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Safety and efficacy of a feed additive consisting of *Weizmannia faecalis* DSM 32016 (TechnoSpore50®) for poultry for fattening, poultry reared for laying/breeding, ornamental birds and suckling and weaned *Suidae* piglets (Biochem Zusatzstoffe Handels- und Produktionsgesellschaft GmbH)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of *Weizmannia faecalis* (formerly identified as *Bacillus coagulans*) DSM 32016 (TechnoSpore50®) as a zootechnical feed additive for poultry reared for breeding/laying/fattening, ornamental birds and suckling and weaned *Suidae* piglets. The additive is authorised for use in feed for poultry for fattening, ornamental birds and suckling and weaned *Suidae* piglets. This application sought the extension of use in feed for poultry reared for breeding/laying and the new authorisation in water for drinking for suckling and weaned *Suidae* piglets, poultry for fattening, reared for breeding/laying and ornamental birds. Moreover, the applicant requested the authorisation of simultaneous use in feed for poultry reared for breeding and laying with coccidiostats. The identity and the lack of toxigenic activity of the active agent was confirmed, and it did not show resistance to relevant antibiotics; therefore, the strain was presumed safe for the target species, consumers and the environment. Since other components did not introduce concerns, TechnoSpore50® was also considered safe for the target species, consumers and the environment. The additive is not a skin/eye irritant but is a respiratory sensitiser. No conclusions could be drawn on the skin sensitisation potential of the additive. TechnoSpore50® was considered 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, poultry reared for laying/breeding, ornamental birds and for suckling and weaned *Suidae* piglets at 5×10^8 CFU/L. TechnoSpore50® is compatible with halofuginone, diclazuril, monensin sodium, robenidine hydrochloride, salinomycin sodium and monensin sodium + nicarbazin, but not with narasin or narasin + nicarbazin. No conclusions could be drawn on the compatibility of TechnoSpore50® with decoquinate, lasalocid A sodium, semduramicin sodium, nicarbazin or amprolium hydrochloride.

Keywords: zootechnical additives, gut flora stabilisers, *Weizmannia faecalis* DSM 32016, efficacy, compatibility, coccidiostats

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7. In particular, Article 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received two requests from Biochem Zusatzstoffe Handels- und Produktionsges. GmbH,[2] one for the authorisation of the additive consisting of *Weizmannia faecalis*[3] DSM 32016 (TechnoSpore50®), when used as a feed additive for poultry for fattening, poultry reared for laying/breeding, ornamental birds and suckling and weaned *Suidae* piglets (category: zootechnical additive; functional group: gut flora stabilisers) and one for the modification of the terms of the authorisation of the additive when used with poultry reared for laying/breeding.

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) and under Article 13(3) (modification of the authorisation of a feed additive). The dossiers were received on 23 March and 19 May 2022 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00221 and https://open.efsa.europa.eu/questions/EFSA-Q-2022-00316. The particulars and documents in support of the applications were considered valid by EFSA as of 11 August and 7 September 2022.

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 efficacy of the feed additive consisting of *W. faecalis* DSM 32016 (TechnoSpore50®), when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The additive is a preparation containing viable spores of *W. faecalis* DSM 32016. EFSA issued an opinion on the safety and efficacy of this product when used in feed for piglets, other growing *Suidae*, chickens for fattening, other poultry for fattening and ornamental birds (EFSA FEEDAP, 2020).

The additive is currently authorised for use in feed for poultry for fattening, ornamental birds and suckling and weaned *Suidae* piglets (4b1900).[4]

The applicant wants an extension of use in feed for poultry reared for laying/breeding and also a new use in water for drinking for all the species (suckling and weaned *Suidae* piglets, poultry for fattening, reared for breeding/laying and ornamental birds). In addition, the applicant wishes to obtain the authorisation for the simultaneous use of TechnoSpore50® with coccidiostats.

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 *Weizmannia faecalis* DSM 32016 (TechnoSpore50®) as a feed additive.

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Biochem Zusatzstoffe Handels- und Produktionsges. mbH, Küstermeyerstr. 16, 49393 Lohne, Germany.
[3] Formerly identified as *Weizmannia coagulans*.
[4] Commission Implementing Regulation (EU) No 2020/1755 of 24 November 2020; OJ L 395, 25.11.2020, p. 5.
[5] FEED-2022-3470 (article 13) and FEED-2022-3991 (article 4).

In accordance with Article 38 of the Regulation (EC) No 178/2002[6] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[7] a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[7] EFSA carried out a public consultation on the non-confidential version of the application from 6 June to 27 June 2023 for which no comments were received.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 07 September 2022 to 07 December 2022 for which the received comments were considered for the assessment.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers to deliver the present opinion.

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.[8]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of active substance (trade name of the product) is in line with the principles laid down in Regulation (EC) No 429/2008[9] and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEEDAP 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 environment (EFSA FEEDAP Panel, 2019) and the EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2021).

3. Assessment

The additive under assessment is a preparation of viable spores of *W. faecalis* DSM 32016 (tradename TechnoSpore50®) currently authorised for use in feed for poultry for fattening, ornamental birds and suckling and weaned *Suidae* piglets.

With this application, the applicant is seeking an extension of use of the additive in feed for poultry reared for laying/breeding, and the new use in water for drinking for these animal species and those for which it is currently authorised (i.e. suckling and weaned *Suidae* piglets, poultry for fattening and ornamental birds). Moreover, the applicant wishes to obtain the authorisation for simultaneous use in feed for poultry for fattening and reared for laying/breeding with the coccidiostats: halofuginone, diclazuril, monensin sodium, decoquinate, robenidine hydrochloride, lasalocid A sodium, narasin, salinomycin sodium, narasin/nicarbazin, semduramicin sodium, nicarbazin, monensin/nicarbazin and amprolium hydrochloride.

[6] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, pp. 1–48.

[7] Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

[8] The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

[9] 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.

3.1. Characterisation

3.1.1. Characterisation of the active agent

The active agent was isolated from canned tomatoes. It is deposited in the Deutsche Sammlung von Mikroorganismen und Zellkulturen with the accession number DSM 32016.[10] It has not been genetically modified, and it harbours no plasmids.

In the previous assessment (EFSA FEEDAP Panel, 2020), the active agent DSM 32016 had been taxonomically identified as *Bacillus coagulans*, a species that was reclassified as *Weizmannia coagulans* (Gupta et al., 2020). A few strains of *W. coagulans* have recently been assigned to the new species *Weizmannia faecalis* (Kieu et al., 2022). During the current assessment, the taxonomical identification of the active agent was carried out by bioinformatic analysis using whole genome sequence (WGS) data and allocated the DSM 32016 strain to the *W. faecalis* species. The taxonomic re-assignment was based on the analysis of the [redacted] confirming that the strain belongs to the *W. faecalis* species.[11]

Even more recently the species of the genus *Weizmannia* have been transferred to a new genus, *Heyndrickxia* (Narsing Rao et al., 2023). Thus, the actual validly published species name for the strain under assessment is *Heyndrickxia faecalis*, retaining *Weizmannia faecalis* the taxonomic status of synonym.

The susceptibility of the active agent to antimicrobials was tested using a broth dilution method and including the data set of antibiotics recommended by EFSA (EFSA FEEDAP Panel, 2018b).[12] All the minimum inhibitory concentration values were equal to or fell below the cut-off values for *Bacillus*. Therefore, the strain is considered to be susceptible to all the relevant antibiotics.

A search for antimicrobial resistance genes by WGS was done in the NCBI antimicrobial resistance nucleotide database at nucleotide and predicted proteins levels (minimum 45% identity and 25% length coverage as thresholds). The results were filtered with thresholds of 80% identity and 70% length coverage. A second search was done in the ResFinder database at nucleotide level with 80% identity and 70% length coverage as thresholds.[13] No acquired antimicrobial resistance genes or predicted proteins of concern were identified.

In the former opinion (EFSA FEEDAP Panel, 2020), the toxigenic potential of the active agent was excluded in a test compliant with the provisions in the corresponding guidance.

3.1.2. Characterisation of the additive

The additive TechnoSpore50® contains viable spores of *W. faecalis* DSM 32016 as an active agent. It has the same formulation (viable spores with a minimum concentration of 2×10^{10} CFU/g of additive, silicic acid (1%)[13] and calcium carbonate (up to 100%)) and method of manufacture as that considered a previous opinion on the additive adopted by the FEEDAP Panel in 2020 (EFSA FEEDAP Panel, 2020). Thus, the data pertaining to composition, impurities, physico-chemical properties and shelf-life described in that opinion apply to the current assessment. The applicant provided data on the stability in water that are described below.

The stability of the additive (three batches) in water for drinking was studied when supplemented at 5×10^{10} CFU/L and stored at 25°C for 48 h.[14] No viability losses at the end of the storage period were observed (< 0.5 Log).

3.1.3. Conditions of use

The additive is intended for use in water for drinking for poultry for fattening, ornamental birds and suckling and weaned *Suidae* piglets at the minimum proposed concentration of 5×10^8 CFU/L.

The additive is also intended for use in complete feed for poultry reared for laying/breeding at the minimum proposed inclusion level of 1×10^9 CFU/kg and in water for drinking at 5×10^8 CFU/L.

[10] Annex_II_NEW_Certificate safe deposit_Weizmannia faecalis.
[11] Annex_II_9_Bioinformatic analysis_062023.
[12] Annex_II_12_Antibiotic susceptibility_NEW.
[13] Currently under re-evaluation according to art. 10 of Regulation EC No 1831/2003.
[14] Annex II_26.

The additive is intended for simultaneous use in feed for poultry for fattening and reared for laying/breeding with the coccidiostats: halofuginone, dicalzuril, monensin sodium, decoquinate, robenidine hydrochloride, lasalocid A sodium, narasin, salinomycin sodium, narasin + nicarbazin, semduramicin sodium, nicarbazin, monensin sodium + nicarbazin and amprolium hydrochloride.

3.2. Safety

3.2.1. Safety for the target species, consumers and environment

In the previous assessment (EFSA FEEDAP Panel, 2020), the active agent DSM 32016 was taxonomically identified as *B. coagulans*, a species considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach (EFSA, 2007; EFSA BIOHAZ Panel, 2020). This approach requires the identity of the strain to be conclusively established and evidence to be provided that the strain lacks toxigenic activity and does not show acquired antimicrobial resistance genes for antibiotics of human and veterinary importance. *B. coagulans* has been recently allocated to the *Weizmannia* genus as *Weizmannia coagulans* (Gupta et al., 2020), which is a species also suitable for the QPS approach (EFSA, 2007; EFSA BIOHAZ Panel, 2022). In 2022, the species *W. faecalis*, showing an ANI value of 94.6% with the *W. coagulans*, has been described (Kieu et al., 2022). In the course of the current assessment, the active agent has been reallocated first to *W. coagulans* and then to *W. f*aecalis (synonym of *H. faecalis*; Narsing Rao et al., 2023). Based on the above, the FEEDAP Panel considers that the criteria applied to assess the safety of *W. coagulans* are applicable also to *W. faecalis*. In the view of the FEEDAP Panel, the identity of the active agent as *W. faecalis* is established, and the lack of toxigenic activity confirmed. *W. faecalis* DSM 32016 does not show acquired antimicrobial resistance for antibiotics of human and veterinary importance; therefore, it can be considered safe for the target species, consumers and the environment. Since the other components of the additive do not give rise to concerns, TechnoSpore50® is also considered safe for the target species, consumers and the environment.

3.2.2. Safety for the user

In a former opinion, it was concluded that TechnoSpore50® is not a skin/eye irritant but owing to the proteinaceous nature of the active agent, the additive is considered a respiratory sensitiser (EFSA FEEDAP Panel, 2020). No additional studies were provided in the current application. The FEEDAP Panel considers that the new uses of the additive, i.e. extension of use to poultry reared for laying/breeding and use in water, would not introduce hazards for users of the product not already considered as part of the previous assessment. Therefore, these conclusions reached in the previous assessment apply to the current application.

In the course of the previous assessment, the applicant submitted a skin sensitisation study (OECD TG 406) with the product under assessment suggesting that TechnoSpore50® is not a skin sensitiser. However, the FEEDAP Panel notes that the OECD test guidelines available at present are designed to assess the skin sensitisation potential of chemical substances only and that currently no validated assays for assessing the sensitisation potential of microorganisms are available. Therefore, no conclusion can be drawn on the skin sensitisation potential of the additive.

3.2.2.1. Conclusions on safety

The Panel concludes that TechnoSpore50® is considered to be safe for the target species, consumers and the environment.

The additive is not a skin/eye irritant but is a respiratory sensitiser. No conclusions can be drawn on the skin sensitisation potential of the additive.

3.3. Efficacy

In the former opinion (FEEDAP Panel, 2020), TechnoSpore50® was considered to be efficacious in weaned piglets and chickens for fattening at 1×10^9 CFU/kg complete feed. This conclusion was extended to suckling piglets and extrapolated to other birds for fattening and ornamental birds and to other growing *Suidae* at the same physiological stage and at the same use level.

The applicant is intending to use the additive at the same minimum proposed inclusion level (1×10^9 CFU/kg complete feed) in feed for poultry reared for laying/breeding. The FEEDAP Panel considers that the previous conclusion in chickens for fattening can be extended/extrapolated to poultry reared for laying/breeding when used at the same use level.

Similarly, TechnoSpore50® is intended for use in water for drinking for poultry for fattening, poultry reared for laying/breeding, ornamental birds and for suckling and weaned *Suidae* piglets at the minimum proposed concentration of 5×10^8 CFU/L. Considering that TechnoSpore50® was considered to be efficacious in chickens for fattening and weaned piglets at 1×10^9 CFU/kg complete feed and that the water intake of these target species would be two to three times the amount of dry matter feed intake, TechnoSpore® can also be considered to be efficacious in water for drinking for the target species at the minimum proposed concentration of 5×10^8 CFU/L.

3.3.1. Compatibility with coccidiostats

In the former opinion (EFSA FEEDAP Panel, 2020), TechnoSpore50® was considered to be compatible with halofuginone and diclazuril, while no conclusion could be reached on its compatibility with monensin sodium, decoquinate, robenidine hydrochloride, lasalocid sodium, narasin, salinomycin sodium, maduramicin ammonium, nicarbazin and narasin/nicarbazin.

A new *in vivo* study was conducted to support the compatibility of TechnoSpore50® with monensin sodium, robenidine hydrochloride, narasin, salinomycin sodium, narasin + nicarbazin and monensin sodium + nicarbazin.[15]

A total of 6,240 birds were distributed into eight treatments (six replicates per treatment).[16] The duration of the trial was 28 days. The feed (containing TechnoSpore50® at 1×10^9 CFU/kg feed) was either not supplemented or supplemented with the corresponding coccidiostat at the respective maximum authorised level: monensin sodium ([redacted] mg/kg feed), robenidine hydrochloride ([redacted] mg/kg), narasin ([redacted] mg/kg), salinomycin sodium ([redacted] mg/kg), narasin + nicarbazin ([redacted] mg/kg narasin + [redacted] mg/kg nicarbazin) or monensin sodium + nicarbazin ([redacted] mg/kg monensin sodium + [redacted] mg/kg nicarbazin). A control group, not supplemented with TechnoSpore50® nor coccidiostats, was also included.

At the end of the trial, the birds were killed, and their caecal contents were sampled on [redacted] to enumerate the active agent. The analysis of the samples was also performed with heat treatment in order to differentiate between the vegetative cells and spores (Table 1).

TABLE 1: Effect of coccidiostats on the counts of caecal contents of birds fed with TechnoSpore50®

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
TechnoSpore50® (control)	3.3 ± 0.6	3.5 ± 0.3
TechnoSpore50® + [redacted] mg monensin sodium/kg feed	2.9 ± 0.6	3.5 ± 0.3
TechnoSpore50® + [redacted] mg robenidine hydrochloride/kg	2.8 ± 0.6	3.4 ± 0.3
TechnoSpore50® + [redacted] mg narasin/kg feed	2.5 ± 0.5	3.2 ± 0.5
TechnoSpore50® + [redacted] mg salinomycin sodium /kg feed	3.1 ± 0.3	3.4 ± 0.3
TechnoSpore50® + [redacted] mg narasin/kg feed + [redacted] mg nicarbazin/kg feed	2.7 ± 0.5	3.5 ± 0.4
TechnoSpore50® + [redacted] mg monensin sodium + [redacted] mg nicarbazin/kg feed	2.9 ± 0.6	3.5 ± 0.3

A random selection of *Weizmannia*-like colonies in the samples tested were isolated from counting plates ([redacted]), purified and identified using an [redacted] method. The profiles obtained confirmed that 99% of 240 colonies were identified as *W. faecalis* and demonstrated that *Weizmannia*-like colonies isolated from chicken caecum samples belonged to those included in the TechnoSpore50® product.

The counts for *Weizmannia*-like colonies in the groups supplemented with the additive and coccidiostats were similar to the counts in the control group receiving only the additive (< 0.5 log), except for the group receiving narasin alone and in combination with nicarbazin.

[15] Annexes II_29.a-g.
[16] Supplementary Information_Question 4.

Therefore, the Panel concludes that TechnoSpore50® is compatible with monensin sodium, robenidine hydrochloride, salinomycin sodium and monensin sodium + nicarbazin, but not with narasin alone or in combination with nicarbazin. In the absence of data, no conclusions can be drawn on the compatibility of TechnoSpore50® with decoquinate, nicarbazin, lasalocid A sodium, semduramicin sodium, nicarbazin or amprolium hydrochloride.

3.3.1.1. Conclusion of efficacy

TechnoSpore50® is considered to be efficacious in feed for poultry reared for laying/breeding at the minimum inclusion level of 1×10^9 CFU/kg complete feed and in water for drinking for poultry for fattening, poultry reared for laying/breeding, ornamental birds and for suckling and weaned *Suidae* piglets at the minimum proposed concentration of 5×10^8 CFU/L of water.

TechnoSpore50® is compatible with halofuginone, diclazuril, monensin sodium, robenidine hydrochloride, salinomycin sodium and monensin sodium + nicarbazin, but not with narasin or narasin + nicarbazin. No conclusions can be drawn on the compatibility of TechnoSpore50® with decoquinate, lasalocid A sodium, semduramicin sodium, nicarbazin or amprolium hydrochloride.

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[17] and good manufacturing practice.

4. Conclusions

TechnoSpore50® is considered to be safe for the target species, consumers and the environment.

The additive is not a skin/eye irritant but is a respiratory sensitiser. No conclusions can be drawn on the skin sensitisation potential of the additive.

TechnoSpore50® is considered to be efficacious in feed for poultry reared for laying/breeding at the minimum inclusion level of 1×10^9 CFU/kg and in water for drinking for poultry for fattening, poultry reared for laying/breeding, ornamental birds and for suckling and weaned *Suidae* piglets at the minimum proposed concentration of 5×10^8 CFU/L.

TechnoSpore50® is compatible with halofuginone, diclazuril, monensin sodium, robenidine hydrochloride, salinomycin sodium and monensin sodium + nicarbazin, but not with narasin or narasin + nicarbazin. No conclusions can be drawn on the compatibility of TechnoSpore50® with decoquinate, lasalocid A sodium, semduramicin sodium, nicarbazin or amprolium hydrochloride.

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Abbreviations

CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
MIC	minimum inhibitory concentration