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Safety and efficacy of the feed additive consisting of *Bacillus licheniformis* DSM 28710 (B-Act®) for laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds (HuvePharma N.V.)

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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 safety and efficacy of the feed additive consisting of *Bacillus licheniformis* DSM 28710 (trade name: B-Act®) when used in feed for laying hens, minor poultry species for laying and for breeding purposes and ornamental birds. *B. licheniformis* is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment. The identity of the active agent was established, and it does not harbour acquired antimicrobial resistance genes or has toxigenic potential. Following the QPS approach, *B. licheniformis* DSM 28710 is presumed safe for the target species, consumers and the environment. Since no concerns are expected from the other components of the additive, B-Act® is also considered safe for the target species, consumers and the environment. No conclusions can be drawn on the skin/eye irritation or skin sensitisation potential of the additive, but B-Act® is considered a respiratory sensitiser. B-Act® when supplemented at 1.6×10^9 CFU/kg complete feed has the potential to be efficacious in laying hens. Considering also that the efficacy of the product was already shown in chickens and turkeys for fattening, the Panel concludes that the additive has the potential to be efficacious in minor poultry species for laying, poultry species for breeding purposes and for ornamental birds at the same inclusion level. The conclusions on the compatibility of B-Act® with coccidiostats previously drawn apply to the current application provided that the maximum authorised concentrations of the coccidiostats for the target species are equal or lower than those for chickens.

Keywords: zootechnical additive, B-Act®, *Bacillus licheniformis* DSM 28710, safety, QPS, efficacy

Requestor: European Commission

Question number: EFSA-Q-2019-00525

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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 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 HuvePharma N.V.[2] for authorisation of the feed additive consisting of *Bacillus licheniformis* DSM 28710, when used as a feed additive for laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds (category: Zootechnical additives; functional group: Gut flora stabilisers).

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 14 November 2019.

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 *Bacillus licheniformis* DSM 28710, when used under the proposed conditions of use (see **Section** 3.1.2).

1.2. Additional information

The additive is currently authorised for use as a zootechnical feed additive (gut flora stabiliser) in feed for chickens for fattening, chickens reared for laying,[3] turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening and reared for laying (4b1828).[4]

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[5] in support of the authorisation request for the use of the product consisting of *B. licheniformis* DSM 28710 as a feed additive.

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.[6]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of B-Act® is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the characterisation of microorganisms used as

[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] HuvePharma N.V. Uitbreidingstraat 80, 2600, Antwerp, Belgium.
[3] Commission Implementing Regulation (EU) 2017/1904 of 18 October 2017 concerning the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for chickens for fattening and chickens reared for laying. OJ L 269, 19.10.2017, p. 27.
[4] Commission Implementing Regulation (EU) 2019/914 of 29 May 2019 concerning the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening and reared for laying (holder of authorisation HuvePharma N.V.), OJ L 146, 5.6.2019, p. 60.
[5] FEED dossier reference: FAD-2019-0051.
[6] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2015-0016%20bacillus_licheniformis.pdf
[7] 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.

feed additives or as production organisms (EFSA FEEDAP Panel, 2018a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019a,b).

3. Assessment

The subject of the assessment is a product containing viable spores of a single strain of *B. licheniformis* (DSM 28710) with trade name B-Act®, intended for use as a zootechnical additive (gut flora stabiliser) in feeds for laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds. It will be hereafter referred to as B-Act®.

3.1. Characterisation

3.1.1. Characterisation of the additive

B-Act® is a powder with a minimum declared content of 3.2×10^9 colony forming units (CFU) of *B. licheniformis* DSM 28710 per gram of additive.

It has the same formulation [redacted] and method of manufacture as that considered in a previous opinion (EFSA FEEDAP Panel, 2016). Thus, the data pertaining to composition, impurities, physical properties and shelf-life still apply.

The stability and capacity of the additive to homogeneously mix with poultry feed and premixtures were established in the previous opinion (EFSA FEEDAP Panel, 2016). The FEEDAP Panel is of the opinion that these existing data are sufficient to establish the stability and capacity to homogeneously mix in premixtures and feeds for the target species.

Taxonomic identification of the active agent as *B. licheniformis* was established by bioinformatic analysis of the whole genome sequence (WGS).[8] A phylogenomic analysis was performed based on the comparison of the WGS (at nucleotide level with a minimum 77.2% threshold homology) with genomes of 10 *B. licheniformis* strains and of 28 strains of other 10 *Bacillus* species (*B. anthracis, B. cereus, B. megaterium, B. mycoides, B. pseudomycoides, B. pumilus, B. subtilis, B. thuringiensis, B. toyonensis* and *B. wiedmannii)*. The active agent clustered together with *B. licheniformis* strains, confirming its identification. Additionally, a comparison of the partial sequence (900–1,000 bp) of the 16S rRNA gene of the active agent with sequences deposited in the NCBI Gene Bank and the Greengenes 16S rRNA gene database showed 99.6% homology with sequences from other *B. licheniformis*.

A cytotoxicity test with Vero cells was conducted in accordance with the provisions of the FEEDAP guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018a,b).[9] The level of protein inhibition caused by *B. licheniformis* was below the threshold (20%), thus the strain can be considered to be non-toxigenic. This is confirmed by the results of a polymerase chain reaction (PCR) for the detection of non-ribosomal peptides synthetase genes and a haemolysis test.[10] Moreover, the WGS of the strain was interrogated for the presence of toxins and virulence factors.[11] The open reading frames (ORFs) of the contigs were annotated for function in the public NCBI non-redundant protein database using the blastp algorithm. The search evidenced the presence of two lichenysin synthetase genes and a putative haemolysin A gene. However, since the phenotypic analyses of the strain showed that it is not haemolytic or toxigenic, these genes are not seen as of concern.

The susceptibility of the active agent to the antibiotics recommended by the FEEDAP Panel was tested by broth microdilution following the method of the Clinical and Laboratory Standards Institute (CLSI)).[12] All minimum inhibitory concentration (MIC) values were equal or below the corresponding cut-off values defined by the FEEDAP Panel, except for streptomycin which was exceeded by a one dilution (16 mg/L vs 8 mg/L). Exceeding the cut-off value by one dilution is considered to be within the normal range of variation and, thus, it is not a matter of concern.

[8] Technical dossier/Supplementary information June 2020/Annexes RTQ_I and II.
[9] Technical dossier/Section II/Annex II.17.
[10] Technical dossier/Section II/Annex II.09.
[11] Technical dossier/Section II/Annexes II.15 and II.16.
[12] Technical dossier/Section II/Annex II.08.

The WGS was also interrogated for the presence of genes involved in antibiotic resistance against the ARG-Annot (80% identity and 80% coverage) and ResFinder databases (90% identity and 60% coverage) and the ABRicate tool (which uses the two aforementioned databases, 79% identity and 80% coverage). No hits were identified by these analyses.[13] However, a gene associated with rifampin resistance (*rphD,* rifamycin-inactivating phosphotransferase RphD, 79.1% identity and 98.6% coverage) and a gene codifying for beta-lactam resistance (*blaZ, B. cereus blaZ* gene encoding beta-lactamase III, 71.9% identity and 78.2% coverage) were identified in these databases when applying less stringent search criteria (70% identity and 70% coverage).

Due to the presence of genes involved in beta-lactam and rifampin resistance, the applicant was asked to provide the MIC for ampicillin[14] and rifampin[15] for the product strain. The MIC for ampicillin was 0.25 mg/L when tested using a broth microdilution method. EFSA does not currently have specific cut-off values for *B. licheniformis*, but for the genus *Bacillus* and they do not include ampicillin. Agersø et al. (2018) tested the MIC for ampicillin of 35 *B. licheniformis* strains of various sources using a modified CLSI broth microdilution method and found that MIC values for ampicillin of the tested strains were low, varying between 0.12 and 2 mg/L, indicating that the MIC of the production strains is within the range of the other tested *B. licheniformis* strains. The MIC for rifampicin was 0.064 mg/L when tested using a broth microdilution method. Rifampin is not included in the panel of antibiotics included in the FEEDAP guidance and no epidemiological cut-off value for rifampicin for *B. licheniformis* has been established by EUCAST. Luna et al. (2007) tested the MIC value for rifampin using commercial automated microbroth dilution and an agar gradient diffusion tests for 95 isolates of the *Bacillus cereus* group including *B. anthracis*, *B. cereus*, *B. mycoides*, *B. mycoides/pseudomycoides* and *B. pseudomycoides* and for 19 *B. thuringiensis* strains, albeit not *B. licheniformis*.[16] The MIC values for rifampin were low, ranging between 0.002 and 0.1 mg/L. Thus, that of the B-Act® strain is within the range of the MIC values of other *Bacillus* spp. strains. Therefore, the MIC values of *B. licheniformis* DSM 28710 for ampicillin and rifampin are not considered of concern.

3.1.2. Conditions of use

The additive B-Act® is intended for use in feed for laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds at the proposed level of 1.6×10^9 CFU/kg complete feed.

It is intended for use in the presence of the permitted coccidiostats: salinomycin, lasalocid, robenidine, maduramicin, decoquinate, monensin, narasin, nicarbazin, semduramicin, diclazuril and halofuginone.

3.2. Safety

3.2.1. Safety for the target species consumer and environment

The species *B. licheniformis* is considered to be suitable for the qualified presumption of safety (QPS) approach to safety assessment (EFSA, 2007, EFSA BIOHAZ Panel, 2020). This approach requires the identity of the strain to be conclusively established and evidence that it lacks toxigenic potential and does not show resistance to antibiotics of human and veterinary importance. The identification of the strain and compliance with the QPS qualifications was confirmed. Therefore, *B. licheniformis* DSM 28710 is presumed safe for the target animals, consumers of products derived from the animals fed the additive and the environment. Since no concerns arise from other components of the additive, B-Act® is also presumed safe for the target animals, consumers and the environment.

3.2.2. Safety for user

In the previous opinion, owing to the absence of data, no conclusions could be drawn on the skin/eye irritation or skin sensitisation potential of the additive, but the Panel considered B-Act® to be a potential respiratory sensitiser (EFSA FEEDAP Panel, 2019a,b). No additional studies were provided in

[13] Technical dossier/Supplementary information June 2020/EFSA-Q-2019-00525 RTQ B-Act laying breeding poultry and Annexes RTQ I, II and III.
[14] Technical dossier/Section II/Annex II.08 and Supplementary information June 2020/Validated RTQ EFSA-Q-2019-0525 B-Act laying breeding poultry and Annex RTQ IV MIC ampicillin.
[15] Technical dossier/Supplementary information September 2020/Annex RTQII_2_MIC rifampicin.
[16] Technical dossier/Supplementary information September 2020/Annex_RTQII_4.

the current application. The use of the additive with laying hens, minor poultry species for laying and for breeding purposes and ornamental birds is considered unlikely to introduce hazards for users of the product not already considered as part of the previous assessment. Therefore, the conclusions reached in the previous assessment apply to the current application.

3.2.3. Conclusions on safety for the user

No conclusions can be drawn on the skin/eye irritation or skin sensitisation potential of the additive, but B-Act® is considered to be a respiratory sensitiser.

3.3. Efficacy

3.3.1. Efficacy for laying hens

Five efficacy trials were submitted aiming to demonstrate the effects of B-Act® on the zootechnical performance of laying hens. However, the experimental design of one study conducted in a non-EU country was not compliant with the EU legislation on animal protection[17] (e.g. the surface allowed per hen was 400 cm^2 against the 750 cm^2 requested, cages were not enriched).[18] Therefore, this study was not further considered. The details of the design of the four trials are presented in Table 1 and the results in Table 2.

In all four trials, hens were caged and allocated to one of the two treatments, a non-supplemented diet (control) or a diet supplemented with B-Act® at 1.6×10^9 CFU/kg feed (confirmed by analysis and showed in Table 1). The diets were fed in mash form and on *ad libitum* basis. Mortality and general health were monitored throughout the study. Body weight per replicate (cage) was recorded at the beginning and at the end of the trial. Feed consumption, egg production per cage and egg weight were recorded every four weeks. Egg mass to feed ratio was calculated. The data, corrected for mortality, were analysed according to a completely randomised design with cage as the experimental unit. The analysis of variance (ANOVA) was performed and differences were considered significant at a level of at least $p < 0.05$. In addition to the ANOVA, the non-parametric test of Kruskall–Wallis was used in Trial 1 when data did not follow a normal distribution.

In the first study, after a 4-week period of acclimatisation (16–20 weeks of age), 768 Hy-Line Brown hens (21 weeks old) were distributed in 192 cages of four hens each and allocated to two dietary treatments (96 replicates (cages) per treatment).[19] No information was provided on the diet the animals received during the acclimatisation period.

In the second study, 100 Hy-Line Brown hens (19 weeks old) were distributed in 50 cages of 2 hens each.[20] From 20 to 22 weeks of age the animals were fed a diet without the additive (acclimatisation period). At 23 weeks of age, they were allocated to two dietary treatments (25 replicates (cages) per treatment).

In the third study, 360 Isa Brown hens (22 weeks old) were distributed in 40 cages of 9 hens each and allocated to two dietary treatments, each with 20 replicates (cages).[21]

In the fourth study, a total of 160 Hy Line Brown hens (22 weeks old) were distributed in 40 cages of 4 hens each.[22] From 17 to 21 weeks of age, the animals were fed a diet without the additive (acclimatisation period). At 22 weeks of age, they were allocated to two dietary treatments (20 replicates (cages) per treatment).

[17] Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens OJ L 203 3.8.1999, p. 53.
[18] Technical dossier/Section IV/Annex IV_02 and Supplementary information September 2020/EFSA-Q-2019-00525-RTQII-B-Act_laying hens.pdf and Annex_RTQII_6 _.
[19] Technical dossier/Section IV/Annex IV_01 and Supplementary information September 2020/EFSA-Q-2019-00525-RTQII-B-Act_laying hens and Annex_RTQII_51.
[20] Technical dossier/Section IV/Annex IV_02 and Supplementary information September 2020/EFSA-Q-2019-00525-RTQII-B-Act_laying hens and Annex_RTQII_7.
[21] Technical dossier/Supplementary information September 2020/Annex_RTQII_8.
[22] Technical dossier/Supplementary information September 2020/Annex_RTQII_9.

Table 1: Trial design and dosages of the efficacy trials performed in laying hens

Study	Total no of animals (animals × replicate) replicates × treatment	Breed (age at start) duration	Composition feed (form)	Groups (CFU/kg feed)	
				Intended	Analysed
1	768 (4) 96	Hy-Line Brown (21 weeks old) 168 days	Wheat, maize and soybean meal (mash)	0 1.6×10^9	– $1.6–2.8 \times 10^9$
2	100 (2) 25	Hy-Line Brown (20–22 weeks old) 84 days	Wheat, rye, and soybean (mash)	0 1.6×10^9	– 2.5×10^9
3	360 (9) 20	Isa Brown (22 weeks old) 84 days	Wheat, maize, soybean meal and sunflower meal (mash)	0 1.6×10^9	– 1.7×10^9
4	160 (4) 20	Hy-Line Brown (17–21 weeks old) 84 days	Wheat, soybean meal and barley (mash)	0 1.6×10^9	– 1.7×10^9

CFU: colony forming unit.

Table 2: Summary of performance results of laying hens receiving B-Act®

Trial	Groups	Daily feed intake (g)	Laying rate (%)	Daily egg mass per hen (g)[1]	Egg weight (g)	Feed to egg mass[2]	Mortality and culling (%)
1	Control	123	95.0[b]	60.0	63.1	0.489	5.9
	B-Act®	123	95.6[a]	60.3	63.1	0.492	3.5
2	Control	121	95.6	4,880	60.4	2.077[a]	0
	B-Act®	119	97.0	4,932	60.7	2.010[b]	0
3	Control	123[a]	95.7	57.7	60.3	2.127[a]	0
	B-Act®	119[b]	96.8	58.6	60.6	2.035[b]	0
4	Control	119[a]	91.5	18.1	59.0	2.221[a]	0
	B-Act®	112[b]	96.2	19.1	59.0	1.982[b]	0

1: Total egg mass per hen in study 2 and total egg mas per cage (kg) in study 4.
2: Egg mass to feed ratio in study 1.
a, b: For each study, values in the same column with different superscript letters are significantly different ($p < 0.05$).

No mortality was seen in trials 2–4, while in trial 1 mortality was on average 4.7%, not treatment related. The hens in the B-Act® group showed a significantly better feed to egg mass ratio compared to control animals in three out of four studies and a higher laying rate in the remaining study. Therefore, B-Act® when supplemented at 1.6×10^9 CFU/kg complete feed has the potential to be efficacious in laying hens as a zootechnical additive.

Efficacy for minor poultry species for laying, poultry species for breeding purposes and ornamental birds.

The efficacy B-Act® for laying hens was established in the studies described above and that for chickens for fattening and turkeys for fattening was established in previous opinions (EFSA FEEDAP Panel, 2016, 2019a,b). Since the applicant proposes the use of the same level (1.6×10^9 CFU/kg complete feed) for minor poultry species for laying, poultry species for breeding purposes and for ornamental birds, the conclusions reached in laying hens and chickens and turkeys for fattening can be extended/extrapolated to these avian species/categories at the same use level.

3.3.2. Compatibility with coccidiostats

In the previous opinion on the use of B-Act® in feed for chickens for fattening and reared for laying, the compatibility of *B. licheniformis* DSM 28710 with the coccidiostats salinomycin, lasalocid, robenidine, maduramicin, decoquinate, monensin, narasin, nicarbazin, semduramicin, diclazuril and halofuginone at the highest authorised levels for chickens for fattening was established (EFSA FEEDAP Panel, 2016). Conclusions previously drawn apply to the current application, provided that the maximum authorised concentration of the coccidiostats for minor poultry species for laying, poultry

species for breeding purposes and for ornamental birds (when maximum authorised concentrations exist), are equal or lower than those for chickens for fattening.

3.3.3. Conclusions on efficacy

B-Act® when supplemented at 1.6×10^9 CFU/kg complete feed has the potential to be efficacious in laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds.

B. licheniformis DSM 28710 is compatible with salinomycin, lasalocid, robenidine, maduramicin, decoquinate, monensin, narasin, nicarbazin, semduramicin, diclazuril and halofuginone at the highest authorised levels for chickens for fattening. The strain is also expected to be compatible with coccidiostats for minor poultry species for laying, poultry species for breeding purposes and for ornamental birds, provided that the maximum authorised concentrations of these coccidiostats (when maximum authorised concentrations exist) are equal or lower than those for chickens for fattening.

3.3.4. 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[23] and Good Manufacturing Practice.

4. Conclusions

The active agent (*B. licheniformis* DSM 28710) fulfils the requirements of the QPS approach to the assessment of safety and no concerns are expected from other components of the additive. Consequently, B-Act® can be presumed to be safe for the target animals, consumers of products from animals fed with the additive and the environment.

In the absence of data, no conclusions could be drawn on the skin/eye irritation or skin sensitisation potential of the additive, but B-Act® is considered a respiratory sensitiser.

B-Act® when supplemented at 1.6×10^9 CFU/kg complete feed has the potential to be efficacious in laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds.

B. licheniformis DSM 28710 is compatible with salinomycin, lasalocid, robenidine, maduramicin, decoquinate, monensin, narasin, nicarbazin, semduramicin, diclazuril and halofuginone at the highest authorised levels for chickens for fattening which was established, provided that the maximum authorised concentration of the coccidiostats for minor poultry species for laying, poultry species for breeding purposes and for ornamental birds (when maximum authorised concentrations exist), are equal or lower than those for chickens for fattening.

5. Documentation as provided to EFSA/Chronology

Date	Event
30/07/2019	Dossier received by EFSA. B-Act® for laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds. Submitted by Huvepharma N.V.
13/08/2019	Reception mandate from the European Commission
14/11/2019	Application validated by EFSA – Start of the scientific assessment
06/02/2020	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 strain*
17/02/2020	Comments received from Member States
08/06/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
30/06/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterization and efficacy*
30/09/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
28/01/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

[23] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

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Abbreviations

ANOVA	analysis of variance
CFU	colony forming unit
CLSI	Clinical and Laboratory Standards Institute
EURL	European Union Reference Laboratory
EUCAST	The European Committee on Antimicrobial Susceptibility Testing
MIC	minimum inhibitory concentration
ORF	open reading frame
PCR	polymerase chain reaction
QPS	qualified presumption of safety
WGS	whole genome sequence