing Practice.

4. Conclusions

The use of Bonvital in water for drinking for sows is considered safe for the target species, consumers and the environment. It is considered a skin and respiratory sensitiser. The use of Bonvital at a minimum level of 2.5×10^8 CFU/L in water for drinking is considered efficacious in sows.

Documentation provided to EFSA

1) Bonvital for use in water for drinking for sows. August 2018. Submitted by Lactosan GmbH & Co. KG.
2) Comments from Member States.

Chronology

Date	Event
8/8/2018	Dossier received by EFSA
27/8/2018	Reception mandate from the European Commission
13/11/2018	Application validated by EFSA – Start of the scientific assessment
11/1/2019	Comments received from Member States (FAD-2018-0058)
23/1/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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EFSA (European Food Safety Authority), 2007a. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on the safety and efficacy of product Bonvital, a preparation of Enterococcus faecium, as a feed additive for piglets and pigs for fattening in accordance with Regulation (EC) No 1831/2003. EFSA Journal 2007;5(1):440, 9 pp. https://doi.org/10.2903/j.efsa.2007.440

EFSA (European Food Safety Authority), 2007b. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on the safety and efficacy of product Bonvital, a preparation of Enterococcus faecium, as a feed additive for sows in accordance with Regulation (EC) No 1831/2003. EFSA Journal 2007;5(7):521, 8 pp. https://doi.org/10.2903/j.efsa.2007.521

[11] 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.

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EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2014. Scientific Opinion on the safety and efficacy of Bonvital (*Enterococcus faecium*) as a feed additive for sows. EFSA Journal 2014;12(2):3565, 9 pp. https://doi.org/10.2903/j.efsa.2014.3565

EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2017. Guidance on the identity, characterisation and conditions of use of feed additives. EFSA Journal 2017;15(10):5023, 12 pp. https://doi.org/10.2903/j.efsa.2017.5023

Abbreviations

CFU	colony forming unit
CV	coefficient of variation
EURL	European Union Reference Laboratory
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed
LOD	limit of detection