# A. Executive Summary

Eden Brew Pty Ltd (Eden Brew) is seeking approval from Food Standards Australia New Zealand (FSANZ) for the sale and use of a non-animal Beta-casein Protein Preparation (BCPP1) as a novel food produced using gene technology. The purpose for adding BCPP1 to food is to provide a high-quality protein source that includes A2 beta-casein nutritionally equivalent to its bovine counterpart. The preparation is produced via precision fermentation using a proprietary, genetically modified (GM) strain of *Komagataella phaffii* (strain EB-ST-537) and is intended for use as a functional and nutritional ingredient in a wide range of foods, providing a substitute for conventional milk- and plant-derived proteins.

The application is driven by growing consumer interest in sustainable and animal-free food options. Precision fermentation provides an efficient production method with potential advantages in resource use. Regulatory approval would broaden consumer choice and encourage food industry innovation in Australia and New Zealand.

To permit the sale and use of BCPP1, Eden Brew requests that FSANZ assess this application under the General Procedure. The requested regulatory change is a variation to Standard 1.5.2–Food produced using gene technology, to include the preparation in Schedule 26. A consequential amendment is also proposed for Schedule 3–Identity and Purity to establish a product specification.

A comprehensive safety assessment demonstrates that BCPP1 is as safe for use in food applications. Key findings include:

- **Safe Host and Donor Organisms**: The host organism, *K. phaffii*, has a long history of safe use in food production and holds Qualified Presumption of Safety (QPS) status in Europe. The donor organisms for the genetic elements also have a history of safe use.
- **Well-Characterised Genetic Modification**: The genetic modifications are precise, stable, and fully characterised. Whole-genome sequencing confirms the correct integration of genetic material and the absence of off-target effects or residual antibiotic resistance markers.
- **Composition and Protein Quality**: The protein in the BCPP1 preparation is a composite, comprising approximately 25% A2 beta-casein and 75% co-purified host cell proteins. While the overall composition differs from purified milk protein, analysis confirms the protein quality of the entire preparation (via PDCAAS) is equivalent to conventional beta-casein.
- **No Evidence of Toxicity or Novel Allergenicity**: Bioinformatic analyses confirm no new toxins or allergens are produced. The expressed Beta-casein is a known milk allergen and will be labelled accordingly. The protein is readily digestible, behaving similarly to bovine Beta-casein.
- **Dietary Intake Assessment**: Dietary exposure modelling for Australian and New Zealand populations indicates that consumption of BCPP1, even at high intake levels, falls within safe limits and is not expected to pose any risk.

Based on the comprehensive data provided, Eden Brew concludes that BCPP1 derived from GM *K. phaffii* strain EB-ST-537 is as safe and nutritious for its intended use as its conventional, dairy-derived counterpart. The manufacturing process is robust and controlled, delivering a highly consistent ingredient that meets all relevant safety standards