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SCIENTIFIC OPINION

# Safety and efficacy of a feed additive consisting of *Saccharomyces cerevisiae* DSM 34246 (Canobios-BL) for cats and dogs (ACEL pharma s.r.l.)

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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 *Saccharomyces cerevisiae* DSM 34246 as a zootechnical feed additive for dogs and cats. The additive, with the trade name Canobios-BL, is intended for use in feed for cats and dogs at a proposed minimum inclusion level of $5 \times 10^9$ CFU/kg complete feed. *Saccharomyces cerevisiae* is considered by EFSA to be suitable for the qualified presumption of safety approach to safety assessment. Since the identity of the active agent has been clearly established and the additive is composed by dried cells of the active agent and an emulsifier, that are not expected to introduce any risk, the additive is considered safe for the target species. Canobios-BL is not a skin or eye irritant but should be considered a skin and respiratory sensitiser. Canobios-BL is considered to be efficacious in feedingstuffs for dogs and cats at the use level $5 \times 10^9$ CFU/kg complete feed.

**KEYWORDS**

Canobios-BL, efficacy, gut flora stabilisers, QPS, *Saccharomyces cerevisiae* DSM 34246, safety, zootechnical additive

# CONTENTS

# 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.

The European Commission received a request from ACEL pharma S.r.l.[2] for the authorisation of the additive consisting of *Saccharomyces cerevisiae* DSM 34246 (Canobios-BL), when used as a feed additive for cats and dogs (category: zootechnical; functional group: gut flora stabilisers).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 17 January 2023.

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 and user and on the efficacy of the feed additive consisting of *Saccharomyces cerevisiae* DSM 34246 (Canabios-BL), when used under the proposed conditions of use (see **Section 3.1.5**).

## 1.2 | Additional information

The additive is a preparation containing *Saccharomyces cerevisiae* DSM 34246. It has not been previously authorised as a feed additive in the European Union.

# 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[3] in support of the authorisation request for the use of *Saccharomyces cerevisiae* DSM 34246 (Canabios-BL) as a feed additive. The dossier was received on 16 June 2022 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00373.

In accordance with Article 38 of the Regulation (EC) No 178/2002[4] 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,[5] a non-confidential version of the dossier has been published on Open.EFSA at https://open.efsa.europa.eu/questions/FEED-2021-1473.

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,[6] EFSA carried out a public consultation on the non-confidential version of the technical dossier from 5 June to 26 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 17 January 2023 to 17 April 2023 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 peer-reviewed scientific papers to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active agent in animal feed.[7]

[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]ACEL pharma s.r.l., Via A. Manzoni 2, 10092 Beinasco (TO) – Italy.

[3]Dossier reference: FEED-2021-1473.

[4]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.

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

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

[7]Evaluation report received on 18/04/2023 and 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

## 2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *Saccharomyces cerevisiae* DSM 34246 (Canobios-BL) is in line with the principles laid down in Regulation (EC) No 429/2008[8] and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (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 environment (EFSA FEEDAP Panel, 2019), EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2021) and Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023).

# 3 | ASSESSMENT

The additive under assessment, with the trade name Canobios-BL, contains viable cells of *Saccharomyces cerevisiae* DSM 34246 and is intended to be used as a zootechnical additive in feed for cats and dogs under the functional group 'gut flora stabilisers'.

## 3.1 | Characterisation

### 3.1.1 | Characterisation of the active agent

The active agent was isolated from *Litchi chinensis* and is deposited in the Deutsche Sammlung von Mikroorganismen und Zellkulturen under the collection number DSM 34246.[9] It has not been genetically modified.

The taxonomic identification of the strain as *S. cerevisiae* was confirmed based on the whole genome sequence data. A phylogenomic analysis based on 210 orthologous genes from 163 *Saccharomyces* strains placed the production strain in a cluster with several *S. cerevisiae* strains and close to all *S. cerevisiae* var. *boulardii* strains.[10] The identification of the strain as *S. cerevisiae* was also suggested by the results of a multilocus sequence typing based on seven phylogenetic markers (ADP1, ACC1, RPN2, GLN4, ALA1, MET4 and NUP116) (Ayoub et al., 2006) against 145 strains of *S. cerevisiae* and 5 of *S. boulardii* (Khatri et al., 2017), and a comparison of the ribosomal 5.8S-ITS (Internal Transcribed Spacer) sequence with that of the type strains of species of the *Saccharomyces* genus.[11]

### 3.1.2 | Characterisation of the additive

The product under assessment is a dry powder consisting of 99.5% *S. cerevisiae* DSM 34246 cells and 0.5% lecithin as an emulsifier. The minimum guaranteed content of the active agent is $2 \times 10^{10}$ colony forming units (CFU)/g of additive.[12] Analysis of five batches showed compliance with the minimum specifications (mean: $2.18 \times 10^{10}$ CFU/g of additive, range: $2.1–2.3 \times 10^{10}$ CFU/g additive).[13]

Specifications are set for microbial contaminants: total microbial counts ($\leq 10^6$ CFU/g), *Enterobacteriaceae* ($\leq 100$ CFU/g), *Salmonella* spp. (no detection in 25 g) and *Escherichia coli* (no detection in 1 g). The analysis of the above-mentioned batches of the additive showed compliance with these limits.[14]

Several batches of the additive were subject to the investigation of chemical impurities including arsenic, cadmium, mercury ([redacted]), lead, nickel ([redacted]), mycotoxins and to a multipesticides analysis ([redacted]).[15] Results showed levels in the following ranges: 0.021–0.023 mg As/kg, 0.020–0.021 mg Cd/kg; 0.010–0.150 mg Pb/kg; 0.030–0.830 mg Ni/kg, while mercury was below the limit of detection (LOD).[16] Levels of aflatoxins (B1, G1, B2, G2), deoxynivalenol, HT-2

[8]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.

[9]Safe_Deposit_DSM34246.

[10]Saccharomyces Cerevisiae Canobios-BL_Det Char_Annex5_a.

[11]Annex 5.

[12]Saccharomyces Cerevisiae Canobios-BL_Det Char.

[13]Saccharomyces Cerevisiae Canobios-BL_Det Char_Annex2.

[14]Saccharomyces Cerevisiae Canobios-BL_Det Char_Annex2.

[15]Saccharomyces Cerevisiae Canobios-BL_Det Char_Annex3, Saccharomyces Cerevisiae Canobios-BL_Det, Decleration _Lot numbers CY0737_CY1129_CY1013, Saccharomyces Cerevisiae Canobios-BL_CY1013 Char_Annex3_CY0737 Saccharomyces, Cerevisiae Canobios-BL_Det Char_Annex3_CY1129 and Decleration_ Saccharomyces Cerevisiae Canobios-BL.

[16]Limit of detection (LOD): As (0.0067 mg/kg); Pb, Cd and Hg (0.0017 mg/kg), Ni (0.0083 mg/kg).

and T-2 toxins and pesticides were all below the LOD of the analytical methods except [redacted] and some traces of pesticides.[17]

The FEEDAP Panel considers that the microbial contamination and the amounts of the detected impurities in the test items do not raise safety concerns (except for the presence of nickel).

The dusting potential of three batches of the additive was determined using the Stauber-Heubach method and showed values in the range 1–3 mg/m$^3$. The same batches were tested for particle size distribution by laser diffraction method; the results showed that all particles had a diameter above 250 μm.[18]

### 3.1.3 | Manufacturing process

The active agent is grown by fermentation. Then, the biomass is concentrated by centrifugation, mixed with lecithin and dried to obtain the final pellet.[19] The applicant declared that no antimicrobials are used during the manufacturing process.[20]

### 3.1.4 | Stability and homogeneity

The shelf-life of the additive (three batches) was studied when stored at 25°C and 40°C in a multilayer bag (polyethylene–aluminium–polyethylene) for 24 and 3 months, respectively.[21] No losses (< 0.5 log) were observed at the end of the storage periods.

The stability of the additive was tested when mixed with a mash feed for dogs, a mash feed for cats and a pelleted feed (pelleting conditions not described) for dogs (three batches each) to reach the intended inclusion level in feed of $1 \times 10^{10}$ CFU/kg feed. Samples were stored at 25°C in multilayer bag (polyethylene–aluminium–polyethylene) for 24 months. At the end of the storage period, no losses (< 0.5 log) were observed. Data supporting the stability of the additive to the pelleting process were not provided.

The homogeneous distribution of the additive (three batches) in mash feed for dogs, mash feed for cats and pelleted feed for dogs was studied in the same feeds described above (based on 5 subsamples per batch (15 subsamples per feed)). The coefficient of variation was 6% in all cases.[22]

### 3.1.5 | Conditions of use

The additive is intended for use in feed for cats and dogs at a proposed minimum inclusion level of $5 \times 10^9$ CFU per kg complete feed.[23]

## 3.2 | Safety

The additive is intended to be used only in feed for cats and dogs, and therefore, there is no need to perform an assessment of the safety for the consumer and the environment.

The species *S. cerevisiae* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach (EFSA BIOHAZ Panel, 2023). The identity of the active agent was confirmed as *S. cerevisiae*. Accordingly, this strain is presumed safe for the target species. Since the additive is composed by dried cells of the active agent and an emulsifier, which is not expected to introduce any risk, the additive is also considered safe for the target species.

### 3.2.1 | Safety for the user

No specific studies investigating the effects of the additive on the respiratory system were submitted. The highest analysed nickel content in the additive was 0.83 mg/kg. Considering the dusting potential of 3 mg/m$^3$ and assuming a similar proportion of nickel in the dust as in the additive, the nickel content in the dust would be up to 0.0025 μg Ni/m$^3$. This value would not exceed the transitional limit value of 0.1 mg Ni/m$^3$ for the inhalable fraction and 8 h time-weighted

[17]LOD: Aflatoxins B1, G1, B2 and G2 (0.5 μg/kg), deoxynivalenol (0.020 μg/kg), toxins HT-2 (0.0050 μg/kg) and T-2 (0.0025 μg/kg), pesticides (0.12–0.20 mg/kg).

[18]Saccharomyces Cerevisiae Canobios-BL_Det Char_Annex4.

[19]Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Manufacturing process.

[20]Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Manufacturing process_Annex 1 and Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Manufacturing process_Annex 2.

[21]Saccharomyces Cerevisiae Canobios-BL_Physical Chemical and Tech properties.

[22]Saccharomyces Cerevisiae Canobios-BL_Physical Chemical and Tech properties.

[23]Saccharomyces Cerevisiae Canobios-BL_Details on the conditions of use and Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Manufacturing process.

average (8 h TWA) exposure established in Directive (EU) 2022/431.[24] Owing to the proteinaceous nature of the active agent and the presence of nickel, the additive should be considered a skin and respiratory sensitiser.[25]

The applicant provided two experiments regarding skin and eye irritation conducted with the additive under assessment.

The skin irritation potential of Canobios-BL was investigated in an in vitro skin irritation study according to OECD TG 439. The results showed that the additive should be classified as non-irritant to the skin (UN GHS 'No Category').[26]

The eye irritation potential of Canobios-BL was investigated in an in vitro eye irritation study according to OECD TG 492. Based on the results of the study, the additive should be considered as non-irritant to eyes (UN GHS 'No Category').[27]

#### 3.2.1.1 | *Conclusions on safety for the user*

On the basis of the studies submitted, Canobios-BL was shown to be non-irritant to skin or eyes but should be considered a skin and respiratory sensitiser.

## 3.3 | Efficacy

The applicant submitted three long-term trials in dogs and one in cats to support the efficacy as a zootechnical additive (functional group: gut flora stabiliser).[28]

### 3.3.1 | Efficacy for dogs

The three trials with dogs followed a similar experimental design. The details on the study design are provided in Table 1 and the main results in Table 2. The breeds of dogs involved in the different trials were of small (Trial 1[29]), medium (Trial 2[30]) and large (Trial 3[31]) size, with ages from 1 to 8 years and of mixed sexes. In all trials, the dogs were housed individually, with access to a common outdoor area (2–3 dogs) to allow socialising and exercise during part of the day. Dogs were randomly allocated to two experimental groups, a control group and a group treated with Canobios-BL to reach $5 \times 10^9$ CFU/kg complete feed (confirmed by analysis). The additive was incorporated to the basal diet by top-dressing via a premix with maltodextrin. The control group diet was top dressed with maltodextrin only. The experimental diet consisted of dry commercial food in kibbles administered twice daily for 35 days.

The overall health status of the animals was monitored daily. The body weight and feed intake were weekly recorded. The body condition score[32] and faecal score[33] were also assessed at weekly intervals following a blind procedure. The faecal samples were collected weekly right after defecation and pooled per animal and analysed for the dry matter content.

**TABLE 1** Trial design of the efficacy trials performed in dogs.

| Trial | Total no animals (replicates/group) trial duration | Breed age body weight sex | Composition feed (form) | Groups (CFU/kg complete feed) | |
|---|---|---|---|---|---|
| | | | | Intended | Analysed |
| 1 | 28<br>(14)<br>35 days | West Highland White Terrier<br>1–5 years<br>5–10 kg<br>64% ♀ /36% ♂ | Anchovies, potato and whole egg flour (dry kibbles) | 0<br>$5.0 \times 10^9$ | n.a.<br>$5.0 \times 10^9$ |
| 2 | 25<br>(12/13)<br>35 days | American Staffordshire Terrier<br>1–8 years<br>12–26 kg<br>68% ♀ /32% ♂ | Rice, maize, poultry protein (dry kibbles) | 0<br>$5.0 \times 10^9$ | n.a.<br>$5.1 \times 10^9$ |

[24]Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. 16.3.2022, OJ 88/1. According to Directive (EU) 2022/431, the limit value for the inhalable fraction of nickel until 18 January 2025 is 0.1 mg/m3 (measured as nickel). After this date limit, values of 0.05 mg/m$^3$ and 0.01 mg/m$^3$ (measured as nickel) shall apply for the respirable and the inhalable fractions, respectively.

[25]Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_User Safety.

[26]Test_In vitro eye irritation test_032017_OECD492_Biobasic.

[27]Test_In vitro skin irritation test_032017_OECD439_Biobasic.

[28]Efficacy section.

[29]Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Efficacy Allevamento1_Research, Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Efficacy_20240201.pdf, Statistical report 20240201, modello 1 and Declaretion CoA.

[30]Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Efficacy Allevamento2_Research, Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Efficacy_20240201.pdf, Statistical report 20240201, modello 1 and Declaretion CoA.

[31]Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Efficacy Allevamento3 dogs_Research, Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Efficacy_20240201.pdf, Statistical report 20240201, modello 1 and Declaretion CoA.

[32]Body condition score: 9-point scale (1 = too thin – 9 = too heavy; Optimum = 4–5).

[33]Faecal score: 7-point scale (1 = hard, dry pellets – 7 = watery, no texture, flat, occurs as puddles and leaves residue; Optimum = 2).

**TABLE 1** (Continued)

| Trial | Total no animals (replicates/group) trial duration | Breed age body weight sex | Composition feed (form) | Groups (CFU/kg complete feed) | |
|---|---|---|---|---|---|
| | | | | Intended | Analysed |
| **3** | 25<br>(12/13)<br>35 days | German Shepherd<br>1–5 years<br>24–39 kg<br>48% ♀ /52% ♂ | Poultry protein, maize, wheat (dry kibbles) | 0<br>$5.0\times10^9$ | n.a.<br>$5.0\times10^9$ |

Abbreviation: n.a., not analysed.

The body weight and faecal dry matter data were analysed with a mixed model, including diet, sex, time (as repeated measures) and the interaction diet × time as fixed effects. The faecal score was compared with a Kruskal–Wallis test. The dog was considered the experimental unit in all cases. The significance level was set at 0.10.

In the three trials, the inclusion of Canobios-BL in the diet of dogs at $5\times10^9$ CFU/kg complete feed resulted in an overall higher faecal dry matter content and lower faecal score in comparison to the control group. The animals' body weight and feed intake (data not shown) did not change throughout the experiment. In all cases, the body condition score remained within the optimal levels according to the scale used (data not shown).

**TABLE 2** Effects of Canobios-BL supplementation on the faecal dry matter and faecal score of dogs after 35 days.

| Trial | Groups (CFU/ kg complete feed) | Faecal dry matter | | Faecal score[1] | |
|---|---|---|---|---|---|
| | | Final (%) | Overall (%) | Final | Overall |
| **1** | 0<br>$5\times10^9$ | $33.5^b$<br>$44.7^a$ | $32.9^b$<br>$40.9^a$ | $4.1^a$<br>$3.4^b$ | $4.2^a$<br>$3.7^b$ |
| **2** | 0<br>$5\times10^9$ | $34.6^b$<br>$45.6^a$ | $33.3^b$<br>$44.5^a$ | $4.0^a$<br>$3.1^b$ | $4.1^a$<br>$3.2^b$ |
| **3** | 0<br>$5\times10^9$ | $32.3^b$<br>$44.0^a$ | $29.8^b$<br>$40.9^a$ | $4.3^a$<br>$3.2^b$ | $4.4^a$<br>$3.4^b$ |

[a,b]Mean values within a trial and within a column with a different superscript are significantly different $p < 0.10$.

[1]Faecal score: 7-point scale (1 = hard, dry pellets – 7 = watery, no texture, flat, occurs as puddles and leaves residue; Optimum = 2).

### 3.3.2 | Efficacy for cats

Fourteen Chartreux cats (3–5 kg; 3–6 years old) of both sexes (70% ♀; 30% ♂) were individually housed and randomly allocated to two experimental groups.[34] One group received a control diet and the second group received the same basal diet with Canobios-BL to reach $5\times10^9$ CFU/kg complete feed (confirmed by analysis). The additive was incorporated to the basal diet by top-dressing via a premix with maltodextrin. The control group diet was top-dressed with maltodextrin only. The experimental diet consisted of dry commercial food in kibbles (based on poultry protein, animal fat, rice and maize) administered twice a day for 35 days.[35]

The overall health status of the animals was monitored daily. The body weight and feed intake were weekly recorded. The body condition score[36] and faecal score[37] were also assessed at weekly intervals following a blind procedure, and faecal samples were collected weekly right after defecation and pooled per animal. The faecal samples were analysed for the dry matter.

The body weight and faecal dry matter data were analysed with a mixed model, including diet, sex, time (as repeated measures) and the interaction diet × time as fixed effects. The faecal score was compared with a Kruskal–Wallis test. The cat was considered the experimental unit in all cases. The significance level was set at 0.10. The main results are shown in Table 5.

[34]Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Efficacy Allevamento3 cats; Body condition score (BCS) of cats, Saccharomyces Cerevisiae Canobios-BL_Gut flora stabiliser_Efficacy_20240201.pdf and Statistical report 20240201.

[35]Control: not analysed; Canobios BL: average of $5\times10^9$ CFU/kg feed.

[36]9-point scale: 1 (too thin) to 9 (too heavy); Optimum = 4–5.

[37]7-point scale: 1 (very hard and dry, often expelled as individual pellets, requires much effort to expel from body, leaves no residue on ground when picked up) to 7 (watery, no texture, flat, present in flat puddles); Optimum = 2.

**TABLE 5** Effects of Canobios-BL supplementation on the faecal dry matter and faecal score of cats after 35 days.

| Groups | Faecal dry matter | | Faecal score[1] | |
|---|---|---|---|---|
| (CFU/kg complete feed) | Final (%) | Overall (%) | Final | Overall |
| 0 | 32.5[b] | 33.4[b] | 4.6[a] | 4.3[a] |
| $5 \times 10^9$ | 57.7[a] | 48.9[a] | 3.0[b] | 3.4[b] |

[a,b]Mean values within a column with a different superscript are significantly different $p < 0.1$.

[1]Faecal score: 7-point scale: 1 (very hard and dry, often expelled as individual pellets, requires much effort to expel from body, leaves no residue on ground when picked up) to 7 (watery, no texture, flat, present in flat puddles); Optimum = 2.

The inclusion of Canobios-BL in the diet of cats at $5 \times 10^9$ CFU/kg complete feed resulted in an overall higher faecal dry matter content and lower faecal score in comparison to the control group.

The animals' body weight and feed intake did not change throughout the experiment and the body condition score remained within the optimal levels according to the scale used (data not shown).

#### 3.3.2.1 | *Conclusions on efficacy*

Based on the data provided, the panel concludes that the additive has the potential to be efficacious in dogs and cats when added to complete feed at $5 \times 10^9$ CFU/kg.

### 3.3.3 | 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[38] and good manufacturing practice.

## 4 | CONCLUSIONS

Canobios-BL is considered safe for the target species.

The additive is non-irritant to skin or eyes but should be considered a skin and respiratory sensitiser.

Canobios-BL is considered to be efficacious in feedingstuffs for dogs and cats at the use level $5 \times 10^9$ CFU/kg complete feed.

### ABBREVIATIONS

BW body weight
CFU colony-forming unit
CV coefficient of variation
DM dry matter
EURL European Union Reference Laboratory
FEEDAP EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LOD limit of detection
LOQ limit of quantification
OECD Organisation for Economic Co-operation and Development
RH relative humidity

### CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

### REQUESTOR

European Commission

### QUESTION NUMBER

EFSA-Q-2022-00373



[38]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.

## PANEL MEMBERS

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