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Safety and efficacy of Sorbiflore® ADVANCE (*Lactobacillus rhamnosus* CNCM I-3698 and *Lactobacillus farciminis* CNCM I-3699) as a feed additive for weaned piglets

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Abstract

Following a request from the European Commission, the EFSA 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 Sorbiflore® ADVANCE when used as a zootechnical feed additive for weaned piglets. Sorbiflore® ADVANCE results from the fermentation of milk based-broth with *Lactobacillus rhamnosus* CNCM I-3698 and *Lactobacillus farciminis* CNCM I-3699. The additive is intended for use in feed for weaned piglets at the minimum concentration of 1.25×10^8 viable forming units (VFU)/kg and the maximum concentration of 5×10^8 VFU/kg complete feed. The data submitted did not allow a full characterisation of the additive, and therefore, uncertainty remains on the nature of the product in terms of viability, on the ratio between the active agents and on the stability of the additive. The active agents fulfil the requirements of the qualified presumption of safety (QPS) approach to the assessment of safety and no concerns are expected from other components of the additive. Consequently, Sorbiflore® ADVANCE is presumed to be safe for the target animals, consumers of products from animals receiving the additive and the environment. The additive should be considered a respiratory sensitiser. In the absence of data, no conclusions could be drawn on the irritancy of Sorbiflore® ADVANCE to skin and eyes and on its dermal sensitisation potential. Sorbiflore® ADVANCE at 1.25×10^8 VFU/kg feed has the potential to be efficacious in weaned piglets.

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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 requesst from STI Biotechnologie[2] for authorisation of the product Sorbiflore®ADVANCE (*Lactobacillus rhamnosus* CNCM I-3698 and *Lactobacillus farciminis* CNCM I-3699), when used as a feed additive for weaned piglets (category: Zootechnical additives; functional group: Other zootechnical additives).

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 24 August 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 Sorbiflore® ADVANCE (*Lactobacillus rhamnosus* CNCM I-3698 and *Lactobacillus farciminis* CNCM I-3699), when used under the proposed conditions of use (see Section 3.1.4).

1.2. Additional information

Sorbiflore® ADVANCE is a product consisting of cells of *L. rhamnosus* CNCM I-3698 and *L. farciminis* CNCM I-3699. EFSA has issued one opinion on the safety and efficacy of Sorbiflore® when used with piglets (EFSA, 2008) and one opinion on the safety and efficacy of Sorbiflore® ADVANCE when used with chickens for fattening (EFSA FEEDAP Panel, 2020a). EFSA issued an opinion on the safety and efficacy of a microbial product containing *L. rhamnosus* CNCM I-3698 and *L. farciminis* CNCM I-3699 when used as a silage additive for all animal species (EFSA FEEDAP Panel, 2020b).

Sorbiflore® was authorised for use in feed for piglets at the minimum concentration of 5×10^8 FU/kg complete feed and the maximum concentration of 9×10^8 FU/kg complete feed.[3,4,5] This authorisation expired on 8 January 2019.

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[6] in support of the authorisation request for the use of Sorbiflore® ADVANCE as a feed additive.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active agents in animal feed. In the Sorbiflore® report (EFSA, 2008) the EURL evaluated analytical methods based on the original proposal of register entry that described the conditions of use for piglets with concentrations expressed in colony forming units (CFU)

[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] STI Biotechnologie, Zone Artisanale du Coglais, 35460 St. Etienne en Coglès, France.
[3] Commission Regulation (EC) No 1290/2008 of 18 December 2008 concerning the authorisation of a preparation of *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699) (Sorbiflore) as a feed additive. OJ L 340, 19.12.2008, p. 20.
[4] Commission Regulation (EC) No 899/2009 of 25 September 2009 amending Regulation (EC) No 1290/2008 as regards the name of the holder of the authorisation of a preparation of *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699) (Sorbiflore). OJ L 256, 29.9.2009, p. 11.
[5] Commission Regulation (EC) No 1334/2013 of 13 December 2013 amending Regulation (EC) No 1290/2008 as regards the name of the holder of the authorisation and as regards the recommended dose of a preparation of *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699) (Sorbiflore). OJ L 256, 29.9.2009, p. 11.
[6] FEED dossier reference: FAD-2018-0027.

per kg of complete feedingstuffs. Subsequently and upon submission of new information from the applicant, the EURL has produced two amendments to the original report.[7]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Sorbiflore® ADVANCE is in line with the principles laid down in Regulation (EC) No 429/2008[8] and the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012a), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b) and Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018).

3. Assessment

Sorbiflore® ADVANCE, containing *L. rhamnosus* CNCM I-3698 and *L. farciminis* CNCM I-3699, is intended to be used as a zootechnical additive (other zootechnical additives) in feed for weaned piglets, in order to improve their performance.

3.1. Characterisation

3.1.1. Characterisation of the additive

Sorbiflore® ADVANCE is an additive resulting from the fermentation of a milk based-broth with *L. rhamnosus* CNCM I-3698 and *L. farciminis* CNCM I-3699. The manufacturing process foresees a two-stage process in which cultures are first grown separately in a skimmed milk-based medium and then used to inoculate the production broth, in which the skimmed milk content is increased and molasses are added. Subsequently, the co-culture is mixed with the carrier materials to reach the final composition of 10% biomass, 60.4% extruded corn meal, 11.34% soybean meal, 10% micronised wheat hulls, 7.2% algae meal, 1% silicon oxide[9] and 0.06% of an antifungal preservative based on calcium propionate, sodium diacetate and calcium formate with a mineral carrier.

The applicant describes the product as containing viable but not cultivable cells of the two strains in a 1:1 ratio, with a minimum total lactobacilli (LAB) number of 5×10^8 viable forming units (VFU)/g additive.[10] In the dossier, reference is made also to other intermediate formulations (e.g. Enviva starter containing 3×10^8 VFU/g additive) used in some efficacy studies.

To characterise the additive and confirm the inclusion level in the feed used in the efficacy studies, the applicant has developed a method [redacted][11]

Compliance with the specifications, in terms of total lactobacilli counts, was confirmed by analysis of 10 batches (mean value of 5.7×10^8 VFU/g, range = $5.2–6.5 \times 10^8$ VFU/g, coefficient of variation CV = 8.5%), using the PMA-qPCR method.[12] Individual counts of the two strains were tested in the same 10 batches to support the declared qualitative and quantitative (1:1 ratio) composition.[13]

The Panel notes that following the EURL report on the methodology and the data provided by the applicant, the unambiguous discrimination between the two lactobacilli strains is not possible, which does not allow to conclude on the ratio between the two strains in the product. Therefore, the method does not allow full characterisation of the additive, and uncertainty remains on the nature of the product and on its stability and homogeneity.

[7] The full report is available on the EURL website: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports?title=FAD-2018-0027&combine=&field_eurl_date_of_report_value%5Bvalue%5D%5Byear%5D=&field_eurl_date_of_report_value_1%5Bvalue%5D%5Byear%5D=

[8] 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.

[9] Feed additive currently under re-evaluation.

[10] Technical dossier/Supplementary information April 19/FAD-2017-0066.

[11] Technical dossier/Section II/Annexes II-8[redacted].

[12] Technical dossier/Section II/Annex II-8.

[13] Technical dossier/Section II/Annex II.

Based on the above, the method used by the applicant does not allow a full characterisation of the additive, and therefore, uncertainty remains on the nature of the product in terms of viability, on the ratio between the active agents and on its stability.

Three batches of the additive were analysed for microbial contaminants.[14] Results confirmed compliance with limit levels (coliforms < 500 CFU/g, *Salmonella* absence in 25 g, *Listeria monocytogenes* absence in 25 g, yeasts and filamentous fungi < 1.5×10^4 CFU/g. Chemical contaminants were analysed in one batch of the additive (lead < 1.0 mg/kg, arsenic < 1.0 mg/kg, cadmium < 0.25 mg/kg, mercury < 0.01 mg/kg, aflatoxins B1, B2, G1 and G2 < 0.01 mg/kg, deoxynivalenol: 1.11 mg/kg, ochratoxin A (< 0.01 mg/kg).[15,16]

Five batches of the additive were analysed for dusting potential with the Stauber–Heubach dustmeter. Results showed values of 36–83 g/m^3 (average: 58 g/m^3).[17]

3.1.2. Characterisation of the active agents

Both strains of the additive were isolated from the rumen of healthy goats and deposited in the National Micro-organism Collection of Pasteur Institute (CNCM, Paris) with the accession numbers CNCM I-3698 and CNCM I-3699.[18]

The full genome sequence of both strains was obtained and used for characterisation purposes. [redacted] Although the analysis was not conducted in full compliance with the relevant FEEDAP Guidance, [redacted] the data are deemed sufficient to identify the strains as *L. rhamnosus* and *L. farciminis*.

The susceptibility of both strains to the antibiotics recommended by the relevant FEEDAP Guidance (EFSA FEEDAP Panel, 2018) was tested by broth microdilution.[20] All the minimum inhibitory concentration (MIC) values for *L. rhamnosus* CNCM I-3698 were lower than the EFSA cut-off values; consequently, the strain is considered to be susceptible to these relevant antibiotics. The only exception was the MIC for chloramphenicol which was exceeded by two dilutions (MIC: 16 mg/L vs. cut-off value: 4 mg/L).

The applicant provided two sets of data on the WGS interrogation for the presence of antimicrobial resistance (AMR) genes. [redacted]

Regarding *L. farciminis* CNCM I-3699, the MIC values for ampicillin, gentamicin and streptomycin were below or equal to the corresponding EFSA cut-off values, consequently, the strain is considered to be susceptible to these relevant antibiotics. The MIC values for the remaining antibiotics were exceeded by one or more dilutions (i.e. vancomycin by several dilutions (MIC: > 128 mg/L vs. cut-off value: 2 mg/L), erythromycin by more than 3 dilutions (> 8 mg/L vs. 1 mg/L), kanamycin and tetracycline by two dilutions (64 vs. 16 μg/mL and 16 mg/L vs. 4 mg/L), and clindamycin and chloramphenicol and by one dilution (8 mg/L vs. 4 mg/L)). Exceedance of the cut-off value by one dilution is considered to be within the normal range of variation and thus, not a matter of concern. In

[14] Technical dossier/Section II/Annex II-9.
[15] Technical dossier/Supplementary information April 19/Annex 3.
[16] Limit of detection and/or limit of quantification not provided.
[17] Technical dossier/Supplementary information April 19/Annex 5.
[18] Technical dossier/Section II/Annex II-11.
[redacted]
[20] Technical dossier/Section II.
[redacted]

order to analyse the elevated MICs observed for erythromycin, kanamycin and tetracycline, the genome interrogation was performed as described above. [redacted] Therefore, these resistances are not related to the presence of acquired resistance genes and are considered of no concern.

3.1.3. Stability and homogeneity

The shelf-life of Sorbiflore® during storage was studied using three batches stored for 12 months at 25°C/60% relative humidity (RH) and at 40°C/75 RH% (packaging during storage not described).[23] Losses in total LAB counts (measured using the qPCR PMA-coupled method) were negligible (< 0.5 log) in the first case after 12 months whilst it reached 0.8 log after 6 months in the second case.

Three batches of Sorbiflore® ADVANCE were individually mixed into a commercial vitamin-mineral premixture (composition or target species not provided) at a concentration of 1.3×10^{11} VFU/kg and samples were taken and stored for six months at the same conditions described above.[24] Results showed that numbers of LAB in the vitamin-mineral premixture after six months were within $\pm$ 0.5 $\log_{10}$ of the time zero count when stored at 25°C, but were 0.6 $\log_{10}$ when stored at the higher temperature.

Stability in complete feed was investigated using a batch of Sorbiflore® ADVANCE incorporated at three inclusion levels (1.3×10^8 VFU/kg and 5×10^8 VFU/kg) into a typical mash feed (barley, soybean meal, wheat and maize) and into a pelleted feed of the same composition (pelleting conditions 90°C for 30 s) (target species not specified).[25] Samples of the mash and pelleted feed were stored at two ambient conditions (25°C/60 RH% and at 40°C/75 RH%) and LAB counts were made at monthly intervals up to three months. Essentially no reduction in LAB counts was seen in either the mash feed or the pelleted feed.

A separate study was conducted to investigate the effect of pelleting on viability.[26] Sorbiflore® ADVANCE was incorporated at two inclusion levels (1.3×10^8 VFU/kg and 5×10^8 VFU/kg) in the mash feed subjected to pelleting at 90°C. Differences in counts obtained by comparison of the LAB counts before and after pelleting were small and less than 0.5 $\log_{10}$ at both concentrations.

The ability of the additive (one batch) at the concentration of 1.25×10^8 VFU/kg, 2.5×10^8 VFU/kg and 5×10^8 VFU/kg to be uniformly distributed in a mash feed[27] and a pelleted feed[28] was examined. Analyses of individual counts of 12 subsamples showed a coefficient of variation of 2% in mash feed and 3–5% in pelleted feed.

3.1.4. Conditions of use

The applicant proposes using Sorbiflore® ADVANCE in feed for weaned piglets at the minimum concentration of 1.25×10^8 VFU/kg and the maximum concentration of 5×10^8 VFU/kg complete feed.

3.2. Safety

3.2.1. Safety for the target species, consumers and environment

The bacterial species *L. rhamnosus* and *L. farciminis* are considered by EFSA to be suitable for the qualified presumption of safety approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2020). This approach requires the identity of the strains to be conclusively established and evidence that the strains do not harbour acquired antimicrobial genes to clinically relevant antibiotics. In the view of the FEEDAP Panel, the antibiotic resistance qualification has been met and the identity of the strains established as *Lactobacillus farciminis* and *L. rhamnosus*. Therefore, both active agents are considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment and, consequently, are presumed safe for the target species, consumers of products from animals fed the additive and the environment. Since other components of the additive are not expected to raise safety concerns,[29] Sorbiflore® ADVANCE is also presumed safe for the target animals, consumers and the environment.

[23] Technical dossier/Section II/Annexes II-19 and 20.
[24] Technical dossier/Section II/Annexes II-21 and 22.
[25] Technical dossier/Section II/Annexes II-23 and 24.
[26] Technical dossier/Section II/Annex II-25.
[27] Technical dossier/Section II/Annex II-26.
[28] Technical dossier/Section II/Annex II-27.
[29] Silicon oxide currently under re-evaluation.

3.2.2. Safety for the user

Despite the request, no information was provided on the potential inhalation toxicity of the additive or on its skin/eye irritation and skin sensitisation potential. The dustiness of the preparations tested indicated a potential for users to be exposed via inhalation. Given the proteinaceous nature of the active agents, the additive should be considered a respiratory sensitiser. In the absence of data, the FEEDAP Panel cannot conclude on the irritancy of Sorbiflore® ADVANCE to skin and eyes and on its dermal sensitisation.

3.3. Efficacy for weaned piglets

The applicant submitted four studies to support the efficacy of the additive in weaned piglets. The design of the studies is presented in Table 1 and the results in Table 2.

In all studies, piglets were divided based on weight in two (or four in study 2) homogeneous experimental groups and within each group; animals were randomly assigned to 18 pens (study 1[30]), 48 pens (study 2[31]) or 16 pens (studies 3[32] and 4[33]). The groups received either a basal diet (unsupplemented) or the basal diet supplemented with the additive at different inclusion levels, including in three cases the minimum proposed concentration of 1.25×10^8 VFU/kg. In the fourth study (study 3), the maximum inclusion level was tested, while study 2 was a dose–response study where also two greater inclusion levels were tested. This study was run in two batches. For all the four studies, intended cell counts in complete feed were confirmed by analysis. The diets were offered to the animals *ad libitum*. Health status and mortality were monitored throughout the experimental period of 42 days. Body weight on animal basis (on days 1, 21 and 42 in the first two studies and on a weekly basis in the last two studies) and pen feed intake (on days 21 and 42) were measured and the feed to gain ratio (per pen) was calculated. Data were analysed using analysis of variance (ANOVA) and the pen as experimental unit for all parameters.

Table 1: Details on the study design for the studies performed in piglets.

Study	Sorbiflore® ADVANCE (VFU/kg feed)		Total number of animals Replicates/ treatment × animals/replicate Breed Sex (distribution/sex)	Basal diets Main ingredients (form)
	Intended inclusion level	Analysed inclusion level		
1	0 1.25×10^8	0 1.31×10^8	72 9 × 4 Landrace × (Duroc × Large white) castrates and gilts (mixed sex pens)	Wheat/maize/soybean meal (mash)
2	0 1.25×10^8 2.5×10^8 5×10^8	0 $1.2/1.3 \times 10^8$ 2.5×10^8 5×10^8	192 12 × 4 Piétrain × (Duroc × Landrace) males + females (mixed sex pens)	Wheat/barley (mash)
3	0 5×10^8	0 5×10^8	48 8 × 3 Duroc × Large White males + females (single-sexed pens)	Maize/wheat/wheat powder/soya (mash)

[30] Technical dossier/Section IV/Annexes IV-1 to IV-4, Supplementary information April 2019/Annex 6 and Spontaneous supplementary information October 2019/Annex IV-21.
[31] Technical dossier/Section IV/Annexes IV-5 to IV-8 and Supplementary information April 2019/Annexes 7 and 8.
[32] Technical dossier/Section IV/Annexes IV-9 to IV-11 and Supplementary information April 2019/Annex 9.
[33] Technical dossier/Section IV/Annexes IV-13 to IV-16, Supplementary information April 2019/Annex 10 and Spontaneous supplementary information October 2019/Annex IV-26.

Study	Sorbiflore® ADVANCE (VFU/kg feed)		Total number of animals Replicates/ treatment × animals/replicate Breed Sex (distribution/sex)	Basal diets Main ingredients (form)
	Intended inclusion level	Analysed inclusion level		
4	1.25×10^8	0 $4.7/3.9 \times 10^7$	64 8 × 4 Duroc × (Yorkshire × Hampshire) males + females (single-sexed pens)	Wheat/maize/ soybean meal (mash)

VFU: viable forming units.

Table 2: Overview of results of efficacy studies with Sorbiflore® in piglets

Study	Additive (FU/kg feed)	Daily feed intake (g/day)	Initial weight (kg)	Final weight (kg)	Daily weight gain (kg/day)	Feed to gain	Mortality (%)
1	0	813	8.4	30.7	0.533	1.53[a]	0
	1.25×10^8	786	8.2	30.8	0.540	1.46[b]	0
2	0	644	8.5	25.9	0.412	1.57[a]	6.3
	1.25×10^8	623	8.5	26.0	0.418	1.49[b]	4.2
	2.5×10^8	628	8.5	26.3	0.423	1.48[b]	2.1
	5×10^8	628	8.5	26.1	0.419	1.50[b]	4.2
3	0	1,090	9.2	35.4	0.624	1.75[a]	0
	5×10^8	1,041	9.3	35.2	0.618	1.68[b]	4.2
4	0	845	7.1	27.0	0.475	1.78[a]	0
	1.25×10^8	820	6.9	27.0	0.479	1.71[b]	0

[a,b]: Within a study, means in a column with different superscript letters are significantly different ($p \leq 0.05$).

Mortality of piglets was not treatment-related. Supplementation of the additive at the minimum inclusion level led to an improved feed to gain ratio in three studies and at the maximum inclusion level in two studies. Therefore, the FEEDAP Panel concludes that the additive has the potential to be efficacious in improving growth performance of weaned piglets at 1.25×10^8 VFU/kg feed.

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[34] and Good Manufacturing Practice.

4. Conclusions

The data provided do not allow a full characterisation of the additive, and therefore, uncertainty remains on the nature of the product in terms of viability, on the ratio between the active agents and on the stability of the additive.

The active agents of Sorbiflore® ADVANCE (*L. rhamnosus* CNCM I-3698 and *L. farciminis* CNCM I-3699) fulfil the requirements of the QPS approach to the assessment of safety and no concerns are expected from other components of the additive. Consequently, Sorbiflore® ADVANCE can be presumed to be safe for the target animals, consumers of products derived from animals fed with the additive and the environment.

The dusting potential of the additive is high. The additive should be considered a respiratory sensitiser. In the absence of data, the FEEDAP Panel cannot conclude on the irritancy of Sorbiflore® ADVANCE to skin and eyes and on its dermal sensitisation.

Sorbiflore® ADVANCE at 1.25×10^8 VFU/kg feed has the potential to be efficacious in weaned piglets.

[34] 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.

5. Documentation as provided to EFSA/Chronology

Date	Event
04/05/2018	Dossier received by EFSA. Dossier name. Submitted by STI Biotechnologie
18/05/2018	Reception mandate from the European Commission
24/08/2018	Application validated by EFSA – Start of the scientific assessment
13/11/2018	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterization, safety and efficacy*
24/11/2018	Comments received from Member States
10/04/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
14/06/2019	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*
03/10/2019	Reception of spontaneous supplementary information from the applicant
17/10/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
05/11/2019	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
19/03/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

AMR	antimicrobial resistance
ANOVA	analysis of variance
BW	body weight
CFU	colony forming unit
CV	coefficient of variation
DM	dry matter
EURL	European Union Reference Laboratory
LAB	lactobacilli
MIC	minimum inhibitory concentration
PCR	polymerase chain reaction
PMA	propidium monoazide
QPS	qualified presumption of safety
RH	relative humidity
VFU	viable forming units