REGULATED PRODUCTS SAFETY ASSESSMENT

Assessment on the Safety and Efficacy of a Feed Additive Consisting of *Saccharomyces cerevisiae* CNCM I-1079 for Dogs and All Other Canidae (Lallemand Animal Nutrition UK Ltd.) (RP2105)

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 (FSA) and Food Standards Scotland (FSS) in July 2023 from Lallemand Animal Nutrition UK Ltd. ("the applicant") for the authorisation of an additive consisting of *Saccharomyces cerevisiae* CNCM I-1079 under the category 'zootechnical additives', functional group 'gut flora stabilisers', for a new use in dogs and other Canidae.

In 2024, the European Food Safety Authority (EFSA) published a scientific opinion on the safety and efficacy of a feed additive consisting of *Saccharomyces cerevisiae* CNCM I-1079 for dogs and all other Canidae. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that the active agent is suitable for the EFSA Qualified Presumption of Safety (QPS) approach and is safe for the target species, consumers and the environment. The non-coated form of the additive is not a skin or eye irritant, but no conclusion could be drawn on the eye irritation potential of the coated form. Both forms are presumed skin and respiratory sensitisers.

The FEEDAP Panel were unable to conclude on efficacy in dogs and other Canidae. In 2025, following EFSA's assessment, the applicant provided the FSA with additional information on efficacy in dogs. The FSA asked the Advisory Committee on Animal Feedingstuffs (ACAF) for advice on the efficacy data provided. The ACAF advised that *S. cerevisiae* CNCM I-1079 has the potential to be efficacious in gestating and lactating bitches and their puppies at the proposed dose of 1×10^9 CFU/kg feed. This conclusion can be extrapolated to all dogs and all other Canidae under the proposed conditions of use.

The FSA/FSS have reviewed the applicant's authorisation application, supporting documentation, ACAF's assessment on efficacy, and other regulator's risk assessments, most notably the EFSA risk assessment opinion, and considers that 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 Lallemand Animal Nutrition UK Ltd. (Spring Lane North, Malvern link, Worcestershire, WR14 1BU, UK) consisting of *Saccharomyces cerevisiae* CNCM I-1079 under assimilated Regulation (EC) No 1831/2003 (EC, 2003) in each nation of Great Britain (GB). The applicant seeks authorisation for a new use in feed for dogs and all other Canidae, under the category 'zootechnical additives', functional group 'gut flora stabilisers'.

In line with Article 8 of assimilated Regulation No 1831/2003 (EC, 2003), the assessment has considered and concluded whether the feed additive complies with the conditions laid down in Article 5, including: safety considerations for human, animal and environmental health; efficacy of the additive for its intended effect; potential impairment of the distinctive features of animal products. This, and the 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, the FSA and FSS have used the evidence submitted by the applicant and other information in the public domain, including the EFSA risk assessment opinion, to provide a summary assessment of the evidence of safety presented in this report.

In 2016, EFSA published a risk assessment opinion on the safety and efficacy of a feed additive containing *S. cerevisiae* CNCM I-1079 when used as a zootechnical additive in feed for weaned piglets and sows (EFSA FEEDAP Panel, 2016). Following the 2016 opinion, EFSA published a risk assessment in 2019 on the safety and efficacy of *S. cerevisiae* CNCM I-1079 as a feed additive for turkeys for fattening (EFSA FEEDAP Panel, 2019b). These opinions were published when the UK was still part of the EU, therefore the conclusions are considered applicable to GB.

In 2024 EFSA published a risk assessment opinion on the safety and efficacy of an additive containing *S. cerevisiae* CNCM I-1079 for use in all dogs and other Canidae (EFSA FEEDAP Panel, 2024), but the Panel were unable to conclude on efficacy in dogs and other Canidae. This opinion has been reviewed by FSA/FSS risk assessors.

In 2025, following EFSA's assessment of *S. cerevisiae* CNCM I-1079, the FSA was provided with the published study of the efficacy trial in dogs and a detailed rationale outlining why some of the endpoints not reported in the EFSA opinion were considered relevant to dogs. The FSA asked the Advisory Committee on Animal Feedingstuffs (ACAF) for advice on the efficacy data provided. Based on the efficacy trial and the additional information provided, the ACAF advised that *S. cerevisiae* CNCM I-1079 has the potential to be efficacious in dogs and all other Canidae under the proposed conditions of use. The result of EFSA's assessment combined with the advice from the ACAF has provided sufficient evidence of safety and efficacy for the FSA and FSS to conclude on the additive's safety and efficacy 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
Saccharomyces cerevisiae CNCM I-1079	Feed additive	Zootechnical additive/gut flora stabiliser	Minimum content of 1 x 10^9 CFU/kg

2. Assessment

2.1. Details of other regulators opinions

2.1.1. Current authorisation

S. cerevisiae CNCM I-1079 is currently authorised as a zootechnical feed additive in GB and EU (4d1703) for use in the following animal categories:

- Sows and weaned piglets, under assimilated EU Regulation 2018/347 and Commission Implementing Regulation (EU) No 2018/347 (EC, 2018).
- All pigs other than sows and weaned piglets, and all minor porcine species, under assimilated EU Regulation 2019/892 and Commission Implementing Regulation (EU) No 2019/892 (EC, 2019).
- Chickens for fattening and minor poultry species for fattening, under assimilated EU Regulation 2017/1905 and Commission Implementing Regulation (EU) 2017/1905 (EC, 2017).

- Turkeys for fattening, under assimilated EU Regulation 2020/162 and Commission Implementing Regulation (EU) 2020/162 (EC, 2020).

The additive is authorised in all pigs in the same functional group that is requested in the current application (gut flora stabilisers), but is authorised in chickens, minor poultry species and turkeys for fattening in the functional group "other zootechnical additives", specifically for reducing carcass contamination with *Salmonella* spp.

In 2024, EFSA released a scientific opinion on the safety and efficacy of *S. cerevisiae* CNCM I-1079 for use in dogs and all other Canidae. However, they were unable to conclude on the efficacy of the additive under the proposed conditions of use. The additive is not authorised in the EU or GB for use in dogs and other Canidae.

2.1.2. Other regulators opinions

In 2016, the EFSA published a scientific opinion on the safety and efficacy of an additive containing *S. cerevisiae* CNCM I-1079 when used as a zootechnical additive in feed for weaned piglets and sows (EFSA FEEDAP Panel, 2016). The identity of the additive and the active agent was demonstrated, and the active agent is suitable for the EFSA QPS approach and safe for the target species, consumers and the environment. The additive has the potential to be efficacious in sows when used at a dose of 1×10^9 CFU/kg feed.

In 2019, the EFSA published a scientific opinion on the safety and efficacy of *S. cerevisiae* CNCM I-1079 as a feed additive for turkeys for fattening (EFSA FEEDAP Panel, 2019b). The Panel evaluated new data provided relating to the physical-chemical properties of the additive and no concerns were raised.

In 2024, the EFSA published a risk assessment on the safety and efficacy of an additive containing *S. cerevisiae* CNCM I-1079 for use in all dogs and other Canidae (EFSA FEEDAP Panel, 2024). The Panel reiterated their conclusion that the active agent is suitable for the QPS approach and safe for the target species, consumers and the environment. The additive is considered a skin and respiratory sensitiser, and a potential eye irritant. The non-coated form of the additive is non-irritating to skin and eyes, but no conclusion could be made regarding the eye irritation potential of the coated formulation. No conclusion could be made on efficacy of the additive for dogs and other Canidae.

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

2.1.3. Methodology applied in the EFSA opinion

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

- EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2021);
- 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, 2019a);
- Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023);

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

These guidance documents also apply to the assessment framework of applications submitted to the FSA for authorisation.

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

2.2.1. Characterisation of the active agent

S. cerevisiae CNCM I-1079 was originally isolated from grape must and has not been genetically modified. The strain has been deposited with the Collection Nationale de Cultures de Microorganismes (CNCM), under the accession number I-1079.

The taxonomic identity of the strain as *S. cerevisiae* was confirmed, based on whole-genome sequence (WGS) analysis against other *Saccharomyces* spp. Using a read-mapping approach, the highest alignment was found to be to the reference genome *S. cerevisiae* S288C. Additionally, the applicant provided taxonomic analysis via internal transcribed spacer analysis; the closest match was the type-strain *S. cerevisiae* NRRL Y-12632^{T} (CBS 1171).

2.2.2. Characterisation of the additive

There are two formulations of the additive, both containing the active agent:

- A non-coated formulation (minimum 2 x 10^{10} CFU/g)
- A coated or microencapsulated formulation (minimum 1 x 10^{10} CFU/g)

The non-coated form has the appearance of brown/beige granular particles. The coated form includes vegetable oil fatty acids as coating agents (40%–50%), with the appearance of glossy beige/brown beadlets.

Batch-to-batch variation data were provided for 5 batches of each form of the additive; all batches exceeded the minimum specification. Mean cell counts for each formulation were as follows:

- Non coated formulation: 3.5 x 10^{10} CFU/g (3 x 10^{10} to 4 x 10^{10} CFU/g)
- Coated formulation: 1.6 x 10^{10} CFU/g (1.5 x 10^{10} to 1.6 x 10^{10} CFU/g)

The composition and the manufacturing process were reviewed in by the Panel in the 2016 opinion, and no concerns were identified (EFSA FEEDAP Panel, 2016). Data reviewed in previous opinions (EFSA FEEDAP Panel, 2016, 2017d, 2019b, 2019c, 2022) relating to composition, purity, physical-chemical properties and shelf-life were considered valid in the 2024 opinion.

Data on microbiological impurities were provided for three batches of each form of the additive. All results were within the specifications set by the applicant (<10 CFU/g *Escherichia coli*; *Salmonella* spp. absent in 25g; <1000 CFU/g Enterobacteriaceae and coliforms). The FEEDAP Panel agreed that the observed levels of microbial impurities did not raise safety concerns.

Data on dusting potential showed that the coated form did not produce any dust, and the non-coated form had a dusting potential ranging from 300 to 600 mg/m^3 air. Particle size distribution (PSD) was evaluated in the 2019 EFSA FEEDAP opinion. PSD was determined using a molecular sieve method and found that 99.7% of particles were >45 µm for the non-coated form, and 100% of particles were >355 µm for the coated form (EFSA FEEDAP Panel, 2019b).

In the 2024 opinion, the stability of both forms of the additive in three batches of cold-extruded complementary dog feed (dog chews) was evaluated (EFSA FEEDAP Panel, 2024). The maximum temperature reached during processing was 50 °C. The additive was added prior to extrusion, and viable cell counts of the active agent were measured both prior to extrusion and during the storage period after extrusion. Analysed cell counts prior to extrusion ranged from 1.8 x 10^{11} to 1.4 x 10^{12} CFU/kg feed. Cell counts after storage at 20-25 °C in high-density polyethylene plastic jars at ambient humidity were within 0.5 $\log_{10}$ of initial cell counts after 6 months (coated form) and 24 months (non-coated form) for all three batches, which the FEEDAP Panel consider to be a negligible loss. 10 sub-samples of the feed were analysed to determine the capacity for homogeneous distribution in the feed. The coefficient of variation (CV) was 14.4% and 18.9% for the coated and non-coated form, respectively.

The FSA and FSS agree with the conclusions reached for the characterisation of the additive and the active agent. The taxonomic identification of the active agent as *S. cerevisiae* has been confirmed, and the amounts of the detected impurities do not raise safety concerns. The certificates of analysis were reviewed by the FSA and FSS and confirmed compliance with the specifications.

Based on the stability data provided, the FSA/FSS conclude that *S. cerevisiae* CNCM I-1079 is stable for processing at temperatures up to 50 °C, and stable in cold-extruded dog feed at room temperature for 6 months and 24 months for the coated and non-coated forms, respectively. The FSA/FSS note that 50 °C is below the temperature typically used during the processing of pet feed and therefore recommend that the stability to heat treatment is stated in the directions for use of the feed additive as a condition of any potential authorisation. The FSA/FSS note that the CV for both formulations is relatively high. However, the data were not log-transformed, and these CVs are within the expected range for

untransformed homogeneity data for microbial additives. The FSA/FSS therefore conclude that both formulations of the additive are capable of homogenous distribution in feed.

2.2.3. Conditions of use

The additive is intended to be added to all types of feed for dogs and other Canidae, at a minimum use level of 1 x 10^9 CFU per kg complete feed. It is not intended for use in water.

The FSA/FSS agree with the conditions of use as proposed by the applicant but recommend that stability to heat treatment is stated in the directions for use of the feed additive as a condition of any potential authorisation.

2.2.4. Conclusion on Section II: Identity, characterisation and conditions of use

The FEEDAP Panel concluded that the active agent and both forms of the additive were fully characterised, and the amounts of the detected impurities do not raise safety concerns. Information on the stability and homogeneity in complementary dog feed was provided.

The FSA/FSS conclude that *S. cerevisiae* CNCM I-1079 is stable for processing at temperatures up to 50 °C, and stable in feed for 6 months and 24 months for the coated and non-coated forms, respectively. Both forms of the additive are capable of homogenous distribution in feed. The FSA/FSS agree with the conditions of use as proposed by the applicant but recommend that stability to heat treatment is stated in the directions for use of the feed additive as a condition of any potential authorisation.

2.3. Section III: Safety

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

The active agent is confirmed as suitable for the EFSA QPS approach and none of the other components of the additive pose a risk to the target species; therefore, the FEEDAP Panel concluded that the additive is safe for the target species. The additive is not intended to be used in food-producing animals; therefore, in line with technical guidance, an assessment of safety for consumers and the environment is not required.

2.3.2 Safety for the user

The non-coated form of the additive has a maximum analysed dusting potential of 600 mg/m^3 air; therefore, the FEEDAP Panel concluded that exposure by inhalation is possible. Conversely, the coated form did not

produce dust, so the FEEDAP Panel concluded that exposure by inhalation is unlikely. As a microbial additive, the additive is considered a respiratory sensitiser, and any exposure is considered a risk.

The skin and eye irritation potential of the non-coated form of the additive was assessed using *in vivo* studies conducted in accordance with OECD test guideline 404 and OECD test guideline 405, respectively. Based on the results of the studies, the FEEDAP panel concluded that the non-coated form is non-irritating to skin and eyes. No data were provided for the eye irritation potential of the coated form; therefore, in the absence of data the Panel were unable to conclude on the eye irritation potential of the coated form.

A skin sensitisation study conducted in accordance with OECD test guideline 429 was provided for the non-coated form. However, the FEEDAP panel were unable to conclude on skin sensitisation potential based on this study, as the OECD test guideline is not validated for use with microorganisms. The FEEDAP Panel therefore concluded that both forms of the additive are skin and respiratory sensitisers, and that any level of dermal or respiratory exposure is a risk.

FSA and FSS agree with the conclusions reached on the safety for the user.

2.3.3. Conclusion on Section III: Safety

The FEEDAP Panel concluded that both forms of the additive should be considered skin and respiratory sensitisers, and that any level of exposure is considered a risk. The non-coated form is not a skin or eye irritant, but the Panel could not conclude on the eye irritation potential of the coated form.

The FSA and FSS agree that the additive can be considered safe for the target species, consumer and the environment without the need for further studies. The FSA/FSS note that the coating agent used in the coated form is an authorised feed material in GB. The FSA/FSS agree with the user safety conclusions and agree that both forms of the additive should be considered skin and respiratory sensitisers, with any level of exposure considered a risk. The non-coated form is not a skin or eye irritant, but in the absence of data the coated form is considered a presumed eye irritant.

2.4. Section IV: Efficacy

The applicant submitted a single long-term trial evaluating the effect of supplementation with *S. cerevisiae* CNCM I-1079 on zootechnical performance of dogs (*Canis familiaris*) and their puppies. In 2024, the FEEDAP Panel were unable to conclude on efficacy in dogs and other

Canidae as the Panel consider that effects on growth parameters are only evidence of efficacy when related to the health of the animals, for example, a subsequent improvement in morbidity or mortality.

In 2025, the applicant provided the FSA/FSS with additional information on efficacy, including the peer-reviewed journal article for the submitted study in dogs, which had been recently published (Garrigues, et al., 2024), in addition to a detailed rationale outlining why some of the endpoints not reported in the EFSA opinion were of important relevance to dog breeders. The FSA/FSS requested advice from the ACAF to evaluate the efficacy trial in dogs and the additional information submitted by the applicant.

The additive is authorised for use in all pigs (including sows) in GB at an inclusion rate of 1 x 10^9 CFU/kg feed, and therefore efficacy has already been demonstrated in this animal category. The applicant reasoned that a single study in dogs was sufficient, on the grounds that the observed benefits in sows and piglets are predicted to also occur in bitches and puppies, due to similarities between the two species. For example, sows and bitches both produce multiple offspring at a time, and both experience a stressful periparturient period. The ACAF agreed that the effects observed in the studies in sows were biologically relevant to dogs. Because the intended effect is the same, a single study in dogs was deemed acceptable.

The study in dogs and their puppies compared a control group with a treatment group, in which the basal feed of the bitches during gestation and lactation was supplemented with an intended dose of 1 x 10^9 CFU/kg complete feed. The health of bitches was monitored daily throughout the study, and mortality in the puppies was recorded. Zootechnical performance parameters were measured in both the bitches and the litters. A number of other endpoints were monitored during the study, some of which were not considered relevant by the ACAF. The ACAF raised concerns that the experimental design of the study was not optimal but agreed that the study could be considered suitable for assessment.

There were no differences between adult bitches in the control and treatment group for gestation or lactation duration, feed intake, body weight or Body Condition Score (p>0.1). However, there was an increase in faecal immunoglobulin A (IgA) between the end of gestation and the end of lactation for the treatment group, relative to the control (p<0.1). Additionally, faecal dry matter (DM) content was more stable in the treatment group, as evidenced by a decline in faecal DM in the control group, relative to the treatment group (p<0.1). The ACAF discussed the utility of faecal IgA as a biomarker of gut health, noting that although it may indicate an improved immune state, it can also be a result of other effects,

such as an inflammatory response, for example. However, the ACAF agreed that the increase in faecal IgA could be considered as potential evidence of a beneficial effect of the additive in the adult dogs.

With regards to the effects on the litter, no differences were observed between treatment groups relating to the total number of puppies born, litter feed intake or pre-weaning mortality ($p>0.1$). There was a significant reduction in the number of low birthweight puppies, an improvement in growth rate homogeneity and increase in litter initial weight in the treatment group relative to the control ($p<0.1$). However, the increase in litter weight did not persist at weaning.

The ACAF noted that the published journal article (Garrigues, et al., 2024) included some endpoints that were not mentioned in the original trial report but were relevant to efficacy, including significant beneficial effects of the additive on the colostrum and milk composition of the bitches. These included an increase in the gross energy of the colostrum, and an increase in the protein concentration of the milk in the treatment group ($p<0.05$). The ACAF also accepted the applicant's rationale that some of the differences seen in the treatment group (relative to the control) are particularly valuable to dog breeders. These include the observed improvement in the growth rate homogeneity of the litter, and the reduction in the risk of low birthweight puppies.

Considering all the evidence, the ACAF agreed that the additive has the potential to be efficacious in gestating and lactating bitches and their puppies at the proposed dose of 1×10^9 CFU/kg feed. This conclusion can be extrapolated to all dogs and other Canidae.

2.4.1. Conclusion on Section IV: Efficacy

Based on the efficacy study in dogs and the additional efficacy information provided by the applicant for the FSA/FSS submission, the ACAF concluded that the additive has the potential to be efficacious in dogs and all other Canidae at the proposed dose of 1×10^9 CFU/kg complete feed.

The FSA/FSS reviewed the ACAF's advice on the updated efficacy data and agreed with the ACAF's conclusions.

3. Analytical method evaluation

The FSA/FSS evaluated the EURL analytical method evaluation, noting it was carried out in 2015, 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, 2015). The FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

4. Conclusions

In their 2016, 2019 and 2024 opinions, the FEEDAP Panel were satisfied with the identity and characterisation of both forms of the additive and the active agent. Stability and homogeneity data were provided in dog feed.

S. cerevisiae CNCM I-1079 is considered safe for the target species, the consumer and the environment. In 2024, the FEEDAP Panel concluded that both forms of the additive should be considered skin and respiratory sensitisers, and that any level of exposure is considered a risk. The non-coated form is not a skin or eye irritant, but the Panel could not conclude on the eye irritation potential of the coated form.

The FEEDAP Panel could not conclude on the potential efficacy of the additive in dogs and all other Canidae. Based on the efficacy trial in dogs and the additional efficacy information provided, the ACAF advised that the additive has the potential to be efficacious in gestating and lactating bitches and their puppies at the proposed dose of 1×10^9 CFU/kg feed. This conclusion can be extrapolated to all dogs and other Canidae.

5. Caveats and uncertainties

No caveats or uncertainties are noted.

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 Decision Panel, which were also submitted to the FSA and FSS. The EFSA opinions (EFSA FEEDAP Panel, 2016, 2019b, 2024) identify and characterise the hazards present which are also relevant to GB. The conclusions of the EFSA opinion alongside the efficacy assessment and conclusions reached by the ACAF have been reviewed in detail by the 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
ACAF	Advisory Committee on Animal Feedingstuffs
CFU	Colony forming units
CNCM	Collection Nationale de Cultures de Microorganismes
CV	Coefficient of Variation
DM	Dry matter

Abbreviation	Definition
EC	European Commission
EU	European Union
EFSA	European Food Safety Authority
EURL	European Union Reference Laboratories
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FSA	Food Standards Agency
FSS	Food Standards Scotland
GB	Great Britain
IgA	Immunoglobulin A
OECD	Organisation for Economic Co-operation and Development
PSD	Particle size distribution
QPS	Qualified Presumption of Safety
UK	United Kingdom
WGS	Whole genome sequence

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References

EC (European Commission). (2003). *Regulation No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition*. https://www.legislation.gov.uk/eur/2003/1831/contents

EC (European Commission). (2017). *Commission Implementing Regulation (EU) 2017/1905 of 18 October 2017 concerning an authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for chickens for fattening and for minor poultry species for fattening (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)*. https://www.legislation.gov.uk/eur/2017/1905

EC (European Commission). (2018). *Commission Implementing Regulation (EU) 2018/347 of 5 March 2018 concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for piglets and sows and amending Regulations (EC) No 1847/2003 and (EC) No 2036/2005 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)*. https://www.legislation.gov.uk/eur/2018/347

EC (European Commission). (2019). *Commission Implementing Regulation (EU) 2019/892 of 28 May 2019 concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for all pigs other than weaned piglets and sows and all minor porcine species (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)*. https://www.legislation.gov.uk/eur/2019/892

EC (European Commission). (2020). *Commission Implementing Regulation (EU) 2020/162 of 5 February 2020 concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for turkeys for fattening (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)*. https://www.legislation.gov.uk/eur/2020/162

EFSA (European Food Safety Authority). (2021). EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain. *EFSA Journal*, *19*(7), 6506. https://doi.org/10.2903/j.efsa.2021.6506

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2016). Safety and efficacy of Levucell® SB (Saccharomyces cerevisiae CNCM I-1079) as a feed additive for weaned piglets and sows. *EFSA Journal*, *14*(6), 4478. https://doi.org/10.2903/j.efsa.2016.4478

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2017a). Guidance on the assessment of the safety of feed additives for the consumer. *EFSA Journal*, *15*(10), 5022. https://doi.org/10.2903/j.efsa.2017.5022

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2017b). Guidance on the assessment of the safety of feed additives for the target species. *EFSA Journal*, *15*(10), 5021. https://doi.org/10.2903/j.efsa.2017.5021

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2017c). Guidance on the identity, characterisation and conditions of use of feed additives. *EFSA Journal*, *15*(10), 5023. https://doi.org/10.2903/j.efsa.2017.5023

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2017d). Scientific Opinion on the safety and efficacy of Levucell® SB (Saccharomyces cerevisiae CNCM I-1079) as a feed additive for chickens for fattening and minor poultry species. *EFSA Journal*, *15*(1), 4674. https://doi.org/10.2903/j.efsa.2017.4674

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2018a). Guidance on the assessment of the efficacy of feed additives. *EFSA Journal*, *16*(5), 5274. https://doi.org/10.2903/j.efsa.2018.5274

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2018b). Guidance on the characterisation of microorganisms used as feed additives or as production organisms. *EFSA Journal*, *16*(3), 5206. https://doi.org/10.2903/j.efsa.2018.5206

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2019a). Guidance on the assessment of the safety of feed additives for the environment. *EFSA Journal*, *17*(4), 5648. https://doi.org/10.2903/j.efsa.2019.5648

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2019b). Safety and efficacy of Levucell® SB (Saccharomyces cerevisiae CNCM I-1079) as a feed additive for turkeys for fattening. *EFSA Journal*, *17*(4), 5693. https://doi.org/10.2903/j.efsa.2019.5693

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2019c). Scientific Opinion on the safety and efficacy of Levucell® SB (Saccharomyces cerevisiae CNCM I-1079) as a feed additive for all pigs. *EFSA Journal*, *17*(1), 5535. https://doi.org/10.2903/j.efsa.2019.5535

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2022). Scientific Opinion on the safety and efficacy of a feed additive consisting of Saccharomyces cerevisiae CNCM I1079 for calves, all other ruminant species and camelids for rearing and for fattening (Danstart ferment AG). *EFSA Journal*, *20*(10), 7605. https://doi.org/10.2903/j.efsa.2022.7605

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2023). Guidance on the assessment of the safety of feed additives for the users. *EFSA Journal*, *21*(12), e8469. https://doi.org/10.2903/j.efsa.2023.8469

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2024). Safety and efficacy of a feed additive consisting of Saccharomyces cerevisiae CNCM I-1079 for dogs and all other Canidae (Danstar Ferment AG). *EFSA Journal*, *22*(7), e8847. https://doi.org/10.2903/j.efsa.2024.8847

EURL-FA (European Reference Laboratory for Feed Additives). (2015). *Evaluation Report on the Analytical Methods submitted in connection with the Application for Authorisation of a Feed Additive according to Regulation (EC) No 1831/2003 Saccharomyces cerevisiae CNCM I-1079 (FAD-2010-0121; CRL/100166)*. https://joint-research-centre.ec.europa.eu/reports-and-technical-documentation/fad-2010-0121_en

Garrigues, et al. (2024). The supplementation of female dogs with live yeast Saccharomyces cerevisiae var. boulardii CNCM I-1079 acts as gut stabilizer at whelping and modulates immunometabolic phenotype of the puppies. *Front Nutr*, *11*, 1366256. https://doi.org/10.3389/fnut.2024.1366256