APPLICATION TO AMEND THE *AUSTRALIA AND NEW ZEALAND FOOD STANDARDS CODE* TO ALLOW FOR THE USE OF *LENTINULA EDODES* (SHIITAKE MUSHROOM) MYCELIA AS A PROCESSING AID (STANDARD 1.3.3)

EXECUTIVE SUMMARY

[redacted]

12 June 2023

EXECUTIVE SUMMARY

MycoTechnology, Inc. (MycoTechnology) is seeking to amend Schedules 3 and 18 of the *Australia New Zealand Food Standards Code* to include *Lentinula edodes* (shiitake mushroom) mycelia as a processing aid. Specifically, the *L. edodes* mycelia is used for fermentation of pea and rice protein in the manufacture of FermentIQ™ protein, referred to herein as fermented pea and rice protein (FPRP) or "FPRP ingredient." The FPRP ingredient contains ≥75% protein (comprising ≥95% protein concentrates of the raw material inputs) on a dry basis, with an estimated content of shiitake mycelia biomass of <0.1% (with any detected residual shiitake mycelia being heat-killed during the manufacturing process). This ingredient is used in a wide variety of food and beverage products for nutritional purposes and in foods needing protein-source properties such as promotion of ease of dry flow, masking of off-flavours, texturing of meat analogues, increasing water-holding capacity and gelation, and increasing water solubility.

The FPRP ingredient is Generally Recognized as Safe (GRAS) for use in foods in the United States, and is permitted for use as a food ingredient in the European Union, Brazil, Canada, India, Japan, South Korea, Singapore, Malaysia, Indonesia, Philippines, Thailand, Chile, Ecuador, and Hong Kong. Specifications are in place for the pea and rice protein starting materials, the *L. edodes* mycelia, and the FPRP ingredient to ensure a consistent final product. The specifications also ensure product safety by placing limits on microbial contamination, aflatoxins, and heavy metals. The FPRP ingredient is composed primarily of protein, and a methodology is in place to minimize the presence of shiitake mycelia in the final FPRP ingredient (*i.e.,* ≤0.1%). The FPRP ingredient is manufactured in accordance with Title 21 of the *Code of Federal Regulations* (CFR) §117 "*Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive Controls for Human Food*."

At a maximum potential concentration of <0.1% heat-killed shiitake mycelia in the final FPRP ingredient, and assuming the worst-case estimated high-level intake (95th to 98th percentile) of FPRP of 86.3 g/day for adults, MycoTechnology concludes that the corresponding high-level intake of shiitake mycelia would be 86.3 mg/day. At <0.1% heat-killed shiitake mycelia in FPRP, and assuming a more realistic-case estimated mean intake of the ingredient of 29.3 g/day for adults, MycoTechnology concludes that the corresponding level of intake of shiitake mycelia would be 29.3 mg/day. At a mean body weight of 60 kg, this would result in an intake of approximately 1.4 mg heat-killed shiitake mycelia/kg body weight/day at the 95th to 98th percentile level of estimated daily consumption of the FPRP ingredient, or 0.48 mg heat-killed shiitake mycelia/kg body weight/day at the mean level of estimated daily consumption for adults.

The safety of MycoTechnology's shiitake mycelia processing aid is supported primarily by the very long history of consumption of the shiitake mushroom, as well as the virtually identical composition of the shiitake mycelia and shiitake mushroom. Shiitake mycelia also have been demonstrated to produce no unique fungal toxins. Genotoxicity, repeat-dose toxicity, and reproductive and developmental toxicity studies of *L. edodes* were identified in comprehensive searches of the published, peer-reviewed scientific literature, the results of which demonstrate a favourable safety profile. Furthermore, the results of clinical studies, post-marketing surveillance, and *in silico* analysis demonstrate that consumption of *L. edodes* mycelia is well tolerated, and that the potential allergenicity of *L. edodes* mycelia is low. Overall, the available evidence and long history of human consumption of the shiitake mushroom support the safety and suitability of the use of *L. edodes* mycelia as a processing aid in the manufacture of MycoTechnology's FPRP ingredient.