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SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of Bonvital (*Enterococcus faecium*) as a feed additive for sows[1]

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Bonvital is a preparation of a strain of *Enterococcus faecium* authorised for piglets, pigs for fattening, sows, chickens for fattening, chickens reared for laying and minor poultry species. EFSA was requested to assess the safety and efficacy of Bonvital when used with sows throughout the complete reproductive cycle at the dose of 5×10^8 CFU/kg feed. The safety for the target species, consumers of products derived from animals fed the additive, users and the environment has been considered in the context of the previous opinions. The FEEDAP Panel is not aware of any information that would lead it to revise these conclusions. Consequently, the FEEDAP Panel has considered only the efficacy of Bonvital for sows. The results of three studies each performed over two complete reproductive cycles showed that Bonvital, at the minimum recommended dose of 5×10^8 CFU/kg feed, has the potential to increase litter weight gain or maintain sow condition. Based on these results, the FEEDAP Panel concludes that the data provided support the extension of use of the additive to the entire reproductive cycle.

KEY WORDS

zootechnical additive, gut flora stabiliser, Bonvital, *Enterococcus faecium*, sows, efficacy

[1] On request from the European Commission, Question No EFSA-Q-2013-00635, adopted on 29 January 2014.

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SUMMARY

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 safety and efficacy of Bonvital at the minimum recommended dose of 5×10^8 CFU/kg feed in sows.

The additive Bonvital is a preparation of a strain of *Enterococcus faecium*. This product is authorised for use in piglets, pigs for fattening, sows, chickens for fattening, chickens reared for laying and minor poultry species. The current authorisation of Bonvital for use with sows (zootechnical additive, functional group: gut flora stabiliser) is limited to the period "from day 90 of pregnancy to the end of lactation". The applicant is requesting the extension of use to the entire reproductive cycle.

The safety for the target species, consumers of products derived from animals fed the additive, users and the environment has been considered in the context of the previous opinions. The FEEDAP Panel is not aware of any information that would lead it to revise these conclusions. Consequently, in the present opinion, the FEEDAP Panel has considered only the efficacy of Bonvital for sows.

The results of three studies each performed over two complete reproductive cycles showed that Bonvital, at the minimum recommended dose of 5×10^8 CFU/kg feed, has the potential to increase litter weight gain or maintain sow condition. Based on these results, the FEEDAP Panel concludes that the data provided support the extension of use of the additive to the entire reproductive cycle.

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BACKGROUND

Regulation (EC) No 1831/2003[4] 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 the company Lactosan GmbH & Co. KG[5] for authorisation of the product Bonvital, *Enterococcus faecium* DSM 7134, when used as a feed additive for sows (category: Zootechnical additives; functional group: Gut flora stabilisers) under the conditions mentioned in Table 1.

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). EFSA received directly from the applicant the technical dossier in support of this application.[6] According to Article 8 of that Regulation, 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. The particulars and documents in support of the application were considered valid by EFSA as of 30 September 2013.

The additive Bonvital is a preparation of *Enterococcus faecium* (DSM 7134). This product is authorised for use in piglets and pigs for fattening,[7] sows,[8] chickens for fattening,[9] chickens reared for laying and minor poultry species.[10] The same strain is also authorised in combination with *Lactobacillus rhamnosus* (DSM 7133) under a different trade name for calves for rearing[11] and piglets.[12]

The Scientific Committee on Animal Nutrition (SCAN) issued an opinion on the safety for pigs for fattening and calves, the consumer, user and environment of a microbial product containing *Enterococcus faecium* (DSM 7134) and *Lactobacillus rhamnosus* (DSM 7133) (EC, 1997, updated 2003) and another opinion on the safety of *Enterococcus faecium* (DSM 7134) for piglets, pigs for fattening and sows (EC, 2003). EFSA published an opinion on the safety of Bonvital (Provita E) for chickens for fattening (EFSA, 2004), an opinion on the safety and efficacy for piglets and pigs for fattening (EFSA, 2007a), an opinion on the safety and efficacy for sows (EFSA, 2007b), and two opinions on Bonvital when used as a feed additive in chickens for fattening (EFSA, 2009; EFSA FEEDAP Panel, 2010). Another opinion on the safety and efficacy of Bonvital (*Enterococcus faecium*) for chickens reared for laying and minor avian species was published in 2013 (EFSA

[4] 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.
[5] Lactosan GmbH & Co.Kg, Industriestrasse West 5, 8605 Kapfenberg, Austria.
[6] EFSA Dossier reference: FAD-2013-0023.
[7] Commission Regulation (EC) No 538/2007 of 15 May 2007 concerning the authorisation of a new use of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive. OJ L 128, 16.5.2007, p. 16.
[8] Commission Regulation (EC) No 1521/2007 of 19 December 2007 concerning the authorisation of a new use of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive. OJ L 335, 20.12.2007, p. 24.
[9] 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.
[10] 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 217, 13.8.2013, p. 32.
[11] Commission Implementing Regulation (EU) No 1101/2013 of 6 November 2013 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133 as a feed additive for calves for rearing and amending Regulation (EC) No 1288/2004 (holder of authorisation Lactosan GmbH & CoKG). OJ L 296, 7.11.2013, p. 1.
[12] Commission Regulation (EC) No 2148/2004 of 16 December 2004 concerning the permanent and provisional authorisations of certain additives and the authorisation of new uses of an additive already authorised in feedingstuffs. OJ L 370, 14.12.2004, p. 24.

FEEDAP Panel, 2013a). The most EFSA recent opinion on *Enterococcus faecium* (DSM 7134) and *Lactobacillus rhamnosus* (DSM 7133) for calves for rearing was adopted by the FEEDAP Panel in March 2013 (EFSA FEEDAP Panel, 2013b)

TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall 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 the efficacy of the Bonvital (*Enterococcus faecium*), when used under the conditions described in Table 1.

Table 1: Description and conditions of use of the additive as proposed by the applicant

Additive	*Enterococcus faecium* DSM 7134
Registration number/EC No/No	4b1841
Category of additive	4 (zootechnical additive)
Functional group of additive	b (gut flora stabiliser)

Description			
Composition, description	Chemical formula	Purity criteria	Method of analysis
Preparation of *Enterococcus faecium* containing a minimum content of: Powder: 1 x 10^{10} CFU/g additive Granules (micro-encapsulated): 1 x 10^{10} CFU/g additive			Quantification of *Enterococcus faecium* according ISO 15788:2009

Trade name	Bonvital
Name of the holder of authorisation	Lactosan GmbH & Co.Kg

Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period
		CFU/kg of complete feedingstuffs		
Sows	-	5 x 10^{8}	-	n.a.

Other provisions and additional requirements for the labelling	
Specific conditions or restrictions for use	n.a.
Specific conditions or restrictions for handling	The directions for use must indicate storage temperature, shelf life
Post-market monitoring	Lactosan GmbH & Co.Kg will conduct post-market monitoring in compliance with EU law on feed hygiene, namely by use of HACCP and treaceability systems, and formal monitoring of customer feedback through product or service complaints.
Specific conditions for use in complementary feedingstuffs	The directions for use must indicate pelleting stability both of the additive and the premixure

Maximum Residue Limit (MRL)			
Marker residue	Species or category of animal	Target tissue(s) or food products	Maximum content in tissues
n.a.	n.a.	n.a.	n.a.

ASSESSMENT

1. Introduction

The additive Bonvital is a preparation of *Enterococcus faecium* (DSM 7134). This product is authorised for use in piglets, pigs for fattening, sows, chickens for fattening, chickens reared for laying and minor poultry species. The same *E. faecium* strain in combination with *Lactobacillus rhamnosus* (DSM 7133) is also authorised for calves for rearing and piglets.

The current authorisation of Bonvital for use with sows (zootechnical additive, functional group: gut flora stabiliser) is limited to the period "from day 90 of pregnancy to the end of lactation". The applicant is requesting the extension of use to the entire reproductive cycle.

The safety for the target species, consumers of products derived from animals fed the additive, users and the environment has been considered in the context of the previous opinions (EFSA, 2007b, 2009; EFSA FEEDAP Panel, 2013a). The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) is not aware of any information that would lead it to revise these conclusions. Consequently, the FEEDAP Panel has considered only the efficacy of Bonvital for sows.

1.1. Conditions of use

The product is intended for use in feed for sows at a minimum dose of 5×10^8 CFU/kg of complete feedingstuff for the entire reproductive cycle.

1.2. Evaluation of the analytical methods by the European Union Reference Laboratory (EURL)

The EURL considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[13]

2. Efficacy for sows

Three studies with Bonvital were made covering the entire reproductive cycle. Two of these studies were already considered with a positive outcome in the previous opinion (EFSA, 2007b) and are summarised below. The third one is a new study.

The first study was performed on 290 sows over two complete reproductive cycles from mating to the following service.[14] Sows were evenly assigned to two groups: a control group and a group supplemented with the minimum recommended dose of Bonvital (5×10^8 CFU/kg feed, confirmed by analysis). After farrowing, litter sizes within each group were equalised by moving some piglets to other sows. Each litter was weighed at birth, after cross-fostering and at weaning (after a suckling period of about 21 days). In addition, the number of piglets born (alive or stillborn), the number of weaned piglets and piglet mortality during the suckling period were recorded. Data were subjected to analysis of variance (ANOVA).

Supplementation of Bonvital at the minimum recommended dose significantly ($P < 0.05$) improved the weight gain of the litter in the second cycle (41.2 kg vs. 43.7 kg) and over both reproductive cycles (41.5 kg vs. 43.0 kg). Moreover, in the second reproductive cycle, the daily weight gain of piglets during the suckling period was significantly improved (222.8 g/day vs. 237.6 g/day).

The second efficacy study was conducted on 20 sows to assess the efficacy of Bonvital on reproduction performances over two complete reproductive cycles, from mating to the subsequent

[13] The full report is available on the EURL website: http://irmm.jrc.ec.europa.eu/SiteCollectionDocuments/FinRep-FAD-2008-0007.pdf
[14] Technical dossier/Section IV/Annex IV-2.

service.[15] The animals were equally divided into two groups: a control group and a treated group fed with Bonvital at the minimum recommended dose (5×10^8 CFU/kg feed, confirmed by analysis). The sows were weighed on arrival, at four-weekly intervals and after farrowing at weekly intervals. The piglets were weighed individually at weekly intervals. In addition, milk composition was analysed on day 14 of lactation. Data were analysed using ANOVA.

Bonvital supplementation at the minimum recommended dose produced a small but significant ($P < 0.05$) reduction in the body weight losses (by approximately 5 kg) of lactating sows in both reproductive cycles. Milk fat was increased and lactose concentration was reduced by Bonvital supplementation during the first cycle, but were unaffected during the second cycle. The other parameters were not significantly affected by the treatment.

The most recent study was conducted with 150 sows to assess the efficacy of Bonvital on reproduction performances over two complete reproductive cycles, from mating to the following service.[16] Piglets were weaned after a suckling period of about 21 days. Sows with adjusted litter numbers were allocated to two experimental groups: a control group and a treated group fed with Bonvital at the minimum recommended dose (5×10^8 CFU/kg feed, confirmed by analysis). After artificial insemination, the sows of both sections were kept from day 1 to 108 of pregnancy in individual sow feeding pens with straw bedding using two compartments for the trial groups. From day 109 of pregnancy onwards sows of both sections were transferred to farrowing stables with straw bedding and 75 pens each. Separate rations were assembled for each production phase. Both rations were barley-based mixtures.

The measured parameters included live weight of sows (before farrowing and at weaning at day 21), piglets per litter at day 21, live weight of piglets at day 21, litter weight at day 21, litter weight gain from day 1 to 21. A statistical analysis including testing on normality, homogeneity and analysis of variance considering the factors “group”, “farrowing group” and “cycle” was performed.

The number of piglets at weaning over both cycles was significantly higher in the Bonvital group than in the control group ($P < 0.05$, 11.5 vs. 11.7). The use of Bonvital led to significantly higher live weights of piglets at the end of the lactation period accompanied by a significantly higher weight gain in each reproductive cycle and in the combined analysis over the whole trial period ($P < 0.05$, 5.3 kg vs. 5.5 kg). The same significant effects were shown for the litter weight ($P < 0.05$, 60.4 kg vs. 64.6 kg) and the litter weight gain ($P < 0.05$, 44.9 kg vs. 48.2 kg).

CONCLUSION

Three efficacy studies, each performed over two complete reproductive cycles, demonstrated significant effects of Bonvital at the minimum recommended dose (5×10^8 CFU/kg feed) in sows: weight gain of the litter (trial 1, trial 3), body weight of sows (trial 2) and piglet number and live weight at weaning (trial 3).

Based on these results, the FEEDAP Panel concludes that the data provided support the extension of use of the additive to the entire reproductive cycle of sows.

3. 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[17] and Good Manufacturing Practice.

[15] Technical dossier /Section IV/Annexes IV-1.
[16] Technical dossier /Section IV/Annexes IV-3.
[17] 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.

DOCUMENTATION PROVIDED TO EFSA

1. Bonvital for sows. June 2013. Submitted by Lactosan GmbH & Co. KG.

2. Comments from Member States received through the ScienceNet.

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EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2013b. Scientific Opinion on the safety and efficacy of Provita LE (*Enterococcus faecium* and *Lactobacillus rhamnosus*) as a feed additive for calves for rearing. EFSA Journal 2013;11(4):3175, 14 pp. doi:10.2903/j.efsa.2013.3175