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Safety and efficacy of a feed additive consisting of *Saccharomyces cerevisiae* MUCL 39885 (Biosprint®) for cats and dogs (Prosol S.p.A.)

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Abstract

The additive Biosprint® contains viable cells of *Saccharomyces cerevisiae* MUCL 39885 and is authorised as a feed additive in sows, dairy cows, horses, piglets (weaned), cattle for fattening, minor ruminants for fattening and minor ruminants for dairy products. The applicant has requested to extend the use of the additive to cats and dogs at a minimum inclusion level of 7×10^{10} CFU/kg of complete feed. *S. cerevisiae* is considered by EFSA to have qualified presumption of safety status and consequently is considered safe for the target species. The additive is considered as a potential skin and eye irritant and a skin and respiratory sensitiser. Based on the results on efficacy studies provided, the FEEDAP Panel concludes that Biosprint® is efficacious when used in feeds for dogs. However, the FEEDAP Panel considered that the biological relevance of the magnitude of the effect detected is questionable. Based on the trial available, the FEEDAP Panel was unable to conclude on the efficacy of the additive when administered to cats.

Keywords: zootechnical additive, Biosprint®, *Saccharomyces cerevisiae*, renewal, QPS, dogs, cats

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

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 a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Prosol S.p.A.[2] for authorisation of the preparation of *Saccharomyces cerevisiae* MUCL 39885 (Biosprint®), when used as a feed additive for cats and dogs (category: zootechnical additives; 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 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 27 January 2021.

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 preparation of *Saccharomyces cerevisiae* MUCL 39885 (Biosprint®), when used under the proposed conditions of use (see Section 3.1.2).

1.2. Additional information

Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) is currently authorised in sows,[3] dairy cows, horses,[4] piglets (weaned),[5] cattle for fattening,[6] minor ruminants for fattening and minor ruminants for dairy production (4b1710).[7]

The EFSA FEEDAP Panel issued several opinions on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) in different target species (EFSA, 2004, 2009, 2010a,b,c; EFSA FEEDAP Panel, 2013a, 2015, 2019a,b).

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[8] in support of the authorisation request for the use of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) as a feed additive.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[9]

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Prosol S.p.A. via Carso 99, Madone (Italy).
[3] Commission Regulation (EC) No 896/2009 of 25 September 2009 concerning the authorisation of a new use of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows (holder of the authorisation Prosol SpA). OJ L 256, 29.9.2009, p. 6.
[4] Commission Regulation (EU) No 1119/2010 of 2 December 2010 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses and amending Regulation (EC) No 1520/2007 (holder of the authorisation Prosol SpA). OJ L 317, 3.12.2010, p. 9.
[5] Commission Regulation (EU) No 170/2011 of 23 February 2011 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for piglets (weaned) and amending Regulation (EC) No 1200/2005 (holder of authorisation Prosol SpA), OJ L 49, 24.2.2011, p. 8.
[6] Commission implementing Regulation (EU) No 1059/2013 of 29 October 2013 concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for cattle for fattening and amending Regulation (EC) No 492/2006 (holder of the authorisation Prosol SpA) OJ L 289, 31.10.2013, p. 30.
[7] Commission implementing Regulation (EU) 2016/104 of 27 January 2016 concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for minor ruminant species for fattening and dairy production (holder of the authorisation Prosol SpA), OJ L 21, 28.1.2016, p. 71.
[8] FEED dossier reference: FAD-2020-0054.
[9] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2009-0028.pdf

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) is in line with the principles laid down in Guidance on the identity, characterisation and conditions of use of feed additives (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 characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018a) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b).

3. Assessment

The additive Biosprint® contains viable cells of *S. cerevisiae* MUCL 39885. The additive is currently authorised for several target species. The present application seeks the extension of the authorisation as a zootechnical additive (functional group: gut flora stabiliser) for cats and dogs.

3.1. Characterisation

The additive contains viable cells of the strain *S. cerevisiae* MUCL 39885 (no carriers or excipients are present in the final product) with a minimum declared content of 1×10^9 colony forming unit (CFU)/g.

The additive is marketed in two forms, 'spherical' (Biosprint® S) and 'granulated' (Biosprint® G). Compliance with the specifications was confirmed by analysis of five batches of the G form (range 1.62–1.79 $\times$ 10^{10} CFU/g, mean 1.70 $\times$ 10^{10} CFU/g) and five batches of the S form (range 1.69–1.77 $\times$ 10^{10} CFU/g mean 1.74 $\times$ 10^{10} CFU/g). The same batches of the additive were analysed for microbial contamination. The results confirm compliance with limits set for *Escherichia coli* < 10 CFU/g, *Salmonella* spp. not detected in 25 g, moulds < 10 CFU/g, *Listeria monocytogenes* not detected in 1 g, coliforms < 100 CFU/g, *Staphylococcus aureus* < 10 CFU/g.[10]

The possible presence of chemical contaminants was measured on three recent batches of the product. In all the three batches the concentration of heavy metals and arsenic were below the corresponding limit of quantification (LOQ).[11] Levels of chromium (three batches below the LOQ),[12] cobalt (two batches were below the LOQ – 0.001 mg/kg; one batch measured 0.36 mg/kg), iron (range 5.89–49.5 mg/kg), nickel (two batches were below the LOQ – 0.0013 mg/kg; one batch measured 0.09 mg/kg), copper (range 3.7–7.92 mg/kg) and zinc (range 83.5–152 mg/kg) were also determined. In the same batches, the concentration of aflatoxins B1, B2, G1 and G2 were < LOQ (0.3 or 0.5 mg/kg), deoxynivalenol < 20 μg/kg (analysed in two batches only), ochratoxin A < 1 μg/kg (analysed in two batches only), zearalenone < 10 μg/kg (analysed in two batches only). Pesticides screened in a multiresidue analysis were < 0.01 mg/kg, with the exception of 2,4,6,-trichlorophenol (0.04 mg/kg), epoxiconazole (0.076 mg/kg), tetraconazole (0.018 mg/kg) and difenoconazole (0.025 mg/kg) in one batch.[13] Based on the results, no concern is identified.

The same batches of the G form of the additive were tested in triplicate for dusting potential[14] according to the Stauber–Heubach method. The average value of dust was 260 mg/m^3 (range: 217–290 mg/m^3).

The particle size distribution measured by sieving of three batches of the product for both formulations was provided. Regarding the S form, most of the particles had a diameter > 355 μm, with no particles below 125 μm. The G form of the additive had most of the particles with a diameter > 125 μm, with no particles below 90 μm.

The non-genetically modified strain of *S. cerevisiae* composing the additive is deposited in the Belgian Coordinated Collection of Microorganism/Culture Collection – Mycothéque de l'Université Catholique de Louvain (BCCM/MUCL) with the accession number 39885.[15]

A phylogenetic analysis based on ribosomal and mitochondrial protein sequences deduced from whole genome sequence data confirmed the taxonomic identification of the strain as *S. cerevisiae*. The analysis of the whole genome single nucleotide polymorphism (SNP) against *S. cerevisiae* S288C and

[10] Technical Dossier/Section II/Annex_2-3.
[11] LOQs: cadmium, mercury and lead 0.001 mg/kg, arsenic 0.005 mg/kg.
[12] LOQ: 0.001 mg/kg.
[13] Technical dossier/Section II/Annex 4-6.
[14] Technical Dossier/Section II/ /Annex_II_7.
[15] Technical Dossier/Supplementary_Information/Section II/Annex_II_8.

other six *Saccharomyces* species was also submitted and supports the identification of the BCCM/MUCL 39885 strain as *S. cerevisiae*.[16]

3.1.1. Stability and homogeneity

Stability and homogeneity of Biosprint® has been previously assessed (EFSA, 2010a). In the current dossier, the applicant has provided a new shelf-life study and new stability studies in feedingstuffs and premixture which are reported below.

The shelf life of one batch of the additive (form not specified) was studied when stored in vacuum aluminium bags (storage temperature was not reported) for 24 months. At the end of the storage period, the *S. cerevisiae* counts losses were negligible (below 0.5 log).

The stability of one batch of the additive was tested in a commercial premixture (made of 'food inulin' 92.8%, mixture of flavouring compounds (30% hydrogenated glycerol tributyrate) 4%, magnesium stearate 2% and silicon dioxide 1%) supplemented with 3.5×10^7 CFU/g.[17] Samples were stored in two different packages (sealed bags, the main difference being an additional plastic inlayer) at a temperature that was not reported for 12 months. *S. cerevisiae* counts losses observed after 6 months storage were below 0.5 log, while after 12 months storage losses were about 2 log, regardless of the packaging used.

The stability of one batch of the additive when applied via coating on a dog dry food (23% protein, 16% raw fat, 2.5% raw fibre and 7.1% raw ash) at 3.7×10^{10} CFU/kg feed supplementation was studied.[18] Post-coating losses of *S. cerevisiae* viable cells (measured in 5 samples) were below 0.5 log. Food samples were subsequently stored (temperature not reported) in bags (no further description) for 6 months. At the end of the storage period, the losses were below 0.5 log.

The stability of one batch of the additive was studied in a compound feed for cats (made of 'food inulin' 92.8%; mixture of flavouring compounds with hydrogenated palm oil and glycerol tributyrate 4%; magnesium stearate 2%, and silica oxide 1%) supplemented with Biosprint® at 3.5×10^{10} CFU/kg.[19] Samples were stored in two different packages (sealed bags, the main difference being an additional plastic inlayer) at a temperature that was not reported for 18 months. Losses observed after 3- and 6-month storage were below 0.5 log, while after 12- and 18-month storage losses were about 2 and 3 log, respectively, regardless the packaging used.

3.1.2. Conditions of use

The additive is intended to be used in feed for cats and dogs at a minimum inclusion level of 7×10^{10} CFU/kg of complete feed.

The applicant also proposes to express the use levels as 1.0×10^9 CFU/kg body weight (bw).

3.2. Safety

The species *S. cerevisiae* is considered by EFSA to be suitable for the Qualified Presumption of Safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2020). This approach requires the identity of the strain under assessment to be conclusively established. In the context of the current application, the identity of the active agent strain was confirmed as *S. cerevisiae*. Accordingly, this strain is presumed safe for the target species.

The safety for the user has been evaluated in a previous opinion (EFSA, 2010a,b,c). In 2010, the Panel concluded that the additive should be considered as a potential skin and eye irritant and a skin sensitiser and that the inhalation exposure would be minimal. No additional data were provided in the current application that would lead to a revision of the previous conclusions. Considering the proteinaceous nature of the additive, it should be considered a respiratory sensitiser.

The applicant in support of the safety of the additive has submitted results from several literature searches.

Three literature searches on the safety of the additive for different target species other than cats and dogs, consumer, environment and user, covering the periods 2008-2018, 2018-2019 and 2019-March 2020, were evaluated by EFSA FEEDAP Panel in previous assessments (EFSA FEEDAP Panel, 2019a,b, 2020). These searches did not reveal any safety issue related to the additive under assessment.

[16] Technical Dossier/Section II/Annex_9-15.
[17] Technical dossier/Section II/Annex_23.
[18] Technical dossier/Section II/Annex_22.
[19] Technical dossier/Section II/Annex_37.

The applicant performed a new literature search on the safety of the additive for cats and dogs, covering the period 2008-2020, using the following databases: CAB Abstracts, PubMed, ToxNet/ToxLine and Scopus.[20] It included '*Saccharomyces cerevisiae*' and other terms relevant for target species safety and for toxicological aspects.

No relevant papers were identified that would highlight a safety concern for the target species. Moreover, no relevant papers were identified that would add any additional concerns to those already identified for the safety for the user.

3.2.1. Conclusions of safety

The FEEDAP Panel concludes that Biosprint® is considered safe for the target species. The additive should be considered as a potential skin and eye irritant and a skin and respiratory sensitiser.

3.3. Efficacy

The additive is intended to exert beneficial effects in the gastrointestinal tract of cats and dogs, leading to an increase in faecal consistency/harder stools.

In support of the efficacy of the additive, the applicant has submitted three efficacy trials in dogs and one in cats.

3.3.1. Efficacy in dogs

The three efficacy trials conducted in dogs shared the same experimental design.[21,22,23] Each study was carried out on 16 healthy adult dogs of both sexes (proportion not indicated), as well as different breed and body weight (Table 1). Dogs were individually housed and randomly allocated, based on the initial body weight (bw), to two dietary treatments: control and Biosprint® at 7×10^{10} CFU/kg feed. There were 8 replicates for each treatment.

In all trials, dogs received the experimental diets for 35 days. Dogs were fed a commercial diet to which Biosprint was added top-dressing at an intended level of 7×10^{10} CFU/kg feed. Water was available *ad libitum* with free access to a nipple drinker.

Feed intake and health status were recorded daily during the entire experimental period. Dogs were weighed on days 0 (start of the study), 7, 14, 21, 28 and 35 of the study and faecal samples were collected on the same days in the shortest time as possible from defecation. Faeces were immediately frozen to be analysed at the end of the trial for dry matter (DM) content as an indicator of the faecal consistency.

To exclude any difference in the DM content of the faeces at the beginning of the trial, an analysis of variance on the DM content of faecal samples on day 0 was conducted by Generalised linear model (GLM) procedure accounting for the effect of the treatment. Subsequently, data were analysed using one-way analysis of variance applying a MIXED procedure for repeated measurements. The mixed model included the effect of the treatment, the time and the interaction treatment × time. Faecal dry matter measured on day 0 was used as covariate for faecal DM statistical analysis. The individual animal was the experimental unit. Treatment comparisons were done using Tukey's test for multiple testing.

Table 1: Trial design and dosages of the efficacy trials performed in dogs

Trial	Total number of animals (replicates per treatment)	Breed, age and mean body weight (duration)	Composition feed	Intended (CFU/kg feed)	Analysed (CFU/kg feed)	Measurements: (days)
1	16 (8)	English Setter 3- to 6-year old 14.5 kg (36 days)	Extruded corn, meat, lard, corn gluten meal, mineral/vitamin premix	0 7×10^{10}	– 8.0×10^{10}	Body weight and Faecal dry matter (0, 7, 14, 21, 28 and 35)

[20] Technical dossier/Section III/Annex_ III_2_0.
[21] Technical dossier/Section IV/Annex_1-10.
[22] Technical dossier/Supplementary Information (May 2021)/Section IV/EFSA_letter_20_05_2021.
[23] Technical dossier/Supplementary Information (May 2021)/Section IV/EFSA_letter_27_04_2021.

Trial	Total number of animals (replicates per treatment)	Breed, age and mean body weight (duration)	Composition feed	Intended (CFU/kg feed)	Analysed (CFU/kg feed)	Measurements: (days)
2	16 (8)	Basenji and Lagotto Romagnolo 5- to 7-year old 10.5 kg (36 days)	Corn flakes, dehydrated processed pork animal protein, chicken fat, hydrolysed chicken proteins, dried beet pulp, sodium chloride, minerals/vitamin premix	0 7×10^{10}	– 6.2×10^{10}	Body weight and Faecal dry matter (0, 7, 14, 21, 28 and 35)
3	16 (8)	German Shorthaired Pointer and Bracco Italiano age not specified 26.8 kg (36 days)	Cereals, meat and animal derivates, oil and fats, vegetable protein extract, derivates of vegetable origin, minerals/ vitamin premix	0 7×10^{10}	– 8.8×10^{10}	Body weight and Faecal dry matter (0, 7, 14, 21, 28 and 35)

No signs of morbidity were observed throughout all trials. No significant differences were found with regard to the body weight or feed intake of the animals. The analysis of the overall data showed a small (ranging from 0.95 in trial 1 to 3.3 percentage points in trials 2 and 3), but significant, increase in faecal DM content in all studies (Table 2). However, the biological relevance of changes of this magnitude for the animal is questionable, as also are the practical benefits for the owner.

Table 2: Effects of Biosprint® on body weight, feed intake and faecal dry matter content of dogs

Trial	Treatment (CFU/kg)	Body weight (kg)[(a)]	Feed intake (kg/week)[(b)]	Faecal dry matter (%)[(c)]
1	0	14.62	1.35	37.44
	7×10^{10} CFU/kg	14.34	1.33	38.39**
2	0	10.45	1.34	35.49
	7×10^{10} CFU/kg	10.53	1.41	38.77*
3	0	26.88	2.53	40.90
	7×10^{10} CFU/kg	26.76	2.53	43.37*

(a): Recorded at day 35.
(b): Recorded from day 29 to day 35.
(c): Overall values over 35 days.
*: Significantly different from the control at $p < 0.05$.
**: Significantly different from the control at $p < 0.1$.

3.3.2. Efficacy in cats

In one efficacy trial in cats, the experimental design was similar to those above-described for dogs.

Ten cats (3–5 years old, European shorthair) were individually housed and distributed (based on weight) between two dietary treatments (5 replicates per treatment): control or Biosprint® at 7.5×10^{10} CFU/kg feed.[22,24] The product was top-dressed on the feed and all cats were fed the same amount of a commercial diet (DM 23%) offered twice a day (feed composition: meat and animals derivatives (of which chicken 4%), vegetable protein extract, fish and fish derivatives, minerals and sugars).

Feed intake and health status were recorded daily during the entire experimental period (35 days). Cats were weighed on days 0, 7, 14, 21, 28 and 35 of study and faecal samples were collected on the same days in the shortest time as possible from defecation. The faecal samples were immediately frozen and analysed at the end of the trial for DM content as an indicator of the faecal consistency.

[24] Technical dossier/Section IV/Annex_11-14.

To exclude any difference in the DM content of the faeces at the beginning of the trial, an analysis of variance on faecal samples was conducted by GLM procedure on day 0 accounting for the effect of the treatment. Subsequently, data were analysed using one-way analysis of variance applying a MIXED procedure for repeated measurements. The mixed model included the effect of the treatment, the time and the interaction treatment × time. Faecal DM measured on day 0 was used as covariate for faecal DM statistical analysis. The individual animal was the experimental unit. Treatment comparisons were done using a Tukey's test for multiple testing.

No signs of morbidity were observed throughout the trial. No significant differences were found with regard to the cats' weight, feed intake or DM content of the faeces (Table 3). With respect to the faecal DM, a significance was noted for time effect and time × treatment interaction. This interaction effect was due to a high faecal DM content on day 28 in the treated group (52.49%) which was different to control group values at time 7, 14 and 28 (43.91, 43.64 and 46.39%, respectively), but no difference was observed at any other time point between the groups.

Table 3: Effects of Biosprint® on body weight, feed intake and faecal dry matter content of cats

Trial	Groups (CFU/kg)	Body weight (kg)[(a)]	Feed intake (kg/week per cat)[(b)]	Faecal dry matter (%)[(b)]
1	0	3.82	2.52	44.86
	7×10^{10} CFU/kg	3.72	2.52	45.98

CFU: colony forming unit.
(a): Recorded at day 35.
(b): Overall values over 35 days.

3.3.3. Conclusions on efficacy

The FEEDAP Panel concludes that Biosprint® has the potential to be efficacious in improving the faecal consistency in dogs at 7×10^{10} CFU/kg of complete feed. However, the FEEDAP Panel considered that the biological relevance of the magnitude of the effect detected is questionable.

Based on the trial provided, the FEEDAP Panel was unable to conclude on the efficacy of the additive when administered to cats.

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[25] and Good Manufacturing Practice.

4. Conclusions

The additive is considered safe for cats and dogs.

The additive is considered a potential skin and eye irritant and skin and respiratory sensitiser.

Biosprint® has the potential to be efficacious in dogs at 7×10^{10} CFU/kg of complete feed. However, the FEEDAP Panel considers that the biological relevance of the magnitude of the effect detected is questionable.

The FEEDAP Panel is unable to conclude on the efficacy of the additive when administered to cats.

5. Documentation as provided to EFSA/Chronology

Date	Event
09/07/2020	Dossier received by EFSA. Biosprint® for all pigs (other than sows, suckling and weaned piglets) and other minor porcine species. Submitted by Prosol S.p.A.
11/09/2020	Reception mandate from the European Commission
08/01/2021	Application validated by EFSA – Start of the scientific assessment
27/01/2021	Comments received from Member States

[25] 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.

Date	Event
08/04/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: characterisation, efficacy.
28/04/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
28/05/2021	Spontaneous submission of information by the applicant. Issues: efficacy
23/06/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013a. Scientific Opinion on the efficacy of Biosprint® (*Saccharomyces cerevisiae*) as a feed additive for cattle for fattening. EFSA Journal 2013;11(4):3174, 6 pp. https://doi.org/10.2903/j.efsa.2013.3174

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) for minor ruminant species for meat and milk production. EFSA Journal 2015;13(7):4199, 8 pp. https://doi.org/10.2903/j.efsa.2015.4199

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Abbreviations

BCCM	Belgian Coordinated Collections of Microorganisms
BW	body weight
CFU	colony forming unit
DM	dry matter
EURL	European Union Reference Laboratory
GLM	Generalised linear model
LOQ	limit of quantification
MUCL	Mycothéque de l'Université Catholique de Louvain
QPS	Qualified presumption of Safety
SNP	single nucleotide polymorphism
WGS	whole genome sequence