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Assessment of the application for modification of the terms of the authorisation of the feed additive consisting of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 (GalliPro® Fit) for all poultry species for fattening and reared for laying/breeding (Chr. Hansen A/S)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Miguel Prieto Maradona, Montserrat Anguita, Jaume Galobart, Elisa Pettenati, Rosella Brozzi and Natalia Alija Novo

Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 (GalliPro® Fit) as a zootechnical feed additive for all poultry species for fattening and reared for laying or for breeding. The additive is already authorised for use in feed and water for drinking for the above-mentioned species. With this application, the company requested the modification of the current authorisations as regards the simultaneous use of the additive with the coccidiostats monensin, salinomycin, narasin, nicarbazin+narasin and lasalocid. The proposed modification in the conditions of the authorisation would not modify the conclusions previously drawn regarding the safety of GalliPro® Fit. The additive is safe for the target species, consumers and the environment. The additive is not a dermal/eye irritant but should be considered a respiratory sensitiser. The FEEDAP Panel was not in the position to conclude on the skin sensitisation potential. The Panel concluded that GalliPro® Fit is compatible with the coccidiostats monensin, salinomycin, narasin, nicarbazin+narasin and lasalocid.

Keywords: zootechnical additives, gut flora stabilisers, *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325, *Bacillus amyloliquefaciens* DSM 25840, safety, QPS

Requestor: European Commission

Question number: EFSA-Q-2022-00325

Correspondence: feedap@efsa.europa.eu

Panel members: Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

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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 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 a request from Chr. Hansen A/S[2] for the modification of the terms of the authorisation of the additive consisting of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 (GalliPro® Fit), when used as a feed additive for all poultry species for fattening or reared for laying and reared for breeding (category: zootechnical; functional group: gut flora stabiliser).

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 13(3) (modification of the authorisation of a feed additive). *The dossier was received on* 19 May 2022 *and the general information and supporting documentation are available at* https://open.efsa.europa.eu/questions/EFSA-Q-2022-00325. The particulars and documents in support of the application were considered valid by EFSA as of 16 November 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 safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 (GalliPro® Fit), when used under the proposed conditions of use (see **Section 3.1.3**).

1.2. Additional information

The additive is a preparation containing spores of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840. EFSA issued an opinion on the safety and efficacy of this product when used in feed and water for drinking for all poultry species for fattening or reared for laying or reared for breeding (EFSA FEEDAP Panel, 2020).

The additive is currently authorised for use in feed and water for all poultry species for fattening or reared for laying or reared for breeding (4b1894).[3]

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[4] in support of the modification of the terms of the authorisation of the feed additive consisting of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 (GalliPro® Fit).

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the

[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] Chr. Hansen A/S, 10–12 Boege Allé, DK-2970 Hoersholm, Denmark.
[3] Commission Implementing Regulation (EU) 2020/1762 of 25 November 2020 concerning the authorisation of a preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 as a feed additive for all poultry species for fattening or reared for laying or reared for breeding.
[4] Dossier reference: FEED-2022-3273.
[5] 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, p.1–48.

same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality, a non-confidential version of the dossier has been published on Open.EFSA.[7]

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 presubmission phase and public consultations,[6] EFSA carried out a public consultation on the non-confidential version of the technical dossier from 15 May to 5 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 16 November 2022 to 16 February 2023 for which the received comments were considered for the assessment.

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]

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA to deliver the present output.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 (GalliPro® Fit) is in line with the principles laid down in Regulation (EC) No 429/2008[9] and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017), 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) and EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2021).

3. Assessment

The subject of the assessment is a feed additive currently authorised consisting of *B. subtilis* DSM 32324, *B. subtilis* DSM 32325 and *B. amyloliquefaciens* DSM 25840 (zootechnical additive, functional group: gut flora stabilisers) for use in feed and water for all poultry species for fattening, reared for laying or reared for breeding (see **Section 1.2**). With the current application, the applicant is seeking the modification of the current authorisation, to allow the simultaneous use of the additive with the authorised coccidiostats monensin, salinomycin, narasin, nicarbazin + narasin and lasalocid.

3.1. Characterisation

3.1.1. Characterisation of the active agents

In the 2020 opinion (EFSA FEEDAP Panel, 2020), the active agents (two strains of *Bacillus subtilis* (DSM 32324 and DSM 32325) and one strain of *B. amyloliquefaciens* (DSM 25840)) were fully characterised as per the requirements of the FEEDAP guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b). In the present application, new data have been submitted confirming the taxonomical identification of the active agents and their susceptibility to antibiotics which are described below.

The taxonomical identification of *B. subtilis* DSM 32324 and DSM 32325 and *B. amyloliquefaciens* DSM 25840 was achieved by a bioinformatic analysis using whole genome sequence (WGS) data. The taxonomic assignment of the *B. subtilis* strains was based on average nucleotide identity (ANI) with a similarity of 97.7% and 98.1%, respectively, with the reference strain *B. subtilis* 168. Using the same methodology, the identity of *B. amyloliquefaciens* DSM 25840 was also confirmed, with an ANI value of 98.8% with the type strain *B. amyloliquefaciens* DSM 7^T.[10]

[6] Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements
[7] Available at: https://open.efsa.europa.eu/dossier/FEED-2022-3273
[8] The report linked to the previous dossier (related to FAD-2019-0009) is available on the EU Science Hub: 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.
[10] ID_certificate_DSM 32324, ID_certificate_DSM 32325 and ID_certificate_DSM 25840.

The susceptibility of the three strains to antimicrobials was evaluated using a broth dilution method and including the list of antibiotics recommended by EFSA (EFSA FEEDAP Panel, 2018b). All the minimum inhibitory concentration (MIC) values were equal or fell below the cut-off values. Therefore, the strains are considered to be susceptible to all the relevant antibiotics.[11]

The WGS data of the active agents were interrogated for the presence of antimicrobial resistance (AMR) genes against two curated databases, with a threshold of 80% identity and 70% coverage. The interrogation was performed at protein level at the NCBI Bacterial Antimicrobial Resistance Reference Gene database and at nucleotide level with ResFinder.[12] The interrogation of *B. subtilis* DSM 32324, *B. subtilis* DSM 32325 and *B. amyloliquefaciens* DSM 25840 genomes identified some hits but none of them was considered of safety concern.

3.1.2. Characterisation of the additive

The product is a dry powder containing viable spores of the three active agents (*B. subtilis* DSM 32324 and DSM 32325 and *B. amyloliquefaciens* DSM 25840; 8:5:3 ratio), reaching a minimum guaranteed total concentration of the three active agents of 3.2×10^9 colony forming units (CFU)/g additive.

The additive has the same formulation of 2% of the active agents and a 98% of limestone/calcium carbonate (carriers) and method of manufacture as that considered in the most recent opinion adopted by the FEEDAP Panel in 2020 (EFSA FEEDAP Panel, 2020). Thus, the data pertaining to impurities, physico-chemical properties and shelf-life described in that opinion apply to the current assessment.[13]

3.1.3. Conditions of use

GalliPro® Fit is authorised for use in feed and water for drinking for all poultry species for fattening and reared for laying/breeding at a minimum content of 1.6×10^9 CFU/kg complete feed or 5.4×10^8 CFU/L of water for drinking.

The applicant is seeking to modify the conditions of use by allowing the simultaneous use of the additive with the approved coccidiostats: monensin, salinomycin, narasin, nicarbazin+narasin and lasalocid.[14]

3.2. Safety

In the former opinion, the three active agents included in the additive (*B. subtilis* DSM 32324, *B. subtilis* DSM 32325 and *B. amyloliquefaciens* DSM 25840) were considered to meet the requirements of the QPS approach to safety assessment and were presumed safe for the target animals, consumers of products derived from animals fed the additive and the environment (EFSA, 2007; EFSA BIOHAZ Panel, 2023). No new data have been provided that would make the Panel reconsider its previous conclusions. The Panel considers that the proposed modifications to the terms of the authorisation of the additive will not introduce safety concerns not already considered in the previous assessment.

With regard to user safety, in the former opinion the Panel concluded that 'in the absence of data, no conclusions on the skin/eye irritancy or skin sensitisation of the additive can be made. Due to the proteinaceous nature of the active agents, the additive should be considered a respiratory sensitiser'.

The applicant has provided new data that are described below.

The skin irritation potential of GalliPro® Fit was investigated in an *in vitro* skin irritation study according to OECD TG 439.[15] The results of the study indicated that the additive is non-irritant to the skin (UN GHS 'No Category').

The eye irritation potential of GalliPro® Fit was investigated in an *in vitro* eye irritation study according to OECD TG 492.[16] The results of the study showed that the additive is non-irritant to eyes (UN GHS 'No Category').

[11] Annex_II_2_2_2b_MIC_statements_2023.
[12] AmR_statement_DSM25840_B_amylo, AmR_statement_DSM32324_B_subtilis and AmR_statement_DSM32325_B_subtilis.
[13] Sect_II_Identity_GPFit_1.ID+2.Charact_2022.
[14] Sect_II_Identity_GPFit_5.Cond_of_use_2022.
[15] Annex_III_3.1b_439_GPF_Skin.
[16] Annex_III_3.1a_492_GPF_Eye.

No data were made available regarding the skin sensitisation potential. 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.[17]

On the basis of the studies submitted, the additive is considered non-irritant to skin and eyes, but should be considered a respiratory sensitiser. The FEEDAP Panel is not in the position to conclude on the skin sensitisation potential of the additive.

3.3. Compatibility with coccidiostats

In the previous opinion, the FEEDAP Panel concluded that the strains *B. subtilis* DSM 32324 and DSM 32325 and *B. amyloliquefaciens* DSM 25840 are compatible with diclazuril, decoquinate and halofuginone, but could not conclude on the compatibility of the additive with monensin sodium, salinomycin sodium, narasin, robenidine hydrochloride and maduramicin ammonium.

The applicant has submitted new data to support the compatibility of the additive with some coccidiostats that are described below.

An *in vivo* study was conducted to support the compatibility of *B. subtilis* DSM 32324 and DSM 32325 and *B. amyloliquefaciens* DSM 25840 with monensin, narasin, salinomycin, nicarbazin + narasin and lasalocid.

A total of 560 1-day-old Ross 308 male chicks were distributed into seven treatment groups (4 pens of 20 birds per treatment group).[18] The feed containing GalliPro® Fit at 1.6×10^9 CFU/kg feed was either not supplemented (control) or supplemented with the corresponding coccidiostat at the maximum authorised level: monensin (125 mg/kg feed), salinomycin (70 mg/kg), narasin (70 mg/kg), nicarbazin + narasin (50 mg/kg feed nicarbazin + 50 mg/kg narasin) or lasalocid (125 mg/kg feed). A negative control group, not supplemented with GalliPro® Fit nor with coccidiostats was also included. The duration of the trial was 28 days.

At the end of the trial, the birds (5 birds/pen per treatment) were killed and their caecal contents were sampled and plated on tryptone soya agar plates to individually enumerate the three active agents (*B. subtilis* DSM 32324 and DSM 32325 and *B. amyloliquefaciens* DSM 25840). The analysis was also performed on samples subject to heat treatment in order to differentiate between the vegetative cells and spores.

The lasalocid group was retested in a new trial setup because it did not reach the target levels of coccidiostat and the additive in the first analysis. Results are given in Table 1.

Table 1: Effect of coccidiostats on the counts of caecal contents of birds fed with GalliPro® Fit

Treatment	Mean of the colony counts of *Bacillus*-like colonies (log CFU/g ± standard deviation) in broiler caecum samples		
	Number of samples	Non-heat treated samples	Heat treated samples
Negative control	17	2.2 ± 0.5	2.2 ± 0.3
GalliPro® Fit (control)	14/20	4.6 ± 0.3 4.5 ± 0.3*	4.6 ± 0.3 4.5 ± 0.3*
GalliPro® Fit + 125 mg Monensin/kg feed	17	4.6 ± 0.3	4.6 ± 0.2
GalliPro® Fit + 70 mg Narasin/kg feed	18	4.6 ± 0.3	4.6 ± 0.4
GalliPro® Fit + 70 mg Salinomycin/kg feed	16	4.5 ± 0.3	4.6 ± 0.3
GalliPro® Fit + 50 mg Nicarbazin/kg feed + 50 mg narasin/kg feed	14	4.7 ± 0.2	4.8 ± 0.2
GalliPro® Fit + 125 mg lasalocid/kg feed	20	4.7 ± 0.4	4.7 ± 0.4

*: Control used in lasalocid test.

A random selection of *Bacillus*-like colonies in the samples tested were isolated from counting plates (approx. 50 isolates per treatment, 346 in total), purified and identified using an internally developed quantitative polymerase chain reaction (qPCR) method, with validated individual specificity for the

[17] https://www.efsa.europa.eu/sites/default/files/2022-07/feedap20220629-30_m.pdf
[18] Annex_II_4_4 Compatibility

three *Bacillus* strains. The profiles obtained confirmed that 98% of 346 colonies were identified as *B. subtilis* DSM 32324, DSM 32325 or *B. amyloliquefaciens* DSM 25840, and demonstrated that the *Bacillus*-like colonies isolated from broiler caecum samples belonged to those included in the GalliPro® Fit product. No differences ($\leq$ 0.5 log) were observed between the *Bacillus*-like colonies counts in the groups supplemented with the additive and coccidiostats and those in the control group supplemented with the additive but not receiving any coccidiostat. Therefore, the Panel concludes that GalliPro® Fit is compatible with monensin, salinomycin, narasin, nicarbazin+narasin and lasalocid.

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[19] and good manufacturing practice.

4. Conclusions

The proposed modification in the conditions of the authorisation would not modify the conclusions previously drawn regarding the safety of GalliPro® Fit. The additive is safe for the target species, consumers and the environment.

The additive is not a skin/eye irritant, but should be considered a respiratory sensitiser. The FEEDAP Panel is not in the position to conclude on the skin sensitisation potential of the additive.

The Panel concludes that GalliPro® Fit is compatible with the coccidiostats monensin, salinomycin, narasin, nicarbazin+narasin and lasalocid.

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[19] 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

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