

Summary of the application: Postbiotic protein from bacteria (*Clostridium tyrobutyricum*)

Applicant: Superbrewed Food Inc., 239 Lisa Drive New Castle Delaware, United States of America

Postbiotic protein from bacteria (*Clostridium tyrobutyricum*) as manufactured by Superbrewed Food, Inc. is the dried killed cells obtained from *Clostridium tyrobutyricum* fermentation using a corn derived sugar feedstock. It is an off-white powder comprising a minimum of 80 g/100 g of protein and maximum of 3 g/100 g of fat, 5 g/100 g of carbohydrates, 6 g/100 g of ash and 10 g/100 g of moisture. The ingredient is intended as a direct protein replacement of animal-, fungal- or vegetable-based protein currently used in foods and beverages in the European Union (EU).

The food uses will include meat and poultry analogues, dairy analogues, prepared meals, meal replacement products, milk and non-milk-based nutritional beverages, vegetable and fruit-based drinks, baked goods, breakfast cereals, soups, dressings and sauces at levels ranging from 1 to 40% by weight of the ready-to-eat (RTE) or ready-to-drink (RTD) product. In protein powders for formulation into beverages using milk or water for consumption as a supplemental protein source in the diet, use levels will vary up to a maximum of 90% by weight in the powder.

The *in vitro* digestibility of postbiotic protein from bacteria (*C. tyrobutyricum*) is high indicating that the protein will be utilised by humans. The amino acid profile indicates that postbiotic protein from bacteria (*C. tyrobutyricum*) will contribute to the essential amino acid intakes from the diet under the proposed conditions of use. An assessment of the contribution of postbiotic protein from bacteria (*C. tyrobutyricum*) to the mineral and vitamin intakes of consumers indicates no nutritional disadvantages will be associated with the ingredient under the proposed conditions of use. The production strain is fully characterised and demonstrated to be non-toxicogenic and non-pathogenic. A NOAEL of 10.0% in the diet, the highest level tested, corresponding to 5,558 and 6,671 mg/kg body weight/day for male and female rates, respectively was determined from a GLP compliant 90-day dietary feeding study conducted according to OECD TG 408. The basic battery of *in vitro* genotoxicity studies demonstrate that postbiotic protein from bacteria (*C. tyrobutyricum*) is non-genotoxic. The allergenic potential of postbiotic protein from bacteria (*C. tyrobutyricum*) was evaluated by *in silico* methods using the criteria described by Codex Alimentarius Commission on foods derived from. The results of protein analysis support that postbiotic protein from bacteria (*C. tyrobutyricum*) has low oral allergenic potential.

Taken together, the nutritional and toxicological data support the safety of postbiotic protein from bacteria (*C. tyrobutyricum*) as a source of protein for use in conventional foods and beverages in the EU under the proposed conditions of use.