

Summary of the dossier: Fungal protein-fiber rich biomass

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This novel food dossier contains the application for the authorisation of fungal protein-fiber rich biomass (Fermotein™) as a novel food according to the Regulation (EU) No 2015/2283. Fermotein™ falls under the novel food category “Foods consisting of, isolated from or produced from microorganisms, fungi or algae” as per Article 3(2)(a)(ii) of Regulation (EU) 2015/2283.

The novel food Fermotein™ is a single cell protein (SCP) product obtained from the fermentation of non-allergic carbon sources. The fermentation process is led by a filamentous fungus which is verified according to The Index Fungorum. Fermotein™ is produced under two forms, Fermotein™ wet (30% dry matter) and Fermotein™ dry (96% dry matter). The main components of Fermotein™ include proteins and dietary fibers.

The processing is performed in accordance with the ISO 22000:2018 standard, the general food safety principles, food contaminants requirements and microbiological requirements laid in Regulation (EC) No 178/2002, Regulation (EC) No 1881/2006 and Regulation (EC) No 2073/2005. Fermotein™ wet and Fermotein™ dry are targeted at the general population and are intended to be used as protein and fiber rich ingredient in different food categories, at different use levels. The conditions of use of Fermotein™ wet and Fermotein™ dry are as follows: Meat balls, Pizza and pizza-like dishes; Savoury pies and tarts; Soups (ready to eat); Pasta and similar products; Pre-mixes (dry) for baked products; Biscuits, sweet, plain; Plain cakes; Pancakes; Porridge (in dry form, to be diluted); Porridge (ready to eat); Cereal bars; Cereal flakes and similar; Muesli and similar mixed breakfast cereals; Bread and rolls with special ingredients added; Pizza base, cooked; Gluten free bread; Meat imitates; Food for sporting people; Food for weight reduction; Fresh raw sausages; Bovine and pig, minced meat; Bovine, minced meat; Pig minced meat; Chicken, minced meat; Turkey, minced meat; Dairy ice creams and similar; Fermented milk products; and Chocolate and chocolate products.

History of use of related food products produced with the same Fermotein™ fungus showed no adverse effects. The safety of the Fermotein™ fungus, is assessed based on taxonomic classification at species level and complete strain characterization by fully assembled and validated whole-genome sequence analysis. Studies revealed that the fungus is not capable to produce mycotoxins, antibiotics and virulence factors. Analyses and scientific studies show no safety concerns for heavy metals, mycotoxins and microorganisms in Fermotein™. No antinutritional factors were identified. No undesired compounds have been found in Fermotein™ to be further investigated through in vivo or in vitro toxicity studies. When maximum use levels are observed, no adverse nutritional effects are expected when Fermotein™ habitually used in the European dietary context. Results from in silico homology analysis and proteomics showed that five proteins in Fermotein™ may give a cross-reaction with salmon, tuna, shrimp, crab and pistachio nuts. Consumers will be notified about the risk for an allergic reaction due to cross reactivity when consuming food containing Fermotein™.

We conclude that Fermotein™ is safe as a food ingredient at the proposed conditions of use and the proposed intake levels.

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.