Summary of the dossier: Bacterial cellulose aqueous suspension

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This is an application for authorisation to place on the market a bacterial cellulose aqueous suspension obtained by the fermentation with *Komagataeibacter sucrofermentans* (an acetic acid bacteria), for human consumption as a food ingredient in the European Union. It is intended to be used in a variety of food products such as composite food, meat and meat products, milk and dairy products, fruit and vegetable juices, ice creams and bakery wares, to be consumed by the adult population including the elderly. The intended usage level of bacterial cellulose in food ranges from 2% to 20% in the final food product.

The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with 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.

In Asian Countries, bacterial cellulose has been traditionally produced from the fermentation of coconut wastewaters by cellulose-producing acetic acid bacteria, and marketed as “Nata de coco” in low-calorie sweetened desserts, fruit salads and high-fibre foods. However, bacterial cellulose has not been recorded as being consumed to a significant degree by consumers in the EU prior to May

The application is also supported by a number of toxicological studies, which aim to demonstrate the safety of this novel food. In acute, subacute and sub chronic oral toxicity studies, no adverse effects treatment related were observed even at the highest dose levels . The No Adverse Observed Effect Level (NOAEL) in the 28 subacute oral toxicity study was set at the highest dose of 5.0% “fermented cellulose” in the feed, equivalent to 5,331 mg/kg bw/day for males and 5,230 mg/kg/day for females. In the sub chronic study, no treatment related effects were at bacterial cellulose intakes of 5% and I0% (bacterial cellulose in the diet) which were calculated to be at 3,200 and 7,000 mg/kg/day, respectively, for male rats and 4,000 and 8,500 mg/kg/day, respectively, for female rats. In addition, bacterial cellulose in not genotoxic, does not present a mutagenic behaviour and it is non-pyrogenic.