

SUBSTANTIAL EQUIVALENCE OPINION

Fruit pulp derived from the fruit of *Adansonia digitata* (Baobab tree)

The Food Safety Authority of Ireland (FSAI) received an application in August of 2013 from Bio-Innovation Zimbabwe for an opinion on the substantial equivalence of its Baobab (*Adansonia digitata*) fruit pulp to a similar ingredient already on the EU market as a novel food and which was authorised to PhytoTrade Africa (Commission Decision 2008/575/EC).

The novel Baobab fruit pulp is produced by the same standard mechanical procedures that are used to produce the authorised counterpart. The applicant contends that some of the Baobab fruit pulp authorised to PhytoTrade Africa was sourced from regions close to where they source their Baobab fruit. The applicant considers Baobab fruit pulp to fall within the scope of the novel food Regulation (EC No 258/97, specifically under *Article 1.2(e)* “Foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating and breeding practices and which have a history of safe food use”).

Composition

The primary bulk constituents of Baobab fruit pulp are carbohydrate and dietary fibre, with minor levels of protein, fat and ash. The composition of the novel Baobab fruit pulp in terms of protein, fat, ash and carbohydrate is similar to the authorised product. The sodium level in the novel ingredient is two to three times higher than that for the authorised product. However, this is not of particular concern as the sodium content of this ingredient is very low in absolute terms and should not have a significant impact on overall sodium intake. The applicant noted that some of the Baobab fruit pulp authorised to PhytoTrade Africa was sourced from regions close to where Bio-Innovation Zimbabwe sources their Baobab fruit and therefore a similar composition would be expected. The applicant demonstrates that the novel ingredient is stable for at least a year.

Nutritional Value and Metabolism

The novel Baobab fruit pulp and its authorised comparator contain similar levels of the major nutritional components including carbohydrate, fibre, protein and fat, as well as micronutrients such as vitamins and minerals. The metabolism of both products would not be expected to differ considering the close similarities in composition and nutritional content. The relatively higher sodium content in the novel ingredient is not of nutritional significance.

Intended Uses

Though there are no specific restrictions on the food uses for Baobab fruit pulp set out in Commission Decision 2008/575/EC, the applicant intends using Baobab fruit pulp in the same food groups as those in which the authorised ingredient is used.

Level of Undesirable Substances

The microbial specifications for both products are almost identical while the specifications for arsenic, mercury, lead and cadmium are very similar. The applicant provided satisfactory aflatoxin test results and undertakes to audit suppliers on a variety of parameters including microbial load, aflatoxins and foreign matter.

Conclusions

The FSAI is satisfied from the information provided by the applicant that Baobab fruit pulp to be marketed by Bio-Innovation Zimbabwe is substantially equivalent to Baobab fruit pulp already on the EU market and authorised to PhytoTrade Africa through Commission Decision 2008/575/EC. The designation of this novel ingredient will be “Baobab fruit pulp” in accordance with Commission Decision 2008/575/EC.