

EXECUTIVE SUMMARY

Application to amend the Australia New Zealand Food Standards Code to permit whole *Neurospora crassa* mycelium (Rhiza™ mycelium) as a novel food

Applicant: BMC Ingredients (dba The Better Meat Co.), West Sacramento, California, USA

Purpose of the application

BMC Ingredients (BMC) seeks to amend the *Australia New Zealand Food Standards Code* to permit the sale and use of Rhiza™ mycelium—the whole, non-genetically-modified mycelial biomass of the filamentous fungus *Neurospora crassa* (strain NRRL 68076)—as a novel food. Approval would list the ingredient in Schedule 25 (Permitted Novel Foods) and insert identity and purity specifications in Schedule 3. The ingredient is a whole food matrix produced by controlled submerged fermentation, containing not less than 40% protein and approximately 30% dietary fibre on a dry-weight basis. BMC requests assessment under the general procedure and does not seek exclusive-use permission or an exclusive capturable commercial benefit; the requested Schedule 25 listing is a generic permission available to any party meeting the specification.

Rhiza™ mycelium at a glance

Ingredient	Whole, non-GMO mycelial biomass of the filamentous fungus <i>Neurospora crassa</i> (strain NRRL 68076), trade name Rhiza™ mycelium
Production	Controlled submerged fermentation on a food-grade substrate, followed by dewatering, hot-air drying and size reduction; supplied dry as granules (8–10 mm) or powder
Protein	> 40% dry weight (batch range 41.8–47.8%); high quality, PDCAAS 0.89; in vitro digestibility 0.99–1.00
Dietary fibre	~30% dry weight, including β -glucans (mean 18.6 g/100 g)
Fat	Low (3–6% dry weight), predominantly unsaturated
Toxicology	NOAEL 5,000 mg/kg bw/day (highest dose tested, 90-day rat study); non-genotoxic, non-mutagenic, non-clastogenic

Shelf life	18 months at ambient temperature (water activity < 0.65, moisture ≤ 8.5%)
Proposed uses	Meat/dairy analogues, hybrid meat products, protein blends and bars, pasta, baked goods, soups, snacks and composite foods; use levels 15–90% (dehydrated basis)
Approved elsewhere	United States (FDA GRAS GRN 1117, “no questions” 2024); Singapore (SFA, Oct 2024); Canada (Health Canada, Letter of No Objection, Jul 2026)

The ingredient and its manufacture

Rhiza™ mycelium consists of 100% *N. crassa* biomass with no added ingredients. It is produced by submerged fermentation of a proprietary food-grade substrate under sterile, monitored conditions, with no antibiotics used. At harvest the biomass is mechanically dewatered, diced, and dehydrated (65–90°C for 60–90 minutes) to a water activity below 0.65, then packaged as granules or milled to powder. Two critical control points govern the process—thermal dehydration to ensure microbial stability, and metal detection of finished product. Fermentation nutrients are consumed during growth (≥90% reduction of sugar and nitrogen), and a downstream rinse step removes residual extracellular components, so no medium components remain at levels of concern. The ingredient is well characterised and reproducible: three-lot analyses confirm consistent protein (41.8–47.8%), low moisture (~6%), and heavy metals (arsenic, lead, mercury, cadmium) far below specification limits.

Composition and nutritional profile

Rhiza™ mycelium is a nutrient-dense whole food. It provides high-quality protein with a PDCAAS of 0.89—comparable to soy (0.91) and pea protein concentrate (0.89)—and near-complete in vitro digestibility (0.99–1.00), digesting more rapidly than pea protein under simulated gastric conditions. It supplies all essential amino acids and approximately 30% dietary fibre (dry basis), including β-glucans (mean 18.6 g/100 g). Total fat is low (3–6%) and rich in unsaturated fatty acids (mean 39% linoleic, 31% oleic). The biomass naturally contains B-group vitamins—notably niacin, vitamin B6 and pantothenic acid—plus potassium, iron, ergosterol and bioactives such as ergothioneine and spermidine. Antinutrients (tannins, phytic acid, oxalates, lectins) are present at low levels relative to legumes and grains, and are not expected to impair nutrient absorption.

Safety assessment

The safety case draws on the history of the source organism, the controlled production process, and a comprehensive body of compositional, toxicological and microbiological data. *N. crassa* has a long record of safe use in traditional fermented foods, including Indonesian oncom, Chinese fermented soybean products, Brazilian beiju and French Roquefort. Key findings supporting safety are:

- **No toxin production.** *N. crassa* has no known mycotoxin-coding genes; three lots tested non-detect for all common mycotoxins (aflatoxins, fumonisins, ochratoxin, trichothecenes, vomitoxin, zearalenone). Bioinformatic interrogation of the genome and whole-genome sequencing of the production strain found no toxin, virulence or antimicrobial-resistance genes of concern.
- **No genotoxicity or systemic toxicity.** Published OECD-compliant studies (Lozy et al., 2022) show the biomass is non-mutagenic (Ames), non-clastogenic (chromosomal aberration) and non-genotoxic (in vivo micronucleus). A 90-day repeated-dose oral study in rats established a No-Observed-Adverse-Effect Level (NOAEL) of 5,000 mg/kg bw/day—the highest dose tested.
- **Low allergenic potential.** Bioinformatic assessment against the FARRP AllergenOnline database identified no clinically relevant allergenic risk, including for consumers with coeliac disease.
- **No antimicrobial activity** was detected by literature review, chemical analysis or agar disk-diffusion testing.
- **Low nucleic-acid exposure.** Worst-case (90th-percentile) purine intake is approximately 0.46 g/day—well below the 2 g/day reference limit.
- **Real-world tolerance.** *N. crassa* mycelium has been consumed by tens of thousands of people; comparable products have reached an estimated ~10 million servings per year in the US without documented tolerability issues (noting the absence of formal post-market surveillance).

Dietary exposure

A quantitative dietary intake assessment was commissioned from Exponent, Inc. for the United States and Canadian populations, used as appropriate reference markets because the proposed food categories are well represented in the most recent Australian and New Zealand nutrition surveys. Estimated intakes for consumers of the target categories are summarised below.

Population	Mean – dry (g/day)	Mean – hydrated (g/day)	P90 – dry (g/day)	P90 – hydrated (g/day)
United States	14	41	33	98
Canada	15	45	35	105

These estimates reflect consumers of the target food categories rather than the whole population, and are therefore conservative. Because the proposed uses are substitutional or complementary within existing food categories, introduction of Rhiza™ mycelium is not expected to increase overall food consumption or create new consumption patterns, or to cause a nutritional imbalance or negative public-health impact. No population sub-groups have been identified as being at risk at the proposed use levels.

International regulatory status

Rhiza™ mycelium has been sold in the United States since 2021. The FDA reviewed GRAS Notice GRN 1117 and issued a “no questions” letter on 9 July 2024. The Singapore Food Agency approved the ingredient as a novel food in October 2024, and Health Canada has also issued a “letter of no objection” in July 2026. Approval in Australia and New Zealand would align with these jurisdictions, supporting trade and reducing technical barriers.

Conclusion

Rhiza™ mycelium is a well-characterised, reproducibly manufactured whole-food ingredient supported by a robust safety dataset, a favourable nutritional profile, and established regulatory acceptance in the United States, Singapore, and Canada. The evidence demonstrates that the ingredient is safe at the proposed uses and levels, delivers high-quality protein and dietary fibre, and can be introduced without adverse nutritional, public-health or consumer-behaviour effects. On this basis, BMC submits that permitting Rhiza™ mycelium under Standard 1.5.1 is justified and would deliver net benefits to consumers, industry and public health in Australia and New Zealand.