REGULATED PRODUCTS SAFETY ASSESSMENT

Assessment on the Safety and Efficacy of a Feed Additive Consisting of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 (GalliPro® Fit & GalliPro® Fit 10) for All Poultry (Chr. Hansen A/S)(RP2245)

Food Standards Agency[1], Food Standards Scotland[2]

[1] Regulated Products Risk Assessment, Food Standards Agency, UK, [2] Risk Assessment, Food Standards Scotland, UK

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FSA Research and Evidence

An application was submitted to the Food Standards Agency and Food Standards Scotland in January 2024 from Chr. Hansen A/S ("the applicant") for the authorisation of an additive consisting of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840, under the category of 'zootechnical additive' and functional group 'gut flora stabiliser' for a supplementary use in feed and water for laying hens and other poultry kept for egg production or breeding. The applicant also seeks authorisation for the modification of the terms of the existing authorisation by introducing a new formulation with a 10-fold increase in concentration of the active agents in the additive (from 3.2×10^9 to 3.2×10^{10} colony forming units (CFU)/g additive). Additionally, the applicant is seeking the authorisation for use in feed and water for drinking for all poultry.

In 2025, the European Food Safety Authority (EFSA) published a scientific opinion on the safety and efficacy of a feed additive consisting of *B. subtilis* DSM 32324, *B. subtilis* DSM 32325 and *B. amyloliquefaciens* DSM 25840 (EFSA FEEDAP Panel, 2025). The FEEDAP Panel concluded that the additive is safe for the target species (including poultry species for laying and breeding), the environment and consumers when used under the proposed conditions of use. Both forms of the additive are non-irritant to the eyes but are considered skin and respiratory sensitisers. It was also concluded that the additive has the potential to be efficacious as a zootechnical additive in all poultry at 1.6×10^9 CFU/kg feed and 5.4×10^8 CFU/L water for drinking.

The FSA/FSS have reviewed the applicant's authorisation application, supporting documentation, and other regulators' risk assessments, most notably the EFSA risk assessment opinion, and considers sufficient evidence has been demonstrated to conclude without the need for further questions or risk assessment.

This is a joint FSA and FSS publication.

1. Introduction

The FSA and FSS have received a request from Chr. Hansen A/S and have undertaken an assessment of a feed additive consisting of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 under Assimilated Regulation (EC) No 1831/2003 (EC, 2003) in each nation of Great Britain (GB) for a new authorisation, including a modification and extension of use, under the category 'zootechnical additive,' functional group 'gut flora stabiliser' for supplementary use in feed and water for laying hens and other poultry kept for egg production or breeding (e.g., chickens, turkeys, ducks, geese, pheasants, quail, guinea fowl, ostrich).

In line with Article 8 of Assimilated Regulation No 1831/2003 (EC, 2003), the assessment has considered and concluded whether 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 guidance for the evaluation of feed additive applications, has formed the basis and structure for the assessment.

To ensure the regulatory systems of the FSA/FSS are risk proportionate, and resources are used effectively, the FSA and FSS have used the evidence submitted by the applicant and other information in the public domain, including the EFSA risk assessment opinion, to provide a summary assessment of the evidence of safety and efficacy presented in this report.

In 2025, EFSA published a risk assessment opinion on the safety and efficacy of the feed additive GalliPro® Fit 10, consisting of *B. subtilis* DSM 32324, *B. subtilis* DSM 32325 and *B. amyloliquefaciens* DSM 25840 (EFSA FEEDAP Panel, 2025). The FEEDAP Panel was able to conclude on the safety and efficacy of the additive seeking authorisation.

These opinions have been reviewed by FSA/FSS risk assessors. It has been verified that the standard approach, when compared to the relevant guidance applied in GB, has been followed and the conclusions made are consistent with the data summarised in the opinion.

The result of the assessment is that there is sufficient evidence of safety and efficacy for the Panel to conclude this assessment at this time. This assessment represents the opinion of the FSA and FSS.

Table 1. Table showing products included in this assessment.

Title	Product type	Intended use/s	Intended dose/intake
GalliPro® Fit 10	Feed additive	Zootechnical additive: gut flora stabiliser	1.6×10^9 CFU/kg feed; 5.4×10^8 CFU/L water for drinking.

2. Assessment

2.1. Details of other regulators opinions

2.1.1. Current authorisation

The additive GalliPro® Fit consisting of *B. subtilis* DSM 32324, *B. subtilis* DSM 32325 and *B. amyloliquefaciens* DSM 25840 is authorised as a feed additive in the EU and Great Britain (GB) at a minimum level of 3.2×10^9 colony forming units (CFU)/g additive in feed and water for drinking (1.6×10^9 CFU/kg feed and at 5.4×10^8 CFU/L water for drinking) for poultry for fattening, reared for laying or reared for breeding (EFSA FEEEDAP Panel, 2020).

The initial assessment of GalliPro® Fit was published prior to the UK's exit from the EU; therefore, the assessment is applicable to GB. Only the modification of the additive to allow simultaneous use with the approved coccidiostats monensin, salinomycin, narasin, nicarbazin+narasin and lasalocid was assessed by the FSA/FSS (Food Standards Agency & Food Standards Scotland, 2025).

2.1.2. Other regulators opinions

In 2025, the European Food Safety Authority (EFSA) published a scientific opinion on the efficacy of the feed additive, GalliPro® Fit 10, consisting of *B. subtilis* DSM 32324, *B. subtilis* DSM 32325 and *B. amyloliquefaciens* DSM 25840 (EFSA FEEDAP Panel, 2025).

The FEEDAP Panel have previously assessed the safety and efficacy, and also a modification of a less concentrated form of the product that is currently under assessment by the FSA/FSS (EFSA FEEDAP Panel, 2020, 2023a).

The FEEDAP Panel's opinions have been reviewed by FSA/FSS risk assessors. It has been verified that the standard approach, when compared to the relevant guidance applied in GB, has been followed and the conclusions made are consistent with the data summarised in the opinion.

2.1.3. Methodology applied in the EFSA opinion

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) assessed the safety and the efficacy of the additive, in accordance with guidance documents:

- Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017c);
- Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a);
- Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b);
- Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018);
- Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019);
- Guidance on studies concerning the safety of use of the additive for users (EFSA FEEDAP Panel, 2023b);
- Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024);

and principles in Assimilated Regulation (EC) No 429/2008.

These guidance documents were developed and implemented prior to the UK's exit from the EU and were also adopted by the FSA and FSS on exit, with the exception of 'Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024)' and 'Guidance on studies concerning the safety of use of the additive for users (EFSA FEEDAP Panel, 2023b)', which were incorporated by FSA and FSS in August 2025.

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

2.2.1. Characterisation of the active agents

GalliPro® Fit 10 is a feed additive containing a mixture of spores of *B. subtilis* DSM32324, *B. subtilis* DSM32325 and *B. amyloliquefaciens* DSM25840 as active agents, the three strains meet the requirements of the qualified presumption of safety (QPS) approach to safety assessment (EFSA FEEDAP Panel, 2023c).The three strains were fully characterised in a previous opinion in line with the guidance requirements (EFSA FEEDAP Panel, 2020, 2023a). In the opinion, the FEEDAP Panel concluded that the strains did not have any toxigenic potential and were susceptible to all relevant antibiotics. The applicant used bioinformatic analyses of the whole genome sequence (WGS) data to confirm the taxonomic identification of the active agents.

The genomes of the active agents were analysed for the presence of antimicrobial resistance (AMR); several instances of AMR were identified that exceeded the established thresholds (EFSA FEEDAP Panel, 2021). Following EFSA's criteria, the applicant conducted further analyses, no evidence of acquired AMR gene was detected, therefore, the FEEDAP Panel concluded that the strains do not contain acquired AMR genes and are not a safety concern.

2.2.2. Characterisation of the additive

The current authorisation of GalliPro® Fit contains spores of the three active agents reaching a minimum guaranteed total concentration of 3.2 × 10^9 CFU/g additive (1.6 × 10^9 CFU *B. subtilis DSM* 32324/g; 1.0 × 10^9 CFU *B. subtilis DSM* 32325/g and 0.6 × 10^9 CFU *B. amyloliquefaciens* /g. With this application (GalliPro® Fit 10), the applicant seeks to increase the concentration of the active ingredient 10-fold to reach a minimum guaranteed total concentration of the three active agents of 3.2 × 10^{10} CFU/g additive while preserving the same ratio (i.e. minimum of 1.6 × 10^{10} CFU *B. subtilis* DSM 32324/g; 1.0 × 10^{10} CFU *B. subtilis* DSM 32325/g and 0.6 × 10^{10} CFU *B. amyloliquefaciens*/g).

The applicant has provided evidence that confirms compliance with the specifications in terms of the ratio between the three active agents; five batches of GalliPro® Fit 10 were analysed showing total bacterial cell counts in the range 5.8–6.2 × 10^{10} CFU/g.

Chemical impurities were analysed in three independent batches, the results showed cadmium, lead, mercury, arsenic and aflatoxin B1 concentrations at the following values: Cd: 0.083–0.114 mg/kg; Pb: 0.517–0.868 mg/kg; Hg: 0.0039–0.0065 mg/kg; As: 0.323–0.505 mg/kg; and aflatoxin B1: below the limit of quantification of the analytical method.

The applicant also conducted analyses across five batches to investigate microbial contamination. Coliforms, yeasts and moulds, *Escherichia coli*, *Salmonella* spp., Enterobacteriaceae (three batches) and *B. cereus* (three batches) were tested for. The results showed < 17 CFU/g for coliforms, < 50 CFU/g for yeasts and filamentous fungi, < 10 CFU/g for *E. coli* and Enterobacteriaceae, < 10 CFU/g for *B. cereus* and no *Salmonella* spp. detection in 25 g of additive.

The additive is described as a white to yellowish, free-flowing powder that is slightly hygroscopic. Three batches of the additive were analysed; the mean value of bulk density was determined to be 1329 (1280–1373) kg/m^3, the mean value of tapped density was 1830 (1778–1881) kg/m^3.

The applicant used the Stauber-Heubach method to determine the dusting potential of the additive of three independent batches; the mean value was 1700 mg/m^3 (600–2400 mg/m^3). The same three batches were used to determine particle size using laser diffraction; particles below 100µm amounted up to 29.0%, and particles below 10µm amounted up to 13%.

The FEEDAP Panel concluded that the detected impurities and the level of microbial contamination raised no safety concerns.

The FSA and FSS agree with the conclusions reached for the identity and characterisation of the additive.

The FSA and FSS agree that the levels of detected impurities and microbial contamination do not pose safety concerns. It is also agreed that the three strains do not carry acquired antimicrobial resistance (AMR) genes, and therefore, are not considered a safety risk.

2.2.3. Manufacturing process

The manufacturing process remains unchanged since the previous assessments performed by EFSA. The composition of the additive remains 20% active agents and 80% carriers (limestone/calcium carbonate). The applicant has submitted new data on purity, physico-chemical properties, shelf-life and homogeneity. The FEEDAP Panel considered the stability data discussed in previous opinions to be applicable to the current assessment (EFSA FEEDAP Panel, 2020, 2023a).

The FSA and FSS have reviewed these documents and have determined that the applicant provided sufficient information for assessment.

2.2.4. Stability and homogeneity

The additive was stored under different conditions, and the bacilli counts were monitored to determine the shelf-life of the additive. Only 3-month results for three batches are reported for the additive stored at 25°C with ambient relative humidity (%RH) which showed no loss in viability. No viability losses (< 0.5 log) were observed after 24-month storage at 30°C and 37°C with ambient RH (one batch) or at 30°C with 65% RH (one batch). Although the individual counts of the active agents were not monitored, the FEEDAP Panel consider this data acceptable as the active agents are in spore form.

One batch of the additive was tested in a mineral-vitamin premixture for poultry to confirm homogenous distribution, 12 subsamples were analysed for total bacilli counts and showed a coefficient of variation (cv) of 13%.

The FSA and FSS conclude that the applicant has sufficiently demonstrated the stability and homogeneity of the additive.

2.2.5. Conditions of use

The applicant is seeking an extension of use to the current authorisation to include all poultry with the same conditions of use. The additive is intended for supplementary use in feed and water for laying hens and other poultry kept for egg production or breeding at an intake of 1.6×10^9 CFU/kg feed; 5.4×10^8 CFU/L water for drinking. The additive is currently authorised with an active substance content of a minimum 3.2×10^9 CFU/g; this extension of use authorisation seeks an active substance content of a minimum 3.2×10^{10} CFU/g.

The FEEDAP Panel noted that the current authorisation allows the simultaneous use of the additive with the following coccidiostats: diclazuril, decoquinate, halofuginone, monensin, salinomycin, narasin, as well as the combination of nicarbazin and narasin and lasalocid.

The applicant requests the same conditions of use for GB as EFSA evaluated in their 2025 opinion (EFSA FEEDAP Panel, 2025). The FSA/FSS agree that the conditions of use proposed by the applicant are clearly described and consistent with those presented in the evaluation carried out by EFSA. It is also agreed that the additive can be used simultaneously with the coccidiostats mentioned above.

2.3. Section III: Safety

2.3.1. Safety for the target species, consumers and the environment

The additive is manufactured using strains that meet the requirements of the (QPS) approach to safety assessment (EFSA FEEDAP Panel, 2020, 2023a). The QPS approach is applicable to this application as the applicant has provided data that demonstrates the absence of acquired antimicrobial resistance genes. The FEEDAP Panel determined that no additional safety concerns will be introduced by the use of the more concentrated form of GalliPro® Fit as the exposure of animals will be the same, therefore, use of the additive in all poultry for laying or breeding is considered safe for the target species, the consumers and the environment.

2.3.2. Safety for the user

The applicant is seeking authorisation of an extension of use, as well as a 10-fold increase in concentration (3.2×10^9 CFU/g to 3.2×10^{10} CFU/g) of the active ingredients of the additive GalliPro® Fit, which is already authorised in GB and EU. GalliPro® Fit is considered to be a respiratory sensitiser, it is shown to be non-irritant to eyes or skin (EFSA FEEDAP Panel, 2023a). The EFSA FEEDAP Panel states that the extension of use to all poultry for laying/ breeding would not introduce hazards for users not already considered.

Exposure by inhalation is possible as the highest dusting potential of GalliPro Fit 10 was reported as 2400 mg/m^3. Testing according to OECD TG 438 was carried out by the applicant in an isolated chicken eye (ICE) test, the results showed the additive is non-irritant to eyes. The additive is considered a skin and respiratory sensitiser due to the presence of microorganisms in the additive, any exposure through skin and the respiratory tract is considered a risk.

The FEEDAP Panel determined that both forms of the additive are not irritant to the eyes but are considered skin and respiratory sensitisers. Inhalation and dermal exposure are considered a risk.

The FSA/FSS agree that both forms of the additive are non-irritant to the eyes but are considered skin and respiratory sensitisers and that inhalation and dermal exposure are considered a risk.

2.4. Section IV: Efficacy

The EFSA FEEDAP Panel previously concluded that GalliPro® Fit has the potential to be efficacious when added at 1.6×10^9 CFU/kg in the feed for all poultry for fattening and reared for laying/breeding (EFSA FEEDAP Panel, 2020, 2023a).

2.4.1. Efficacy for laying hens

The applicant submitted four trials involving laying hens from various genetic backgrounds. In each trial, hens were housed in cages and randomly assigned to experimental groups: two groups in trials 2, 3, and 4, and six groups in trial 1. The basal diets were either unsupplemented (control) or supplemented with the additive at the minimum recommended level of 1.6×10^9 CFU/kg. Trial 1 also included additional inclusion levels. The additive concentration in the experimental feeds was verified by analysis.

Mortality and overall health were monitored daily throughout the experimental period and the most likely causes of death/culling was recorded. The hens were weighed at the start and end of each experiment in all four trials, with initial ages ranging from 21 to 25 weeks and final ages from 34 to 45 weeks. Feed intake, egg production, and egg weight/ size were recorded at regular intervals, results showed slight variation across trials. Egg quality was assessed at multiple points during the trials. The average daily feed intake, laying rate, egg mass, and feed-to-egg mass ratio were calculated for the entire experimental period.

Data analysis for the trials was performed; the statistical significance level was set at 0.05. The results from these analyses are presented in Table 2.

No differences between groups were observed in the rate of mortality, which was within commercial standards. A higher laying rate than the control group was observed within group 1 which was supplemented with the additive at 1.6×10^9 CFU/kg feed. A higher average daily feed intake was also observed, but it did not result in worsening of the feed-to-egg mass ratio. Lower feed intake, which led to improved feed-to-egg mass ratio compared to the control, was observed in trial 3 which was also supplemented with the additive at 1.6×10^9 CFU/kg feed. In trial 2, hens receiving the additive at the proposed use level laid eggs with a higher average weight compared to those in the control group. However, the FEEDAP Panel considered that this single parameter is insufficient to substantiate an improvement in laying performance. Furthermore, no effects from the dietary supplementation of the additive were observed in trial 4.

Table 2. Effects of GalliPro® Fit and GalliPro® Fit 10 on the laying performance of laying hens.

Trial	Groups (CFU/kg feed)	Average daily feed intake (g/hen/day)	Final body weight (g)	Laying Rate (%)	Egg Weight (g)	Egg Mass[(1)] (g/hen)	Feed-to-egg mass ratio	Mortality (%)
1	0	116.6	1684	94.0	60.3	56.8	2.06	0.7
	3.2×10^8	118.1	1662	93.7	60.3	56.6	2.09*	1.6
	8.0×10^8	117.8	1659	94.2	60.0	56.6	2.09*	1.4
	1.6×10^9	119.1*	1633	95.2*	60.2	57.3	2.08	1.0
	3.2×10^9	117.9	1625*	94.9	60.2	57.2	2.07	1.0
	6.4×10^9	118.2*	1672	95.0	60.4	57.4	2.06	3.0
2	0	119.7	1897	94.1	57.6	54.2	2.21	1.7
	1.6×10^9	119.5	1898	93.3	58.2*	54.3	2.21	1.0
3	0	124.7	1914	95.3	60.6	404	2.16	0.3
	1.6×10^9	121.8*	1919	95.3	60.3	402	2.13*	1.3
4	0	113.4	2106	98.0	59.1	57.6	1.97	0
	1.6×10^9	113.5	2119	98.0	59.4	57.9	1.96	0

*: Mean values within a trial and a column with an asterisk are significantly different to the control group $p < 0.05$

(1) : In g/hen per day with the exception of trial 3 where it is expressed as g/hen per week

Overall, the FEEDAP Panel concluded that the inclusion of the additive in the feed for laying hens at 1.6×10^9 CFU/kg improved the laying performance in two studies (laying rate in trial 1 and feed-to-egg mass ratio in trial 3).

2.4.2. Efficacy for all poultry

In the 2020 opinion, the FEEDAP Panel concluded that GalliPro® Fit had the potential to be efficacious as a zootechnical additive in chickens for fattening at 1.6×10^9 CFU/kg feed (EFSA FEEDAP Panel, 2020). In the 2025 opinion, the FEEDAP Panel stated that, in two trials in laying hens provided by the applicant, the additive showed potential to be efficacious at the same level as a zootechnical additive. Therefore, the FEEDAP Panel concluded that the additive in both forms (GalliPro® Fit and GalliPro® Fit 10) has the potential to be efficacious as a zootechnical additive in all poultry at 1.6×10^9 CFU/kg feed and 5.4×10^8 CFU/L water for drinking (EFSA FEEDAP Panel, 2025).

2.4.3. Compatibility with coccidiostats

The EFSA FEEDAP Panel noted that, at present, there are no coccidiostats authorised for laying hens and limited authorisations for other minor species. The current authorisation allows the simultaneous use of the additive with the following coccidiostats: diclazuril, decoquinate, halofuginone, monensin, salinomycin, narasin, a combination of nicarbazin and narasin, and lasalocid. The compatibility with the above-listed coccidiostats has been already established at the highest inclusion level of the coccidiostat authorised for chickens for fattening (EFSA FEEDAP Panel, 2020, 2023a). Therefore, compatibility can also be assumed when the additive is used in other poultry species and categories, provided the inclusion level does not exceed that authorised for chickens for fattening.

2.4.4. Conclusions on efficacy

In the 2025 opinion, the FEEDAP Panel concluded that the additive in both forms (GalliPro® Fit and GalliPro® Fit 10) has the potential to be efficacious as a zootechnical additive in all poultry at a minimum use level of 1.6×10^9 CFU/kg feed or 5.4×10^8 CFU/L water for drinking (EFSA FEEDAP Panel, 2025).

The FSA and FSS agree with the conclusion that both forms of the additive have the potential to be efficacious as a zootechnical additive in all poultry at a minimum use level of 1.6×10^9 CFU/kg feed or 5.4×10^8 CFU/L water for drinking.

2.4.5. Post-market monitoring

In the 2025 opinion, the EFSA FEEDAP Panel concluded that there is no need for additional post-market monitoring requirements beyond those already established under the Feed Hygiene Regulation and Good Manufacturing Practice (EFSA FEEDAP Panel, 2025).

The FSA/FSS agree with the conclusion that there is no need for additional post-market monitoring requirements beyond those already established under the Feed Hygiene Regulation and Good Manufacturing Practice.

Analytical method evaluation

The FSA/FSS consider the EURL to be a competent and reliable body for the evaluation of analytical methods for the authorisation of feed additives. The EURL evaluation standards were agreed when the UK was part of the EU, and they have remained relevant for the standards expected at UK level. Based on these premises, the conclusions on the evaluation of the analytical methods for this application have been reviewed and accepted to be applicable to the GB authorisation process. No concerns are raised at this stage for the validity of the methods for UK/GB use, and therefore, the FSA/FSS accept the EURL analytical method evaluation report (EURL, 2019).

Conclusions

The FSA/FSS conclude that the additive has been correctly identified and characterised. The amounts of the detected impurities as well as microbial contamination, do not raise safety concerns. The certificates of analysis were reviewed and confirmed compliance with the specifications.

The manufacturing details of the additive were reviewed, the FSA/FSS determine that the applicant has provided sufficient information for assessment and the processes described comply with all manufacturing specifications.

The homogeneity and stability of the additive have been evidenced in the documentation provided.

The applicant requested the same conditions of use for GB as EFSA evaluated in their 2025 opinion (EFSA FEEDAP Panel, 2025). The applicant is seeking an extension of use so that the authorisation covers all poultry at the same conditions of use. The additive is currently authorised with active substance content of a minimum 3.2×10^{9} CFU/g, this authorisation seeks an active substance content of a minimum 3.2×10^{10} CFU/g. The FSA/FSS agree with the conditions of use proposed by the applicant.

The FSA/FSS have determined that there is no need for additional post-market monitoring requirements beyond those already established under the Feed Hygiene Regulation and Good Manufacturing Practice.

The FSA and FSS conclude that the additive is safe for the target species, including poultry for fattening, laying and breeding, as well as for consumers and the environment, when used at the maximum authorised levels. In terms of user safety, exposure via skin contact or inhalation is considered a risk. Both forms of the additive are considered skin and respiratory sensitisers; they are not considered as eye irritants.

Finally, the FSA/FSS conclude that both forms of the additive have the potential to be efficacious as a zootechnical additive in all poultry at 1.6×10^9 CFU/kg feed and 5.4×10^8 CFU/L water for drinking

Caveats and uncertainties

No caveats or uncertainties were identified within this assessment.

FSA/FSS conclusions for GB risk analysis

The application has been assessed in line with the applicable guidance and is partially based on considerations of detailed proprietary information available to the Panel, which were also submitted to the FSA and FSS. The EFSA opinions identify and characterise the hazards present from the use of the additive in all animal species and there is sufficient information to enable an assessment of exposure, which is also relevant to GB. The conclusions of the EFSA opinion have been reviewed in detail by FSA and FSS and are considered appropriate and consistent, including the caveats and uncertainties identified in the opinion which are applicable to GB. Sufficient evidence has been demonstrated to conclude without further questions or risk assessment.

Abbreviations

Acronym	Definition
AMR	Antimicrobial resistance
CFU	Colony forming unit
cv	Coefficient of variation
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FSA	Food Standards Agency
FSS	Food Standards Scotland

Acronym	Definition
GB	Great Britain
ICE	Isolated chicken eye
IUPAC	International Union of Pure and Applied Chemistry
OECD	Organisation for Economic Co-operation and Development
QPS	Qualified presumption of safety
RH	Relative humidity
RP	Regulated Product
UK	United Kingdom
WGS	Whole genome sequence

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