Summary of the dossier

Applicant: Microphyt, 713, route de Mudaison 34670 Baillargues, France

The novel food subject to the authorisation is an extract of the microalgae *Phaeodactylum tricornutum*. The novel food (PhaeoSOL) is standardized to a 2.0 % (w:w) Fucoxanthin (FX) content by adding a food grade medium-chain triglyceride (MCT)-oil and a tocopherol-rich extract (0.5 % w:w). PhaeoSOL is intended for use in the European Union as a source of the naturally occurring carotenoid, fucoxanthin, in food supplement products for the general population at levels not to exceed 437 mg/person/day of PhaeoSOL as recommended by the manufacturer (equivalent to 10 mg fucoxanthin/person/day).

Six independent, industrial-scale batches of PhaeoSOL were produced and fully characterised: proximate analysis, physical characteristics, oxidation properties, fatty acids profile, amino acids profile, carotenoids, amino acids profile, minerals profile, vitamins profile. Analysis were also conducted in order to demonstrate that potential contaminants were not detected or detected at levels which are not of toxicological concern. The analytical results demonstrate that the production process is robust and repeatable, producing a product which complies with the proposed regulatory specifications. A stability study was launched in order to determine the best storage temperature and the shelf life of the product and the available data confirmed that under the proposed conditions of 5°C in the absence of light or moisture, the shelf-life is at least 12 months.

PhaeoSOL is comprised primarily of lipids (ca. 79%), proteins (ca.10 %), carbohydrates (ca.5 %) and ashes (ca. 5%) and is standardised to contain 2 % of fucoxanthin. These are normal dietary components which will be metabolised by humans via established processes. A body of published literature indicates that fucoxanthin is rapidly absorded and metabolised by humans and laboratory animals. A toxicokinetic study in rats using PhaeoSOL has confirmed ADME data from the literature.

A battery of toxicological studies were conducted on PhaeoSOL following EFSA' recommendations for establishing the safety of novel foods and food additives in the EU. The results of an in vitro bacterial reverse mutation assay and in vitro micronucleus assay were negative indicating that PhaeoSOL is not genotoxic. Results of the 90-day toxicity study in rats fed PhaeoSOL by gavage established a NOAEL of 1250 mg/kg bw/day for both male and female rats. Compared to the maximum proposed use level of PhaeoSOL in food supplements of 437 mg/person/day a safety factor of 200 can be calculated.

Therefore, based on the analytical data, the risk evaluation along the production process and the safety studies reports, the maximum proposed use level of PhaeoSOL in food supplements, the applicant is considering that the novel food subject does not pose a safety risk to human health.