SUBSTANTIAL EQUIVALENCE OPINION

Phytoglycogen

The Food Safety Authority of Ireland (FSAI) received an application in March of 2017 from Mirexus Biotechnologies Inc. of Canada for an opinion on the substantial equivalence of phytoglycogen (Susttain™). Phytoglycogen (plant glycogen) is compared with amylopectin (waxy corn starch) which has a history of consumption within the EU prior to 1997 and is therefore outside the scope of the novel food Regulation. The novel phytoglycogen is an odourless, colourless, flavourless polysaccharide derived from non-GM sweet corn using conventional food processing techniques. The novel ingredient is produced to GMP standards in Canada in a process that includes grinding, mixing, dewatering, screening, clarification, microfiltration, ultrafiltration and spray drying. Phytoglycogen is to be marketed as a food ingredient in processed foods at between 5% and 25% of the final product. It is intended as a thickening agent and a carrier for food additives and/or food ingredients while enhancing the carbohydrate content of processed foods. It is not considered a food additive under EU law.

The applicant considers the ingredient to be novel and fall within the category of "*food and food ingredients consisting of or isolated from plants"* as set out in *Article 1(2) (e)* of the novel food Regulation (EC) No. 258/97.

Composition

Phytoglycogen (CAS Number 9005-79-2) is a white to off white powder with particles in the size range of 30 – 150nm.

Parameter (average of 3 batches)	Susttain™	Amylopectin
Carbohydrate (%)	97	87
Fibre (%)	0.8	0.4
Sugars (%)	0.53	0
Fat (%)	0.16	0.15
Protein (%)	0.63	0.5

Phytoglycogen and amylopectin are primarily sources of starch, and are made up of glucose monomers linearly linked by α(1-4) glycosidic bonds. Branching occurs through α(1-6) glycosidic bonds at a frequency of 8-12 glucose units in phytoglycogen and a lower

frequency of 24-30 glucose units in amylopectin. Other components of phytoglycogen include fat and protein at very low levels.

Nutritional Value and Metabolism

Starch is the primary component of phytoglycogen and amylopectin, with very low but similar amounts of other nutrients such as protein and fat. The calorific value presented per 100g of phytoglycogen is 389 calories, while that for 100g of amylopectin is 400 calories. Starch is a polysaccharide and regardless of its form (phytoglycogen or amylopectin) it is metabolised to individual glucose sugar moieties by an enzymatic process beginning in the mouth with salivary amylases, all the way through to the small intestine where the majority of the digestion occurs. The applicant contends that the metabolism of phytoglycogen results in a relatively slower release of free sugar compared to that of amylopectin due to the fact that α(1-6) linkages (more frequent in phytoglycogen) are not as quickly broken down as the α(1-4) linkages.

Intended uses

The applicant intends to place phytoglycogen on the EU market in a range of processed foods at levels of 5% - 25% of the final product. It is anticipated that phytoglycogen may substitute for or replace amylopectin as a stabiliser, thickener or formulation aid.

Level of undesirable substances

Phytoglycogen and amylopectin are both starch forms similarly derived from non-GM maize. Batch analyses of the novel ingredient demonstrate that potential microbial contaminants (yeasts, moulds, *E. coli*, *Salmonella* and *L. monocytogenes*) and heavy metals including arsenic, lead, cadmium, mercury among others are not a significant concern. Similar analyses for environmental contaminants such as mycotoxins, PCBs and dioxins indicate that (Susttain™) meets the standard for plant based food ingredients.

Conclusion

The FSAI is satisfied from the information provided by Mirexus Biotechnologies that phytoglycogen (Susttain™) is substantially equivalent in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances to amylopectin, which was on the EU market prior to 1997. The novel ingredient will be used in processed food as a stabiliser, thickener, and/or texturiser at levels of between 5% and 25% of the final product. The marketing of the novel ingredient will be subject to all relevant general and specific EU food legislation.