Summary of the dossier: Beta-Lactoglobulin

Applicant: Arla Foods Ingredients Group P/S, Sønderhøj 10 -12, Viby J, 8260 Denmark

The application is submitted pursuant to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, for the authorisation of Beta-Lactoglobulin (β-Lactoglobulin, BLG) obtained from whey. The final product contains more than 90% BLG.

The applicant proposes the uses of BLG in favoured drinks, milk based products (drinks, yoghurts and spoonable milk products), and vegetable juices, food, especially sports nutrition, and in food for special medical purposes (FSMP) at levels ranging from 6 g/100 ml to 35 g/serving.

BLG is naturally present in whey at a level of about 50 - 58 % (w/w) of the total protein content. Not only is BLG the predominant protein in whey but it is also substantially equivalent to normal whey protein concentrate/isolate in terms of its nutritional value, intended use and levels of undesirable substances. The novel food BLG is produced as a highly soluble source of protein and is intended to be used as an ingredient in food, especially sports nutrition and in food for special medical purposes (FSMP). The novel food BLG is well suited for use in FSMP for patients with chronic kidney disease (CKD) due to its low mineral profile – especially due to its low phosphate content.

In medical nutrition, dietary supplementation is commonly used for patients who are unable to meet normal dietary requirements and/or may have specific nutritional needs. Supplementation of BLG in form of FSMP to patients may particularly help prevent sarcopenia and muscle loss as well as improve recovery after illness. In sports nutrition, protein supplementation is commonly used post-exercise to improve endurance, increase muscle mass gains and faster recovery after training.

The manufacturing process of the novel food can be described as follows: a) providing a whey protein solution comprising BLG and other whey proteins. The whey protein solution is supersaturated with respect to BLG and has a pH in the range of 5-6 and a low conductivity; b) crystallizing BLG in the supersaturated whey protein solution; c) separating BLG crystals from the remaining whey protein solution; d) optionally change pH and/or concentrate the BLG fraction. If the pH is changed to a low pH and subsequently dried, the end product will be the acidic variant. If the pH is changed to a neutral pH the end product will be the neutral variant; e) dry the BLG to obtain a powder.

The applicant has followed the tiered toxicity testing approach proposed for food additives in accordance with EFSA ANS Panel (2012). The first step of this tiered approach includes genotoxicity testing and sub-chronic toxicity testing. A basic battery of genotoxicity tests was performed with BLG, comprising a bacterial reverse mutation test (OECD 471) and an in vitro micronucleus test (OECD 487) as recommended by EFSA's Scientific Committee (EFSA, 2011c). The results showed that BLG did not induce gene mutations nor structural and/or numerical chromosomal damage in human lymphocytes, and is therefore considered to be non-mutagenic and has no genotoxic potential.

A repeated dose 90-day oral toxicity study in rats (OECD 408) was carried out after initial information on toxicity had been obtained from a 14-day dose range finding study. The test showed absence of any toxicologically significant changes at the highest tested dose, therefore it was shown that BLG does not cause adverse effects at the highest dose of 1000 mg/kg bw per day. No studies from the literature have reported adverse effects from consumption of BLG on human health. Human studies

involving acute and long-term consumption of BLG and commercially available whey proteins reported no adverse reactions. The novel food BLG does not pose a safety risk to human health, based on the scientific evidence available. BLG is intended to replace the source of whey proteins consumed by the targeted consumers without sacrificing the high nutritional value, digestibility and bioavailability of essential amino acids.

EFSA (2011c). Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Journal, 2011; 9(9):2379.

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to food), 2012. Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760, 60 pp. doi:10.2903/j.efsa.2012.2760