

Summary of the application: Dried *C. reinhardtii* algae (synonymous to *Chlamydomonas reinhardtii* dried biomass powder)

Applicant: Triton Algae Innovations, Ltd., 11760 Sorrento Valley Road, Suite R, San Diego, CA 92121, USA

This novel food application is related to a non-GMO dried biomass powder of the single cell alga of the (i.e. not “related to” or “obtained from”; it is the whole cell dried algae) Genus *Chlamydomonas*: *Chlamydomonas reinhardtii*. Approval is sought under Regulation (EC) No 2283/2015 of the European Parliament and of the Council of 25th November 2015 concerning novel foods. The ingredient falls under the following category: ‘food consisting of, isolated from or produced from microorganisms, fungi or algae’.

The applicant requests the authorization to use dried *C. reinhardtii* algae in cereal- and dough-based products including bread and bread rolls (A0DRD, A006Z, A005R), crackers (A005Y, A0CHT), cookies (A009V), and cakes (A00AN), breakfast cereals (A04QY), snack foods (cereal bars, chips/crisps) (A0EQY, A00EY), pasta and noodles (A007D), soups and sauces (A0B9J, A041L, A042N), composite meals including ready-to-eat meals and pizzas (A03VB), smoothies and functional/fortified beverages (A03DF, A03RS, A03RX, A03KL), at a maximal use level of 10% (i.e. 10 g/100 g) in the described food products, as an alternative source of dietary protein. The novel food has a “no questions” letter from the US FDA, regarding its status as GRAS (Generally Recognized As Safe) for its intended use in foods as a replacement for dietary protein (with no percentage inclusion limitations).

Raw materials used in the production of Triton’s *C. reinhardtii* dried biomass powder are food grade and/or suitable for use in the production of food grade products for human consumption.

The analysed batches have demonstrated the lack of various contaminants: heavy metals, microbiological contaminants.

The safety of dried *C. reinhardtii* algae has been highlighted by four toxicity study (GLP and OECD compliant studies): a bacterial reverse mutation test (OECD 471), one in vitro chromosome aberration test (OECD 473), one in vivo micronucleus test (OECD 474) and one sub-chronic 28-day toxicity study (OECD 407). In this last study, the NOAEL has been measured at 4000 mg/kg bw/day. Furthermore, the proteins of the *C. reinhardtii* were found to be rapidly digested, suggesting a low likelihood of allergenic potential.

Therefore, dried *C. reinhardtii* algae is well-characterized and compliant with European regulations. The novel food is safe and devoid of significant allergic potential. Dried *C. reinhardtii* algae does not present consequently any potential hazard to the European population, in the conditions proposed by the applicant.