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Assessment of the feed additive consisting of *Enterococcus faecium* DSM 7134 (Bonvital®) for chickens for fattening for the renewal of its authorisation (Lactosan GmbH & Co. KG)

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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 assessment of the application for renewal of authorisation of the additive consisting of *Enterococcus faecium* DSM 7134 (trade name: Bonvital®) as a zootechnical additive (gut flora stabiliser) for chickens for fattening. The additive is produced in powder and granulate (microencapsulated) forms. The applicant has provided data demonstrating that the additive currently in the market complies with the conditions of authorisation. The FEEDAP Panel confirms that the use of Bonvital® under the current authorised conditions of use is safe for the target species, the consumers and the environment. Bonvital® is not irritant to skin and eyes but should be considered a potential skin sensitiser and a respiratory sensitiser. There is no need to assess the efficacy of Bonvital® in the context of the renewal of the authorisation. The FEEDAP Panel reiterates its previous conclusions that *E. faecium* DSM 7134 is compatible with the coccidiostats robenidine hydrochloride, maduramicin ammonium, diclazuril, decoquinate, halofuginone hydrobromide, monensin sodium and lasalocid A sodium.

Keywords: zootechnical additive, gut flora stabiliser, Bonvital®, *Enterococcus faecium* DSM7134, renewal, chickens for fattening

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Question number: EFSA-Q-2019-00741

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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 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from the company Lactosan GmbH & Co. KG[2] for renewal of the feed additive consisting of *Enterococcus faecium* DSM 7134 (Bonvital®), when used as a feed additive for chickens for fattening (category: zootechnical additive; functional group: gut flora stabiliser).

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 14(1) (renewal of the authorisation). EFSA received directly from the applicant the technical dossier in support of this application.[3] The particulars and documents in support of the application were considered valid by EFSA as of 06 January 2020.

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

1.2. Additional information

The subject of the assessment is a preparation of *E. faecium* DSM 7134.

EFSA has issued several opinions on the safety and efficacy of the additive for different target species: dogs (EFSA, 2009b), chickens for fattening (EFSA, 2004, 2009a; EFSA FEEDAP Panel, 2010), chickens reared for laying and minor avian species (EFSA FEEDAP Panel, 2013a), piglets and pigs for fattening (EFSA, 2007a), piglets (weaned) and pigs for fattening (EFSA FEEDAP Panel, 2019b) and sows (EFSA, 2007b; EFSA FEEDAP Panel, 2014, 2019a).

Bonvital® is currently authorised in feed for chickens for fattening,[4] chickens reared for laying and minor poultry species other than those used for laying,[5] piglets (weaned) and pigs for fattening,[6] sows (entire reproductive cycle)[7] and in water for drinking for sows (4b1841[8]).

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[9] in support of the authorisation request for the use of the product consisting of *E. faecium* DSM 7134 (Bonvital®) as a feed additive for chickens for fattening.

[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, 8605 Kapfenberg, Austria.
[3] EFSA Dossier reference: FAD-2019-0064.
[4] Commission Regulation (EU) No 998/2010 of 5 November 2010 concerning the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens for fattening (holder of the authorisation Lactosan GmbH & Co KG). OJ L 290, 6.11.2010, p. 22.
[5] Commission Implementing Regulation (EU) No 775/2013 of 12 August 2013 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for chickens reared for laying and minor poultry species other than those used for laying (holder of authorisation Lactosan GmbH & Co KG). OJ L 170, 13.8.2013, p. 32.
[6] Commission Implementing Regulation (EU) No 2020/159 of 5 February 2020 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive for piglets (weaned) and pigs for fattening. OJ L 34, 6.2.2020, p.22.
[7] Commission Implementing Regulation (EU) No 1083/2014 of 15 October 2014 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive for sows. OJ L 298, 16.10.2014, p. 5.
[8] Commission Implementing Regulation (EU) No 2019/1315 of 2 August 2019 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive (in water for drinking) for sows (holder of authorisation Lactosan GmbH & Co) OJ L 205, 5.8.2019, p. 7.
[9] FEED dossier reference: FAD-2019-0064.

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.[10]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Bonvital® is in line with the principles laid down in Regulation (EC) No 429/2008[11] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013b) and Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018).

3. Assessment

The subject of the assessment is a preparation of viable cells of *Enterococcus faecium* DSM 7134 with trade name Bonvital®. The current assessment is performed in the context of the renewal of the authorisation for use as a zootechnical additive (functional group: gut flora stabiliser) in feed for chickens for fattening. It will be hereafter referred to as Bonvital®.

3.1. Characterisation

3.1.1. Characterisation of the additive

Bonvital® is currently authorised and marketed in two forms[12]:

- Bonvital® powder: composed of [redacted] (CFU)/g additive.
- Bonvital® granules: [redacted] CFU/g additive.

The applicant declared that no changes in the manufacturing process[13] or composition of the two forms of the additive have been introduced since the previous authorisation.

Compliance with the specifications set in the authorisation was confirmed by analysis of three recent batches of each form. The mean *E. faecium* count of the powder form was 1.3×10^{10} CFU/g (range $1.2–1.4 \times 10^{10}$ CFU/g) and that of the granular form was 1.3×10^{10} CFU/g (range $1.3–1.4 \times 10^{10}$ CFU/g).[14]

Specifications for microbiological contamination include Enterobacteriaceae ($< 10^3$ CFU/g), yeast and filamentous fungi ($< 10^3$ CFU/g) and *Salmonella* spp. (absent in 25 g). Analysis in three batches of each form of the additive confirmed compliance with these limits.[15] The chemical purity was also confirmed by the analysis of three recent batches of each marketed form. The results showed values bellow the respective limit of quantification[16] for mycotoxins (aflatoxins B1, B2, G1 and G2, deoxynivalenol and zearalenone),[17] arsenic and heavy metals (lead, cadmium and mercury), except for one batch that showed 0.40 mg As/kg additive and another one that showed 0.18 mg Pb/kg additive.[18]

[10] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2008-0007.pdf
[11] 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.
[12] Technical Dossier/Section II.
[13] Technical Dossier/Section II/Annex_II.3.1.
[14] Technical Dossier/Section II/Annex II.1.9.
[15] Technical Dossier/Section II/Annex_1.12.
[16] Limit of quantification (LOQ): yeast and filamentous fungi 1000 CFU/g, Enterobacteriaceae 1000 CFU/g, *Salmonella* spp. no detection in 25 g, aflatoxin B1 0.03 μg/kg, aflatoxin B2 0.03 μg/kg, aflatoxin G1 0.03 μg/kg, aflatoxin G2 0.03 μg/kg, deoxynivalenol 10 μg/kg, zearelenone 5 μg/kg, arsenic 0.156 mg/kg, lead 0.141 mg/kg, cadmium 0.064 mg/kg and mercury 0.001 mg/kg.
[17] Technical Dossier/Section II/Annex_1.13.
[18] Technical Dossier/Section II/Annex_1.14.

No new data have been provided regarding the physico-chemical properties or stability of the additive. Since no changes have been introduced in the additive or its manufacturing process, the data described in previous opinions still apply.

3.1.2. Characterisation of the active agent

The active agent was isolated from plant material (grass) and is deposited at the Deutsche Sammlung von Mikroorganismen und Zellkulturen (DSMZ) with the accession number 7134.[19] The strain is not genetically modified.

Taxonomic identification of the active agent as *E. faecium* was established by bioinformatic analysis of the whole genome sequence (WGS).[20] [redacted].[21]

The susceptibility of the active agent to the battery of antibiotics recommended by the FEEDAP Panel was tested [redacted]. Therefore, the strain is considered susceptible to the relevant antibiotics.

[redacted]

3.1.3. Conditions of use

The additive is currently authorised for use in feed for chickens for fattening at a minimum inclusion level of 5×10^8 CFU/kg complete feed.

The authorisation[4] under other provisions foresees:

[19] Technical Dossier/Section II/Annex_2.1.
[20] Technical Dossier/Supplementary information December 2020/Annex 1.
[21] Technical Dossier/Supplementary information July 2020/Annex_1_7134_.
[22] Technical Dossier/Supplementary information July 2020/Annex 2.
[23] Technical Dossier/Supplementary information July 2020/Annex 3.
[24] Technical Dossier/Supplementary information December 2020/Annex 2; Annex 3; Annex 4 and Annex 5.
[25] Technical dossier/Supplementary information July 2020/Annex 4.

- In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
- The use is permitted in feed containing the authorised coccidiostats: diclazuril, halofuginone hydrobromide, robenidine hydrochloride, decoquinate, lasalocid A sodium, maduramicin ammonium or monensin sodium.

In the former application/opinion the applicant proposed the same minimum inclusion level of 5×10^8 CFU/kg complete feed and a maximum inclusion level of 2×10^9 CFU/kg complete feed. This maximum inclusion level was disregarded in the concerned authorisation. The applicant is proposing to maintain the same conditions of use proposed in the former application.

3.2. Safety

The active agent has been identified as *E. faecium*. The metabolic end products of the species are typical of lactic acid bacteria and do not raise concerns. *E. faecium* is not a recognised pathogen for chickens. This was confirmed in a tolerance study where zootechnical performance of chickens for fattening was not adversely affected by the supplementation at 100 times the maximum recommended inclusion level of Bonvital® (EFSA FEEDAP Panel, 2010). Moreover, *E. faecium* DSM 7134 lacks the marker genes associated with human clinical isolates and is susceptible to relevant antibiotics. Therefore, the use of *E. faecium* DSM 7134 in animal nutrition is not expected to raise concerns for the target animals or consumers of animal products. Since neither the active agent nor the other components of the additive give rise to concerns, the FEEDAP Panel considers the use of Bonvital® safe for the target animals and consumers.

In a previous opinion, Bonvital® was found to be not irritant to skin and eyes, but a potential skin sensitiser and a respiratory sensitiser (EFSA FEEDAP Panel, 2013a). In the same opinion, the Panel concluded that Bonvital® is safe for the environment.

A literature search covering the period from 2006 to 2017 was carried out by the applicant in a previous dossier underpinning the request for the renewal of the authorisation of Bonvital® for pigs for fattening and piglets[26]; this search did not retrieve any scientific paper which could have led to a safety concern. For the current assessment, in order to confirm that the additive remains safe for target species, consumers, users and environment under the authorised conditions of use, the applicant provided the results of an additional literature search covering a period of ten years (January 2009–July 2019). Nine databases (Agricola, Agris, Basenet, Google Scholar, Ingenta, PMC hubmed, PubMed, ScienceDirect and World Cat Library), covering interdisciplinary and specific scientific areas, were interrogated. The search terms included references to the additive, active agent, safety for humans, target species and the environment. In total, 15 papers were identified as potentially relevant. All these 15 papers were checked for data referring to the safety of Bonvital/*Enterococcus faecium* DSM 7134. Thereof eight publications were EFSA Opinions on *Enterococcus faecium* DSM 7134 and the remaining seven papers concerned only efficacy trials. None of the scientific publications finally considered reported safety concerns with the additive under assessment.[27]

3.2.1. Conclusions on safety

Based on the above and the fact that the manufacturing process of the additive, its composition and the conditions of use for chickens for fattening have not been modified, the FEEDAP Panel considers that there is no evidence to reconsider the conclusions reached in previous assessments. The Panel concludes that Bonvital® (*E. faecium* DSM 7134) remains safe for the target species, for the consumer of products derived from animals fed Bonvital® and the environment under the authorised conditions of use. Bonvital® is not irritant to skin and eyes, but it should be considered a potential skin sensitiser and a respiratory sensitiser. The maximum inclusion level proposed is not expected to affect these conclusions.

3.3. Efficacy for chickens for fattening

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy

[26] Technical Dossier/Section III/Annex III-III.
[27] Technical Dossier/Section III.IV.

of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

The compatibility of *E. faecium* DSM 7134 with the coccidiostats robenidine hydrochloride, maduramicin ammonium, diclazuril, decoquinate, halofuginone hydrobromide, monensin sodium and lasalocid A sodium has been previously demonstrated (EFSA, 2009a,b).[28] No new information has been provided that would lead the Panel to revise the previous assessment.

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[29] and Good Manufacturing Practice.

4. Conclusions

The applicant has provided evidence demonstrating that the additive currently in the market complies with the conditions of authorisation.

The FEEDAP Panel concludes that the use of Bonvital® under the current authorised conditions of use remains safe for chickens for fattening, consumers and the environment. Bonvital® is not irritant to skin and eyes, but it should be considered a potential skin sensitiser and a respiratory sensitiser. The maximum inclusion level proposed is not expected to affect these conclusions.

There is no need to assess the efficacy of Bonvital® in the context of the renewal of the authorisation.

The FEEDAP Panel reiterates its previous conclusions that *E. faecium* DSM 7134 is compatible with the coccidiostats robenidine hydrochloride, maduramicin ammonium, diclazuril, decoquinate, halofuginone hydrobromide, monensin sodium and lasalocid A sodium.

5. Documentation as provided to EFSA/Chronology

Date	Event
14/10/2019	Dossier received by EFSA. Request for re-authorization of Bonvital® in the animal category "Chickens for fattening". Submitted by Lactosan GmbH & Co. KG.
13/11/2019	Reception mandate from the European Commission
06/01/2020	Application validated by EFSA – Start of the scientific assessment
10/02/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: characterisation of the additive
07/04/2020	Reception comments from Member States
02/07/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
01/10/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: characterisation of the additive
01/12/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
27/01/2021	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

[28] Technical Dossier/Section II/Annex 4.13.

[29] 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.

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

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EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2013a. Scientific Opinion on the safety and efficacy of Bonvital (*Enterococcus faecium*) for chickens reared for laying and minor avian species. EFSA Journal 2013;11(4):3167, 10 pp. https://doi.org/10.2903/j.efsa.2013.3167

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Abbreviations

CFU	colony forming unit
DSMZ	Deutsche Sammlung von Mikroorganismen und Zellkulturen
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
LOD	limit of detection
MIC	minimum inhibitory concentration
WGS	whole genome sequence