REGULATED PRODUCTS SAFETY ASSESSMENT

Assessment on the Safety and Efficacy of a Feed Additive Consisting of *Weizmannia Faecalis* DSM 32016 (Formerly *Bacillus Coagulas* DSM 32016) for Poultry for Fattening, Poultry Reared for Laying/ breeding, Ornamental Birds and Suckling and Weaned Suidae Piglets (Biochem Zusatzstoffe Handels- Und Produktionsgesellschaft mbH) (RP2010)

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 in April 2023 from Biochem Zusatzstoffe Handels- und Produktionsgesellschaft mbH ("the applicant") for the extension of use to the authorisation and new use of an additive consisting of *Weizmannia faecalis* (formerly identified as *Bacillus coagulans*) DSM 32016 (TechnoSpore® 50), under the category 'zootechnical feed additive', functional group 'gut flora stabiliser' for its use in poultry reared for breeding/laying/fattening, ornamental birds and suckling and weaned Suidae piglets.

Under Assimilated Regulation (EU) No 2020/1755 the additive is authorised for use in feed for poultry for fattening, ornamental birds, and suckling and weaned Suidae piglets. This application requested the extension for use in feed for poultry reared for breeding/laying, as well as new authorisation for use in drinking water for poultry for fattening, reared for breeding/laying, ornamental birds, and suckling and weaned Suidae piglets. Additionally, the authorisation of simultaneous use of the additive in feed for poultry reared for breeding and laying with coccidiostats was requested.

The identity of the active agent was confirmed, showing no toxigenic activity or resistance to relevant antibiotics, and therefore safety of the strain for target species, consumers, and the environment was presumed. As no concerns arose from other components, TechnoSpore® 50 was also

considered safe for target species, consumers, and the environment. The additive is not an eye or skin irritant but is considered to be a respiratory sensitiser, with no conclusions drawn on its skin sensitisation potential.

TechnoSpore® 50 was found to be efficacious in feed for poultry reared for laying/breeding at 1×10^9 CFU/kg, and in water for drinking for poultry reared for fattening, laying/breeding, ornamental birds, and for suckling and weaned Suidae piglets at 5×10^8 CFU/L. The additive is compatible with other cocciodiostat feed additives monensin sodium, robenidine hydrochloride, salinomycin sodium, and monensin sodium + nicarbazin, but not with narasin or narasin + nicarbazin. Compatibility of TechnoSpore® 50 with decoquinate, lasalocid A sodium, semduramicin sodium, nicarbazin, or amprolium hydrochloride could not be determined, because data was not provided.

FSA/FSS has reviewed the applicant's extension to use and new use 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 undertaken an assessment of a feed additive submitted by Biochem Zusatzstoffe Handels- und Produktionsgesellschaft mbH, (Küstermeyerstraße 16, 49393 Lohne, Germany αDE NI 400076) consisting of *Weizmannia faecalis* (formerly identified as *Bacillus coagulans*) DSM 32016 (TechnoSpore® 50) under Assimilated Regulation (EC) No 1831/2003 (EC, 2003) in each nation of Great Britain (GB). Under Assimilated Regulation (EU) No 2020/1755 (EC, 2020), the additive is authorised for use in feed for poultry for fattening, ornamental birds, and suckling and weaned Suidae piglets. The applicant seeks to extend the current authorisation under the category 'zootechnical feed additive', functional group 'gut flora stabiliser' for its use in feed to poultry reared for breeding/laying, as well as new authorisation for use in drinking water

for poultry for fattening, reared for breeding/laying, ornamental birds, and suckling and weaned Suidae piglets. Additionally, the authorisation of simultaneous use of the additive in feed for poultry reared for breeding and laying with coccidiostats was requested.

In line with Article 8 of Assimilated Regulation No 1831/2003 (EC, 2003), the assessment has considered and concluded that 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 guidance put in place by the European Food Safety Authority (EFSA) for the evaluation of feed additive applications, has formed the basis and structure for the assessment.

To ensure the regulatory systems of FSA/FSS are risk proportionate and resources are used effectively, 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 presented in this report.

In 2023, EFSA published a risk assessment opinion (EFSA, 2023) on the safety and efficacy of a feed additive consisting of *Weizmannia faecalis* DSM 32016 (TechnoSpore® 50) for poultry for fattening, poultry reared for laying/breeding, ornamental birds, and suckling and weaned Suidae piglets. This opinion has been reviewed by FSA/FSS risk assessors. It has been verified that the standard approach taken, 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 UK 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
TechnoSpore® 50	Feed additive	Zootechnical additive / gut flora stabiliser	For poultry for fattening, poultry reared for laying/breeding, ornamental birds, and suckling and weaned piglets (Suidae) at a minimum concentration of 5×10^8 CFU/L drinking water For poultry reared for laying/breeding complete feed at minimum inclusion level of 1×10^9 CFU/kg

2. Assessment

2.1. Details of other regulators opinions

2.1.1. Other regulators opinions and current authorisation

In 2020, the FEEDAP Panel concluded that the active agent in the additive, *B. coagulans* DSM 32016, meets the requirements of the Qualified Presumption of Safety (QPS) approach for safety assessment and is considered safe for target animals, consumers of animal-derived products, and the environment (EFSA, 2020). As the other components of the additive did not raise concerns, TechnoSpore® 50 was deemed safe for the target species, consumers, and the environment. The additive is not a skin sensitiser, eye or skin irritant but should be considered a respiratory sensitiser. As a zootechnical additive, TechnoSpore® has the potential to be efficacious in chickens for fattening and weaned piglets at 1 x 10^9 CFU/kg of complete feed. This conclusion is also applicable to suckling piglets and can be extrapolated to other growing Suidae at the same physiological stages, as well as to other birds for fattening and ornamental birds at the same dosage level.

The FEEDAP Panel concluded that *B. coagulans* DSM 32016 in TechnoSpore® is compatible with diclazuril and halofuginone, but compatibility with decoquinate, monensin sodium, narasin, lasalocid sodium, robenidine hydrochloride, salinomycin sodium, maduramicin ammonium, nicarbazin, and narasin/nicarbazin cannot be determined, because data was not provided.

The additive is currently authorised for use in feed for poultry for fattening, ornamental birds, and suckling and weaned Suidae piglets under Commission Implementing Regulation (EU) No 2020/1755 (EC, 2020) in the European Union (EU) as well as GB.

2.1.2. 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 active substance, 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 efficacy of feed additives (EFSA FEEDAP Panel, 2018a);

- Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b);
- 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 assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019);
- the EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2021);

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 FSA and FSS on exit.

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

2.2.1. Characterization of the active substance and the additive

The active substance, isolated from canned tomatoes, has not been genetically modified and harbours no plasmids. The active agent DSM 32016 was identified as *B. coagulans*, later reclassified as *Weizmannia coagulans* (Gupta et al., 2020), in the previous assessment (EFSA, 2020). Recently, certain *W. coagulans* strains were reassigned to a new species, *Weizmannia faecalis* (Kieu et al., 2022). In this assessment, bioinformatic analysis of whole genome sequence (WGS) data confirmed that DSM 32016 aligns with *W. faecalis*. The species of the genus *Weizmannia* has since been updated to a new genus *Heyndrickxia* (Narsing Rao et al., 2023), making the current valid name for DSM 32016 *Heyndrickxia faecalis*, with *W. faecalis* as a taxonomic synonym.

A broth dilution method was used to test the antimicrobial susceptibility of the active agent with antibiotics recommended by EFSA (EFSA FEEDAP Panel, 2018b). All minimum inhibitory concentration values were at or below *Bacillus* cut-off levels, indicating susceptibility to all relevant antibiotics. The strain's whole genome sequence (WGS) was examined for the presence of antimicrobial resistance (AMR) genes by cross-referencing against the NCBI and ResFinder databases. No concerns were identified from the search at nucleotide level with set thresholds of 80% identity

and 70% length coverage for ResFinder, and 80% identity and 70% length coverage for NCBI at nucleotide and predicted proteins levels. In the previous opinion (EFSA FEEDAP Panel, 2020), testing in accordance with relevant guidance provisions ruled out the toxigenic potential of the active agent.

TechnoSpore® 50 contains viable spores of *W. faecalis* DSM 32016 at a minimum concentration of 2 x 10^{10} CFU/g of additive, along with 1% silicic acid and calcium carbonate up to 100%. The formulation and manufacturing process remain the same as those previously evaluated by the FEEDAP Panel in 2020 (EFSA, 2020), so data on composition, impurities, physico-chemical properties, and shelf life from that assessment apply to the current assessment.

In the 2020 EFSA opinion, compliance with specifications was confirmed in six batches of the additive with an average count 3.5 x 10^{10} CFU/g (range 3.2–4 x 10^{10} CFU/g) (EFSA, 2020). With the exception of lead (0.72–0.74 mg/kg), yeasts and filamentous fungi (50 CFU/g in one sample), analytical results of 3 batches of the additive were below the detection limits, demonstrating compliance with predefined specifications: *Bacillus cereus* (< 10^2 CFU/g), *Enterobacteriaceae* (< 10^3 CFU/g), *Salmonella* spp. (absent in 25 g), yeasts and filamentous fungi (< 10^2 CFU/g), aflatoxin B1 (< 5 µg/kg), ochratoxin A (< 1 µg/kg), arsenic (< 4 mg/kg), cadmium (< 5 mg/kg), lead (< 10 mg/kg) and mercury (< 0.2 mg/kg). The product is a free-flowing powder. In three batches, particle size distribution measured by laser diffraction showed 25% of particles (v/v) < 50 µm, 7% < 10 µm, and a dusting potential of 1.9–3.1 g/m^3 was measured by the Stauber–Heubach method. Dust particles collected during the dusting potential measurement were all below 100 µm, with approximately 69% < 10 µm, and a median diameter of approximately 6 µm.

The additive's shelf life was assessed by storing six batches in sealed bottles at 25°C for 18 months, showing no reduction in total *Bacillus* counts (EFSA, 2020). Four batches were mixed into a commercial vitamin–mineral premix (2 x 10^{11} CFU/kg), one into mash feed (1 x 10^9 CFU/kg), and two into piglet pelleted feed (1 x 10^9 CFU/kg), then stored at 25°C for 3 months (premixes) and 6 months (feeds). Counts remained stable within ±0.5 $\log_{10}$ CFU/g of the time zero count in all cases, and therefore were considered stable. Pelleting tests at 80°C, 90°C, and 100°C for 8 seconds caused minimal reduction (< 0.5 $\log_{10}$) in bacilli counts. Distribution tests showed coefficients of variation at 6% for mash and 5% for pelleted feed based on the 10 samples. These results are also applicable to poultry feed and premixes.

Additionally, stability tests, discussed in the latest EFSA opinion (EFSA, 2023), showed no significant loss in viability (<0.5 Log) when supplemented at 5 x 10^{10} CFU/L in water stored at 25°C for 48 hours.

The FSA and FSS agree with the conclusions reached for the characterisation of the additive and active agent. The data was reviewed by EFSA in 2020, prior to the UK's exit from the EU; thus, this opinion is applicable to GB. These studies formed part of the assessment leading to the current authorisation of the additive in GB. The certificates of analysis were reviewed by the FSA and FSS and confirmed compliance with the specifications. The identity and the manufacturing process of the additive are not changed by the current application made to the FSA and FSS and as such has not been subject to further assessment. The characterisation of the feed additive is provided as per the existing authorisation and as assessed by EFSA. The FSA and FSS identified no concerns regarding reclassification of the strain as *Weizmannia faecalis* DSM 32016.

2.2.2. Condition of use

The additive is intended for use in drinking water for poultry for fattening, ornamental birds, and suckling and weaned piglets (Suidae) at a minimum concentration of 5 x 10^8 CFU/L. For poultry reared for laying/breeding, it is intended for complete feed at minimum inclusion level of 1 x 10^9 CFU/kg and in drinking water at 5 x 10^8 CFU/L. It is also intended for use in feed for poultry reared for laying/breeding alongside coccidiostats, including monensin sodium, decoquinate, robenidine hydrochloride, lasalocid A sodium, narasin, salinomycin sodium, narasin + nicarbazin, semduramicin sodium, nicarbazin, monensin sodium + nicarbazin, and amprolium hydrochloride.

The applicant requested the same conditions of use for GB as EFSA evaluated in their latest opinion (EFSA, 2023).

2.2.3. Conclusion on Section II: Identity, characterisation and condition of use

The formulation and manufacturing process remain the same as those previously evaluated by the FEEDAP Panel in 2020 (EFSA, 2020) therefore the data on composition, impurities, physico-chemical properties, and shelf life from that assessment apply to the current assessment. The FEEDAP Panel concluded that the amounts of the detected impurities, as well as microbial contamination, do not raise safety concerns.

FSA and FSS agree with the conclusions reached for the characterisation of the additive and active agent and that these existing conclusions are applicable to this new application. The FSA/FSS agree with the conditions of use proposed by the applicant.

2.3. Section III: Safety

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

The active agent DSM 32016, taxonomically identified as *B. coagulans* in the previous assessment (EFSA FEEDAP Panel, 2020), is considered suitable by EFSA for the qualified presumption of safety (QPS) approach (EFSA BIOHAZ Panel, 2020; EFSA, 2007). This required verification of strain identity, evidence of the strain's lack of toxigenic activity, and confirmation of no acquired antibiotic resistance genes for antibiotics important to human and veterinary medicine. *B. coagulans* was reclassified as *W. coagulans*, and later as *W. faecalis*, now synonymous with *Heyndrickxia faecalis*. The FEEDAP Panel considers that the criteria applied to assess the safety of *W. coagulans* are applicable also to *W. faecalis*. The FEEDAP Panel confirmed the strain identity as *W. faecalis*, finding it free of toxigenic activity and acquired antibiotic resistance for antibiotics of human and veterinary importance, therefore can be considered safe for target species, consumers, and the environment. With no additional concerns from other additive components, TechnoSpore® 50 is also considered safe for the target species, consumers and the environment.

The FSA and FSS agree with the conclusions reached on the data and the use of qualified presumption of safety (QPS) approach, as this approach has been previously used in GB and the decisions on QPS were made while the UK were part of the EU.

2.3.2. Safety for the user

In a previous opinion, TechnoSpore® 50 was deemed non-irritating to skin and eyes but considered a respiratory sensitiser due to the proteinaceous nature of its active agent (EFSA, 2020). No new studies were included in the current application. The FEEDAP Panel concluded that the extension of use and new use in water introduce no additional hazards to users beyond those assessed previously. Therefore, the previous conclusions are applicable for the current assessment.

In the previous assessment, a skin sensitisation study (OECD TG 406) suggested TechnoSpore® 50 is not a skin sensitiser. However, the Panel notes that existing OECD guidelines evaluate only chemical substances for skin sensitisation, and no validated methods currently assess the sensitisation potential of microorganisms, leaving the skin sensitisation potential of the additive undetermined.

The FSA and FSS agree with the conclusions reached for the safety of the user. The studies were reviewed by EFSA in 2020, prior to the UK's exit from the EU; thus, this opinion is applicable to GB. These studies formed part of

the assessment leading to the current authorisation of the additive in GB. The FSA and FSS agree with the view that the extension of use and new use do not introduce new hazards to user.

2.3.3. Conclusion on Section III: Safety

The FEEDAP Panel confirmed the strain identity as *W. faecalis*, finding it free of toxigenic activity and acquired antibiotic resistance for antibiotics of human and veterinary importance; therefore it can be considered safe for target species, consumers, and the environment. With no additional concerns from other additive components, TechnoSpore® 50 is also considered safe for the target species, consumers and the environment. In conclusion regarding user safety, the additive should be classified as non-irritant to skin and eyes but considered a respiratory sensitiser due to the proteinaceous nature of its active agent. No conclusions could be drawn on the potential of the additive to be skin sensitiser.

2.4. Section IV: Efficacy

In its previous opinion, the FEEDAP Panel concluded that TechnoSpore® 50 was considered efficacious in weaned piglets and chickens for fattening at levels of 1 x 10^9 CFU/kg complete feed. This conclusion was extended to suckling piglets. In addition, it was extrapolated to the other birds for fattening, ornamental birds, and growing Suidae at similar physiological stages and use levels.

The applicant now proposes the same minimum inclusion level (1 x 10^9 CFU/kg feed) for poultry reared for laying/breeding. The FEEDAP Panel considered that the previous conclusions for chickens for fattening can extrapolated to poultry reared for laying/breeding at this dosage. Additionally, TechnoSpore® 50 is proposed for drinking water for poultry for fattening, poultry reared for laying/breeding, ornamental birds, and for suckling and weaned Suidae piglets at a minimum concentration of 5 x 10^8 CFU/L. As water intake for these target species is two to three times greater than dry feed intake, TechnoSpore® 50 is also considered to be efficacious in drinking water at the minimum proposed concentration.

The FSA and FSS agree with the conclusions reached on the data and the extension to suckling piglets and extrapolation to birds for fattening, ornamental birds, and growing Suidae at similar physiological stages, which is supported by the guidance that is also applicable in GB.

2.4.1. Compatibility with coccidiostats

In the previous assessment (EFSA FEEDAP Panel, 2020), TechnoSpore® 50 was found compatible with halofuginone and diclazuril, though compatibility with other coccidiostats such as decoquinate, lasalocid

sodium, maduramicin ammonium, monensin sodium, narasin, narasin/ nicarbazin, nicarbazin, robenidine hydrochloride and salinomycin sodium remained inconclusive. A new *in vivo* study involving 6,240 birds distributed into 8 treatments (6 replicates per treatment) over 28 days tested TechnoSpore® 50 (1×10^9 CFU/kg feed) with various coccidiostats at maximum authorised levels, including monensin sodium, monensin sodium + nicarbazin, narasin, narasin + nicarbazin, robenidine hydrochloride and salinomycin sodium. Caecal content of the birds was analysed with and without heat treatment to differentiate between the vegetative cells and spores and is summarised in Table 2. It was confirmed that *Weizmannia*-like colonies isolated from chicken caecum samples belonged to those included in the TechnoSpore® 50 product.

Table 2. Effect of coccidiostats on the counts of caecal contents of birds fed with TechnoSpore® 50.

Treatment	Mean of the colony counts of *Weizmannia*-like colonies (log CFU/g ± standard deviation) in broiler caecum samples	
	Non-heat treated samples	Heat-treated samples
Negative control	1.9 ± 0.3	2.1 ± 0.4
TechnoSpore® 50 (control)	3.3 ± 0.6	3.5 ± 0.3
TechnoSpore® 50 + monensin sodium	2.9 ± 0.6	3.5 ± 0.3
TechnoSpore® 50 + robenidine hydrochloride	2.8 ± 0.6	3.4 ± 0.3
TechnoSpore® 50 + narasin	2.5 ± 0.5	3.2 ± 0.5
TechnoSpore® 50 + salinomycin sodium	3.1 ± 0.3	3.4 ± 0.3
TechnoSpore® 50 + narasin + nicarbazin	2.7 ± 0.5	3.5 ± 0.4
TechnoSpore® 50 + monensin sodium + nicarbazin	2.9 ± 0.6	3.5 ± 0.3

Compatibility was confirmed when *Weizmannia*-like colony counts in coccidiostat-supplemented groups were similar with control group counts receiving only additive (< 0.5 log difference), except with narasin (alone and with nicarbazin), indicating incompatibility. The FEEDAP Panel concluded that TechnoSpore® 50 is compatible with monensin sodium, monensin sodium + nicarbazin, robenidine hydrochloride and salinomycin sodium, but not with narasin or narasin + nicarbazin. Compatibility of TechnoSpore® 50 with decoquinate, nicarbazin, lasalocid A sodium, semduramicin sodium and amprolium hydrochloride remains inconclusive as no data was provided.

The FSA and FSS agree with the conclusions reached on the data regarding the compatibility with coccidiostats, which demonstrate a suitable test of compatibility.

2.4.2. Conclusion on Section IV: Efficacy

The FEEDAP Panel concluded that TechnoSpore® 50 is considered to be efficacious in feed for poultry reared for laying/breeding at a minimum level of 1 x 10^9 CFU/kg complete feed and in drinking water for poultry for fattening, poultry reared laying/breeding, ornamental birds, and suckling or weaned Suidae piglets at 5 x 10^8 CFU/L of water. The FEEDAP Panel concluded that TechnoSpore® 50 is compatible with monensin sodium, monensin sodium + nicarbazin, robenidine hydrochloride and salinomycin sodium, but not with narasin or narasin + nicarbazin. Compatibility of TechnoSpore® 50 with decoquinate, nicarbazin, lasalocid A sodium, semduramicin sodium and amprolium hydrochloride remains inconclusive as no data was provided.

The FSA and FSS agree with the conclusions reached on the data and the use of the extension to suckling piglets and extrapolation to birds for fattening, ornamental birds, and growing Suidae at similar physiological stages, which is supported by the guidance that is also applicable in GB. The FSA and FSS agree with the conclusions reached on the data regarding the compatibility with coccidiostats. This demonstrates that the additive favourably affects animal production, performance or welfare, particularly by affecting the gastrointestinal flora of the target species

3. Analytical method evaluation

FSA/FSS evaluated the EURL analytical method evaluation, noting it was carried out in 2019, when the UK was still part of the EU and would have participated of their approval. 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). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

4. Conclusions

The FEEDAP Panel concluded that theTechnoSpore® 50 is considered safe for target species, consumers, and the environment. It is not eye or skin irritant but is considered to be a respiratory sensitiser due to proteinaceous nature of its active agent. No conclusion can be drawn on skin sensitisation potential. The additive is considered efficacious in feed for poultry reared for laying/breeding at 1 x 10^9 CFU/kg complete feed and in drinking water for poultry for fattening, reared for laying/ breeding poultry, ornamental birds, and for suckling and weaned Suidae piglets at minimum inclusion level of 5 x 10^8 CFU/L. The FEEDAP Panel concluded that TechnoSpore50® is compatible with monensin sodium, monensin sodium + nicarbazin, robenidine hydrochloride and salinomycin

sodium, but not with narasin or narasin + nicarbazin. Compatibility of TechnoSpore® 50 with decoquinate, nicarbazin, lasalocid A sodium, semduramicin sodium, and amprolium hydrochloride remains inconclusive as no data was provided.

5. Caveats and uncertainties

No conclusion can be drawn on the skin sensitisation potential of the additive due to lack of data.

Compatibility of TechnoSpore® 50 with decoquinate, nicarbazin, lasalocid A sodium, semduramicin sodium, and amprolium hydrochloride remains inconclusive as no data was provided.

6. 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 opinion identifies and characterises the hazards present from this proposed extension of use and new use in drinking water, and there is sufficient information to enable an assessment of exposure, which is also relevant to GB. The risk characterisation is unchanged from the 2020 opinion for most areas, and appropriate evidence was submitted to support the requested modifications. 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

Abbreviation	Definition
AMR	Antimicrobial resistance
ANI	Average nucleotide identity
CFU	Colony firming units
EC	European Commission
EU	European Union
EFSA	European Food Safety Authority
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
GB	Great Britain
OECD	Organisation for Economic Co-operation and Development

Abbreviation	Definition
QPS	Qualified Presumption of Safety
RP	Regulated Product
UK	United Kingdom
WGS	Whole genome sequence

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