

Summary of the application: Beta-lactoglobulin produced through fermentation by *Komagataella phaffii* (r-βLG)

Applicant: Remilk Ltd., Ilan Ramon 6, 7403639 Nes Ziona, Israel

Remilk Ltd. intends to market animal-free whey protein powder, consisting of β-lactoglobulin, produced through fermentation by *Komagataella phaffii* (previously known as *Pichia Pastoris*) as an animal-free source replacement for milk and plant proteins for use in foods that currently include dietary proteins from either dairy or plant sources. The powder is intended as an alternative protein source in a wide number of food applications, in maximum use levels ranging from 5 to 35%.

Considering the novel source of the food, there is no history of consumption within the European Union prior to 15 May 1997, the application is submitted pursuant to Regulation (EU) 2015/2283 on novel foods.

Evidence provided in this submission verifies that r-βLG is identical to β-lactoglobulin from traditional dairy sources, including its potential for allergenicity in milk-allergic consumers. The production organism *Komagataella phaffii* is a commonly used production organism in the manufacture of food (enzymes) and feed products and enjoys a qualified presumption of safety. The identity of the strain has been established by whole genome sequencing. The targeted genetic modification of the strain is performed through well-established genetic modification techniques and does not give rise to any safety concerns. It has been demonstrated that the production strain is not present in the final product, nor could any DNA of the production strain be detected in the beta-lactoglobulin powder. r-βLG is manufactured under highly controlled conditions to ensure its safety and purity. After the fermentation is complete, centrifugation and filtration methods are used to separate the biomass from the fermentation media that contains soluble rβLG. This is followed by an ultrafiltration step that concentrates the r-βLG. Diafiltration is then used for media exchange prior to spray-drying, creating a shelf-stable functional protein. The media components are effectively removed during the filtration steps.

Applicant has demonstrated consistency of the compositional parameters relevant for the novel food within the proposed specifications, including the lack of significant degradation of the product during storage. The Remilk β-lactoglobulin powder has been evaluated positively by the United States Food and Drug Administration (receiving the “no questions” letter), approved for human consumption by the Singapore Food Agency and authorised as a novel food (ingredient) in Israel.

Furthermore, the powder has been subjected to testing for genotoxic potential, of which the outcome has been negative. Considering the characteristics of the beta-lactoglobulin powder, no toxicological potential is assumed.

Based on the entirety of evidence provided, the applicant considers the beta-lactoglobulin powder produced by *Komagataella phaffii* to be safe and suitable for human consumption.