

Summary of the application: Dried Whole Cell Euglena

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The novel food application concerns request for authorisation of dried whole cell euglena (WCE), a minimally processed dried biomass of *E. gracilis* preparation, containing a minimum of 50% algae beta-glucans, as an ingredient in breakfast, granola and protein bars, yoghurt and yoghurt beverages, fruit juices and flavoured drinks, meal replacement beverages, and food supplements in the European Union (EU).

WCE has a characteristically high concentration of beta-1,3-glucan (paramylon) comprising at least 50% of the material on a dry weight basis. The ingredient contains significant quantities of protein ($\geq 15\%$), small quantities of fat ($\geq 2\%$), ash ($\leq 10\%$), and moisture ($\leq 10\%$). The ingredient also contains trace amounts of vitamins, carotenoids, long-chain polyunsaturated fatty acids, and minerals. Batch data for WCE demonstrate a consistent product that aligns with the proposed specification.

WCE is permitted as an ingredient in conventional food and beverage products in the United States. Furthermore, there is a history of safe consumption of *E. gracilis* dietary supplement products in Japanese and other Asian Marketplaces.

Estimates for the anticipated intake of WCE by the EU population have been determined using consumption data from the EFSA Comprehensive database and the United Kingdom (UK) National Diet and Nutrition Survey (NDNS) 2008-2014. Based on the UK NDNS dataset (which provides more refined estimates of intake overall), adolescents were calculated to have the highest absolute mean and 95th percentile intakes at 282 mg/person/day (6 mg/kg body weight/day) and 732 mg/person/day (14 mg/kg body weight/day), respectively; while toddlers were noted to consume the greatest levels of WCE on a per body weight basis using this dataset, at 15 mg/kg body weight/day at the mean and 34 mg/kg body weight/day at the 95th percentile, as expected for younger individuals who have intakes on a body weight basis. This is also similar to the worst case 95th percentile intake for the target consumer group of adolescents from the EFSA Comprehensive Database of 33.7 mg/kg bodyweight/day. Exposure to WCE from food supplements, assuming an individual chronically consumes a food supplement product containing WCE at the maximum dose, would result in an estimated consumption on a body weight basis ranging from 4.3 to 8.3 mg/kg body weight/day. Furthermore, consumption of meal replacements containing WCE, based on the worst case of 3 meals being replaced with products containing WCE, would result in an estimated consumption of 4.3 to 18.8 mg/kg body weight/day.

WCE is noted to be comprised as a complex ingredient that largely consists of insoluble fibre, lipids, protein, carbohydrates and various minerals and vitamins. The major constituents of the ingredient are normal components of the diet and therefore will be digested and metabolized in established pathways that are, in principle, similar to digestive processes and metabolism pathways that occur following the ingestion of plant matter (e.g., vegetables).

WCE is non-genotoxic as assessed in in vitro and in vivo studies. A single-dose acute toxicity study conducted with non-pregnant female Sprague-Dawley rats resulted in an oral median lethal dose (LD50) greater than 5,000 mg/kg body weight. WCE was well tolerated in a 14-day repeat dose study in Sprague-Dawley rats and subchronic feeding of WCE resulted in the no-observed-adverse-effect level

(NOAEL) of 50,000 mg/kg, equivalent to 3,318 and 3,961 mg WCE/kg body weight/day, the highest dose administered, in male and female Sprague-Dawley rats, respectively. Compared to the worst-case exposure estimates of up to 34 mg/kg bodyweight/day this would represent at least ~100 to 117-fold safety factors for this ingredient. Together, the weight of the available evidence on WCE support the safe use of the ingredient under the proposed conditions of use.