Summary of the dossier

Applicant: Sporomex Limited, Medina House, 2 Station Avenue, Bridlington, East Yorkshire, YO16 4LZ, UK

Sporomex Ltd. proposes to licence the encapsulation of food grade oils such as fish oils loaded within sporopollenin exine capsules for use in food. Sporopollenin is the major component of the tough outer (exine) walls of spores and pollen grains and is grown biosubstainably and already consumed in significant amounts in foods such as honey. This application outlines the proposed use of sporopollenin exine capsules as an enhanced delivery vehicle for such as fish oils consumed in the diet.

For consistency, in this proposal the sporopollenin exine capsules will be abbreviated to exines. Compositionally, the exines are comprised of sporopollenin, which is polycarotenoid-like containing carbon, hydrogen and oxygen. Each particle is identical in size, shape and chemical composition to all the others. In addition, exines have polyphenolic functionality endowing them with light-shielding and antioxidant properties.

Exines are extremely tough, resistant to acid and alkali degradation and have been shown to pass unchanged though the digestive system of animals. To produce exines from *Lycopodium clavatum* (club moss) spores are emptied of all their genetic, protein, carbohydrate and lipid materials to leave a hollow capsule. The process is free from toxic reactants and can be largely physical. The empty exines can then be loaded with the 'active', such as fish oil by simply mixing and placing under vacuum. The filled exines are a powder, which could potentially be consumed by an individual. An exine preparation (up to 0.5g per person per day) will be used to specifically encapsulate lipophilic food compounds such as food grade oil such as fish oil and include use as an ingredient in: baked goods and baking mixes; beverages and beverage bases; breakfast cereals; chewing gum; condiments and relishes; confections and frostings; dairy product analogs; fruit juices; frozen dairy desserts and mixes; fruit and water ices; gelatins, puddings and fillings; grain products and pastas; hard candy; herbs, seeds, spices, seasonings, blends, extracts, and flavorings; jams and jellies; milk; milk products; nuts and nut products; plant protein products; processed fruits; processed vegetables and vegetable juices; snack foods; soft candy; soups and soup mixes; sugar; and sweet sauces, toppings and syrups.

Bioavailability studies in human volunteers have shown enhanced absorption of the fish oil (containing 20% eicosapentaenoic acid in the form of ethyl ester) when delivered in exines (compared to ingestion of free oil). In addition, taste masking of the flavor of the oil and an enhanced shelf life has been shown due to the exines antioxidant effects.

In vitro, and in *vivo* animal and human studies have shown no adverse effects, a result that would be expected from consumption of the exines as they pass through the digestive tract unchanged. There is no allergenic or toxic potential.

To conclude, it is proposed that exines provide a novel and enhanced delivery method for food grade oil such as fish oil. In addition, exines provide taste masking, increase the shelf life of the fish oil by preventing rancidity and enhance bioavailability, thus decreasing the amount of fish oil that needs to be incorporated in a food-stuff.