

Safety Assessment on the Safety and Efficacy of *Bacillus licheniformis* DSM 28710 (B-Act®) as a Feed Additive for Piglets, Pigs for Fattening, Minor Growing Porcine Species and All Reproductive Porcine Species (RP2163)

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FSA Research and Evidence

An application was submitted to the Food Standards Agency (FSA) in December 2023 from Huvepharma NV ('the applicant') for the new authorisation of an additive consisting of viable spores of *Bacillus licheniformis* DSM 28710 (B-Act®) under the category 'zootechnical additives', functional group 'gut flora stabilisers'. The additive is currently authorised in Great Britain (GB) for use in all avian species at a minimum dose of 1.6×10^9 CFU/kg feed, and the applicant is seeking authorisation for a new use in piglets, pigs for fattening and minor growing porcine species at a proposed minimum dose of 1.6×10^9 CFU/kg complete feed, and in all reproductive swine species at a proposed minimum dose of 3.2×10^9 CFU/kg complete feed.

The FSA/FSS concluded that the additive and the active agent were correctly identified and characterised. The additive is stable in mash and pelleted pig feed at 25 °C/60% RH for 3 months, and at 40 °C/75% RH for 4 weeks. The additive is stable during pelleting at 105 °C with a retention time of 45 seconds, and is capable of homogenous distribution in mash and pelleted pig feed. The FSA/FSS do not agree with the minimum dose (1.6×10^9 CFU/kg feed) proposed by the applicant in the conditions of use for pigs for fattening and minor growing porcine species.

B. licheniformis DSM 28710 is suitable for the EFSA Qualified Presumption of Safety (QPS) approach and the additive is safe for the target species, consumer and the environment. B-Act® is a potential respiratory sensitiser and hazardous at any level of exposure. The additive is non-irritating to eyes and skin but is a presumed skin sensitiser. Measures to minimise skin and respiratory exposure are recommended.

To support the FSA and Food Standards Scotland (FSS) in evaluating the dossier, the Advisory Committee on Animal Feedingstuffs (ACAF) were asked to provide advice on the efficacy data provided by the applicant.

Following advice from ACAF, the FSA/FSS concluded that B-Act® has the potential to be efficacious in piglets and other minor porcine species at the same developmental stage at a minimum dose of 1.6×10^9 CFU/kg feedingstuffs. B-Act® has the potential to be efficacious in lactating sows, by means of benefit in the piglets, at a minimum dose of 3.2×10^9 CFU/kg feedingstuffs, and this conclusion can be extrapolated to all reproductive porcine species. Based on the demonstration of potential efficacy in weaned piglets and sows, B-Act® has the potential to be efficacious in pigs for fattening and other minor fattening porcine species at the higher dose of 3.2×10^9 CFU/kg feedingstuffs.

This safety assessment represents the opinion of the FSA and FSS.

This is a joint FSA and FSS publication.



1. Introduction

The FSA and FSS have undertaken an assessment for a feed additive (B-Act®) consisting of a preparation of viable spores of *Bacillus licheniformis* DSM 28710 (Huvepharma NV in Uitbreidingstraat 80, Antwerp, Belgium, 2600) under assimilated Regulation (EC) No 1831/2003 (EC, 2003). The additive is currently authorised in Great Britain (GB) for use in chickens, turkeys and minor poultry species for fattening, chickens and minor poultry species reared for laying, turkeys and minor poultry species reared for breeding, laying hens and minor poultry species for laying, and ornamental birds at a minimum dose of 1.6×10^9 colony forming units (CFU)/kg feed (identification number 4b1828). The applicant seeks authorisation for a new use in piglets, pigs for fattening, minor growing porcine species and all reproductive swine species. The additive falls under the category 'zootechnical additives', functional group 'gut flora stabilisers'.

In line with Article 8 of 1831/2003, the assessment has considered and concluded the feed additive complies with the conditions laid down in Article 5, including: safety considerations for human, animal and environmental health; efficacy of the additive for its intended effect;

potential impairment of the distinctive features of animal products. This, and the FSA/FSS guidance for the evaluation of feed additive applications, has formed the basis and structure for the assessment.

To support the safety assessment by the FSA and FSS, the Advisory Committee on Animal Feedstuffs (ACAF) provided advice to the FSA and FSS on efficacy. The efficacy section of the dossier was evaluated by the ACAF at its June 2025 meeting, after which a request for further information was communicated to the applicant. The applicant's response to this request was evaluated by the ACAF at its October 2025 meeting.

Considering all the data and the ACAF's advice, there is sufficient evidence of safety and efficacy for the FSA and FSS to conclude on the additive's safety and efficacy at this time. This assessment represents the opinion of the FSA and FSS.

Table 1. Products included in this assessment

Title	Product type	Intended use/s	Intended species or animal categories
<i>Bacillus licheniformis</i> DSM 28710 (B-Act®)	Feed additive	Zootechnical additive	Piglets, pigs for fattening, minor growing porcine species and all reproductive swine species

2. Assessment

2.1. Previous assessments and authorisations

Under assimilated Regulations (EU) No 2017/1904 and 2019/914, the additive is currently authorised in GB for use in chickens for fattening and reared for laying (EC, 2017) and turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening or reared for laying (EC, 2019).

In addition, the additive is authorised in GB for use in laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds, under 'The Feed Additives (Authorisations) Regulations 2022' (England; Scotland; Wales; 2022).

The European Food Safety Authority (EFSA) published several opinions reviewing the safety and efficacy of the additive for chickens for fattening and chickens reared for laying (EFSA FEEDAP Panel, 2016), turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening or raised for laying (EFSA FEEDAP Panel, 2019) and laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds (EFSA FEEDAP Panel, 2021). The additive was found to be safe for the target species, consumers, workers and the environment. The

2016 and 2019 conclusions were published at the time when UK was still part of the EU, and the 2021 conclusion was adopted by the UK after EU-exit (FSA/FSS, 2022).

2.2. Section II: Identity, characterisation and conditions of use

The additive consists of dried ferment (containing viable spores of *Bacillus licheniformis* DSM 28710) in a calcium carbonate carrier, at a final minimum concentration of 3.2×10^9 CFU/g. Calcium carbonate is an authorised feed material, and therefore the components of the additive do not raise any safety concerns.

The applicant provided new data from a minimum of three recent batches supporting the identity of the additive ([Table 2](#)). All relevant chemical and microbiological impurities have been tested, and levels are within legal limits, where applicable.

Particle size distribution analysis of the additive was provided, based on the European Pharmacopoeia Sieve Test. However, this method is unable to characterise the fraction of particles smaller than 100 µm; upon request, the applicant supplied particle size distribution analysis using laser diffraction ([Table 2](#)). The FSA and FSS note that the additive contains a relatively high proportion (>1%) of particles smaller than 1 µm and requested further characterisation of this small particle fraction. In response, the applicant provided an electron microscopy study, including an analysis of both the additive and the <38 µm sub-fraction. The particle size distribution of the additive was determined using transmission electron microscopy: 79% of the measured particles (by number) had at least one dimension smaller than 500 nm, 76% of measured particles had at least one dimension smaller than 250 nm, and 16.7% of measured particles had at least one dimension smaller than 100 nm. Based on the distribution, the additive does not meet the definition of a nanomaterial/nanoform, as laid out in assimilated Regulation (EC) No 1907/2006 (REACH) (EC, 2006), as fewer than 50% of the particles are smaller than 100 nm in one or more dimensions. However, the additive does contain a large proportion of particles smaller than 250 µm, which may be a concern.

Considering that the additive consists mainly of the carrier calcium carbonate, which is an authorised feed material, the FSA/FSS are satisfied that the small particle fraction can be largely attributed to calcium carbonate. As calcium carbonate is a widely used, authorised feed material, feed additive and human food additive, the FSA/FSS conclude that further risk assessment relating to the small particle fraction of the additive is not required.

Table 2. Identity table for *B. licheniformis* DSM 28710 (B-Act®)

Composition	
Viable spores of <i>B. licheniformis</i> DSM 28710 (in dried ferment) (range of 5 batches)	3.6×10^9 to 3.8×10^9 CFU/g
Carrier: Calcium carbonate	Up to 100%
Loss on drying (specification <10.0%)	1.2 – 1.4%
Chemical-physical specifications	
Appearance	Off-white to beige powder
Particle size distribution using laser diffraction (mean)	<190 µm – 90% <33 µm – 50% <9.3 µm – 30% <1.2 µm – 10%
Dusting potential (Stauber-Heubach)	2535 - 2925 mg/m ³
Bulk density (poured)	m/V ₀ = 0.57 – 0.65 g/ml
Bulk density (tapped)	m/V ₁₂₅₀ = 0.74 – 0.85 g/ml
Impurities	
<i>Escherichia coli</i>	<10 CFU/g
Coliforms	<10 CFU/g
Enterobacteriaceae	<10 CFU/g
Presumptive <i>Bacillus cereus</i>	<100 CFU/g
Yeasts and moulds	<100 CFU/g
Salmonella	Absent in 25 g
Arsenic	1.507 – 1.587 mg/kg
Mercury	0.007 – 0.008 mg/kg
Cadmium	0.238 – 0.262 mg/kg
Lead	1.61 – 1.77 mg/kg
Aflatoxin B1	<1.0 µg/kg
Aflatoxin B2	<1.0 µg/kg
Aflatoxin G1	<1.0 µg/kg
Aflatoxin G2	<1.0 µg/kg
Aflatoxin A1+A2+G1+G2	<1.5 µg/kg
Ochratoxin A	≤1.2 µg/kg
WHO (PCDD/PCDF)-TEQ 88% DM	0.124 ng/kg
WHO (PCDD/F/PCB)-TEQ 88% DM	0.243 - 0.244 ng/kg
WHO (PCB)-TEQ 88% DM	0.119 - 0.120 ng/kg

Bacillus licheniformis DSM 28710 has been characterised in previous opinions of the Panel on Additives and Products or Substances used in Animal Feed (EFSA FEEDAP Panel, 2016, 2019), when the UK was an EU member state. For this application, the applicant provided an updated whole genome sequence (WGS) analysis to demonstrate the taxonomic identity of the strain and absence of acquired antimicrobial resistance (AMR) genes. Taxonomic identification of the strain was performed using Average Nucleotide Identity (ANI) approach. Briefly, the FastANI tool was used to compare the WGS of the strain under application with a panel of 38 *Bacillus* spp. genomes, including both *B. licheniformis* strains (n=10)

and strains from a variety of other species within the genus. The strain shared an ANI of >99.47% with the 10 *B. licheniformis* genomes, but the ANI with other *Bacillus* species was ≤80.55%. Therefore, taxonomic identity as *Bacillus licheniformis* is confirmed.

To evaluate the possible presence of acquired AMR genes, a search of the WGS data against two up-to-date AMR gene databases, CARD and ResFinder, was performed, using a threshold of 70% identity and 60% coverage for the CARD database search, and a threshold of 80% identity and 60% coverage for the ResFinder database search. A single hit to the *rphB* gene (putatively associated with rifampicin resistance) was returned for both databases. Further analysis demonstrated that this AMR gene is present in the vast majority of *B. licheniformis* strains and is therefore considered intrinsic to *B. licheniformis*, in line with the EFSA definition of intrinsic resistance (EFSA BIOHAZ Panel, 2023). Furthermore, the 2021 FEEDAP opinion, which was adopted by the FSA/FSS (FSA/FSS, 2022), evaluated the phenotypic susceptibility of the strain to rifampicin. The EFSA FEEDAP Panel concluded that the minimum inhibitory concentration (MIC) for rifampicin was within the range of rifampicin MIC values for other *Bacillus* spp., and therefore not a concern.

The applicant provided updated phenotypic AST to determine the MIC of *B. licheniformis* DSM 28710 to a panel of antimicrobials, as recommended in the technical guidance (EFSA FEEDAP Panel, 2018). MICs were determined using the agar dilution method, following Clinical and Laboratory Standards Institute (CLSI) guidelines (CLSI, 2024). The MICs to all antimicrobials were equal to or below the established cut-off value for *Bacillus* spp., with the exception of clindamycin and streptomycin. As the observed phenotypic resistance is not associated with any acquired AMR genes, the FSA/FSS conclude that the strain does not pose an AMR risk.

No new data was provided relating to the toxigenic potential of the organism. The 2016 FEEDAP opinion, published when the UK was an EU member state, concluded that *B. licheniformis* DSM 28710 is non-toxigenic, based on cytotoxicity testing. The FSA/FSS still consider this conclusion applicable to GB and agree that the strain can be considered non-toxigenic without the need for further testing.

The manufacturing process has been evaluated in a previous FEEDAP opinion (EFSA FEEDAP Panel, 2016), when the UK was an EU member state. No concerns were raised. Upon request, the applicant provided Safety Data Sheets (SDSs) for all raw materials used in the production process, in addition to a detailed Hazard Analysis and Critical Control Points (HACCP) plan. The FSA/FSS note that all the raw materials used throughout the manufacturing process and in the final product are authorised feed materials or feed additives in GB.

The stability and homogeneity of the additive were evaluated in a previous FEEDAP opinion (EFSA FEEDAP Panel, 2016) when the UK was an EU member state, and this assessment remains applicable to GB. In line with the proposed new use, a new study was provided examining stability and homogeneity of three batches of B-Act® in mash and pelleted pig feed, at a total minimum concentration of 1.6×10^9 CFU/kg feedingstuffs. The FSA/FSS consider a difference between final and initial *Bacillus* spp. counts of less than or equal to $0.5 \log_{10}$ to be an insignificant loss. Final *Bacillus* spp. counts for all three batches of the additive in both mash and pelleted feed were within $0.5 \log_{10}$ of the initial counts. The FSA/FSS therefore conclude that *B. licheniformis* DSM 28710 is stable in both mash and pelleted pig feed at 25 °C/60% Relative Humidity (RH) for 3 months, and at 40 °C/75% RH for 4 weeks.

To examine the effect of processing on the additive, feed containing the additive was pelleted to a maximum temperature of 105 °C, with an average retention time of 45-60 seconds. *Bacillus* spp. counts after pelleting were $\leq 0.5 \log_{10}$ of the counts prior to pelleting; therefore, the FSA/FSS conclude that the additive is stable during pelleting at 105 °C, with a retention time of 45 seconds. The FSA/FSS could only conclude on the lower value retention period of 45 seconds, due to insufficient data at the higher value retention period of 60 seconds.

To evaluate homogeneity, *Bacillus* spp. counts were determined in 10 samples of mash and pelleted pig feed. The coefficient of variation between the 10 samples was $\leq 10\%$ for all three batches, in both mash and pelleted pig feed. The FSA/FSS conclude that the additive is capable of homogeneous distribution in the final feedingstuff.

The conditions of use as proposed by the applicant are described in [Table 3](#).

The FSA/FSS agree with the conditions of use proposed by the applicant, with two exceptions. The applicant proposed a minimum content of 1.6×10^9 CFU/kg feed in pigs for fattening and all minor growing porcine species, but the efficacy conclusions do not support this. Furthermore, the applicant requested authorisation for “all reproductive swine species”, but the FSA recommend the term “porcine” is used instead, in line with the conclusions on efficacy. The FSA/FSS therefore recommend the following amendments to the conditions of use:

- Minimum content of 1.6×10^9 CFU/kg feed: weaned piglets, suckling piglets during the period in which solid feed is given, and other porcine species at the same developmental stage.

- Minimum content of 3.2×10^9 CFU/kg feed: all reproductive porcine species, pigs for fattening and other minor fattening porcine species.

Table 3. Conditions of use of B-Act® proposed by the applicant

Species or category of animal	Min. content in feed	Max. content in feed	Withdrawal period
Piglets, pigs for fattening and minor growing porcine species	1.6×10^9 CFU/kg feed	-	-
All reproductive swine species	3.2×10^9 CFU/kg feed	--	-
Other provisions and additional requirements for the labelling			
Specific conditions or restrictions for use	In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. The product can be used throughout the entire life cycle of the animal with no withdrawal period. The use is permitted in feed containing the following authorised coccidiostats: decoquinate, diclazuril, halofuginone, nicarbazin, robenidine hydrochloride, lasalocid A sodium, maduramicin ammonium, monensin sodium, narasin, or salinomycin sodium.		
Specific conditions or restrictions for handling	For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment including skin and eye protection.		

2.2.1. Conclusions on Section II

The FSA/FSS conclude that the additive and the active agent have been correctly identified and characterised, and that *B. licheniformis* DSM 28710 is suitable for the EFSA QPS approach. There are no concerns regarding the AMR potential of the strain. The additive is stable in mash and pelleted pig feed at 25 °C / 60% RH for 3 months, and at 40 °C / 75% RH for 4 weeks. The additive is stable during pelleting at 105 °C, with a retention time of 45 seconds, and is capable of homogenous distribution in mash and pelleted pig feed. Based on the efficacy conclusions, the FSA/FSS do not agree with the minimum dose proposed by the applicant in the conditions of use for pigs for fattening and minor growing porcine species.

2.3. Section III: Safety

2.3.1. Safety for the target species

B. licheniformis DSM 28710 is suitable for the EFSA QPS approach and therefore can be considered safe for the target species. As no concerns were raised by any of the other components in the additive, the FSA/FSS are satisfied that no additional information is required.

2.3.2. Safety for the consumer

B. licheniformis DSM 28710 is suitable for the EFSA QPS approach and therefore can be considered safe for the consumer. As no concerns were raised by any of the other components in the additive, the FSA/FSS are satisfied that no additional information is required.

2.3.3. Safety for the user

B-Act® is a microbial-based additive and is therefore considered a potential respiratory sensitiser and hazardous at any level of exposure. In addition, the additive has a high dusting potential and a high proportion of very small particles, with 10% of particles smaller than 1.2 µm (as determined using laser diffraction). Therefore, measures to minimise respiratory exposure are recommended.

Upon FSA/FSS request, the applicant presented the following Good Laboratory Practice (GLP) compliant studies to evaluate skin and eye irritation potential of the additive:

- *In vitro* skin irritation test using a reconstructed human epidermis model (EpiSkin™ Small Model), in accordance with OECD TG 439;
- *In vitro* eye hazard identification Time-To-Toxicity test using the SkinEthic™ human corneal epithelium model, in accordance with OECD TG 492B.

In both studies, the final form of the additive was used as the test substance. The additive was found to be non-irritating to skin and eyes (UN-GHS 'No category'). No study was provided to evaluate the skin sensitisation potential of the additive; in the absence of data, the additive is considered a potential skin sensitiser and measures to minimise dermal exposure are recommended.

2.3.4. Safety for the environment

B. licheniformis DSM 28710 is suitable for the EFSA QPS approach and therefore can be considered safe for the environment. As no concerns were raised by any of the other components in the additive, the FSA/FSS are satisfied that no additional information is required.

2.3.5. Conclusions on safety

B. licheniformis DSM 28710 is suitable for the EFSA QPS approach and the additive can be considered safe for the target species, consumer and the environment without the need for further data.

As a microbial-based additive, B-Act® is considered a respiratory sensitiser and hazardous at any level of exposure. The additive is non-irritating to eyes and skin, but in the absence of data is a presumed skin sensitiser. Measures to minimise skin and respiratory exposure are recommended.

2.4. Section IV: Efficacy

The applicant requested a new authorisation in piglets, pigs for fattening and minor growing porcine species at a proposed minimum dose of 1.6×10^9 CFU/kg feed, and in all reproductive swine species at a proposed minimum dose of 3.2×10^9 CFU/kg. The applicant initially submitted three long-term trials in weaned piglets, and six trials in sows, covering the period of approximately 2 weeks prior to parturition, and lactation. The FSA/FSS requested advice from the Advisory Committee on Animal Feedingstuffs (ACAF) to evaluate the submitted efficacy data.

2.4.1. Long-term efficacy trials in weaned piglets

Three long-term trials in weaned piglets were submitted as part of the original dossier, but the applicant provided a fourth trial during the assessment process. All four trials included a control group, which was fed a basal diet, and a treatment group, which was fed the basal diet supplemented with an intended use level of 1.6×10^9 CFU/kg. All trials had a minimum duration of 42 days.

A high incidence of morbidity and antibiotic usage in Trial 1 was noted. Upon request, the applicant provided further information and justification regarding antibiotic usage, including the reason for antibiotic treatment, dose, duration of treatment and number of animals treatment with each antibiotic. The ACAF reviewed the study and the additional information provided by the applicant and concluded that the trial could be considered suitable for assessment.

A summary of the effect of B-Act® on zootechnical performance in weaned piglets over the entire study period for trials 1 to 3 is given in [Table 4](#). The ACAF agreed that there was evidence of small but significant improvements in some zootechnical performance parameters across the four trials. The ACAF therefore concluded that the additive has the potential to be efficacious in weaned piglets at the proposed minimum dose of 1.6×10^9 CFU/kg feed.

Table 4. Effect of B-Act® on zootechnical performance of weaned piglets

Trial	Intended dose B-Act® (CFU/kg feed)	Initial weight (kg)	Final weight (kg)	ADFI (g/ day)	ADG (g/ day)	Feed to gain ratio
1	0	6.2	17.6 ^a	408 ^a	269 ^a	1.52
	1.6×10^9	6.2	19.0 ^b	452 ^b	297 ^b	1.53
2	0	8.2	25.1	647	373	1.74 ^a
	1.6×10^9	7.7	24.6	653	381	1.71 ^b
3	0	7.1	21.2	534	334	1.60 ^a
	1.6×10^9	7.2	21.2	515	329	1.56 ^b

All performance parameters were corrected for mortality.

Means in a column within a given trial with different superscript letters are significantly different ($p < 0.05$).

ADG = average daily gain. ADFI = average daily feed intake.

2.4.2. Long-term efficacy trials in sows

The applicant provided six studies in sows, covering the period of approximately two weeks prior to parturition and lactation (until weaning of the piglets). Sows were fed a control diet, or a diet supplemented with B-Act® at an intended concentration of 3.2×10^9 CFU/kg feed.

Two of the trials were not considered suitable for assessment due to the experimental design. Further information regarding the layout of housing for two of the remaining trials was requested from the applicant. After reviewing the additional information provided by the applicant, the ACAF agreed that these trials were suitable for assessment.

The ACAF evaluated the effect of B-Act® on the performance of both sows and their litters on the remaining four trials that had been considered suitable for assessment. A summary of the effect of B-Act® on performance parameters of the sows is given in [Table 5](#). There were no statistically significant differences in any of the parameters, with the exception of weight change during lactation in trial 2. The sows in both treatments actually gained weight during lactation, but sows in the treatment group gained less weight than the control.

The ACAF noted some positive effects of the additive in the piglets ([Table 6](#)), including a significant increase in average daily gain (ADG) of the piglets in two of the trials and an increase in average piglet weight at weaning in one

of the trials. In addition, a statistically significant reduction in the combined piglet culling/mortality rate was also seen in trial 2 in the treatment group (data not reported in table).

Table 5. Effect of B-Act® supplementation of the zootechnical performance of lactating sows

Trial	Intended dose B-Act® (CFU/kg)	ADFI during lactation (kg)	Weight of sows (kg)			ADG during lactation (kg)	Weight change (kg)	Back fat change (mm)
			Initial	After farrowing	At weaning (kg)			
1	0	6.40	285	279	261	-0.735	NR	NR
	3.2×10^9	6.33	282	279	259	-0.794	NR	NR
2	0	5.99	231	198	232	NR	+33.6 ^a	-0.80
	3.2×10^9	6.21	233	199	225	NR	+26.3 ^b	-1.12
3	0	6.61	268	265	246	-0.755	NR	NR
	3.2×10^9	6.64	268	263	240	-0.830	NR	NR
4	0	5.52	257	228	243	NR	-15.6	-5.38
	3.2×10^9	5.47	254	222	236	NR	-14.3	-5.21

Means in a column within a given trial with different superscript letters are significantly different ($p < 0.05$).

NR = not reported

For trials 2 and 4, weight after farrowing was estimated.

Weight change refers to the difference from farrowing to weaning.

Back fat change refers to the difference between start and end of trial

Table 6. Effect of B-Act® supplementation in sows on the piglets

Trial	Mean number of piglets born alive (n)	Mean number of piglets weaned (n)	Average piglet weight (kg)			ADG (kg)
			At birth (live piglets)	After cross fostering	At weaning	
1	14.0	11.9	1.42	2.62	7.38	0.256 ^a
	13.0	10.8	1.40	2.66	7.79	0.272 ^b
2	12.0	10.0 ^a	1.55	1.53	6.05 ^a	0.190 ^a
	14.0	11.5 ^b	1.51	1.50	6.82 ^b	0.222 ^b
3	13.1	12.1	1.48	1.43	8.30	0.265 ^a
	14.3	12.7	1.41	1.39	8.13	0.249 ^b
4	10.4 ^a	9.4	1.64 ^a	1.60 ^a	6.60	0.224
	12.4 ^b	9.4	1.45 ^b	1.43 ^b	6.20	0.211

Average daily gain (ADG) is calculated from birth for trials 2 and 4, and from after cross-fostering for trials 1 and 3.

The ACAF agreed that B-Act® has the potential to be efficacious in lactating sows, by means of benefit in the piglets, at the proposed dose of 3.2×10^9 CFU/kg feedingstuffs.

The applicant is requesting authorisation in piglets, pigs for fattening, and minor growing porcine species at a proposed minimum dose of 1.6×10^9 CFU/kg feedingstuffs, and in all reproductive swine species at a dose of 3.2×10^9 CFU/kg feedingstuffs.

The ACAF concluded that the additive has the potential to be efficacious in weaned piglets at a dose of 1.6×10^9 CFU/kg feedingstuffs. In line with technical guidance, this conclusion is taken to include suckling piglets during the period during which solid feed is given. Furthermore, the ACAF agreed that this conclusion can be extrapolated to other minor growing porcine species at the same developmental stage.

Efficacy was demonstrated in sows at a dose of 3.2×10^9 CFU/kg, and the ACAF agreed that this conclusion can be extrapolated to other reproductive porcine species at the same dose.

No studies were provided in pigs for fattening, and the ACAF could not accept the applicant's request for extrapolation from weaned piglets to pigs for fattening and other growing porcine species, due to the lack of physiological similarity between weaned piglets and pigs for fattening. However, the ACAF noted that the technical guidance permits extrapolation to all pigs when efficacy in weaned piglets and sows is demonstrated. Therefore, the ACAF concluded that the additive has the potential to be efficacious in pigs for fattening and other minor fattening porcine species at the higher dose of 3.2×10^9 CFU/kg.

The ACAF concluded that B-Act® has the potential to be efficacious in piglets and all other minor porcine species at the same developmental stage, at a minimum dose of 1.6×10^9 CFU/kg feedingstuffs. B-Act® has the potential to be efficacious in sows and all other reproductive porcine species, and in pigs for fattening and other porcine species for fattening at a minimum dose of 3.2×10^9 CFU/kg feedingstuffs.

2.4.3. Conclusions on efficacy

The ACAF concluded that B-Act® has the potential to be efficacious in weaned piglets at a dose of 1.6×10^9 CFU/kg feedingstuffs. This conclusion can be extended to suckling piglets (during the period in which solid feed is given) and extrapolated to all other minor porcine species at the same developmental stage. B-Act® has the potential to be efficacious in lactating sows, by means of benefit in the piglets, at a minimum dose of 3.2×10^9 CFU/kg feedingstuffs, and this conclusion can be extrapolated to all other reproductive porcine species.

The ACAF could not accept the applicant's request for extrapolation from piglets to pigs for fattening and other minor growing porcine species, due to lack of physiological similarity between weaned piglets and pigs for

fattening. However, as the technical guidance permits extrapolation to all pigs when efficacy in weaned piglets and sows is demonstrated, the ACAF concluded that the additive has the potential to be efficacious in pigs for fattening and other minor fattening porcine species at the higher dose of 3.2×10^9 CFU/kg.

The FSA/FSS reviewed the ACAF's advice on efficacy and agreed with the ACAF's conclusions. The FSA/FSS recommend that the conditions of use are amended in line with the conclusions on efficacy. B-Act® has a favourable effect on animal production, performance and welfare, particularly by affecting the gastrointestinal flora of the target species.

3. Analytical methods evaluation

Conclusions on the analytical methods are presented here as an extract from the Evaluation Report of the European Union Reference Laboratory (EURL) for Feed Additives on the Method(s) of the Analysis for *Bacillus licheniformis* BL 11 (DSM 28710) (EURL, 2015):

"For the identification of *Bacillus licheniformis* BL 11 (DSM 28710) the EURL recommends for official control Pulsed Field Gel Electrophoresis (PFGE), a generally recognised standard methodology for genetic identification. This standard methodology for microbial identification is currently being evaluated by the CEN Technical Committee 327 to become a European Standard. For enumeration of *Bacillus licheniformis* BL 11 (DSM 28710) in feed additive, premixtures and feedingstuffs the Applicant submitted the ring-trial validated spread plate CEN method EN 15784 which was already evaluated by EURL in the frame of previous *Bacillus licheniformis* dossiers. Based on the performance characteristics available the EURL recommends for official control the EN 15784 method for the enumeration of *Bacillus licheniformis* BL 11 (DSM 28710) in the feed additive, premixtures and feedingstuffs. Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary."

FSA/FSS accepts the EURL analytical method evaluation reports.

4. Conclusions

The additive and the active agent were correctly identified and characterised. The additive is stable in mash and pelleted pig feed at 25 °C/60% RH for 3 months, and at 40 °C/75% RH for 4 weeks. The additive is

stable during pelleting at 105 °C, with a retention time of 45 seconds, and is capable of homogenous distribution in mash and pelleted pig feed. The FSA/FSS recommend a change in the conditions of use as proposed by the applicant to reflect the conclusions on efficacy.

B. licheniformis DSM 28710 is suitable for the EFSA QPS approach and the additive can be considered safe for the target species, consumer and the environment without the need for further data.

As a microbial-based additive, B-Act® is considered a respiratory sensitiser and hazardous at any level of exposure. The additive is non-irritating to eyes and skin, but in the absence of data is a presumed skin sensitiser. Measures to minimise skin and respiratory exposure are recommended.

Based on the ACAF's advice, the FSA/FSS concluded that B-Act® has the potential to be efficacious in weaned piglets at a dose of 1.6×10^9 CFU/kg feedingstuffs. This conclusion can be extended to suckling piglets (during the period in which solid feed is given) and extrapolated to all other minor porcine species at the same developmental stage. B-Act® has the potential to be efficacious in lactating sows, by means of benefit in the piglets, at a minimum dose of 3.2×10^9 CFU/kg feedingstuffs, and this conclusion can be extrapolated to all other reproductive porcine species.

The FSA/FSS agree with the ACAF's advice that conclusions on efficacy cannot be extrapolated from weaned piglets to pigs for fattening and other minor growing porcine species, due to lack of physiological similarity between weaned piglets and pigs for fattening. As technical guidance permits extrapolation to all pigs when efficacy in weaned piglets and sows is demonstrated, the FSA/FSS conclude that the additive has the potential to be efficacious in pigs for fattening and other minor fattening porcine species at the higher dose of 3.2×10^9 CFU/kg.

Abbreviations

Abbreviation	Definition
ACAF	Advisory Committee on Animal Feedingstuffs
ADFI	Average daily feed intake
ADG	Average daily gain
AMR	Antimicrobial resistance
ANI	Average nucleotide identity
CFU	Colony forming units
CLSI	Clinical Laboratory and Standards Institute
DM	Dry matter
EC	European Commission
EFSA	European Food Safety Authority
EURL	European Union Reference Laboratories
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed

Abbreviation	Definition
FSA	Food Standards Agency
FSS	Food Standards Scotland
GB	Great Britain
GLP	Good laboratory practice
HACCP	Hazard analysis and critical control points
MIC	Minimum inhibitory concentration
OECD	Organisation for Economic Co-operation and Development
PCBs	Polychlorinated biphenyls
PCDDs	Polychlorinated dibenzo-p-dioxins
PCDFs	Polychlorinated dibenzofurans
QPS	Qualified Presumption of Safety
RH	Relative humidity
SDS	Safety Data Sheet
TEQ	Toxic equivalency factor
TG	Test guideline
UN-GHS	United Nations Globally Harmonized System of Classification and Labelling of Chemicals
WGS	Whole genome sequence
WHO	World Health Organisation

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