**SUBSTANTIAL EQUIVALENCE OPINION**

# *Aloe macroclada* Baker - Gel Extract

The Food Safety Authority of Ireland (FSAI) received an application in November of 2015 from Stemtech France Inc. for an opinion on the substantial equivalence of a dried product derived from the leaves of *Aloe macroclada* Baker to a similar product derived from the leaves of the related *Aloe vera* (common Aloe or *barbadensis*).

The novel ingredient is a colourless mucilaginous gel material found in the parenchymatous leaf cells of *Aloe macroclada* Baker. This is one of more than 450 species of *Aloe* that can be found growing wild in eastern Africa and South America. In the EU, leaf gel extract of *Aloe vera* has a significant history of consumption in food prior to 1997, which means that it is not within the scope of the novel food Regulation (EC) No 258/97. While the novel ingredient is commonly consumed in Madagascar, it does not have a history of consumption within the EU prior to 1997 and therefore requires authorisation as a novel food. The source plants are initially identified in the wild in Madagascar by botanical experts and then cultivated in nurseries and eventually in fields without the use of chemical fertilisers or plant protection products. Leaves from two to three year old healthy plants are harvested, washed and the gel manually removed before it is dried and ground to a fine powder. A quality management system is in place incorporating the HACCP principles. The final powder has a moisture content of less than 5% and is packaged in 500g amounts in heat sealed BoPET bags. The applicant specifies a shelf life of two years for the novel ingredient, and as part of their quality control plan they retain a sample from each batch to monitor stability.

## Composition

The composition of the novel ingredient and the existing comparator are very similar in terms of ash, protein and fat, as well as carbohydrates including polysaccharides and dietary fibre. The chemical profiles of the novel ingredient and existing comparator were compared by nuclear magnetic resonance (NMR), thin layer chromatography (TLC) and gas permeation chromatography (GPC). Of the 21 chemicals measured, the novel ingredient was found to contain slightly lower levels of

glucose and malic acid and relatively higher levels of lactic acid, with no other appreciable differences evident. The levels of the mucopolysaccharide acemannan were comparable for both plants.

| Parameter | Novel Ingredient | Comparator | Units |
|---|---|---|---|
| Ash | 25.0 | 31.0 | % |
| Calorie | 294.8 | 266.0 | cal/100g |
| Carbs | 65.9 | 60.1 | % |
| Dietary fibre | 28.6 | 13.6 | % |
| Fat | 2.7 | 2.2 | % |
| Moisture | 4.7 | 5.2 | % |
| Polysaccharides | 9.5 | 8.6 | % |
| Protein | 1.63 | 1.52 | % |
| Glucose | 8.9 | 14.0 | % |

**Nutritional Value and Metabolism**

The novel ingredient is not a significant source of human nutrition. The composition and calorific value are very similar to those of the existing comparator and so it is safe to assume that the nutritional value and metabolism will not be significantly different.

**Intended Uses**

The novel food is to be used in food supplements at a recommended dosage similar to that for the same material derived from the existing comparator.

**Level of Undesirable Substances**

Analysis of the novel ingredient for the presence of the heavy metals lead, arsenic, cadmium and mercury did not identify any concerns. A satisfactory profile for microbial contaminants was demonstrated by analytical results for total microbial counts, yeasts and moulds, coagulase-positive *Staphylococci*, *Escherichia coli* and *Salmonella*. The novel ingredient was also analysed for the presence of mycotoxins and a range of pesticide residues and PCBs, with no concerns identified.

## Conclusions

The FSAI is satisfied from the information provided by Stemtech France Inc. that the powdered gel extracted derived from the leaves of *Aloe macroclada* Baker is substantially equivalent to the same gel derived from *Aloe vera* leaves and used in food supplements. The novel ingredient is to be used in food supplements at recommended dosage reflecting those for the existing comparator.