Summary of the dossier: Bovine Milk Osteopontin

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

This application for authorisation of a novel food in accordance with Regulation (EU) 2015/2283 concerns the Bovine Milk Osteopontin (Lacprodan® OPN-10). Bovine Milk Osteopontin falls under the novel food category "food consisting of, isolated from or produced from animals or their parts" as per Article 3(2)(a)(v) of Regulation (EU) 2015/2283.

Lacprodan® OPN-10 is produced as a source of OPN that can be used as an ingredient to provide infants and young children with a supplementary source of OPN in their diets. The osteopontin (OPN) fraction is isolated from bovine whey and produced by commonly used ultrafiltration and ion exchange chromatography processes in the whey industry to fractionate whey. It is manufactured in accordance with current Good Manufacturing Practice (cGMP) and with Hazard Analysis and Critical Control Points (HACCP) principles2 pursuant to Regulation (EU) No 852/2004 on the hygiene of foodstuffs.

Lacprodan® OPN-10 is proposed for use in infant formulas, follow-on formula, and milk based drink for young children in the European Union (EU), including ready-to-drink and reconstituted formula products at a use level of up to 151 mg/L (as consumed) in ready-to-drink and reconstituted products.

As regards the safety of the novel food, Lacprodan® OPN-10 has been evaluated for proximate parameters and potential chemical and microbiological contaminants. Analytical data for a minimum of 5 batches of Lacprodan® OPN-10 indicate a high-purity and consistent product largely comprised of protein with small amounts of lactose, fat, ash, and moisture. Furthermore, the finished ingredient is within the regulatory limits established for these heavy metals, pesticide residues, and contaminants. Additionally, Lacprodan® OPN-10 is free from microbiological contamination.

A number of studies and available scientific evidence to assess genotoxicity, subchronic toxicity and teratogenicity have been included to substantiate the safety of the novel food. Lacprodan® OPN-10 is not anticipated to be genotoxic based on consistently negative results observed in Tier 1 (in vitro) and Tier 2 (in vivo) genotoxicity assays.

An human infant feeding study have been included in the safety assessment where the effects of Lacprodan® OPN-10 in infant formula on infant growth, nutritional status, health, immune function, and cytokine expression were evaluated in a double-blind randomised trial. No adverse event was reported within the haematological or biochemical parameters assessed within the study.

Lacprodan® OPN-10 is composed of >95% OPN, and therefore allergenicity concerns are similar to other milk derived proteins.

The application has been prepared in accordance with the requirements of Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, the European Food Safety Authority (EFSA) Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 and EFSA's Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283.