

SUBSTANTIAL EQUIVALENCE OPINION

Baobab Dried Fruit Pulp (*Adansonia digitata*)

The Food Safety Authority of Ireland (FSAI) received an application in March of 2016 from Baobab Foods LLC in the USA for an opinion on the substantial equivalence of its Baobab (*Adansonia digitata*) dried fruit pulp to Baobab dried fruit pulp authorised for the EU market to PhytoTrade Africa by Commission Decision 2008/575/EC.

The applicant considers that their novel Baobab dried fruit pulp falls 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”.

The Baobab dried fruit pulp is sourced from the southern African region, with all suppliers following a harmonised approach for collection and production, similar to that described for the authorised comparator. Only mechanical processes are used in the production and processing of the novel ingredient.

Composition

Compositional analysis demonstrates that the novel baobab fruit pulp is very similar to the authorised comparator in terms of the primary constituent carbohydrate, as well as moisture, protein, fat, ash, and sodium, in line with the specifications set out in the Annex to Commission Decision 2008/575/EC.

Nutritional Value and Metabolism

The main nutritional component of the Baobab fruit pulp is carbohydrate, with vitamin C the main vitamin present. As the novel Baobab fruit pulp is similar to authorised comparator in terms of the major macro- and micronutrients, metabolism is not expected to differ.

Intended Uses

Commission Decision 2008/575/EC does not limit the use of Baobab dried fruit pulp to any specific food categories. The applicant intends to include the novel ingredient in the same food groups as specified in the initial application for EU approved Baobab fruit pulp which includes smoothies, cereal bars and other health food products.

Level of Undesirable Substances

The results of microbiological analysis indicate that yeasts & moulds, TVCs, coliforms, *Escherichia coli*, *Staphylococcus aureus*, *Salmonella* species and *Enterococci* in the novel ingredient are in line with those for the authorised

comparator. Analysis for heavy metals (arsenic, cadmium, mercury and lead) and aflatoxins also do not identify any cause for concern. The control of undesirable substances and monitoring of product quality is achieved through routine testing against specifications along with regular supplier audits.

Conclusions

The FSAI is satisfied from the information provided by the applicant that Baobab dried fruit pulp marketed by Baobab Foods LLC is substantially equivalent to Baobab fruit pulp on the EU market and authorised to PhytoTrade Africa by Commission Decision 2008/575/EC. The designation of the novel ingredient will be “Baobab fruit pulp” in accordance with *Article 2* of Commission Decision 2008/575/EC.