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PhytoTrade
AFRICA

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Division of Biotechnology and GRAS Notice Review
U.S. Food and Drug Administration
5100 Paint Branch Parkway, HFS-255, College Park, MD 20740
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17th December 2008

Dear Mr. Bonnette,

Baobab Dried Fruit Pulp - Claim of Exemption From the Requirement for Premarket Approval Pursuant to Proposed 21 CFR §170.36(c)(1) [62 FR 18938 (17 April 1997)]

Thank you for your correspondence of 15th December 2008 requesting a revision of Part A of the above.

Please find enclosed four signed originals with the suggested revision.

Please let me know if I can provide any further documentation or information.

Yours sincerely,

Cyril Lombard
Market Development
PhytoTrade Africa

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PhytoTrade AFRICA

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BY:

Baobab Dried Fruit Pulp

A GRAS Notification for use as a food ingredient in fruit bars and fruit smoothies

I GRAS Exemption Claim

A. Claim of Exemption From the Requirement for Premarket Approval Pursuant to Proposed 21 CFR §170.36(c)(1) [62 FR 18938 (17 April 1997)]

Baobab fruit pulp has been determined to be Generally Recognized As Safe (GRAS), consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act*. This determination is based on scientific procedures as described in the following sections, under the conditions of its intended use in food. Therefore, the use of Baobab fruit pulp in food, as described below, is exempt from the requirement of premarket approval.

Signed,
Cyril Lombard

28th November 2008
Date

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B. Name and Address of Notifier

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[1] PhytoTrade Africa is registered in South Africa (registration number – 2006/001433/08). The registered name is SANPROTA (ASSOCIATION INCORPORATED UNDER SECTION 21) trading as PhytoTrade Africa. SANPROTA stands for the Southern African Natural Products Trade Association.

C. Common Name of the Notified Substance

The substance is commonly known as Baobab fruit pulp, the name by which it was described in its approval as a novel food ingredient by the European Commission.

D. Conditions of Intended Use in Food

Baobab fruit pulp provides several technical functions in food. It functions as a flavor, nutrient supplement (source of vitamins, minerals, and fiber) and stabilizer/ thickener. There is some evidence that it also enhances other fruit flavors present in the food. It is intended for use in fruit cereal bars and thick fruit drinks known commonly as smoothies. Levels used are 6-10% (by weight) in fruit bars and 10-15% in smoothies.

E. Basis for the GRAS Determination

Pursuant to 21 CFR § 170.30, Baobab fruit pulp has been determined to be GRAS on the basis of scientific procedures.

F. Availability of Information

The data and information that serve as the basis for this GRAS Notification will be sent to the U.S. Food and Drug Administration (FDA) upon request, or will be available for review and copying at reasonable times at the offices of:

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Should the U.S. Food and Drug Administration (FDA) have any questions or additional information requests regarding this notification, PhytoTrade Africa will supply these data and information.

II. Detailed Information about the Identity of the Substance[2]

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[2] This document was drafted for Phytotrade Africa by the natural products consultancy company:
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Baobab fruit pulp is a powder produced from the fruit of the Baobab tree (*Adansonia digitata*) which grows predominantly in Southern Africa. The Baobab dried fruit pulp is intended to be used as a food ingredient in fruit bars and fruit smoothies.

The GRAS notification for Baobab dried fruit pulp discusses the evidence which supports this application and compares this with the available information that could appear to contradict this conclusion.

The evidence that supports this GRAS notification comes from the compositional analysis of the Baobab dried fruit pulp and the supporting discussion which demonstrates that the food ingredient corresponds favorably to other fruit based ingredients. Corroborating evidence comes from the extensive history of safe use for Baobab fruit in Southern Africa. Such information was provided to the food safety authorities in the United Kingdom and Baobab fruit pulp was approved for use as a novel food ingredient. This decision was forwarded to the European Commission which unanimously approved its use throughout the EU (Appendix 1)

The information that could appear to contradict the assessment that Baobab dried fruit pulp is GRAS for the intended use comes from two separate sources – avoidable food contaminants and anti-nutrients. In both cases, the identified contaminants and anti-nutrients were either found to be absent or present at such low levels that they would not be expected to cause any adverse effects on consumers of Baobab dried fruit pulp.

After reviewing all of the available data, PhytoTrade Africa concludes that Baobab dried fruit pulp is GRAS at the anticipated level of intake and for the intended uses described in this notification.

PhytoTrade AFRICA

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1.0 Introduction

Phytotrade Africa concludes that their simple fruit powder, Baobab dried fruit pulp is GRAS based on scientific procedures for. This powder, which also has a traditional history of safe use in Africa, is derived from the fruit of the Baobab tree, *Adansonia digitata*, and is intended to be used as an ingredient in fruit bars and smoothies as discussed below. A series of analyses have been carried out to identify and quantify the individual constituents in Baobab dried fruit pulp. These constituents are then discussed in relation to their expected impact on the diets of US consumers. Taken together, this information will demonstrate that at the anticipated level of intake Baobab dried fruit pulp is GRAS with respect to the intended use of the finished product.

1.1 Source of Baobab Dried Fruit Pulp

Baobab dried fruit pulp is derived from the fruit of the Baobab tree, *Adansonia digitata*. The Baobab tree is a member of the *Bombacaceae* family which consists of around 20 genera and around 180 species (Heywood, 1993), including the closely related species *Adansonia gregori* and *Adansonia madagascariensis* (Shukla *et al.*., 2001).

The Baobab tree is found primarily in the countries of Southern Africa, such as Botswana, Mozambique, Namibia, South Africa and Zimbabwe (Coates Palgrave, 2000). Over the years, the Baobab tree has been exported around the world, so much so that the Baobab tree is also common in Hawaii, Puerto Rico, Virgin Islands and Florida (Sidibe *et al.* 2002), India, Sri Lanka, Malaysia, China, Jamaica and Holland (Sidibe & Williams, 2002).

The taxonomic classification (Watson and Dallwitz, 1992 onwards) of the Baobab tree is listed as follows:

Kingdom	*Plantae*
Division	*Magnoliophyta*
Class	*Magnoliopsida*
Order	*Malvales*
Family	*Bombacaceae*
Genus	*Adansonia*

In Southern Africa, the local people call the Baobab tree the "upside down tree". This local name is due to the fact that in low light conditions, the outline of the Baobab tree gives the appearance of someone having pulled the Baobab tree out of the ground and then re-planted the tree upside down (Owen, 1974).

The Baobab tree is a deciduous tree that normally grows to 20 meters in height. The trunk of the Baobab tree can grow up to 5 meters in diameter and tends to be stouter at the bottom of the tree than at the top. This gives the Baobab tree an appearance similar to the shape of a bottle (Wickens, 1982).

The Baobab tree produces large pendulous white flowers from October to December. These flowers are pollinated by fruit bats that feed on the nectar. This leads to the formation of the Baobab fruit which is typically large (25 to 40 cm long) and ovoid (similar to an egg) to cylindrical-oblong (similar to an aubergine) in shape. The fruit is usually green or brownish and covered in pale yellow-brown hairs. Inside the hard outer shell of the Baobab fruit is a dry, white fruit pulp with red

fibers and black, kidney-shaped seeds randomly distributed inside the fruit pulp (Wickens, 1982).

1.2 Composition of Baobab Dried Fruit Pulp

The supply of Baobab dried fruit pulp comes from a particular region in Southern Africa. Since the Baobab fruit is wild harvested from many different areas within this particular region, the Baobab dried fruit pulp is blended to produce a final consistent product (Appendix 1).

The Baobab dried fruit pulp was analyzed by a food contract laboratory to produce a nutritional profile of the finished product (Appendix 2). This nutritional profile was generated by analyzing duplicate samples of Baobab dried fruit pulp (see Table 1).

Table 1
The nutritional composition of Baobab dried fruit.

Nutrient Component	Baobab dried fruit pulp – 1	Baobab dried fruit pulp – 2
Moisture (loss on drying)	13.6	13.7
Protein	2.04	2.03
Ash	5.5	5.5
Total carbohydrate	78.5	78.3
Total dietary fiber	51.4	52.2
Available carbohydrate	27.1	26.1
Energy	120 kcal (510 kJ)	117 kcal (496 kJ)
Total sugars (as glucose)	21.2	20.9
Sodium	8.64 mg/100g	8.89 mg/100g
Fat	0.4	0.5
Saturated fats	0.21	0.25
Mono-unsaturated fats	0.13	0.16
Polyunsaturated fats	0.04	0.07
Vitamin C	74.1 mg/100g	76.2 mg/100g
Vitamin B1 (HCl)	0.05 mg/100g	0.06 mg/100g
Vitamin B2	0.03 mg/100g	0.02 mg/100g

All data in Table 1 reported as g/100g of Baobab dried fruit pulp unless otherwise stated.

The fat content of the Baobab dried fruit pulp was low with around 0.4 – 0.5g of fat per 100g. The

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analyses showed that 0.2 – 0.25g (up to 50%) of the total fat in Baobab dried fruit pulp was saturated fat and 0.13 – 0.16g was monounsaturated fat.

A more detailed analysis (Appendix 3) of the fatty acids found in Baobab dried pulp showed that the major constituents were oleic acid (24.7 – 24.9% of the total fatty acids), linoleic acid (18.5 – 20.0% of the total fatty acids) and α-linolenic acid (10.4 – 11.4% of the total fatty acids).

The protein content of Baobab dried fruit pulp was also low, with a content of roughly 2g per 100g of fruit.

The carbohydrate content accounted for approximately 80% by weight of the Baobab dried fruit pulp. Over 50%, or 51.4 – 52.2g per 100g, of Baobab dried fruit pulp was found to be dietary fiber, whereas the sugar content in the form of glucose was found to be 20.9 – 21.2g per 100g of Baobab dried fruit.

The calorie content was found to be 117 – 120 kcal or 496 – 510 kJ per 100g of Baobab dried fruit pulp. This means the caloric content of Baobab dried fruit pulp is higher than typical citrus fruit pulps but lower than dried fruit, such as raisins (USDA, 2008a).

The nutritional analysis found that moisture content accounted for 13.6 – 13.7g per 100g of Baobab dried fruit pulp. This moisture content is similar to other dried fruit such as raisins. However, unlike other dried fruit, the moisture content in Baobab dried fruit pulp is naturally low; i.e., no further drying is necessary to produce the dried fruit pulp.

The vitamin C content was found to be high, ranging from 74.1 – 76.2mg per 100g of Baobab dried fruit pulp. Also, there were marked levels of vitamin B1 and B2 in the Baobab dried fruit pulp. Typical values for vitamin B1 and B2 were found to be 0.05 – 0.06mg per 100g and 0.02 – 0.03mg per 100g respectively.

Finally, the sodium content of Baobab dried fruit pulp was found to be very low. The sodium content ranged from 8.64 – 8.89mg per 100g of Baobab dried fruit pulp.

From a nutritional point of view, Baobab dried fruit pulp is similar to other types of fruit – low in fat, low in sodium and relatively low in calories.

1.3 The Production Process of Baobab Dried Fruit Pulp

PhytoTrade Africa has 58 members and every member who wants to supply their Baobab dried fruit pulp to PhytoTrade Africa is required to be assessed for the capacity to manufacture the product to the appropriate standards. For this purpose PhytoTrade Africa operates a Pre-Qualified Supplier (PQS) and a HACCP system (Appendices 4 and 5) which assesses each member according to the following criteria:

(i) Raw material supplies – volumes and quality

Members are assessed to ensure they can supply the correct volumes and quality to the selected market. The PQS of Baobab dried fruit pulp is required to have a training program in quality control for the rural harvesters. This includes a system of grading to eliminate any inappropriate quality, such as material harvested too early or too late in the season, for the supply chain. Rural packaging, storage, and transportation must meet agreed standards. These standards are based on the accepted

raw material supply practices for industries such as the out-sourced production of chili and the manufacture of paprika from peppers, both of which are intended for the EU market.

(ii) Traceability

An internal control system capable of meeting requirements of "organic" certification is required. Individual harvesters are trained and registered, and comprise of supply groups with coordinators or "chairs" of producer groups acting as contact and control points. Material is traceable from storage warehouse back to individual harvesters through practices such as supplying numbered food-grade plastic bags and other audit trail methodologies that are common in the food and the pharmaceutical raw material supply chains. The traceability systems are required to be formal and documented for inspection purposes.

(iii) Collation practices

The warehousing and bulking-up facilities are inspected for cleanliness and appropriateness for supply into the food chain. Pest control systems are also required. Minimum and maximum temperatures, moisture and other relevant conditions are inspected.

(iv) Processing

The suitability of the processing methods and equipment is inspected and required to conform to the approved mechanical processes. Approved equipment includes de-hullers, hammer mills, shakers, and sifters / mesh screens.

All processing steps must accommodate the traceability requirements through batch numbers for each production run.

Baobab dried fruit pulp is processed using a very simple mechanical process. In principle, the manufacturing process can be broken down into 5 key steps:

- Wild harvesting of the Baobab fruit.
- Cracking open the hard shell of the Baobab fruit and removing the inner contents.
- Mechanical separation of the seeds and the fibrous material from the fruit pulp.
- The fruit pulp is milled and separated from the unwanted coarse material using a fine mesh.
- Storage of the milled fruit pulp in clean food-grade packaging.

1.4 Characteristic Properties of the Baobab Dried Fruit Pulp

Baobab dried fruit pulp is a free flowing coarsely milled powder with a particle size in the region of 3 – 600μm.

The color of the Baobab dried fruit pulp ranges from off-white to cream.

The Baobab dried fruit pulp has a distinctive tart and acidic flavor.

Baobab dried fruit pulp can be extracted into water, alcohol and lipophilic solvents.

1.5 Potential Toxicants of Baobab Dried Fruit Pulp

The literature concerning Baobab highlights four potential anti-nutrients that may be present in the Baobab dried fruit pulp.

Ghani and Abejule (1986) reported that Baobab fruit pulp contained small amounts of cyanide. The authors stated that the maximum content of cyanide was 0.0049% by weight of the fruit pulp.

Airan and Desai (1954) reported that Baobab fruit pulp contained high quantities of organic acids including oxalic acid. Proll *et al.* (1998) reported that Baobab seeds contain up to 4.2 g/kg of oxalic acid of which 2.6 g/kg was soluble. A later study by Umara *et al.* (2007) reported that the levels of oxalic acid in Baobab fruit pulp could be as high as 9.5% by weight or 95 g/kg. However, as discussed below, oxalic acid cannot be detected in PhytoTrade Africa's fruit pulp at a detection limit of 400 mg/kg. Umara *et al.* (2007) used a titration method (concentrated sulfuric acid followed by potassium permanganate titration) for determining the oxalic acid content of Baobab fruit pulp. As this method relies on the experimenter to determine when titration is complete it is regarded as being inaccurate. By contrast, the PhytoTrade Africa Baobab dried fruit pulp samples were analysed by HPLC with UV detection against known calibration standards.

The bark of the Baobab tree is reported to contain the alkaloid, adansonin, which is believed to be the active agent responsible for the anti-malarial properties associated with the tree bark (Kerhero and Adam, 1974). Although there are no reports of adansonin being present in the Baobab fruit pulp, alkaloids are known to be present in the funeral tree (*Quararibea funebris* Vischer), a relative of the Baobab tree.

The oil from the Baobab seeds is reported to contain cyclopropene fatty acids which are known to interfere with fatty acid biosynthesis *in vitro* and *in vivo* (Andrianaivo-Rafehivola *et al.*, 1993; Andrianaivo-Rafehivola *et al.*, 1995; Cao *et al.*, 1993; Cao *et al.* 1996). Since these seeds are randomly distributed in the Baobab fruit, potentially, the Baobab dried fruit pulp could be contaminated with cyclopropene fatty acids.

The other sources of potential toxicants come from the avoidable contamination of the Baobab dried fruit pulp by pesticide residues, heavy metals and mycotoxins.

In summary, the scientific literature has highlighted four potential anti-nutrients that could be found in the Baobab dried fruit pulp. These anti-nutrients and the other identified sources of potential contamination in Baobab dried fruit pulp are discussed in more detail in section 4.1 – Anti-nutrients in Baobab dried fruit pulp.

1.6 Specification of Baobab Dried Fruit Pulp

Description

The dried and milled fruit pulp of *Adansonia digitata*, originating from Southern Africa

Appearance	Fine, white to pinkish white powder
Analytical specification	
Foreign Matter	not more then 0.2 %
Loss on drying	not more then 12 %
Solubility	partially soluble in hot and cold water
Ash	not more than 6 %
Heavy metals	
Lead	less than 0.5 mg/kg
Cadmium	less than 0.2 mg/kg
Mercury	less than 0.1 mg/kg
Arsenic	less than 3 mg/kg
Microbiological criteria	
Total aerobic count	less than 100,000 cfu/g
Yeasts and moulds	less than 10,000 cfu/g
Eschericia coli	absent in 1 g
Staphylococcus aureus	absent in 1g
Salmonella	absent in 25 g

2.0 Self-limiting Use of Baobab Dried Fruit Pulp

There are no reports in the literature concerning the amount of Baobab fruit pulp consumed by local people in Southern Africa (Appendix 6).

To support the history of use, and its self limiting use in Africa, a survey (Appendix 7) was carried out by Phytotrade Africa which asked researchers and business people based in Southern Africa whether there were any reported side-effects related to the consumption of Baobab fruit pulp. Overwhelmingly, the feedback reported that there were no adverse effects associated with the consumption of Baobab fruit pulp. However, one respondent to this questionnaire did report that excessive consumption (no quantities reported) could produce laxative effects. This side-effect was resolved without medical treatment and disappeared once the consumption of Baobab fruit pulp ceased.

The excessive consumption of most fruit can result in laxative effects. This is directly due to the fiber content of the fruit, and as in the case reported with Baobab dried fruit pulp, usually resolves itself once the consumption of fruit ceases. The nutritional profile in Table 1 (see page 9) clearly shows that Baobab dried fruit pulp has a very high dietary fiber content of roughly 50% by weight (over 30% of this dietary fiber is water soluble – see Table 1 – page 9). Therefore, the report concerning the laxative effects of Baobab fruit pulp due to excessive consumption would be expected.

3.0 Evidence that supports the GRAS determination of Baobab Dried Fruit Pulp

The evidence that supports the GRAS determination of Baobab dried fruit pulp is based on several key pieces of evidence. These are the corroborative reports concerning the local use of the fruit in Southern Africa where the Baobab tree is indigenous, a full analytical breakdown of the final product and an evaluation of the potential pharmacological properties of the Baobab dried fruit pulp.

3.1 Traditional Use of Baobab Fruit Pulp

Baobab fruit pulp is reported to have numerous uses by the indigenous people of Africa. (Lewicki, 1974). Bosch *et al.* (2004) reported that Baobab fruit contained a soft, white, edible and nutritious flesh that was called monkey bread. Further, this fruit pulp was eaten as a sweet and used to make ice-cream (Bosch *et al.*, 2004).

In the savanna region of Northern Nigeria, the Hausi-speaking farmers and the Fulani cattle owners have a specific use for Baobab fruit pulp. Firstly, they produce an emulsion from the fruit pulp by removing the seeds and fibers, kneading in cold water, and then straining this emulsion through a sieve (Nicol, 1957). The resulting white or whitish yellow fluid is used to dilute thick guinea corn to a thin gruel, a traditional morning or midday meal (Bosch *et al.*, 2004; Nicol, 1957).

The Fulani cattle owners are also reported to have used this emulsion derived from Baobab fruit pulp to adulterate milk (Bosch *et al.*, 2004; Erosmele *et al.*, 1991; Nicol, 1957).

Several authors have reported that the fruit pulp is used to make a refreshing drink (Bosch *et al.* 2004; Carr, 1955; Nicol, 1957). In Sudan, this drink is called "*gubdi*" and this is made from cold water to preserve the vitamin content of the Baobab fruit pulp (Bosch *et al.*, 2004). Amongst the Hausi farmers, the Baobab fruit pulp juice mixture is a popular drink and is normally made available during the hot times of the year (Nicol, 1957).

The Baobab fruit pulp is reported to be used in cooking. Amongst some African people the Baobab tree is sometimes called the '*cream of tartar*' tree because of the acidic nature of the fruit (Carr, 1955). The Baobab dried fruit pulp can also be used in baking as an alternative for cream of tartar (Bosch *et al.*, 2004).

Finally, Diop *et al.* (1988) reported that the pulp was rich in calcium and that this was the main reason that Baobab fruit pulp was largely consumed by pregnant women and children in Senegal. A study of pregnant women in Gambia (Prentice *et al.*, 1993) reported that eating the Baobab fruit pulp once a day without the seeds contributed 30 mg of calcium per day to the diet.

A survey was carried out by Phytotrade Africa amongst their members concerning the use of Baobab fruit pulp. This survey (Appendix 7) confirmed that Baobab fruit pulp was widely consumed wherever the Baobab trees were growing and that the fruit pulp was considered by the local population to be healthy. The survey also confirmed that Baobab fruit was consumed by people of all ages, including the old, young, healthy, infirm and pregnant women.

The safety of Baobab fruit pulp was supported by the work of Ramadan *et al.* (1994). This group carried out an LD_{50} experiment in rats which were administered an aqueous extract of Baobab fruit

pulp via intraperitoneal administration. This experiment produced an LD_{50} value in rats of 8,000 mg/kg. As the fruit pulp is ~ 50% dietary fiber, this would be equivalent to approximately 0.5 pound of fiber for an adult human.

According to the Hodge and Sterner Scale, a chemical that produces an oral LD_{50} value of 8,000 mg/kg can be classified as "practically non-toxic" in humans (Hodge and Sterner, 1956).

3.2 The Anticipated Use of Baobab Dried Fruit Pulp in Foodstuffs

Prior to the submission of this GRAS notification, Phytotrade Africa commissioned Leatherhead Food International to characterize and develop concept products containing Baobab dried fruit pulp as a food ingredient (Appendix 8). The conclusion of this work indicated that the Baobab dried fruit pulp could be used in several different formats. Firstly, Baobab dried fruit pulp could be used as a source of fiber in cereal bars, breakfast cereals and/or biscuits and snacks. Secondly, Baobab dried fruit pulp could be used as a source of fruit in soft drinks/smoothies, jams and/or fruit fillings. Finally, Baobab dried fruit pulp could be used as a structural agent to replace the starches in sauces and desserts or puddings.

The development work carried out by Leatherhead Food International determined that 10% by weight of Baobab dried fruit pulp in fruit bars was the optimal level of incorporation whereas in smoothies, the optimal incorporation of Baobab dried fruit pulp was 8 – 10% by weight.

On the basis of these commissioned reports, Phytotrade Africa have decided that the anticipated levels of use for Baobab dried fruit pulp in smoothies and fruit bars will be 6 – 10% and 10 – 15% by weight respectively.

3.3 Evaluation of the exposure levels of nutrients from Baobab Dried Fruit Pulp to US consumers

The basis of the GRAS determination is to demonstrate that the individual components in Baobab dried fruit will cause no adverse effects in US consumers at the anticipated level of intake. As already stated, Baobab dried fruit pulp is intended to be added to smoothies (6 – 10% by weight) and fruit bars (10 – 15% by weight). In order to calculate the exposure limits to US consumers, data from the Total Diet Survey (CFSAN, 2005) was used and the expected levels of exposure to Baobab dried fruit pulp were calculated.

Two closely related food products were identified in the Total Diet Survey. These were the fruit juice containing 10% fruit (listed as number 307 in the Total Diet Survey) and the granola bar with raisins (listed as number 370 in the Total Diet Survey). These two products were used as guides in the calculation of the expected exposure limits for smoothies with 6 – 10% Baobab dried fruit pulp and fruit bars with 10 – 15% Baobab dried fruit pulp respectively.

Since there are no data for the consumption of food products containing Baobab dried fruit pulp for US consumers, the 50th percentile intake value for the fruit juice and the granola bar was used. To calculate the exposure limit for heavy consumers, a pseudo 90th percentile value was calculated (2 x 50th percentile values) as recommended by the FDA guidance document for estimating dietary intake (FDA, 2006a).

The intake values for Baobab dried fruit pulp in all US consumers has been broken down into the requisite sub-population groups. These calculations were carried out for 6% Baobab dried fruit pulp

in smoothies and 10% Baobab dried fruit pulp in smoothies (see Table 2 – page 17), as well as 10% Baobab dried fruit pulp in fruit bars and 15% Baobab dried fruit pulp in fruit bars (see Table 3 – page 18).

Table 2
The 50th and pseudo 90th percentile consumption figures for Baobab dried pulp (g/day) as an ingredient in smoothies at 6 –10% by weight using the Total Dietary Survey (2003) data for fruit drinks with 10% juice as a guideline.

US Population Groups	Fruit Drink with 10% juice	Smoothie with 6% Baobab (50th percentile)	Smoothie with 6% Baobab (pseudo 90th percentile	Smoothie with 10% Baobab (50th percentile)	Smoothie with 10% Baobab (pseudo 90th percentile)
Total	40.99	2.46	4.92	4.10	8.20
6 – 11 months	20.29	1.22	2.44	2.03	4.06
2 years	54.23	3.25	6.50	5.42	10.84
6 years	77.86	4.67	9.34	7.79	15.58
10 years	81.94	4.92	9.84	8.19	16.38
F 14 – 16 years	79.57	4.77	9.54	7.96	15.92
M 14 – 16 years	**95.41**	**5.72**	**11.44**	**9.54**	**19.08**
F 25 – 30 years	27.71	1.66	3.32	2.77	2.54
M 25 – 30 years	49.45	2.97	5.94	4.96	9.92
F 40 – 45 years	24.21	1.45	2.90	2.42	4.84
M 40 – 45 years	28.75	1.73	3.56	2.88	5.76
F 60 – 65 years	14.73	0.88	1.76	1.47	2.94
M 60 – 65 years	21.13	1.27	2.54	2.11	4.22
F 70 years	14.08	0.84	1.68	1.41	2.82
M 70 years	12.37	0.74	1.58	1.24	2.48

where all figures are quoted in g/day M = male and F = female

male and female data combined for 6 – 11 months, 2 years, 6 years and 10 years age groups

pseudo 90th percentile figures are calculated as twice the 50th percentile figures (FDA, 2006) since there is no data available for the consumption of Baobab dried fruit pulp in smoothies

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Table 3
The 50th and pseudo 90th percentile consumption figures for Baobab dried pulp (g/day) as an ingredient in fruit bars at 10 –15% by weight using the Total Dietary Survey (2003) data for granola bar with raisins as a guideline.

US Population Groups	Granola Bar with raisins	Fruit Bar with 10% Baobab (50th percentile)	Fruit Bar with 10% Baobab (pseudo 90th percentile)	Fruit Bar with 15% Baobab (50th percentile)	Fruit Bar with 15% Baobab (pseudo 90th percentile)
Total	1.24	0.124	0.248	0.186	0.372
6 – 11 months	0.03	0.003	0.006	0.0045	0.009
2 years	0.98	0.098	0.196	0.147	0.294
6 years	1.21	0.121	0.241	0.182	0.363
10 years	1.82	0.182	0.364	0.273	0.546
F 14 – 16 years	1.19	0.119	0.238	0.179	0.357
M 14 – 16 years	**2.04**	**0.204**	**0.408**	**0.306**	**0.612**
F 25 – 30 years	1.25	0.125	0.25	0.188	0.375
M 25 – 30 years	1.43	0.143	0.286	0.215	0.429
F 40 – 45 years	1.01	0.101	0.202	0.152	0.303
M 40 – 45 years	1.41	0.141	0.282	0.212	0.423
F 60 – 65 years	0.5	0.05	0.10	0.075	0.15
M 60 – 65 years	1.77	0.177	0.354	0.266	0.531
F 70 years	1.09	0.109	0.218	0.164	0.327
M 70 years	1.06	0.106	0.212	0.159	0.318

where all figures are quoted in g/day and M = male and F = female

male and female data combined for 6 – 11 months, 2 years, 6 years and 10 years age groups

pseudo 90th percentile figures are calculated as twice the 50th percentile figures (FDA, 2006) since there is no data available for the consumption of Baobab dried fruit pulp in smoothies

In both cases, the population sub-group that is expected to have the highest intake of Baobab dried fruit pulp from fruit bars and smoothies are males aged 14 – 16 years old (see highlighted values in Tables 2 and 3 – pages 17 and 18 respectively). Therefore, when discussing the exposure limits of the individual components found in Baobab dried fruit pulp, exposure limits using this sub-

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population will be used because this is where the highest level of exposure is expected to occur.

3.4 Nutritional Information on Baobab Dried Fruit Pulp

The Baobab dried fruit pulp has a range of nutritional benefits including high pectin content, vitamin C content, vitamin B content and trace elements.

3.4.1 Vitamin C

From the nutritional information in Table 1 (page 9), Baobab dried fruit pulp has a vitamin C content of 74.1 – 76.2mg per 100g. This compares very favorably with the vitamin C content of California oranges which have a reported vitamin C content of 48.5mg per 100g of fruit pulp (USDA 2008a).

According to the dietary reference information tables (USDA, 2008b), the recommended daily allowance for vitamin C ranges from 15mg per day for children (1 – 3 years old) to 90 mg per day for adults of all ages (the upper limit for vitamin C intake in these 2 groups ranges from 400 to 2,000mg per day). Therefore, Baobab dried fruit pulp is a very good source of vitamin C.

The highest intake level for Baobab dried fruit pulp in smoothies is expected to be 10g per 100g of smoothie. This is equivalent to 7.62mg of vitamin C per 100g smoothie (see Table 4).

As highlighted in Tables 2 and 3 (pages 17 and 18 respectively), male teenagers aged 14 – 16 years old are expected to have the highest consumption of fruit juice containing 10% juice and granola bar with raisins. The expected levels of vitamin C exposure that could result from consuming either a 100g smoothie or a 100g fruit bar are shown in Table 4.

Table 4
The highest level of vitamin C intake by US consumers of smoothies containing 10g of Baobab dried fruit pulp (BDFP) and fruit bars containing 15g of Baobab dried fruit pulp (BDFP) at the anticipated level of intake, at the average level of consumer intake (50th percentile) and at the level for heavy consumer intake (90th percentile).

Intake	Smoothie 10g of BDFP	Fruit Bar 15g of BDFP
Anticipated Intake	7.62mg	11.4mg
50th percentile intake	7.27mg	0.23mg
Pseudo 90th percentile intake	14.5mg	0.47mg

The data in Table 4 clearly shows that the highest level of vitamin C exposure would occur through the consumption of a 100g smoothie containing 10g of Baobab dried fruit pulp. This would give an intake of 14.5mg of vitamin C per day.

Since this level is below the upper limit for vitamin C in the diet (USDA, 2008b), the consumption of Baobab dried fruit pulp at the anticipated level of intake is expected to be safe with respect to the vitamin C content.

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3.4.2 Vitamin B1 and B2

Vitamin B1 (thiamine) was found to be present in the Baobab dried fruit pulp at levels of 0.05 – 0.06mg per 100g of dried fruit pulp (Table 1 – page 9). By comparison, the vitamin B1 content of California oranges is typically 0.09mg per 100g of fruit pulp.

According to the dietary reference information tables (USDA, 2008b), the recommended daily allowance for vitamin B1 ranges from 0.5mg per day for children (1 – 3 years old) to 1.2mg per day for adults of all ages (upper limit for vitamin B1 not determined).

Vitamin B2 (riboflavin) was also found to be present in the Baobab dried fruit pulp at levels of 0.02 – 0.03mg per 100g of dried fruit pulp (see Table 1 – page 9). By comparison, the vitamin B2 content of California oranges is typically 0.04mg per 100g of fruit pulp.

According to the dietary reference information tables (USDA 2008b), the recommended daily allowance for vitamin B2 ranges from 0.5mg per day for children (1 – 3 years old) to 1.3mg per day for adults of all ages (upper limit for vitamin B2 not determined).

For both of the B vitamins found in Baobab dried fruit pulp (see Table 1 – page 9), this corresponds to an anticipated intake in smoothies containing 10g of Baobab dried fruit pulp of 6.0μg for vitamin B1 and 3.0μg for vitamin B2 (see Table 5). For a 100g fruit bar containing 15g of Baobab dried fruit pulp, the anticipated intake would be 9.0μg for vitamin B1 and 4.5μg for vitamin B2 (see Table 5).

Table 5
The highest level of vitamin B1 (upper table) and B2 (lower table) intake by US consumers of smoothies containing 10g of Baobab dried fruit pulp (BDFP) and fruit bars containing 15g of Baobab dried fruit pulp (BDFP) at the anticipated level of intake, at the average level of consumer intake (50th percentile) and at the level for heavy consumer intake (90th percentile).

Intake	Smoothie 10g of BDFP	Fruit Bar 15g of BDFP
Anticipated Intake	6.0μg	9.0μg
50th percentile intake	5.72μg	0.18μg
90th percentile intake	11.4μg	0.37μg
Anticipated Intake	3.0μg	4.5μg
50th percentile intake	2.86μg	0.09μg
90th percentile intake	5.72μg	0.18μg

The data in Table 5 shows that highest exposure of vitamins B1 and B2 for Baobab dried fruit pulp intake occurs through the consumption of a 100g smoothie (highest consumption expected in males aged 14 – 16 years old – see Tables 2 and 3 – pages 17 and 18 respectively). For vitamin B1, the highest consumption would be 11.4μg per day, and for vitamin B2, the highest consumption would be 5.72μg per day.

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Since these levels are below the upper limits for vitamin B1 and B2 in the diet (USDA, 2008b), the consumption of Baobab dried fruit pulp at the anticipated level of intake, is expected to be safe with respect to the vitamin B1 and vitamin B2 content.

3.4.3 Dietary Fiber and Pectin

Previous publications by Sanghi *et al.* (1978) and Nour *et al.* (1980) have reported that Baobab fruit pulp contains a high amount of pectin (soluble dietary fiber). According to these researchers, the amount of pectin can be high as 56% by weight of Baobab fruit pulp.

However, the nutritional profile in Table 1 (page 9) shows that the total dietary fiber content of the Baobab dried fruit pulp is 51.4 – 52.2g per 100g of fruit pulp. On further analysis, the pectin (soluble dietary fiber) content of Baobab dried fruit pulp was found to be 30.9g per 100g of fruit pulp with the remainder being insoluble dietary fiber (Appendix 2).

According to the data in Tables 2 and 3 (pages 17 and 18 respectively), males aged 14 – 16 years old are expected to be the heaviest consumers of smoothies and fruit bars containing Baobab dried fruit pulp. At the anticipated level of intake of 10g of Baobab dried fruit pulp in smoothies and 15g of Baobab dried fruit pulp in fruit bars, the highest amount of dietary fiber consumed would be 5.22g and 7.83g respectively (see Table 6).

Table 6
The highest level of dietary fiber intake by US consumers of smoothies containing 10g of Baobab dried fruit pulp (BDFP) and fruit bars containing 15g of Baobab dried fruit pulp (BDFP) at the anticipated level of intake, at the average level of consumer intake (50th percentile) and at the level for heavy consumer intake (90th percentile).

Intake	Smoothie 10g of BDFP	Fruit Bar 15g of BDFP
Anticipated Intake	5.22g	7.83g
50th percentile intake	4.98 g	0.16g
Pseudo 90th percentile intake	9.98g	0.32g

The data in Table 6 clearly show that heavy consumers of the smoothies containing Baobab dried fruit pulp would have the highest intake of dietary fiber. This would be equivalent to 9.98g per day.

The recommended daily allowance for dietary fiber ranges from 19g per day for children (1 – 3 years old) up to 38g per day for adults up to the age of 50 (USDA, 2008c). Above the age of 50, the recommended daily allowance for dietary fiber is 30g per day. There is no upper limit for dietary fiber intake because the bulking action of the fiber tends to make excessive consumption self-limiting.

Baobab dried fruit pulp contains high amounts of dietary fiber and consuming dietary fiber can help to reduce the risk of coronary disease (USDA, 2005). Secondly, the USDA recommends that Americans consume at least 14g of dietary fiber per 1000 calories (USDA, 2005). Typically, foods that are high in dietary fiber are vegetables (USDA, 2008a). Baobab

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dried fruit pulp offers an alternative fruit based solution to increasing the daily intake of dietary fiber for US consumers.

The Baobab dried fruit pulp is expected to be safe for consumers at the anticipated level of intake with respect to the dietary fiber content.

3.4.4 Trace Elements

The trace elements found in Baobab fruit pulp from Malawi, Burkino Faso,and Niger have been the subject of three separate reviews. Kalenga-Saka *et al.* (1994), Glew *et al.* (1997) and Sena *et al.* (1998) have all highlighted the fact that Baobab fruit pulp contains significant levels of calcium and magnesium. Kalenga-Saka *et al.* (1994) also reported that Baobab fruit pulp contains high levels of potassium as well.

The Baobab dried fruit pulp was analyzed for six different elements – calcium, iron, magnesium, phosphorous, potassium and sodium (Appendix 9). The results of these analyses are shown in Table 7 and are compared with the data reported by Kalenga-Saka *et al.* (1994), Glew *et al.* (1997) and Sena *et al.* (1998).

Table 7
The trace element content of Baobab dried fruit pulp compared with the trace element data from three other Baobab fruit pulp samples reported by Kalenga-Saka *et al.* (1994), Glew *et al.* (1997) and Sena *et al.* (1998).

Trace Elements	Data from Kalenga-Saka *et al.* (mg/kg)	Data from Glew *et al.* (mg/kg)	Data from Sena *et al.* (mg/kg)	Baobab dried fruit pulp (mg/kg)
Ca	1156	3410	2160	3300 – 3380
Fe	58	17	29.2	90.2 – 91.3
Mg	2090	2090	3000	1430 – 1460
P	450	733	4520	611 – 621
K	28364	-	7260	20100 – 20300
Na	188	54.6	7.9	8.2 – 12.1

The anticipated level of intake for each of the trace elements in 6 – 10g of Baobab dried fruit pulp in smoothies and in 10 – 15g of Baobab dried fruit pulp in fruit bars is shown in Table 8. The highest exposure level for all US consumers when Baobab dried fruit pulp is an ingredient in smoothies and fruit bars is expected to occur in the 14 – 16 year old male population subgroup. The level of Baobab dried fruit pulp at the 50th percentile and the pseudo 90th percentile intake in both smoothies (10g of Baobab dried fruit pulp) and fruit bars (15g of Baobab dried fruit pulp) is shown in Table 8 (see page 23).

The data in Table 8 clearly shows that the highest intake for all the trace elements in US consumers is likely to occur during the consumption of smoothies containing Baobab dried fruit pulp. According to data in the Dietary Reference Intake Tables for Elements and Electrolytes (USDA, 2008d; USDA, 2008e), the levels of iron, phosphorous and sodium are well below the upper limit of intake for these specific elements (upper limit for iron = 40 –

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45 mg/day, phosphorous = 3,000 – 4,000 mg/day, sodium 1500 – 2300 mg/day). Consumption of Baobab dried fruit pulp smoothies would give an average (50th percentile) calcium exposure limit of 32.2 mg/day, whilst the pseudo 90th percentile calcium exposure limit would be 64.4 mg/day. Both of these figures are below the recommended daily intake for calcium in males (14 – 18 years old) of 1,300 mg/day (USDA, 2008d).

In the case of magnesium, consumption of Baobab dried fruit pulp smoothies would give an average (50th percentile) exposure limit of 13.9 mg/day, whilst the pseudo 90th percentile exposure limit would be 27.8 mg/day. Both of these figures are below the recommended daily intake for magnesium in males (14 – 18 years old) of 410 mg/day (USDA, 2008d).

Finally, the potassium exposures limits for consumers of Baobab dried fruit pulp smoothies would be 194 mg/day at the 50th percentile limit and 387 mg/day at the pseudo 90th percentile limit. Both of these figures are below the adequate intake level for potassium in males (14 – 18 years old) of 4,700 mg/day (USDA, 2008d).

Table 8
The anticipated level of intake and the exposure levels of trace elements in the US consumer sub-group that is likely to ingest the highest quantity of Baobab dried fruit pulp in smoothies and fruit bars.

Elements	Anticipated Intake of trace elements in Smoothies (6 – 10g)	50th Percentile Intake in Smoothies with 10g Baobab (M 14 – 16 yrs)	Pseudo 90th Percentile Intake in Smoothies with 10g Baobab (M 14 – 16 yrs)
Ca	19.8 – 33.8mg	32.2mg	64.5mg
Fe	0.54 – 0.91mg	0.87mg	1.74mg
Mg	8.58 – 14.6mg	13.9mg	27.9mg
P	3.66 – 6.21mg	5.92mg	11.8mg
K	121 – 203mg	194mg	387mg
Na	0.05 – 0.12mg	0.12mg	0.23mg
Elements	**Anticipated Intake in Fruit Bars (10 – 15g)**	**50th Percentile Intake in Fruit Bars with 15g of Baobab (M 14 – 16 yrs)**	**Pseudo 90th Percentile Intake in Fruit Bars with 15g of Baobab (M 14 – 16 yrs)**
Ca	33 – 50.7mg	1.03mg	2.07mg
Fe	0.9 – 1.37mg	0.03mg	0.06mg
Mg	14.3 – 21.9mg	0.45mg	0.89mg
P	6.11 – 9.32mg	0.19mg	0.38mg
K	201 – 305mg	6.21mg	12.4mg
Na	0.08 – 0.18mg	3.70μg	7.41μg

where M 14 – 16 yrs refers to males 14 – 16 years old sub-group of US consumer population.

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Baobab dried fruit pulp is expected to be safe for consumers at the anticipated level of intake with respect to the content of trace elements.

3.4.5 Amino Acids

The amino acid content of Baobab fruit pulp samples from Malawi and Niger have been reported by Glew *et al.* (1997) and Sena *et al.* (1998) respectively. This published data was compared with the analyses carried out in duplicate on the Baobab dried fruit pulp samples (Appendix 10) shown in Table 9 below.

The data reported by Glew *et al.* (1997) is roughly comparable with the data from the analyses of the Baobab dried fruit pulp. The total amino acid content in the Baobab dried fruit pulp samples analyzed by Glew *et al.* (1997) was 28.0 mg/g, whereas the total amino acid content in the Baobab dried fruit pulp was 21.1 – 22.3 mg/g.

Table 9
The amino acid content of Baobab dried fruit pulp compared with the amino acid data from two other Baobab fruit pulp samples reported by Glew *et al.* (1997) and Sena *et al.* (1998).

Amino Acids	Data from Glew *et al.* (mg/g)	Data from Sena *et al.* (mg/g)	Baobab dried fruit pulp – 1 (mg/g)	Baobab dried fruit pulp – 2 (mg/g)
Aspartic acid	3.0	15.9	2.0	2.0
Glutamic acid	3.9	38.8	2.9	2.9
Serine	1.2	8.8	2.3	2.8
Glycine	1.2	7.0	1.3	1.4
Histidine	0.4	3.8	0.6	0.7
Arginine	2.3	19.3	1.0	1.0
Threonine	0.7	5.7	1.2	1.3
Alanine	2.2	7.2	1.3	1.4
Proline	2.4	7.5	1.7	1.6
Tyrosine	1.1	4.7	0.7	0.8
Valine	1.6	9.1	0.9	1.0
Methionine	0.2	1.6	0.2	0.3
Iso-leucine	1.4	6.5	0.7	0.7
Leucine	2.1	10.9	1.3	1.4
Phenylalanine	1.1	8.4	1.2	1.2
Lysine	1.6	8.7	1.0	1.0
Cysteine	1.4	3.6	0.5	0.5
Tryptophan	0.2	2.1	0.3	0.3
Total	**28.0**	**169.6**	**21.1**	**22.3**

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From the analytical data in Table 9, ten of the amino acids were found to be present in higher quantities in the samples analyzed by Glew *et al.* (1997) compared to the Phytotrade Africa samples of Baobab dried fruit pulp. Of the remaining eight amino acids analyzed, six of these were found to be present in similar amounts in both the Glew *et al.* (1997) samples and the Phytotrade samples, whilst the remaining two amino acids were found to be present in higher quantities in the Phytotrade samples compared to the Glew *et al.* (1997) samples.

From Table 9 (see page 24), the data shows that the Sena *et al.* (1998) samples had significantly higher quantities of amino acids compared to the Glew *et al.* (1997) and the Baobab dried fruit pulp samples. The Sena *et al.* (1998) Baobab fruit pulp samples contained 170 mg/g of amino acids, which is nearly six times higher than the Glew *et al.* (1997) and Baobab dried fruit pulp samples. This significant difference between the Sena *et al.* (1998) sample and the other two Baobab samples is due to the fact that the Baobab fruit pulp used by Sena *et al.* (1998) included the Baobab seeds as well as the fruit pulp.

The data in Table 10 clearly shows that the highest intake of amino acids for 14 – 16 year old males would occur through the consumption of Baobab dried fruit pulp in smoothies. At this level of intake, the pseudo 90th percentile consumption would be 425mg. This is significantly lower than the recommended daily allowance of 56 g/day for males aged 14 - 18 years old.

Table 10
The highest level of amino acid intake by US consumers of smoothies containing 10g of Baobab dried fruit pulp (BDFP) and fruit bars containing 15g of Baobab dried fruit pulp (BDFP) at the anticipated level of intake, at the average level of consumer intake (50th percentile) and at the level for heavy consumer intake (90th percentile).

Intake	Smoothie 10g of BDFP	Fruit Bar 15g of BDFP
Anticipated Intake	223mg	335mg
50th percentile intake	213mg	6.82mg
90th percentile intake	425mg	13.6mg

The Baobab dried fruit pulp is expected to be safe for consumers at the anticipated level of intake with respect to the amino acid content.

3.4.6 Organic Acids

The acidic nature of the pulp extracted from the Baobab fruit has been recognized by the people of Africa for many years (Carr, 1955). This fact accounts for the indigenous use of Baobab fruit pulp as an alternative to "*cream of tartar*" in baking (Bosch *et al.*, 2004).

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Table 11
Analysis data of the organic acid content in Baobab dried fruit pulp samples.

Organic Acids	Baobab dried fruit pulp – 1 (mg/kg)	Baobab dried fruit pulp – 2 (mg/kg)	Baobab dried fruit pulp – 3 (mg/kg)
Citric Acid	29000	27000	32000
Malic Acid	1400	1100	1200
Succinic Acid	< 400	< 400	< 400
Tartaric Acid	< 400	< 400	< 400

The high acid content was confirmed by Airan and Desai (1954) who analyzed Baobab fruit pulp for organic acids and found that this class of compounds was present in significant amounts.

Baobab dried fruit pulp samples were analyzed for four different organic acids – malic acid, citric acid, succinic acid and tartaric acid (Appendix 11). The results of theses analyses are shown in Table 11.

Surprisingly, although the Baobab dried fruit pulp is used as an alternative to "*cream of tartar*", the amount of tartaric acid was found to be below the detection limit for these analyses. The levels of succinic acid were also found to be below the limit of detection.

Table 12
The anticipated level of intake and the exposure levels of organic acids in the US consumer sub-group that is likely to ingest the highest quantity of Baobab dried fruit pulp in smoothies and fruit bar.

Organic Acids	Anticipated Intake in Smoothies (6 – 10g)	50th Percentile Intake in Smoothies with 10g Baobab (M 14 – 16 yrs)	Pseudo 90th Percentile Intake in Smoothies with 10g Baobab (M 14 – 16 yrs)
Citric Acid	162 – 320mg	258 – 305 mg	515 – 611mg
Malic Acid	6.6 – 14mg	10.5 – 13.4mg	21.0 – 26.7 mg
Succinic Acid	2.4 – 4.0mg	3.8mg	7.6mg
Tartaric Acid	2.4 – 4.0mg	3.8mg	7.6mg
Organic Acids	**Anticipated Intake in Fruit Bars (10 – 15g)**	**50th Percentile Intake in Fruit Bars with 15g Baobab (M 14 – 16 yrs)**	**Pseudo 90th Percentile Intake in Fruit Bars with 15g Baobab (M 14 – 16 yrs)**
Citric Acid	270 – 480mg	8.26 – 9.79mg	16.5 – 19.6mg
Malic Acid	11 – 21mg	0.34 – 0.43mg	0.67 – 0.86mg
Succinic Acid	4.0 – 6.0mg	0.1mg	0.2mg
Tartaric Acid	4.0 – 6.0mg	0.1mg	0.2mg

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where M 14 – 16 yrs refers to males 14 – 16 years old sub-group of US consumer population.

Malic acid was found in moderate amounts of 1.1 – 1.4 g/kg of Baobab dried fruit pulp. Citric acid was found to be present in significantly higher amounts than any of the other organic acids in Baobab dried fruit pulp. The amount of citric acid ranged from 27 – 32 g/kg of Baobab dried fruit pulp, which is equivalent to 2.7 – 3.2% by weight of fruit pulp.

The SCOGS (Select Committee on GRAS Substances) evaluation of citric acid reports that manufacturers add the equivalent of 500mg of citric acid per person per day to foodstuffs. This is the same amount of citric acid that can be found in 2 ounces of orange juice (SCOGS, 2006). The data in Table 2 (see page 17) clearly shows that male consumers who are 14 – 16 years old would be expected to have the highest exposure to citric acid, through the consumption of 10g of Baobab dried fruit pulp in smoothies. In this age group, the average consumer (50th percentile) would be expected to ingest 258 – 305mg of citric acid per day whereas the pseudo 90th percentile consumer would be expected to ingest as much as 515 – 611mg of citric acid per day (Table 12 – page 26). Therefore, the highest level of citric acid consumption would be equivalent to roughly 2.4 ounces of orange juice (based on the SCOGS data).

According to the review carried out by the Select Committee on GRAS substances (SCOGS, 2006), citric acid (21 CFR 184.1033), malic acid (21 CFR 184.1069) and succinic acid (21 CFR 184.1091) are all considered to pose no hazard to the health of consumers at the current level of consumption. Further support for the safety of citric acid, malic acid and succinic acid comes from the fact that all these organic acids are key intermediates in the Krebs (citric acid) cycle (Nelson and Cox, 2004).

Tartaric acid is another natural organic acid that has numerous uses as a food ingredient. The current JECFA evaluation states that the acceptable daily intake for tartaric acid is 30mg per kg body weight per day (INCHEM, 2002) or 1800 mg/day for a 60kg person. Since the pseudo 90th percentile consumption of Baobab dried fruit pulp would be expected to produce a maximum exposure limit of 7.6 mg/day, consumers would not be exposed to unsafe levels of tartaric acid.

The Baobab dried fruit pulp is expected to be safe for consumers at the anticipated level of intake with respect to the organic acid content.

3.4.7 Other supporting evidence

The Baobab tree, *Adansonia digitata*, belongs to the *Bombacaceae* family of plants; the *Bombacaceae* family is a member of the *Malvales* order of plants.

A literature search has revealed that there are other plants in the *Bombacaceae* family and the closely related *Malvaceae* (Mallow) family that are considered to be edible. Some examples of these edible plants are shown below:

Quararibea cordata Vischer – a member of the *Bombacaceae* family that grows in the South American rainforest. This tree produces an edible fruit known as "*chupa-chupa*" (Purdue, 2005a).

Pachira aquatica – a member of the *Bombacaceae* family that is native to South America.

The seeds of this tree are reported to taste like chestnuts and are usually ground up to make bread (Purdue, 2005b).

Ceiba pentandra (synonym *Eriodendron anfractosum*) – a member of the *Bombacaceae* family that is widely distributed across Central and parts of South America, West Africa and India. The seeds are eaten as a famine food (Purdue, 2005c).

Durio zibethinus – a member of the *Malvaceae* family that is grown widely over South East Asia. This plant is better known as the Durian Tree which produces fruit that are commonly known as the ' King of Fruits ' (Heaton, 2006). The Durian fruit has a number of food uses (Purdue, 2005d).

Bombax ceiba (synonym *Bombax malabaricum*) – a member of the *Malvaceae* family that grows in India and across South East Asia. The calyxes of the flowers, the roots and the leaves of this tree are reported to all be used as a famine food in India (Purdue, 2005e).

The closely related *Malvaceae* family (Heywood, 1993) also contains other edible and economically useful species of plants. These include okra (*Abelmoshcus esculentus*), marshmallow (*Althea officinalis*) and various *Hibiscus* species that are used to make herbal teas.

3.4.8 Summary of the Nutritional Profile of Baobab Dried Fruit Pulp

Baobab dried fruit pulp is a traditional part of the diet in large parts of Africa. The product manufactured by Phytotrade Africa is essentially the fruit pulp from the Baobab fruit minus the fibrous material and the seeds.

Table 13
A comparison of the nutritional profile of Baobab dried fruit pulp with the USDA nutritional profile of five other fruit and vegetables with high levels of specific nutrients per 100 g.

Nutritional Components	California Orange	Seeded Raisins	Uncooked Prunes	Chickpea (Raw)	French Bean (Raw)	Baobab Dried Fruit Pulp
Moisture [1]	86	16.6	30.9	11.5	10.7	13.6 – 13.7
Energy (kcal) [1]	49	296	240	364	343	117 – 120
Energy (kJ) [1]	205	1238	1006	1525	1435	496 – 510
Protein [1]	1.04	2.52	2.18	19.3	18.8	2.03 – 2.04
Fat [1]	0.3	0.54	0.38	6.0	2.0	0.4 – 0.5
Ash [1]	0.42	1.89	2.64	2.5	4.3	5.5
Carbohydrate [1]	11.89	78.5	63.9	60.7	64.1	78.3 – 78.5
Dietary Fibre [1]	2.5	6.8	7.1	17.4	**25.2**	**51.4 – 52.2**
Sugar [1]	-	-	38.1	10.7	-	20.9 – 21.2
Calcium [2]	40	28	43	105	**186**	**330 – 338**
Iron [2]	0.09	2.6	0.9	6.2	3.4	9.02 – 9.13
Magnesium [2]	10	30	41	115	188	143 – 146
Phosphorous [2]	17	75	69	366	304	61.1 – 62.1
Potassium [2]	179	825	732	875	**1316**	**2010 – 2030**
Sodium [2]	0	28	2	24	18	0.82 – 1.21
Zinc [2]	0.06	0.18	0.44	3.4	1.9	-
Vitamin C [2]	**48.5**	5.4	0.6	4.0	4.6	**74.1 – 76.2**
Vitamin B1 [2]	0.09	0.11	0.05	0.48	0.54	0.05 – 0.06
Vitamin B2 [2]	0.04	0.18	0.19	0.21	0.22	0.02 – 0.03

1 All macro-nutrients are reported as g per 100g of fruit or vegetable
2 All vitamins and minerals are reported as mg per 100g of fruit or vegetable

A nutritional analysis of Baobab dried fruit pulp (Appendices 2 and 3) reveals high levels of vitamin C, high levels of dietary fiber, high levels of citric acid, high levels of potassium and low levels of protein. The nutritional analysis data of Baobab dried fruit pulp is shown in Table 13 (see page 28) and compared with other fruit and vegetables that share the same high content in key macro and micro-nutrients.

From the data in Table 13 (see page 28), Baobab dried fruit pulp clearly contains more vitamin C than California oranges per 100g of fruit. The levels of dietary fiber and the trace elements, calcium and potassium, are also higher in Baobab dried fruit pulp compared to any of the other values per 100g of fruit or vegetables (USDA, 2008a).

The metabolism of the macro-nutrients and micro-nutrients found in Baobab dried fruit pulp are well known and commonly discussed in any undergraduate university textbook

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(Eastwood, 2003; Mann and Truswell, 2007). On this basis, these macro-nutrients and micro-nutrients are not expected to cause any adverse effects.

The organic acids (Appendix 11), particularly citric acid, which was found to be present at 270 – 320mg per 100g of Baobab dried fruit pulp, do not present any problems to US consumers because essentially these organic acids are key intermediates in the Krebs cycle (Nelson and Cox, 2004).

The levels of potassium (Appendix 9) in Baobab dried fruit pulp ranged from 2010 – 2030mg per 100g. However, when Baobab dried fruit pulp is included at the anticipated level of 6 – 10g per 100g smoothie and 10 – 15g per 100g fruit bar, the highest exposure level in US consumers is expected to be 387mg (see Table 8 – page 23). By comparison, a medium banana contains 442mg of potassium and 1/8 of a medium honeydew melon contains 365mg of potassium (USDA, 2005). On this basis, the level of potassium introduced into the diet through the ingestion of Baobab dried fruit pulp is not expected to cause any problems to US consumers.

3.5 Traditional Food Use of Baobab

The Baobab (*Adansonia digitata*) tree is believed to have numerous medicinal properties according to African traditional folklore, although these medicinal effects are predominantly associated with the bark, leaves and roots of the Baobab tree rather than the fruit pulp (Haerdi 1964, Kerhero 1974, Kokwaro 1976, Watt and Breyer-Brandwijk 1962).

There are two reported uses for Baobab fruit pulp in traditional medicine. Kerhero (1974) and Watt and Breyer-Brandwijk (1962) both reported that Baobab fruit pulp and seeds were used to treat dysentery. Also, Watt and Breyer-Brandwijk (1962) reported that Baobab fruit pulp had febrifuge properties (febrifuge is more commonly known as anti-pyresis, which is the mechanism, by which elevated body temperature is reduced back to normal body temperature).

3.6 Scientific Reports of Pharmacological Activity

There are three reports published in the scientific literature that appear to show that Baobab fruit pulp can have pharmacological effects. These studies basically confirm the reports of the traditional medicinal use of Baobab fruit pulp – used as a remedy to treat dysentery and used as an anti-pyretic (febrifuge).

3.6.1 Treatment for Dysentery

Tal-Dia *et al.* (1997) compared the efficacy of a local solution made from the fruit of the Baobab against the WHO standard solution for the treatment of dehydration as a result of acute diarrhea. The local name for this Baobab solution is "*pain de singe*". The "*pain de singe*" consists of 5 sugar cubes and 14 spoons of powdered Baobab fruit pulp (approximately equivalent to 36.4 g of dried Baobab fruit powder) which is mixed in 1 liter of water.

Although the standard WHO rehydration solution was superior to the "*pain de singe*" in treating the effects of acute dehydration, there was no statistical difference between the reported effects for these two solutions (Tal-Dia *et al.*, 1997).

Two key observations were made from the work by Tal-Dia *et al.* (1997). Firstly, the "*pain de singe*" could be produced locally as required, without the need for importing the standard WHO rehydration solution into the same geographical areas as Baobab fruit. Secondly, the Baobab fruit pulp used in the "*pain de singe*" did not have any observable medicinal effects in treating the causes of acute diarrhea. The "*pain de singe*" solution was simply used to hydrate people who were suffering from the effects of dehydration caused by acute diarrhea.

3.6.2 Phytochemicals in Baobab Dried Fruit Pulp

The remaining two reports are concerned with two different aspects of the pharmacological activity of Baobab fruit pulp. The first report concerns the potential liver protective effects of Baobab fruit pulp in rats exposed to carbon tetrachloride (Al-Qawari *et al.*, 2003).

Al-Qawari *et al.* (2003) compared the effects of feeding the rats a freeze-dried aqueous extract of Baobab fruit pulp before and after the administration of carbon tetrachloride to rats by intravenous injection. The effect of carbon tetrachloride on each rat liver was monitored by measuring the serum enzyme levels (alanine transferase, aspartate transferase and alkaline phosphatase).

The results showed that the freeze-dried Baobab fruit pulp solution protected the liver provided the solution was administered to the rats before exposure to carbon tetrachloride.

When the freeze-dried Baobab fruit pulp was administered to the rats after exposure to the carbon tetrachloride, the decrease in the level of serum enzymes (corresponds to the carbon tetrachloride induced liver damage) was reversed. The alanine transferase, aspartate transferase and alkaline phosphatase enzyme levels were restored to 76, 77 and 87 % of their original starting values respectively.

Al-Qawari *et al.* (2003) speculated that the liver protecting properties of the freeze-dried aqueous extract of Baobab fruit pulp was due to the presence of β-sitosterol, β-amyrin palmitate, α-amyrin and ursolic acid. The authors of this report also pointed out that previous researchers had already shown that a mixture of β-sitosterol, β-amyrin palmitate and α-amyrin exhibited protective properties against carbon tetrachloride induced liver damage.

The second report concerns the anti-inflammatory, anti-pyretic and analgesic effects of an aqueous extract of Baobab fruit pulp in rats (Ramadan *et al.*, 1994).

Ramadan *et al.* (1994) separated the Baobab fruit pulp from the seeds before repeatedly extracting the Baobab fruit pulp into hot water. This aqueous filtrate was then freeze dried and used to examine the anti-inflammatory, anti-pyretic and analgesic properties of the Baobab fruit pulp.

The rat paw formalin test was used to examine the anti-inflammatory properties of the freeze-dried Baobab fruit pulp and these effects were compared with 15 mg/kg of phenylbutazone, a known anti-inflammatory drug. The results showed that 800 mg/kg of Baobab fruit pulp possessed similar anti-inflammatory properties to 15 mg/kg phenylbutazone.

The hot plate method was used to examine the analgesic properties of the freeze-dried

Baobab fruit pulp and these effects were compared with 50 mg/kg of aspirin, a known analgesic drug. The Baobab fruit pulp produced a marked analgesic effect in rats at 800 mg/kg, whereas the 400 mg/kg dose of Baobab fruit pulp produced a much weaker analgesic effect.

The anti-pyretic effects of Baobab fruit pulp were examined using rats that were made hyperthermic by a 1 mg/kg subcutaneous injection of a 12% yeast suspension. The anti-pyretic effects of the Baobab fruit pulp were compared against 50 mg/kg of aspirin. In this case, both doses of Baobab fruit pulp at 400 and 800 mg/kg produced a marked reduction in the temperature of the hyperthermic rats; the anti-pyretic effects of the Baobab fruit pulp were similar to those produced by the aspirin. The result's of this experiment supported the traditional medicinal use of Baobab fruit pulp as a febrifuge and the traditional food use of Baobab fruit pulp as refreshing drink during the hot season.

All of these reported pharmacological effects were believed to be due to the presence of the sterols and the triterpenes (Ramadan *et al.*, 1994).

3.7 Consumption of phytochemicals in the diet

According to the data published by the Baobab Fruit Company (BFC, 2006), the predominant phytosterol in Baobab seed oil is β-sitosterol. Since the work of Al-Qawari *et al.* (2003) and Ramadan *et al.* (1994) indicated the presence of β-sitosterol in Baobab fruit pulp, it seems likely that the presence occurs by the leaching of β-sitosterol from the Baobab seeds.

A quantitative thin layer chromatographic analysis of the Baobab dried fruit pulp (Appendix 12) confirmed the presence of β-sitosterol, however, this technique was not able to resolve any of the other minor phytosterols that were also reported to present in the Baobab seed oil (BFC, 2006).

The phytochemicals highlighted by Al-Qawari *et al.* (2003) and Ramadan *et al.* (1994) are commonly found in fruit and vegetables that are readily available to US consumers. The α- and β-amyrins are found in aubergines, bell peppers and tomatoes (Bauer *et al.*, 2004a; Bauer *et al.* 2004b). Ursolic acid is found in apples (Frighetto *et al.*, 2008), pears (Markley *et al.*, 1935) blueberries and cranberries (Neto, 2007). Finally, β-sitosterol is found corn (maize) oils, soybeans, rice bran and wheat germ.

All of these foodstuffs, and consequently the phytochemicals (α- and β- amyrins, ursolic acid and β-sitosterol) are commonly consumed in the US diet. Therefore, the inclusion of Baobab dried fruit pulp into fruit bars and smoothies would not expose US consumers to any unique food components.

3.8 Summary of the traditional medicine use of Baobab Fruit Pulp

The reported phytochemicals in Baobab dried fruit pulp were claimed to have pharmacological properties in two separate animal studies carried out by Al-Qawari *et al.* (2003) and Ramadan *et al.* (1994). In both cases, the authors attributed these pharmacological activities to α-amyrin, β-amyrin, β-sitosterol and ursolic acid.

There are two key points here. Firstly, Baobab dried fruit pulp is not being marketed to US consumers on the basis of any pharmacological properties, merely as a food ingredient in fruit bars and smoothies. Secondly, the phytochemicals that are speculated to be responsible for these observed pharmacological effects are not unique to the dietary intake of US consumers, but are

present at comparable, or higher, in other commonly eaten foodstuffs. The phytochemicals reportedly found in Baobab fruit pulp by Al-Qawari *et al.* (2003) and Ramadan *et al.* (1994) will probably be present at very low levels in the Phytotrade Africa product.

4.0 Evidence that may not appear to support the GRAS determination of Baobab Dried Fruit Pulp

The evidence that may not appear to support the GRAS determination of Baobab dried fruit pulp can be broadly divided into two main categories. These are the potential anti-nutrients found in the Baobab dried fruit pulp and potential food contaminants that may occur in Baobab dried fruit pulp and that are addressed by ensuring application of current good manufacturing practices.

4.1 Anti-nutrients in Baobab Dried Fruit Pulp

Anti-nutrients found in plants, generally, basically fall into four broad categories according to a paper published by Tacon (1995). These four categories are:

- **Proteins** (Protease inhibitors, haemagglutinins, toxic amino acids, allergens)
- **Glycosides** (Goitrogens, Saponins, Cyanogens, Estrogens)
- **Phenols** (Gossypol, Tannins)
- **Miscellaneous** (anti-enzymes, anti-vitamins, phytic acid, toxic fatty acids)

As already mentioned earlier (section 1.5 – page 12), the anti-nutrients which could be present in Baobab dried fruit pulp include the following:

- Cyanide – this includes both free cyanide and cyanogenic glucosides which produce cyanide under acidic or enzymic conditions.

- Oxalates – the Baobab dried fruit pulp contains high amounts of organic acids (see section 3.4.6 – page 25). This organic acid content accounts for the indigenous use of Baobab fruit pulp as an alternative to cream of tartar.

- Alkaloids – these compounds are widely distributed in nature. The information concerning specific alkaloids in any part of the Baobab tree is contradictory, however, alkaloids are known to be present in the funeral tree (*Quararibea funebris vischer*), a close relative of the Baobab tree.

- Toxic fatty acids – the main concern here relates to the cyclopropene fatty acids that are known to be present in the Baobab seeds.

4.1.1 Cyanide

Ghani and Abejule (1986) first reported that cyanide could be found in Baobab fruit pulp. According to their research, the level of cyanide detected in Baobab fruit pulp was 0.0049% or 4.9mg per 100g of fruit.

In order to analyze for the potential cyanide content of Baobab dried fruit pulp, two separate analyses were carried out. Firstly, an aqueous extract of Baobab dried fruit pulp was tested for cyanide. Secondly, another extract of Baobab dried fruit pulp was taken and hydrolyzed

in acid prior to analyzing for cyanide.

The reason for this acid hydrolysis step is due to the fact that the cyanide is bound to a glycoside in cyanogens. Under the test conditions for the aqueous only extract, the cyanogens would not release the cyanide and therefore, any cyanide present in Baobab dried fruit pulp as cyanogens would not be detected.

The results of these analyses (Appendix 18) are shown in Table 14.

In all cases, the analyses showed that the level of cyanide in the Baobab dried fruit pulp was below the limit of detection of 5 mg/kg or 0.5 mg/100 g. These results compare very favorably with the data of Ghani and Abejule (1986), who reported that the cyanide levels in their Baobab fruit pulp samples were nearly 10 times higher at 4.9 mg/100 g of fruit pulp.

Table 14
Analysis data of the cyanide content in Baobab dried fruit pulp samples

Cyanide Analysis	Baobab dried fruit pulp – 1 (mg/kg)	Baobab dried fruit pulp – 2 (mg/kg)	Baobab dried fruit pulp – 3 (mg/kg)
Aqueous extract	< 5	< 5	< 5
Hydrolysis mixture	< 5	< 5	< 5

The highest cyanide exposure limit would be expected to occur in heavy consumers (pseudo 90th percentile consumption) who ingested 10g of Baobab dried fruit pulp in smoothies (see Table 15). At this level, the highest dose of cyanide would be expected to be 95.4µg per day.

Table 15
The highest level of cyanide intake by US consumers of smoothies containing 10g of Baobab dried fruit pulp (BDFP) and fruit bars containing 15g of Baobab dried fruit pulp (BDFP) at the anticipated level of intake, at the average level of consumer intake (50th percentile) and at the level for heavy consumer intake (90th percentile).

Intake	Smoothie 10 g of BDFP	Fruit Bar 15 g of BDFP
Anticipated Intake	50µg	75µg
50th percentile intake	47.7µg	1.53µg
Pseudo 90th percentile intake	95.4µg	3.06µg

According to a review by JECFA (1993), "because of a lack of quantitative toxicological and epidemiological information, a safe level of intake of cyanogenic glycosides could not be estimated. However, the Committee concluded that a level of up to 10 mg/kg hydrogen cyanide in the Codex Standard for Cassava Flour (CAC, 1991) is not associated with acute toxicity. As noted above, cyanide in Baubab fruit pulp could not be detected at a 5 mg/kg sensitivity.

On the basis of these analyses and the JECFA (1993) report, Baobab dried fruit pulp is

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expected to be safe for consumers at the level of anticipated intake.

4.1.2 Oxalic acid

Airan and Desai (1954) first reported that Baobab fruit pulp contained high amounts of organic acids including oxalic acid. Proll *et al.* (1998) reported that the Baobab seeds contained up to 4.2 g/kg of oxalic acid, of which, 2.6 g/kg were soluble oxalates. Most recently, Umara *et al.* (2007) reported that the oxalate content of Baobab fruit was as high as 9.5 g per 100 g of fruit. Potentially, Baobab dried fruit pulp could have naturally high levels of oxalic acid.

Baobab dried fruit pulp was analyzed for oxalic acid content and the results of these analyses (Appendix 11) are shown in Table 16 (see page 40).

In all cases, the level of oxalic acid in the Baobab dried fruit pulp samples was found to be below the limit of detection of 400 mg/kg. This is equivalent to less 40mg per 100g of Baobab dried fruit pulp.

A recent review published by Professor Nancy Lowry of Hampshire College, Massachusetts, highlighted the confusion regarding the safe levels for consumers who ingest oxalic acid (Lowry, 2005). The oral LD_{50} for oxalic acid in rats is reported to be 375 mg/kg body weight, whereas the LD_{50} for oxalic acid in dogs is reported to be 1000 mg/kg body weight.

Table 16
Analysis data of the oxalic acid content in Baobab dried fruit pulp samples

Organic acid	Baobab dried fruit pulp – 1 (mg/kg)	Baobab dried fruit pulp – 2 (mg/kg)	Baobab dried fruit pulp – 3 (mg/kg)
Oxalic Acid	< 400	< 400	< 400

As a comparison, we list oxalic acid content for some common vegetables.

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Table 17.
Oxalic acid content of selected vegetables

Vegetable	Oxalic acid (g/100g)
Amaranth	1.09
Asparagus	0.13
Beans, snap	0.36
Beet leaves	0.61
Broccoli	0.19
Brussels sprouts	0.36
Cabbage	0.10
Carrot	0.50
Cassava	1.26
Cauliflower	0.15
Celery	0.19
Chicory	0.21
Chives	1.48
Collards	0.45
Coriander	0.01
Corn, sweet	0.01
Cucumbers	0.02
Eggplant	0.19
Endive	0.11
Garlic	0.36
Kale	0.02
Lettuce	0.33
Okra	0.05
Onion	0.05
Parsley	1.70
Parsnip	0.04
Pea	0.05
Pepper	0.04
Potato	0.05
Purslane	1.31
Radish	0.48
Rutabaga	0.03
Spinach	0.97
Squash	0.02
Sweet potato	0.24
Tomato	0.05
Turnip	0.21
Turnip greens	0.05
Watercress	0.31

(USDA, 2008f)

There does not appear to be an established safety limit for the human consumption of oxalic acid. A recent EU report found that consumers of a typical European diet could ingest oxalic acid from 5mg up to 500mg per day (EMEA, 2003).

At the anticipated intake for Baobab dried fruit pulp in smoothies (10g of Baobab dried fruit pulp) and fruit bars (15g of Baobab dried fruit pulp), the oxalic acid exposure limits are expected to be 4mg and 6mg respectively.

For all US consumers of smoothies and fruit bars containing Baobab dried fruit pulp, the highest exposure levels are expected to be amongst male teenagers aged 14 to 16 (see table 2 – page 17). This translates to 3.82 mg/day at the 50th percentile and 7.63 mg/day at the pseudo 90th percentile for consumers of smoothies containing Baobab dried fruit pulp. In the case of fruit bars containing Baobab dried fruit pulp, the 50th percentile exposure limit for oxalic would be 0.12mg and at the pseudo 90th percentile limit the exposure would be 0.24mg.

On the basis of these calculations, Baobab dried fruit pulp is expected to be safe for consumers at the anticipated intake level with respect to the oxalic acid content.

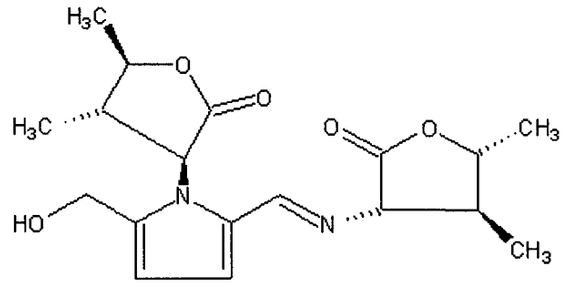
4.1.3 Alkaloids

Adansonin is an alkaloid that can reportedly be extracted from the bark of the Baobab tree and is believed to be the active agent that is responsible for the anti-malarial properties of Baobab tree bark (Kerhero and Adam, 1974). However, the information concerning adansonin is somewhat confused. Apart from the fact that the alkaloid is called adansonin or sometimes adansonine, there are no reports of this alkaloid in either Beilstein or Chemical Abstracts from 1907 to 2005. The only text which appears to reference adansonin is the Merck Index of Chemicals (1952 edition) and even here there is no information on the structure of the alkaloid or the therapeutic/toxicological properties of this compound. Therefore, it is not clear that this alkaloid even exists.

There are no reports in the scientific literature that are concerned with the alkaloid content of Baobab (*Adansonia digitata*). Only Ramadan *et al.* (1994) report that they screened for the presence of alkaloids in Baobab fruit pulp but found no trace of these compounds.

The Funeral tree (*Quararibea fenebris* Vischer), like the Baobab tree, is a member of the *Bombacaceae* family. Unlike the Baobab tree, the Funeral tree is known to contain an alkaloid called funebrine (see Diagram 1). The main source of funebrine appears to be in the flowers of the Funeral tree, although the overall amount of alkaloid extracted was only 0.01 % by weight of dried flowers (Raffauf *et al.*, 1984).

Diagram 1
The molecular structure of the alkaloid, Funebrine, isolated from the flowers of *Quararibea fenebris* Vischer.



There is no evidence that a similar alkaloid to funebrine could be found in the Baobab tree. However, as both of these trees come from the same family, a series of extractions were taken from Baobab dried fruit pulp samples and subjected to phytochemical analyses (Appendix 19) as described in Wagner *et al.* (1984) and Harborne (1999). The results of these analyses are shown in Table 18.

Table 18
Analysis data of the cyanide content in Baobab dried fruit pulp samples

Phytochemical Analysis	Baobab dried fruit pulp – 1 (mg/kg)	Baobab dried fruit pulp – 2 (mg/kg)	Baobab dried fruit pulp – 3 (mg/kg)
Alkaloids	< 10	< 10	< 10

In all of the samples tested, the levels of the alkaloids in the Baobab dried fruit pulp were found to be below the limit of detection of 10 mg/kg. This is equivalent to less than 1 mg per 100 g of Baobab dried fruit pulp.

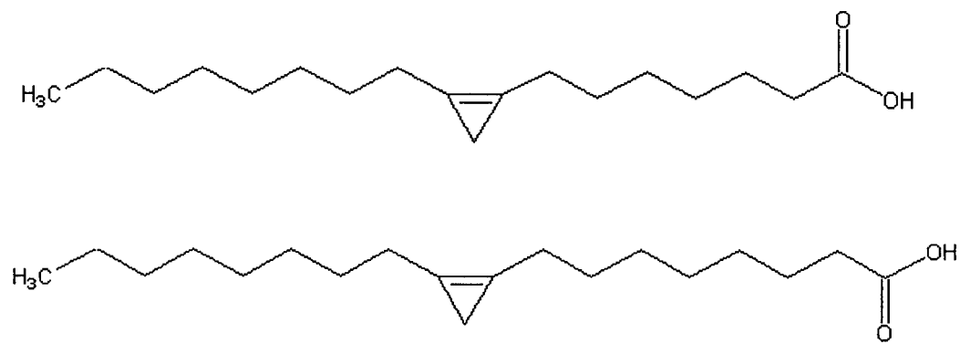
According to Raffauf *et al.* (1984), funebrine, has a unique alkaloid structure and there is no information available about the toxicological properties of this alkaloid. This means that there is no data available on which to make an assessment on the safe dose level for funebrine.

As already stated, there is no scientific evidence that *Adansonia digitata* produces an alkaloid in any part of the tree. Therefore, given the fact that the analyses of the Baobab dried fruit pulp found no alkaloids present at < 10 mg/kg, and that there have been no reports of ill-effects in local people who consume Baobab fruit pulp regularly (Appendix 7), Baobab dried fruit pulp is expected to be safe for consumers at the anticipated level of intake with respect to the alkaloid content.

4.1.4 Cyclopropene Fatty Acids

Malvalic acid and sterculic acid (see Diagram 2) are both cyclopropene fatty acids that are known to be present in the Baobab seed oil (Ralaimanarivo *et al.*, 1982). However, there are no reports in the literature that these particular fatty acids have ever been found in the Baobab fruit pulp.

Diagram 2
The molecular structure of the cyclopropene fatty acids, malvalic acid (first structure) and sterculic acid (second structure)



There have been several reports on the effect of these compounds from *in vitro* rat liver microsomes and *in vivo* rat studies (Andrianaivo-Rafehivola *et al.*, 1993; Andrianaivo-Rafehivola *et al.*, 1995; Cao *et al.*, 1993; Cao *et al.* 1996). In the case of the *in vivo* experiments, all of the rats were fed various diets that included 10% weight oil (cyclopropenoid fatty acid content of this oil was 13.7% by weight). The Baobab oils (heated and unheated) were the sole source of lipids in the diet.

The *in vivo* rat studies reported that the cyclopropene fatty acids were inhibiting the fatty acid biosynthetic pathways, specifically the desaturation pathways of lipids. This resulted in decreased membrane quality, decreased eicosanoid biosynthesis (e.g. arachidonic acid), dysfunction of the adrenals resulting in decreased biosynthesis of corticosteroids, and decreased liver P450 enzyme activity.

Baobab seed oil is used by the local indigenous population as cooking oil. To date, there have been no reports of adverse health effects in the indigenous population who use this oil in cooking. Aitzetmuller (1996) has pointed out that the lack of adverse reports associated with the use of Baobab seed oil is probably due to the fact that the local indigenous people heat the oil during cooking. This is known to reduce the cyclopropene fatty acids to very low levels.

Fatty acid analyses (Appendix 20) were carried out on duplicate samples of the Baobab dried fruit pulp. These analyses included the cyclopropene fatty acids, malvalic acid and sterculic acid. The results are shown in Table 19 (see page 43).

Table 19
Analysis data of the fatty acid content of Baobab dried fruit pulp samples

Fatty Acids	Baobab dried fruit pulp – 1 (mg/g)	Baobab dried fruit pulp – 2 (mg/g)
16:0 palmitic	0.90	0.89
16:1 hexadecenoic	0.02	0.02
17:0 heptadecenoic	0.02	0.02
16:3 hexadecatrienoic	0.03	0.03
malvalic	**0.09**	**0.09**
18:0 stearic	0.10	0.11
18:1 oleic	0.84	0.83
18:2 linoleic	0.67	0.67
sterculic	**0.02**	**0.02**
18:3 α-linolenic	0.51	0.52
20:0 icosanoic	0.04	0.05
22:0	0.06	0.02
Total Fatty Acids	**3.30**	**3.27**

In all of the samples tested, the level of the cyclopropene fatty acids (malvalic acid and sterculic acid) in the Baobab dried fruit pulp was found to be 0.11 mg/g in total (or 0.011%). These cyclopropenoid fatty acids are also found in other edible oils. For example, cyclopropenoid oils (malvalic, sterculic, and dihydrosterculic acids) were reported in cottonseed oils in concentrations ranging from 0.15% - 0.45% (FDA, 2002).

The cyclopropene fatty acids, malvalic acid and sterculic acid, are components of Baobab seed oil and are known to have undesirable toxic effects in animal studies. Although there have been no reports of ill-effects in humans who have consumed Baobab seed oil, this is believed to be due to the fact that the Baobab seed oil is heated during cooking which destroys the malvalic acid and sterculic acid (Aitzetmuller, 1996).

The *in vivo* rat experiments used a 10% fat containing diet, where 13.7% by weight of this fat was made up of cyclopropene fatty acids (Andrianaivo-Rafehivola *et al.*, 1993; Andrianaivo-Rafehivola *et al.*, 1995; Cao *et al.*, 1993; Cao *et al.* 1996). Assuming that a typical consumer ingested a 2000 calorie diet containing only 10% fat (where the fat contained 13.7% by weight of cyclopropene fatty acids), this would be equivalent to consuming 3.04g of cyclopropene fatty acids. The results with unheated oil were dramatic. For example, in a 4 week feeding study (Andrianaivo-Rafehivola *et al.*, 1995) weight gain was decreased by nearly half in rats consuming the unheated oil compared to those in the heated oil and control oil groups. Food intake in the unheated oil group was also approximately half of that in the other groups. While, as discussed above, heating destroys the cyclopropene fatty acids, they were still measureable in the heated oil, (After heating the oil at 220°C for 8 hours, the total of malvalic and sterculic acid was reduxced to

approximately 0.5% of the oil) Concentrations of the saturated dihydrosterculic acid were not reduced by heating. Similarly, in the study by Cao *et al.* (Cao *et al.* 1996), which measured fatty acid composition in various organs and adipose tissue, effects after 8 weeks feeding were seen only with the unheated oil. Again, the same heating regimen dramatically reduced the levels of malvalic and sterculic acids from a total of 13.7 % to 0.9%, but did not eliminate these cyclopropene fatty acids.

While these studies show clearly that cyclopropene fatty acids interfere with normal fat biosynthesis, the effects seen cannot be readily extrapolated to a situation with lower levels of the cyclopropene fatty acids. For example, because they affect biosynthesis, one would expect to see adverse effects when Baobab seed oil with >13% cyclopropene fatty acids is used as the sole source of lipid in the diet. Importantly, with the unheated oil where malvalic and sterculic oils were determined to be present, but at a level 15 - 25 times lower, effects were not seen and effects have not been observed in humans who consume the oil.

At the anticipated intake for Baobab dried fruit pulp in smoothies (10g of Baobab dried fruit pulp) and fruit bars (15g of Baobab dried fruit pulp), the level of cyclopropene fatty acids exposure is expected to be 1.1mg and 1.65mg respectively.

For all US consumers of smoothies and fruit bars containing Baobab dried fruit pulp, the highest exposure levels are expected to be amongst male teenagers aged 14 to 16 (see table 2 – page 17). This translates to 1.05 mg/day at the 50th percentile and 2.10 mg/day at the pseudo 90th percentile for consumers of smoothies containing Baobab dried fruit pulp. In the case of fruit bars containing Baobab dried fruit pulp, the 50th percentile exposure limit for cyclopropene fatty acids would be 0.34μg and at the pseudo 90th percentile limit the exposure would be 0.67μg.

On the basis of these calculations, Baobab dried fruit pulp is expected to be safe for consumers at the anticipated intake level with respect to the cyclopropene fatty acid content.

4.1.5 Other Anti-nutrients in Baobab Dried Fruit Pulp

Recently, other phytochemicals have also been identified in Baobab fruit pulp. Umara *et al.* (2007) carried out a quantitative study on numerous fruits consumed in Northern Nigeria. This study included the analysis of Baobab fruit. According to this report, the levels of phytate, saponins and tannins were found to be 0.69%, 10.51% and 2.22% by weight respectively.

On the basis of the results reported by Umara *et al.* (2007), the levels of phytate in 10g and 15g of Baobab dried fruit pulp would be expected to be 69mg and 104mg respectively. The highest dietary intake for Baobab dried fruit pulp is expected to occur through the consumption of smoothies by 14 – 16 year males. Therefore, the 50th percentile and pseudo 90th percentile intakes for Baobab dried fruit pulp would be expected to be 66mg and 132mg respectively.

Phytates are typically found in bran, wholegrain cereals, pulses and nuts (Wise, 1995).

According to the study carried out by Umara *et al.* (2007), the level of saponins in Baobab fruit pulp was found to by 10.51g per 100g of fruit. At the anticipated intake level of 10g of Baobab dried fruit pulp in smoothies and 15 g of Baobab dried fruit pulp in fruit bars, a

typical consumer would ingest 1.05g and 1.65g of saponins respectively per day. For males aged 14 – 16 years old, who would be expected to consume that highest amount of Baobab dried fruit pulp in smoothies, this is equivalent to 1.00g at the 50th percentile and 2.01g at the pseudo 90th percentile.

Saponins are found in many common types of food. Predominantly, the highest dietary exposure for saponins comes from beans (broad, butter, dried and green), lentils, peas and peanuts (Price *et al.*, 1987).

The level of tannins found by Umara *et al.* (2007) in Baobab fruit pulp was reported to be 2.22g per 100g of fruit pulp. As already stated, there will be 10g of Baobab dried fruit pulp in smoothies and 15g in fruit bars. This is equivalent to a daily dose of 222mg and 333mg of tannins respectively. In terms of the highest exposure level to tannins obtained by consuming Baobab dried fruit pulp, this would be expected to be 212mg (50th percentile) and 424mg (pseudo 90th percentile) for 14 to 16 year old males drinking smoothies.

Tannins are another common component in foods which regularly consumed in the diet. These compounds are found in apples, cranberries, grapes and pomegranates (Kader *et al.*, 2004).

Crucially, Umara *et al.* (2007) concluded their paper by stating that the content of anti-nutrients (phytates, saponins and tannins) in the Baobab fruit was lower than the established toxicity levels for these phytochemicals and that the Baobab fruit pulp could be consumed safely.

4.1.6 Allergenicity of Baobab Dried Fruit Pulp

For food products that have not been a traditional part of the diet or are introduced to a new market, there is a potential risk that consumers could be exposed to new sources of food allergens.

Within the European Union, there are 12 food groups that have been identified as causing allergic responses in certain consumers with intolerance to a specific food group (EC 2003/89). In the case where any one of these 12 food groups is present or likely to be present within any foodstuff, the food label must carry a clear warning of the risk to potential consumers.

The current list of food ingredients likely to cause an allergic reaction in consumers is listed below:

- Cereals containing gluten and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk and dairy products (including lactose)
- Nuts and nut products
- Celery and products thereof
- Mustard and products thereof

- Sesame seeds and products thereof
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO_2

This list will be extended after 23 December 2008, to include lupins and molluscs as foods likely to cause an allergic reaction in consumers (EC 2006/142).

From the above list, all of the relevant plant derived food ingredients were correlated with their respective plant families. Peanuts (*Arachis hypogaea*) and soybeans (*Glycine max*) are members of the *Fabaceae* family. Celery (*Apium graveolens*), sesame seeds (*Sesamum indicum*) and mustard (either *Sinapis* sp. or *Brassica* sp.) are members of the *Apiaceae*, *Pedaliaceae* and *Brassicaceae* families respectively. Finally, nut derived products can come from a number of different plant families. Almond (*Prunus dulcis*) belongs to the *Rosaceae* family, cashew (*Anacardium occidentale*) and pistachio *(Pistacia vera*) belong to the *Anacardiaceae* family, walnut (*Juglans sp.*) and pecan (*Carya illinoinensis*) belong to the *Fagales* family.

Clearly, Baobab (*Adansonia digitata*) does not belong to any of the families that are specifically recognized for causing allergenic reactions in consumers.

There has been no published evidence in the scientific literature that shows a link between people who have consumed Baobab fruit pulp and allergic responses. Indeed, a recent report by Lorenzoni-Chiesura *et al.* (2000) stated that all of the species belonging to the *Malvaceae* order of plants had little or no allergenic potential.

The Baobab dried fruit pulp produced by Phytotrade Africa is a non-genetically modified fruit that has long history of extensive consumption within the African continent and India. There have been no reported allergenic effects associated with the genus of *Adansonia* or the closely related plant families (e.g. *Malvaceae)*. Also, there are other members of the *Bombacaceae* and *Malvaceae* families which are known to be edible (see section 3.4.7 – page 27).

Adansonia gregori, is a species of Baobab tree that is found in Australia. This species of Baobab tree is another member of the *Bombacaceae* family whose trees produce fruit that are commonly eaten by Aborigine people. This indigenous consumption of the fruit from *Adansonia gregori* was sufficient for the Food Standards Agency of Australia and New Zealand to declare this food to have a 'limited history of safe use in indigenous communities with no safety concerns identified and no harmful substances identified' (FSANZ, 2005).

In summary, Baobab fruit pulp (*Adansonia digitata*) is regularly consumed by the local populations across Africa and India without any reported allergic reactions. Other plant species in the *Bombacaceae* and *Malvaceae* families are also reported to cause no adverse effects in consumers as well. Taken together, these reports indicate that Baobab dried fruit pulp is not expected to cause allergic responses in consumers.

4.1.7 Summary of the Anti-nutrients in Baobab Dried Fruit Pulp

Baobab dried fruit pulp was analyzed for potential anti-nutrients. These were cyanide, oxalic acid, alkaloids and cyclopropene fatty acids. In all of these cases, the levels of the anti-nutrients present in Baobab dried fruit pulp were not expected to cause any adverse effects

in US consumers.

The levels of cyanide and cyanogenic glycosides in Baobab dried fruit pulp were found to be below the detection limit of 5 mg/kg (Appendix 18). Consumers of cassava flour, which is known to contain cyanide, reportedly suffer no ill effects when the cyanide content is below 10 mg/kg (JECFA, 1993). On this basis, the cyanide content of Baobab dried fruit pulp is sufficiently low that no adverse effects are expected in US consumers.

The level of oxalic acid was found to below the detection limit of 400 mg/kg (Appendix 11). This means that heavy consumers (pseudo 90th percentile; 14 – 16 year old males) would ingest a maximum of 7.63mg of oxalic acid from a 100g smoothie. This compares favorably with the average EU intake for oxalic acid in the diet which can range from 5 – 500 mg/day (EMEA, 2003) without any reports of ill-effects in consumers. Therefore, consumption of Baobab dried fruit pulp is expected to cause no adverse effects in US consumers.

The level of alkaloids was found to be below the detection limit of 10 mg/kg (Appendix 19). However, the relevance of alkaloid exposure for consumers of Baobab dried fruit pulp is not clear, because there is no definitive evidence that this class of compounds is present. To date, only a relative of *Adansonia digitata* is reported to contain alkaloids (Funeral Tree – *Quararibea fenebris* Vischer), but since Baobab fruit pulp has been widely consumed in Africa without any adverse effects, this supports the notion that no adverse effects are expected in US consumers.

The level of cyclopropene fatty acids in Baobab dried fruit pulp was found to be 0.11 mg/g (Appendix 20). The only adverse effects so far reported are in rats fed a diet with 10% Baobab seed oil (or cyclopropene fatty acids ~ 1.4 % of the diet). Since the level of cyclopropene fatty acids found in Baobab dried fruit pulp, and the resulting level in the human diet, is well below this value, the consumption of Baobab dried fruit pulp is expected to cause no adverse effects in US consumers.

A later study by Umara *et al.* (2007) demonstrated that other anti-nutrients including phytates, saponins and tannins are present in Baobab fruit. The authors of this report indicated that levels of these phytochemicals in Baobab were not likely to present any health concerns.

Finally, the consumption of Baobab dried fruit pulp is not expected to cause an allergenic response in US consumers. This is based on the observation that *Adansonia digitata* does not belong to any plant family that are known to cause allergic responses. Further, closely related members of *Adansonia digitata* are consumed as food in various parts of the world without any reports of allergic responses.

4.2 Possible Food Contaminants in Baobab Dried Fruit Pulp

Contamination of the Baobab dried fruit pulp could potentially come from foreign matter, microbial sources, pesticide residues, heavy metals and/or mycotoxins. The presence of all these contaminants (pesticides, heavy metals and mycotoxins) falls under the category of avoidable contamination which is monitored by the FDA via an action list (http://www.cfsan.fda.gov/~lrd/fdaact.html).

4.2.1 Foreign Matter

The Baobab fruit is sustainably wild-harvested and then the fruit pulp is separated from the other unwanted parts of the fruit. This process could potentially introduce contaminants into the Baobab dried fruit pulp from two sources – extraneous matter such as soil and endogenous matter such as seed and plant fiber.

To quantify this potential source of contamination, both the foreign matter content (2.5x magnification) and the silicon content of the Baobab dried fruit pulp were analyzed (Appendix 13). The results of these analyses are shown in Table 14.

Table 14
Analysis data of the foreign matter content in Baobab dried fruit pulp samples

Foreign Matter	Baobab dried fruit pulp – 1 (g/100g)	Baobab dried fruit pulp – 2 (g/100g)	Baobab dried fruit pulp – 3 (g/100g)
Endogenous Matter	0.019	0.013	0.025
Extraneous Matter	0.0025	0.006	0.003
Silica content	0.1	0.1	0.1

The analytical results in Table 14 show that the levels of the extraneous and the endogenous matter were found to be less than 0.026 % by weight of the Baobab dried fruit pulp when examined at 2.5x magnification.

The analysis of the acid insoluble ash showed that the levels of silicon were just 0.1g per 100g of Baobab dried fruit pulp. This result indicates that there are no significant problems with soil contaminating the Baobab dried fruit pulp during harvesting.

According to the USDA Dietary Reference Intakes, there is currently no recommended daily intake or adequate intake level for silicon in the diet (USDA, 2008d). Furthermore, there is no evidence that silicon found in food causes any health adverse health effects.

Overall, the levels of foreign matter were found to be very low and this result supports the good collection and handling procedures used in the production of the Baobab dried fruit pulp. This means that consumers will not be exposed to unsafe levels of foreign matter at the anticipated level of intake of Baobab dried fruit pulp.

4.2.2 Microbial Levels

The level of microbial contamination of the Baobab dried fruit pulp was analyzed for several potential microbiological organisms (Appendix 14) including *E. coli*, fecal *streptococci* and *Salmonella*. The Baobab dried fruit pulp was analyzed in duplicate and the results are shown in Table 21.

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Table 21
Analysis data of the microbial content in Baobab dried fruit pulp samples

Microbial Contaminant	Baobab dried fruit pulp – 1 (cfu/g)	Baobab dried fruit pulp – 2 (cfu/g)
Total viable count	3.90×10^4	2.50×10^4
Coliforms (presumptive)	< 10	< 10
***E.coli* (presumptive)**	< 10	< 10
Staphylococcus aureus	< 20	< 20
Faecal *streptococci*	< 20	< 20
Yeasts	< 20	< 20
Moulds	1.60×10^4	7.80×10^3
***Salmonella sp.* ***	Not detected	Not detected

* Samples tested for *Salmonella* contamination are reported as per 25 g of Baobab dried fruit pulp

The results of these analyses showed that the levels of presumptive coliforms, presumptive *E. coli*, *Staphylococcus aureus*, fecal *streptococci* and yeasts were below the limit at which the numbers of the colonies are counted. *Salmonella* was found to be totally absent in the Baobab dried fruit pulp samples. Finally, both the total viable count and mould produced colony counts that were in the region of 10^4. These counts are not unduly high or unexpected in a fruit that is wild harvested and processed by a simple mechanical separation.

On the basis of these results, consumers will not be exposed to unsafe levels of microbiological contaminants at the anticipated level of intake of Baobab dried fruit pulp.

4.2.3 Pesticide residues

The Baobab dried fruit pulp produced by Phytotrade Africa is wild-harvested, in contrast to most fruit crops that are normally produced under intensive agricultural conditions. Under such intensive agricultural conditions, the use of pesticides is an accepted practice. However, to ensure that consumers are not exposed unnecessarily to these pesticides, the residues on all types of food are carefully monitored.

The data in Table 22 (page 35) shows the results of a multi-pesticide residue scan on the Baobab dried fruit pulp (Appendix 15). The results are presented in terms of the class of pesticide rather than the individual pesticide.

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Table 22
Analysis data of the Multi-Residue Pesticide Screen in Baobab dried fruit pulp samples

Class of pesticide	Residue detected (mg/kg)
organophosphorous	< 0.05 mg/kg
organochlorine	< 0.02 mg/kg
organonitrogen	< 0.05 mg/kg
dicarboximides	< 0.05 mg/kg
strobilurin	< 0.05 mg/kg
triazine	< 0.05 mg/kg
pyrethoids	< 0.05 mg/kg

The results in Table 16 clearly show that the levels of the pesticide residues are below the limits of detection. These results are to be expected as pesticides are not used at any stage during the growing or harvesting of the Baobab fruit. Therefore, on the basis of these results, consumers of Baobab dried fruit pulp are not likely to be exposed to unsafe levels of pesticide residues.

4.2.4 Heavy Metals

The Baobab dried fruit pulp was analyzed in duplicate for the presence of four types of heavy metals – arsenic, cadmium, lead and mercury (Appendix 16). The results of these analyses are shown in Table 23.

Table 23
Analysis Data of the Heavy Metals Content in the Baobab dried fruit pulp samples

Heavy Metals	Baobab dried fruit pulp – 1 (mg/kg)	Baobab dried fruit pulp – 2 (mg/kg)
Arsenic	< 0.10	< 0.10
Cadmium	< 0.010	< 0.010
Lead	0.09	0.08
Mercury	< 0.004	< 0.004

The levels of arsenic, cadmium and mercury in the Baobab dried fruit pulp samples were all below the detection limit. In contrast, lead was detected in the Baobab fruit pulp samples, but only at low levels.

JECFA set a maximum tolerable daily intake for arsenic at 2 μg/kg body weight/day (WHO, 1983). In a 60kg person this is equivalent to a maximum exposure limit of 120 μg/day.

At the anticipated level of intake for Baobab dried fruit pulp in smoothies (10g of Baobab dried fruit pulp) and fruit bars (15g of Baobab dried fruit pulp) the arsenic exposure is expected to be less than 1.0μg and 1.5μg respectively.
For all US consumers of smoothies and fruit bars containing Baobab dried fruit pulp, the

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highest exposure levels are expected to be amongst male teenagers aged 14 to 16 (see table 2 – page 17). This extrapolates to 0.95 µg/day at the 50th percentile and 1.91 µg/day at the pseudo 90th percentile for consumers of smoothies containing Baobab dried fruit pulp.

The results of these calculations show that Baobab dried fruit pulp is expected to be safe for consumers at the anticipated level of intake with respect to the arsenic content.

Cadmium levels in foodstuffs should not exceed 1 mg/kg (JECFA, 2004). Since the levels of cadmium were below the limit of detection (< 0.010 mg/kg), Baobab dried fruit pulp is expected to be safe for consumers at the anticipated level of intake with respect to the cadmium content.

According to JECFA (Joint FAO/WHO Expert Committee on Food Additives), the recommended maximum concentration for lead in foodstuffs should be 2 mg/kg. The results of the Baobab dried fruit pulp analyses clearly show that the lead content of 0.08 – 0.09 mg/kg is well below this recommended limit.

Recently, the FDA issued guidance to the industry concerning the levels of lead in candy that are likely to be consumed frequently by small children (CFSAN, 2006). This set a maximum permitted level for lead in candy at 0.1 mg/kg. The results of the analyses carried out on the Baobab dried fruit pulp samples clearly show that the lead content is below this action level.

Mercury contamination, specifically in the form of methyl mercury, is typically associated with fish and shellfish products. There does not appear to be any action levels for the potential mercury contamination in the food products where Baobab dried fruit pulp would be an ingredient. Indeed, the Total Diet Study Statistics on Element Result (FDA, 2006b) does not show any reported values for the mercury content in the granola bar with raisins or the fruit drinks containing 10% fruit.

JECFA (2004) have stated that the maximum concentration of mercury in foodstuffs should not exceed 1 mg/kg. Given that the mercury levels were below the limit of detection (see Table 17 – page 35), the Baobab dried fruit pulp is expected to be safe for consumers at the anticipated level of intake with respect to the mercury content.

4.2.5 Mycotoxins

The presence of mycotoxins is strictly controlled in foodstuffs. Although Baobab fruit pulp is a new food ingredient, analyses were carried out on two specific types of mycotoxins, ochratoxin A and aflatoxins. The first type of mycotoxin was ochratoxin A, which is known to contaminate dried fruit such as currants, raisins, and sultanas. By contrast, aflatoxins are known to contaminate a wide range of food products and this contamination normally occurs or increases during storage.

The Baobab dried fruit pulp was analyzed in duplicate (Appendix 17) for these mycotoxins and the results are shown in Table 24.

In both of the samples of the Baobab dried fruit pulp, the levels of ochratoxin A and the aflatoxins were found to be below the limit of detection.

Table 24
Analysis Data of the content of Ochratoxin A and Aflatoxins in the Baobab Dried Fruit Pulp Samples

Mycotoxins	Baobab dried fruit pulp – 1 (µg/kg)	Baobab dried fruit pulp – 2 (µg/kg)
Ochratoxin A	< 0.2	< 0.2
Aflatoxin B1	< 0.09	< 0.09
Aflatoxin B2	< 0.09	< 0.09
Aflatoxin G1	< 0.09	< 0.09
Aflatoxin G2	< 0.09	< 0.09
Total Aflatoxins	< 0.36	< 0.36

According to the action levels published by the FDA (CFSAN, 2000), the maximum permitted level for aflatoxins in foodstuffs is 20 µg/kg. The analyses of the Baobab dried fruit pulp samples clearly show that the aflatoxin levels are well below this level. On this basis, Baobab dried fruit pulp is expected to be safe for consumers at the level of anticipated intake with respect to the content of aflatoxins.

There does not appear to be any FDA action, advisory or guidance levels for ochratoxin A content in foodstuffs (EC, 2007). Since the analyses of the samples found that the levels of ochratoxin A were below the limit of detection of 0.2 µg/kg, Baobab dried fruit pulp is expected to be safe for consumers at the level of anticipated intake with respect to the content of ochratoxin A.

4.2.6 Summary of the Food Contaminants in Baobab Dried Fruit Pulp

The Baobab dried fruit pulp was analyzed for several potential contaminants. These were foreign matter, microbial contaminants, pesticide residues, heavy metals and mycotoxins. All of these potential contaminants were classified as avoidable contaminants and should either, not be present or be present at such low levels as to pose no health risk to consumers.

In all of these categories, the level of potential food contaminants was found to be acceptable and unlikely to cause any harm to consumers. The levels of pesticide residues (Appendix 15) and mycotoxins (Appendix 17) were all below the limit of detection. Three out of four of the heavy metals analyzed were also below the limit of detection. Lead was detected in the Baobab dried fruit pulp but the content was well below permitted safety limits (Appendix 16). The foreign matter content of the Baobab dried fruit pulp was also low and found to be less than 0.026% by weight (Appendix 13). Finally, the level of microbial contamination was found to be acceptable (Appendix 14). Only the total viable count and moulds were found to be present but the levels of these contaminants were not high and unlikely to cause any harm to consumers.

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5.0 Conclusions

The determination of the GRAS status for Baobab dried fruit pulp in fruit bars and smoothies was made by identifying all of the macro-nutrients, micro-nutrients, food contaminants and anti-nutrients that are likely to be found in the finished product.

The nutritional profile of Baobab dried fruit pulp revealed that the macro-nutrients and micro-nutrients were all well known constituents whose metabolism is well defined. The phytochemicals that are known to be present in Baobab dried fruit pulp, were found to be well known compounds that are commonly ingested by US consumers of fruit and vegetables. Further supporting evidence for the safety of Baobab dried fruit pulp comes from the traditional food use of Baobab fruit pulp in the indigenous population of Southern Africa. Also, the closely related members of the *Bombacaceae* and *Malvaceae* families produce edible fruits that are commonly consumed without any reported adverse effects.

The potential for food contamination and the content of anti-nutrients in the Baobab dried fruit pulp were evaluated on the basis that these constituents would not support the GRAS determination for the finished product. The data showed that the level of potential food contamination was found to be within acceptable limits and would not be expected to cause adverse effects in US consumers. This was also the case for the anti-nutrients that were identified as constituents in the Baobab dried fruit. The levels of these anti-nutrients were not expected to cause adverse effects in US consumers.

Therefore, we submit that Baobab dried fruit pulp is GRAS when used as an ingredient in fruit bars and smoothies at the anticipated level of intake, because none of the identified constituents in the finished product are expected to cause adverse effects in US consumers.

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Appendix 1 – European Commission Standing Committee on the Food Chain and Animal Health Section on General Food Law

EUROPEAN COMMISSION
Health and Consumers Directorate-General

Directorate E – Safety of the food chain
E4 – Food Law, nutrition and labelling

STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH SECTION ON GENERAL FOOD LAW
Summary Record of Meeting of 15 April 2008

Chairman: Mr Basil Mathioudakis – all Member States were present

1. **Exchange of views and possible opinion on a Draft Commission Decision authorising the placing on the market of Baobab dried fruit pulp as novel food ingredient under Regulation (EC) N° 258/97 of the European Parliament and of the Council**

The draft decision was slightly modified following the discussion which took place. The definition of the product concerned in Article 1 was clarified, as well as the labelling requirement in Article 2.

The Committee also agreed that, as microbiological criteria for foodstuffs and maximum levels for certain contaminants in foodstuffs are set up in horizontal legislations (respectively Regulation (EC) No 2073/2005 and Regulation (EC) No 1881/2006), certain details of the draft specifications were unnecessary. Therefore in order to avoid duplication and possible confusions the draft decision was modified accordingly.

The SCFCAH gave a favourable opinion by unanimity.

2. **Exchange of views and possible opinion on a Draft Commission Decision authorising the placing on the market of *Allanblackia* seed oil as novel food ingredient under Regulation (EC) N° 258/97 of the European Parliament and of the Council**

As for item 1, the draft decision was slightly modified following the discussion which took place, regarding the labelling requirement in Article 2.

Similarly the Committee also agreed that, as maximum levels for certain contaminants in foodstuffs are set up in horizontal legislations (Regulation (EC) No 1881/2006), certain details of the draft specifications were unnecessary. Therefore in order to avoid duplication and possible confusions the draft decision was modified accordingly.

The SCFCAH gave a favourable opinion by qualified majority (in favour: 338 votes; against: 7 votes).

Exchange of views and possible opinion on a Draft Commission Decision authorising the placing on the market of refined Echium oil as novel food ingredient under Regulation (EC) N° 258/97 of the European Parliament and of the Council

As for items 1 and 2, the draft decision was slightly modified following the discussion which took place, regarding Article 1 and the labelling requirement in Article 2.

Similarly the Committee also agreed that, as maximum levels for certain contaminants in foodstuffs are set up in horizontal legislations (Regulation (EC) No 1881/2006), certain details of the draft specifications were unnecessary. Therefore in order to avoid duplication and possible confusions the draft decision was modified accordingly.

The SCFCAH gave a favourable opinion by unanimity.

Appendix 2 - Determination of the Nutritional Composition of Baobab Dried Fruit Pulp

Method

Moisture Content

Duplicate samples from all the batches of Baobab fruit dried pulp was dried in an oven at 102°C The resultant loss in weight, expressed as a percentage of the whole sample, corresponds to the moisture content.
UKAS accredited method (AM/C/801) is based on BS4401 Part 3, 1970

Protein Content

The total nitrogen content of duplicate samples from all the batches of Baobab dried fruit pulp,was determined by complete combustion of sample in a furnace with an oxygen supply. The elemental nitrogen was converted to nitrogen and nitrogen oxides. These oxides were converted to nitrogen before the gas flowed through a thermal conductivity cell. The resulting voltage was measured and converted to give a value for the protein content.
UKAS accredited method (AM/C/224)

Total Fat Content

Duplicate samples from all the batches of Baobab fruit dried pulp were hydrolysed with 5M hydrochloric acid and the resultant fat was extracted into petroleum spirit. The extracted fat was evaporated to dryness then further dried in an oven before weighing until constant weight achieved.
UKAS accredited method (AM/C/120) based on BS4404 Part 4 1970

Ash Content

Duplicate samples from all the batches of Baobab dried fruit pulp were heated in a muffle furnace at 550°C until all the organic matter was burnt off. Weight of residue expressed as a percentage of the sample taken.
UKAS method (AM/C/803) based on BS4401 Part 1 1980

Dietary Fibre Content

Duplicate samples from all the batches of Baobab dried fruit pulp were gelatinised and treated with heat stable α-amylase and then further digested with enzymatically with protease and amylglucosidase to remove protein and starch respectively. IMS was added to precipitate the soluble dietary fibre. The residue was filtered and washed with IMS and acetone. The residue was dried and weighed. Half of this residue was analysed for protein and the remainder was ashed. Total dietary fibre was calculated from the weight of residue less the weight of protein and ash, expressed as a percentage of the sample weight.
UKAS accredited method (AM/C/309) by AOAC method

Pectin Content

The pectin analysis was based on the IFFJP method No. 26
Aqueous extracts was made from samples of all the batches of Baobab dried fruit pulp.
From each sample, the pectin was then precipitated with ethanol and then given a series of washes with 70% ethanol, before the precipitate was dissolved in water.

The pectin content was quantified using a colourimetric assay.

Energy Content

% Total carbohydrate = 100 - (% moisture + % protein + % fat + % ash)

% Available carbohydrate (by difference) = 100 - (% moisture + % protein + % fat + % ash + % Dietary fibre)

Energy is calculated from the protein, fat, and available carbohydrate
The method is based on 90/496/EEC Nutritional Labelling for Foodstuffs

Sugar Content

Sugars were extracted from duplicate samples of all the batches of Baobab fruit dried pulp, with either aqueous IMS or water, followed by clarification with Carrez solutions I and II. Sugar content was determined by the Luff-Schoorl method.
The sample extracts were refluxed with Luff-Schoorl reagent and then cooled in cold water. Potassium iodide and 3M sulphuric acid were added to the sample extracts. The solutions were then titrated with standardised 0.1M sodium thiosulphate solution.

Sodium Content

Duplicate samples from all the batches of Baobab dried fruit pulp were ashed to remove any organic material. The samples were then digested with hydrochloric acid, prior to diluting to a known volume. The sodium content was quantified using flame photometry against calibration standards of known concentration in the range 0-10 µg/ml.

Fatty Acid Content

The fats are extracted from duplicate samples from of the batches of Baobab dried fruit pulp and converted free fatty acids by saponification. The fatty acids were converted to the corresponding methyl esters and extracted into heptane. Quantification of the fatty acids was achieved by gas chromatography.
Method based on BS684 Part 2 Section 2.34 and 2.35

Vitamin B1 & B2 Content

Thiamine (B1) and riboflavin (B2) are extracted from duplicate samples of all the batches of Baobab dried fruit pulp,by digestion with 0.1M hydrochloric acid followed by enzyme digestion with claradiastase. The filtered solutions were analysed by reversed phase HPLC for riboflavin and normal phase HPLC for thiamine (after thiochrome formation) using fluorescence detection against calibration standard solutions of known concentration.
Reference: Analyst **125** pp353-360 (2000)

Vitamin C

A stabilising agent of an aqueous solution of metaphosphoric acid (MPA) and dithiothreitol (DTT) was used throughout the method. Degradation of the samples was promoted in alkaline conditions and MPA maintained an acidic environment. MPA also prevented catalysis of the oxidation of vitamin C by copper (II) and iron (III) ions and precipitated the proteins. DTT reduced DHAA back to ascorbic acid hence preventing the degradation pathway from proceeding.

The duplicate samples from all the batches of Baobab dried pulp were extracted into an aqueous medium containing stabilising agents.
The vitamin C was then converted to DHAA using an enzymatic spatula, and reacted with ortho-phenylenediamine (OPDA) to form a fluorescent quinoxaline derivative.
The final derivative was unstable and all timings were kept to an absolute minimum.
The extract was assayed by reversed phase HPLC with fluorescence detection.

(reference: Speek, Schrijver and Schreurs J.Agric.Food Chem 1984 **32**, 352-5)

Results

Nutritional Analysis	Baobab dried fruit pulp – 1	Baobab dried fruit pulp – 2
Moisture – loss on drying (g/100g)	13.6	13.7
Protein (g/100g)	2.04	2.03
Fat (g/100g)	0.4	0.5
Ash (g/100g)	5.5	5.5
Total carbohydrate (g/100g)	78.5	78.3
Total dietary fibre (g/100g)	51.4	52.2
Total Pectin (g/100g)	30.9	30.9
Available carbohydrate (g/100g)	27.1	26.1
Energy (kcal/100g)	120	117
Energy (kJ/100g)	510	496
Total sugars (as glucose) (g/100g)	21.2	20.9
Sodium (mg/100g)	8.64	8.83
Saturated fats (g/100g)	0.21	0.25
Monounsaturated fats (g/100g)	0.13	0.16
Polyunsaturated fats (g/100g)	0.04	0.07
Vitamin B1 (HCl) (mg/100g)	0.05	0.06
Vitamin B2 (mg/100g)	0.03	0.02
Vitamin C (mg/100g)	74.1	76.2

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Appendix 3 - Determination of Fatty Acids in Baobab Dried Fruit Pulp by Gas Chromatography

Method

The fat was extracted from the duplicate samples of all the batches of Baobab dried fruit pulp using the Bligh and Dyer method.

The isolated fat samples were transesterified using methanol/sodium methoxide to form the Fatty Acid Methyl Esters (FAME). The methyl esters were then analysed using gas chromatography with a column specifically designed to separate cis and trans isomers.

Reference – in-house method, ISO 17025 accredited

Results

Fatty acid	Baobab dried fruit pulp – 1 (% F.A.)	Baobab dried fruit pulp – 2 (% F.A.)
11-methyltridecanoic acid	< 0.10	< 0.10
12-methyltetradecanoic acid	< 0.10	< 0.10
12-methyltridecanoic acid	< 0.10	< 0.10
13-methyltetradecanoic acid	< 0.10	< 0.10
14-methylhexadecanoic acid	< 0.10	< 0.10
14-methylpentadecanoic acid	< 0.10	< 0.10
15-methylheptadecanoic acid	0.12	0.13
15-methylpalmitic acid	< 0.10	< 0.10
16-methylheptadecanoic acid	< 0.10	< 0.10
alpha-linolenic acid	10.4	11.4
Arachidic acid	0.50	0.52
Arachidonic acid	0.11	0.12
Behenic acid	0.31	0.33
Brassidic acid	< 0.10	< 0.10
Butyric acid	< 0.10	< 0.10
11,14-eicosadienoic acid	< 0.10	< 0.10
13,16-docosadienoic acid	< 0.10	< 0.10
C18:2 (conj)	0.16	< 0.10
Capric acid	0.44	0.21
Caproic acid	0.36	0.22
Caprylic acid	0.60	0.64
Cis-10-heptadecenoic acid	< 0.10	< 0.10

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Fatty acid	Baobab dried fruit pulp – 1 (% F.A.)	Baobab dried fruit pulp – 2 (% F.A.)
Cis-10-peantdecenoic acid	< 0.10	< 0.10
Cis-11,14,17-eicosatrienoic acid	< 0.10	< 0.10
Cis-11-dodecenoic acid	< 0.10	< 0.10
Cis-11-eicosenoic acid	0.2	0.2
Cis-11-hexadecenoic acid	< 0.10	< 0.10
Cis-12-octadecenoic acid	< 0.10	< 0.10
Cis-15-hexadecatetraenoic acid	< 0.10	< 0.10
Cis-5-hexadecenoic acid	< 0.10	< 0.10
Cis-7-pentadecenoic acid	< 0.10	< 0.10
Cis-8,11,14-eicosenoic acid	< 0.10	< 0.10
Cis-8-eicosenoic acid	< 0.10	< 0.10
Cis-9-eicosenoic acid	< 0.10	< 0.10
Cis-9-decenoic acid	< 0.10	< 0.10
Cis-9-dodecenoic acid	< 0.10	< 0.10
Cis-vaccenic acid	1.0	1.0
Docosahexaenoic acid- DHA	< 0.10	< 0.10
Docosapentaenoic acid (n-3)	< 0.10	< 0.10
Docosapentaenoic acid (n-6)	< 0.10	< 0.10
Docosatetraenoic acid	< 0.10	< 0.10
Eicosapentaenoic acid- EPA	< 0.10	< 0.10
Eicospentaenoic acid	< 0.10	< 0.10
Elaidic acid	< 0.10	< 0.10
Erucic acid	< 0.10	< 0.10
Gamma-linolenic acid	< 0.10	< 0.10
Heneicosanoic acid	< 0.10	< 0.10
Heptadecanoic acid	0.43	0.42
Heptanoic acid	< 0.10	< 0.10
Lauric acid	0.79	0.39
Lignoceric acid	0.20	0.20
Linoleic acid	18.5	20.0
Linilelaidic acid	< 0.10	< 0.10
Myristic acid	1.80	0.96
Nervonic acid	< 0.10	< 0.10

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Fatty acid	Baobab dried fruit pulp – 1 (% F.A.)	Baobab dried fruit pulp – 2 (% F.A.)
Nonanoic acid	< 0.10	< 0.10
Octadecatetraenoic acid	< 0.10	< 0.10
Oleic acid	24.9	24.7
Other fatty acids	6.10	6.40
Palmitic acid	27.3	27.1
Palmitoleic acid	0.4	0.4
Pentacosanoic acid	< 0.10	< 0.10
Pentadecanoic acid	0.24	0.17
Stearic acid	4.20	3.80
Trans-12-octadecenoic acid	< 0.10	< 0.10
Trans-5-hexadecenoic acid	< 0.10	< 0.10
Trans-7-octadecenoic acid	< 0.10	< 0.10
Trans-vaccenic acid	0.2	< 0.10
Tridecanoic acid	< 0.10	< 0.10
Valeric acid	< 0.10	< 0.10

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Appendix 4 - PhytoTrade Africa's Pre-Qualified Supplier (PQS) System

The PQS system sets out the conditions that are to be met in supplying Baobab Dried Fruit Pulp (BDFP) to the EU market via Phytotrade Africa. This consists of several parts:

- The collection of whole Baobab fruits by farm workers (rural harvesters)

- The separation of the pulp, fibre and seeds from the fruit

- Delivery of the pulp, fibre and seeds to local processors in Africa (members of Phytotrade Africa) who then separate the pulp from the seeds and fibre to form BDFP and who then deal direct with PhytoTrade Africa for supply of the BDFP to PhytoTrade Africa's customer base in the EU.

- The quality of BDFP to meet Phytotrade Africa's specification sheets (which conform to the requirements of Novel Foods Approval) before being accepted into the EU market place.

The above requirements are conducted to a standard that is similar to Good Agricultural and Collection Practices used in Pharmacognosy and the quality control of herbal medicines. The following guidelines are based on existing practises by PQS members and rural harvesters who have already shown to produce acceptable quality BDFP by analysis, microbiological load and other markers of quality control as outlined in the specification sheets undertaken by PhytoTrade. These methods however, have also been updated by combing existing collection and manufacturing practises with modern day GACP and pharmacognostic principles in order to maximize the quality of the BDFP and minimise any potential safety issues of producing the product.

1.0 Collection of BDFP by Farm workers rural harvesters:

Baobab fruit is sustainably harvested from trees growing wild in their natural habitats in various parts of Southern Africa by trained, registered, certified and inspected rural harvesters who are required to strictly adhere to production standards implemented by each PQS members. The information is delivered to the farm workers through trainings based on training manuals, which themselves may vary slightly from each supplier but have to meet minimum common requirements as set out and required by PhytoTrade Africa.

1.1 Summary of Training Manual

- The training manual contains guidance and training on collection practices, hygiene, handling, storage, transport. These include the following details:

- Records of areas of origin where the fruits are collected, indicating also the geographic collection points. Collected volumes are clearly recorded, including collectors name or registration, date of collection and how much was collected, and which quality.

- Collectors use approved bags only that are provided by the supplier.

- Only recently harvested fruits of the current year are permitted in the market. Immature fruits (i.e., those that are still on the tree) may not meet the requirements of Phytotrade Africa's specifications sheets due to changes for example in moisture content, density and vitamin content and therefore are rejected. Fruits that are cracked, rotting or have been damaged by insects, animals or covered in soil and other detritus etc., are downgraded by the PQS member to

be processed separately and used in other applications than food products.

• Samples that are found to contain excessive foreign matter are rejected by the PQS member. Any evidence of adulteration found in BDFP will result in a permanent ban of the rural harvesters participation in the collection and sale of Baobab fruits.

• Baobab fruits are stored away from direct sunlight and in a separate area from other plant products and chemicals. The storage areas are cleaned on a regular basis, cleanliness of all storing and processing facilities is inspected by the supplier/processor on a regular basis.

• Once the fruits have been harvested, they can be stored for a maximum of 5 months (collection season is from June to October – the dry season) before the fruit pulp, fibre and seeds are removed from the whole fruits.

• Only new, clean, and unspoiled storage bags are used for collection. All bags carry the PQS members' logo for clear identification and an indication of the year of collection through either print or colour. This ensures that any collected material from previous years is excluded in the current years' harvest.

• The number of bags given out to each collector group is known, and the number returned is controlled.

• The separation of the fruit pulp, fibre and seeds from the fruits must be conducted under hygienic conditions. Any wounds must be bandaged, any workers that are ill have to abstain from collection and separation work. Scraping utensils are thoroughly cleaned before and after use. The exact date of the separation of the pulp, fibre and seeds from the fruits must be recorded and this clearly marked on the approved storage bags. The separation must only begun once instruction by the supplier has been given. Only separated material that has been stored for less than 4 weeks will be accepted by PQS member between June and October.

• The PQS member employs an inspector to check on the quality of production and storage during the processing season.

• Written reports to the PQS member state all incidents, and an internal control committee consisting of representatives of the PQS member and the rural collectors impose sanctions to ensure quality of the produce.

• Longer storage times will result in material which will fall below the necessary standards required by PhytoTrade Africa and will be rejected. The storage bags containing the pulp, seed and fibre are sealed to prevent spoilage from absorption of water, and contamination by foreign matter. They are stored away from direct sunlight and in a separate area from other plant products and chemicals. This is checked during inspection.

Harvesters are fully briefed on the above points and have to attend two training sessions per year that are provided by PQS members who are knowledgeable in the collection and quality control requirements of BDFP to Phytotrade Africa's specification sheets.

2.0 Production of BDFP by PhytoTrade Africa Approved Suppliers:

Each supplier must conform to the standards set out in this PQS system document.
The PQS members, in the case of Malawi, buy the pulp, seed and fibre from rural harvesters as described above and who then process the material to produce BDFP. In other regions /

countries, the PQS members both collect Baobab fruits and also process them to produce BDFP. Processing is done with food grade machinery; the BDFP is packed under vacuum in black plastic bags to prevent light. Storage temperature is controlled regularly.

2.1 Traceability of Baobab pulp, seed and fibre

An internal control system (ICS) capable of meeting requirements of "organic" certification is required. Individual harvesters (farm workers, collectors) are trained, registered, certified and inspected regularly, and comprise supply groups with co-ordinators or "chairs" of producer groups acting as contact and control points. Material is traceable from storage warehouse back to individual harvesters by using the following practises:

(a) Supplying food-grade plastic bags to the fruit collectors

(b) The PQS member controls weight, grade, and cleanliness of each delivery and ensures each batch is correctly dated and marked for authenticity by the collector.

(c) Other quality control measures include:

- Visual checks made on the material supplied, such as moisture content (by pinching the powder and observing its stickiness), any obvious adulteration or contamination from insects, particularly termites, or excessive soil and detritus.

- Any signs for the presence of aged material (particularly variation in colour, signs of decomposition).

- The PQS member determines periods of collection and separation of the pulp, seeds and fibre from the fruits confirm to the specifications as laid out in 1.2 above.

- The PQS member operates an internal labelling/batch numbering system to ensure full traceability of eventually contaminated material to a particular harvester or harvester group.

3.0 Collation practices:

In general the warehousing and bulking-up facilities are inspected regularly (i.e. weekly/monthly) for cleanliness and appropriateness for supply into food chains. Pest control systems are required. Minimum and maximum temperatures, moisture and other relevant conditions are inspected.

Specifically this is conducted in the following ways:

3.1 Staff

Personnel hygiene
All staff are trained in personnel hygiene. This includes clean overalls, protective clothing (gloves and masks where necessary). Any illness e.g., wounds etc must be adequately protected and treated. Hand washing facilities need to be available to staff to encourage maximum hygiene practises.

3.2 Buildings

Should be cleaned every day aerated and contain no livestock.

A pest control procedure needs to be in place to prevent against contamination and insect infestations e.g., baits / electronic insect killing machines.

3.3 Storage of unprocessed and processed material

The crude pulp, seed and fibre must be stored in closed bags away from direct sunlight and be properly labelled. This material must be processed within one month after arrival at the suppliers' warehouse.

Once processed, the BDFP must be stored in such a way for it to be easy to clean the warehouse floors and encourage aeration. E.g., in bags, stored on pallets, and at a distance from the walls. Cleaning should comprise of sweeping the warehouse on a daily basis and cleaning with sanitizing materials.

If other plant products are stored in the same warehouse these are clearly marked and stored in a separate area to avoid potential contamination or possible mix up in supplies.

4.0 Processing

In general, the suitability of processing methods and equipment is inspected and required to conform to approved mechanical processes. Approved equipment includes food grade machinery. All processing steps must accommodate traceability requirements through batch numbers for each production run. Specifically:

- The unprocessed Baobab fruit pulp, seed and fibre is separated in a de huller.
- The resulting material is sieved and then packaged in polypropylene bags with black plastic liner and immediately sealed for storage.
- All machinery is cleaned before each batch run (i.e. daily) to avoid contamination of new material with older material.
- Each batch that is processed must be clearly labelled and traceable back to the collector / area in question.
- The resulting BDFP will have to conform to certain specifications as laid out in the specification sheet (see specification sheets – see 4.1).

4.1 Specification of BDFP from suppliers

The following tests are required to be performed on each consignment destined for EU markets by each PQS member before transferring BDFP to PhytoTrade Africa's customer base:

Microbiological limits:	Total Viable Counts	$< 1.0 \times 10^5$ cfu/g
	Yeast and Mold	$< 1.0 \times 10^4$ cfu/g
	E. coli	absent in 1 g
	S. aureus	absent in 1 g
	Salmonella sp. (by USP method)	absent in 25 g
Moisture content:	< 12 %	

Vitamin C content: (HPLC)	Not less than 50mg/100g
Aflatoxins (if present):	< 10 micrograms /g
Detection of Foreign Matter	Not more than 0.2 %

Phytotrade also conducts its own audit by regular analysis (at least three different analysis of different batches are undertaken per year) of the material produced by its suppliers as an independent verification of the quality of the material supplied.

The following are undertaken by PhytoTrade Africa – **Vitamin C content, moisture content, microbiological load, detection of foreign matter, and aflatoxin content.**

5.0 Packaging:

Only food grade packing materials are approved for use, and are monitored in the PQS system.

6.0 Shipping:

Only producers with efficient International export and shipping facilities are approved by the PQS system.

7.0 Other points:

Some suppliers both collect Baobab fruits and process them using the same staff. Other suppliers contract rural harvesters (farm workers) who deliver the unprocessed fruit pulp, seeds and fibre to the supplier for processing. In both cases, the above quality controls and audits apply regardless of how each supplier obtains and process Baobab fruits.

Audit by PhytoTrade Africa internal staff. Conducted at suppliers warehouses every 6 months. PhytoTrade Africa's auditor will fill out a check list **See next page below.**

If all the requirements on the checklist are not met, PhytoTrade Africa will cancel the pre qualified status of the member and said member will not be entitled to supply PhytoTrade Africa's EU client base until these have been rectified.

AUDIT PATH FOR PQS ANALYSIS – BAOBAB

QUALITY ASSURANCE DETAILS

Does the company possess any recongnised quality management systems – HACCP for example?
YES/NO
If YES, view the certificate? Comments thereon including validity, exclusions, etc.
If NO, will the company implement one? When?

Do you operate within a documented Quality System?
Do you have a full time Company Quality Assurance Mananger/Representative?
YES/NO
If YES, who is he/she? Qualifications? Assessed competence thereon

RAW MATERIAL SPECIFICATIONS FOR BAOBAB SEED PLUS PULP:

		Specification	Compliance	View
Moisture content				
Pesticide contamination -	DDT			
	Xxxx			
	Xxxx			
	Lead			
Heavy Metals -	Lead			
Vitamin C content				
Microbiological content –	E. coli			
	Salmonella			
	Moulds			
Mycotoxins -	Aflatoxin			

PROCESS CONTROL

Are specification schedules available to company for baobab powder supplied for export?
YES/NO
Seen by inspector?
YES/NO
Are the adequate?
YES/NO
Copy attached
YES/NO

Are Certificates of Analysis prepared and supplied on request?
YES/NO
Typical copy attached?
YES/NO

Are the materials supplied within the specifications?
YES/NO
Are quality assurance tests undertaken on all products shifted from company premises?
YES/NO
Who undertakes these tests?
Are the materials supplied in compliance?
YES/NO

When are samples taken for quality control purposes?

	Collation	Processing
Before		
During		
After		

Inspector seen sampling procedures? Comments thereon including sampling protocols followed

Sample testing is undertake:

Physically: YES/NO
Microbiologically YES/NO

Testing is undertaking:

In House YES/NO
(Capabilities assessment, viewed, personner talked to, opinions given)

Externally YES/NO
(Through approved laboratory? Details? Typical test report attached?

CONTAMINATION AND PREVENTION

FIELD

Is all material checked for insect contamination at point of collation?
YES/NO
How is this undertaken?

Is baobab pod collected from ground?
YES/NO
Are broken pods collected and stored with good pods?
YES/NO
In the homestead storage area are pods stored whole?
YES/NO

If YES at what stage are they cracked open? Explain
Immediately?
2-3 months before sale to company?
2-3 weeks before sale to company?
Inspector to verify procedures

In what conditions are the pods stored prior cracking open?
In open air?
In covered storage with other crops?
In covered storage with other materials?
In separate covered storage on own?
Other – detail by inspector

How clean is the storage area?
Is it cleaned using sweeping?
How often?
Are chemical pesticides used
Inspector to elaborate

How are the pods cracked open? E.g. Manually, in open air, onto ground or sacks?
Inspector to elaborate

When and how is cracked material stored?
On open ground?
Under cover but in open storage?

How is the pod cracked – knife, etc? Pulp removed by hand?
In sacks and stored in clean areas?
If in sacks where are the sacks secured from?
Provided by the company as clean and new?
As second hand clean?
Are the sacks used secured by the processor and second hand?
Are they clean?
Inspector to elaborate

Are the collection of pods, storage of pods, cracking of pods and storage of cracked material monitored by the company?
Is the cleaning of the storage are monitored by the company?
Who monitors for the company?
If so, how is it monitored and how frequently?
What methods are employed to ensure that no extraneous materials are allowed into the cracked material?
Is this adequate to ensure clean hygienic material supply to the company?
Inspector to elaborate

Possible insect contaminants include which species?
How are they checked?

What other checks for other contaminants are carried out and by whom and at what point?

Is the effectiveness of the process audited?
Is the system sufficiently robust in the oponion of the inspector?
If NOT, where could/should it be improved?

Is the raw material collected traceable back direct to the collection point physically and by the collector?
Described this procedure and include copies of computerised and/or hand receipts that clearly identify batch collection, collector, collection point, collection zone.

Is the raw material identifiable by time of year the pods were collected?
Is there any record made of weather conditions at time of collection?
At time of cracking?
At time of selling to company?
If so, elaborate

Is the raw material collected from the same areas every year?
Explain and Detail

Is there a collection standards procedure establised by the company?
If so, attach a copy
What training procedure are in place?
Do these cover basic collection procedures, storage conditions, personal hygiene requirements for collectors and pod crackers?
Inspector to elaborate on actual procedures observed as well as adequacy of manual

COMPANY

Does the Company carry out regular hygiene audits?
If so, how often? Daily, weekly, monthly?

What cleaning materials are used and where are they stored?

Does the company practice COSHH (Control of Substance Hazardous to Health)?
Details required.

What procedures are used for disposal of production waste from factory area?
How frequent is this procedure? Throughout the day, daily, weekly?

How often is waste removed from the factory premises?
What procedured are used?

What procedures are in place to prevent cross-contamination by waste foods?
Inspector to elaborate

What pest control procedured are in place?
Are chemicals used?
Are physical traps used?
How are they monitored?
Who is responsible for pest control?
Inspector to elaborate

Are there pest control procedures undertaken outside the factory
How and to what effect?

What systems are in place to control pests in the manufacturing and warehousing areas?
What do they cover - Rats and mice?
Crawling insects such as cockcroaches?
Stored product infestations such as flour beetles?
Birds and casual insects?

Are there ultra violed insect killing devices in use?
YES/NO
If YES, how often are they services? Service certificate available? At what frequency?

Are regular pest control reports prepared?
Do they detail corrective action?
Is follow up conducted on such corrective action?

The inspector should prepare an opinion on his/her understanding of the adequacy of the above procedures and include requirements for corrective/improvement measures as required.

How is the pulp processed from the seed?
By machine?
Is it a continuous process from the raw material entering the machine to the packaging point?
Is there material handling by humans during the process?

Hos is the grading procedure for the milled pulp conducted?
By colour? Who is responsible for this?
By particle size, machine sieving? Who is reponsible for this?

What procedures are in place for ensuring separation of the grades?
At storage level?
Are their procedures in place for blending operations between the grades?
If not how are they separate grades disposed of?

What is the period of time between the arrival of the raw material at the factory and its processing?
Less than 1 week
1 week to 1 month
1 month to 3 months
3 months to 6 months
Greater than 6 months

Batching procedured are to be detailed, enabling flow through and identification from supplier collection through to final despactch covering as follows:

- Goods Received Notes per supplier
- GRN covering bag number, supplier name, date of purchase, weight of purchase, grade, pri/Kg and total value of purchase
- Computerised records of above as appropriate
- Procedding schedule for each batch – manual and computer
- Storage schedule for each batch
- Despatch schedule for each batch

PACKAGING/LABELLING & DISTRIBUTION

Are all material supplied from the company clearly labelled and/or identified by name and/or description?
YES/NO
Is shelflife and/or 'best before' information provided and clearly marked on packaging?
YES/NO
Is Date of Manufacture provided and clearly marked on packaging?
YES/NO
Are batch or lot numbers provided and clearly marked on packaging?
YES/NO
Inspector to provide samples of above

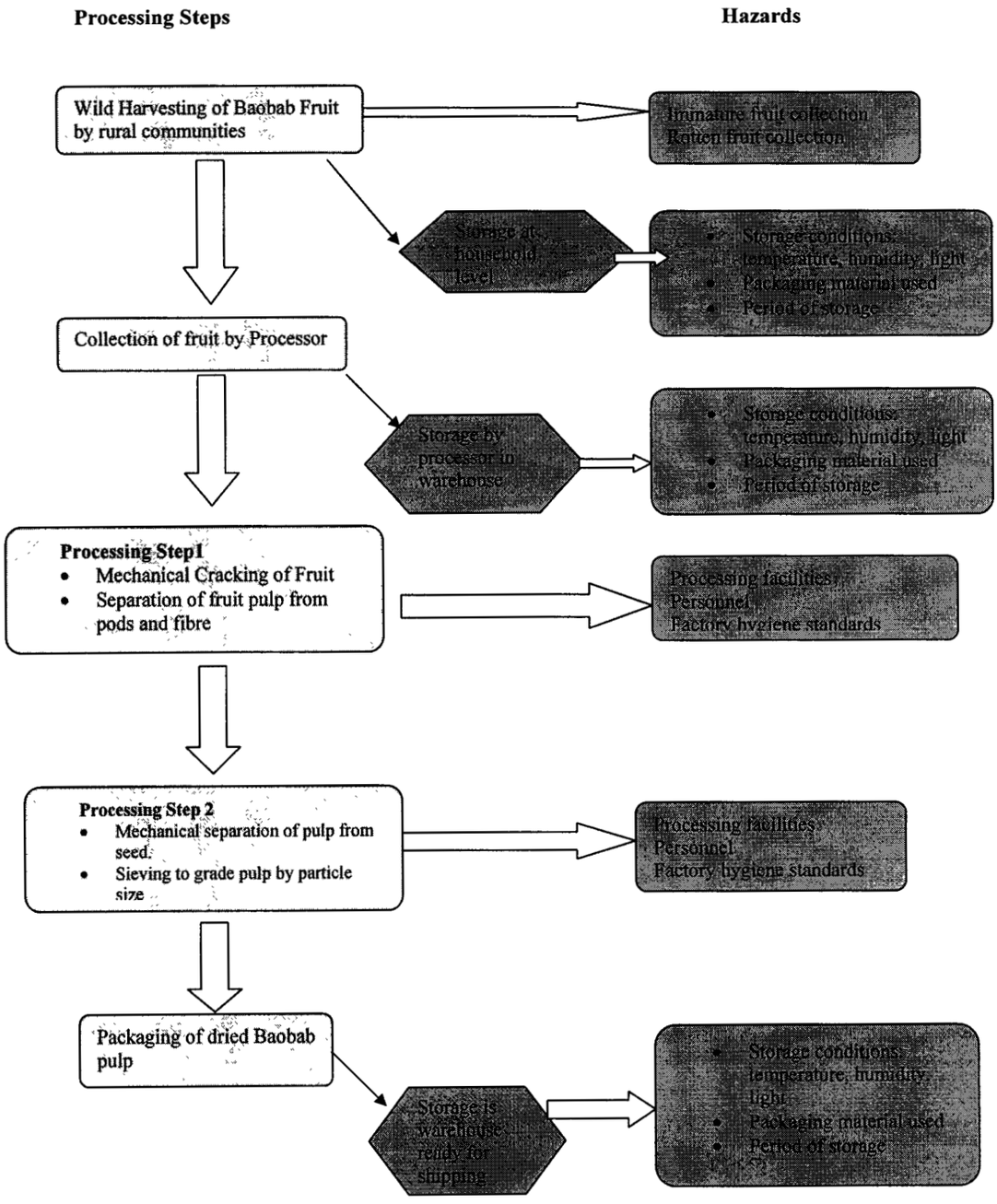
What methods are employed in packaging of finished materials?
- Plastic sacks?
- Heat sealed?
- Vacuum sealed?
- Outer packaged in paper sacks?

How are finished materials stored once packed?
- On pallets off ground?
- Are pallets waterproofed?
- Is the storage area temperature controlled? YES/NO
- If YES at what temperature?
- If NO, what are temperature extremes and averages?
- What light is available in storage? none, dayligh, electric lighting or other?
- What time is light in storage over 24 hour period?

In the opinion of the inspector are the storage arrangements satisfactory to ensure delivery of product in best condition? YES/NO
If NOT, recommendations/requirements to be included

What are the transport arrangement from the collection points to the factory?
Are the raw materials transported on own company vehicles from collection point to factory?
What procedured are in place to ensure cleanliness of transport arrangements so as to prevent any form of contamination
Inspector to elaborate on adequacy of procedures.

Appendix 5 - HACCP Chart for Baobab Pulp Processing



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NOTES

Control Points and appropriate Corrective action

1. **Wild Harvesting of Baobab Fruit**

A harvesting manual on proper harvesting techniques and the right quality fruit to harvest should be developed and given to community groups
Periodic training should be given to community groups on harvesting/ collecting good quality fruit
A trained quality controller should be in place here. Their responsibility is to inspect the fruit and to remove or reject any fruit that does not meet the requirements e.g. immature fruit, cracked fruit and rotten fruit
At collection:

- Collectors should ensure correct identification of species
- Quality collection
- Optimal time of harvest
- Collectors should minimize contact with the soil
- Collectors should be provided with new, clean, bags only in which to place newly collected fruit from the field
- Where possible, collectors should be encouraged to clean their hands prior to picking up fruit for collection
- Collectors should be advised to avoid collecting any rotten or poor quality fruit
- Collectors should be advised to avoid collecting wet fruit
- Collection of fruit should be as soon as possible after it has fallen from the tree

2. **Processing Step 1**

Use of approved processing equipment
Inspection and maintenance of equipment
Periodic monitoring of hygiene of workers
A detailed processing manual should be given to processors
Processors should be adequately and periodically trained in all aspects of processing
Occasional swabs should be taken on equipment and operating environment to check for microbial contamination
Inspection before processing

- visual removal of obvious cross contaminants
- removal of all foreign matter
- removal of damaged or otherwise impaired fruit etc

Primary processing of fruit

- Dried fruit is broken open by mechanical means using a specially designed machine called a beater bar mill
- The pod material is separated from the pulp on seed and excess fibres attached to the seed are carefully removed
- This exercise – whether at village level or at factory level – should be conducted:
    - Off the floor
    - On clean, dry surfaces
    - Under strict hygienic conditions – soap and water should be available at all times and crackers should not handle the fruit

pulp at any time unless their hands have been cleaned with soap and water

- Clean, dry, new receptacles must be available for the storage of the cracked fruit

3. **Processing Step 2**

Use of approved processing equipment
Inspection and maintenance of equipment
Periodic monitoring of hygiene of workers
A detailed processing manual should be given to processors
Processors should be adequately and periodically trained in all aspects of processing
Occasional swabs should be taken on equipment and the operating environment to check for microbial contamination

4. **Packing of dried Baobab pulp**

Use of approved packaging material
Frequent monitoring of hygiene standards during packing

5. **Storage of material (fruit or pulp)**

Environmental monitoring
Humidity should be checked though the use of a hygrometer
Light – Direct sunlight on any material should be avoided
Temperature should be regularly checked through the use of a thermometer that is mounted on the walls of the room. Temperatures should not be higher than 30 deg C.

At storage by collectors:

- Collectors should be encouraged to store collected fruit in clean, dry areas of their houses
- Collectors should be encouraged to store collected fruit away from areas that are frequented by children, dogs, chickens, goats etc
- Co-ordinators should gather in fruit from collectors as frequently as possible during fruit collection periods
- Collectors must be briefed on how to store the fruit in their houses – in clean dry areas, away from children and livestock, off the ground
- Fruit should be collected as frequently as possible for bulk storage at processor

Bulk storage at processor

Cracked Fruit should be kept:

- In new, clean bags
- On receipt for storage all bags should be checked for rotten and substandard fruit, which should be removed from the bags
- Off the floor. Simplest and easiest is placing poles on bricks and piling the bags on top of the poles, giving an airspace of approx 3-6 inches off the floor
- Bags stacked bags away from the walls – at least 6 inches gap from the walls
- Ideally the storage room should be in the dark, at the very least the bags should be kept out of direct sunlight
- Ideally the storage room should be temperature controlled, at around 0-5 degrees C. If not possible, the storage room should be as cool as possible
- The storage room should be dry – no potential for leaking from the roof or for water to drain in from elsewhere on the floor
- No other potential contaminant material should be kept in the same store room

6. **Processing facilities**

Location Processing facilities should be in areas free from bad odours, smoke, dust and all other potential contaminants, including chemicals, and be away from any potential flooding.
Roadways Roadways around the processing facilities should be paved so as to prevent generation of dust and thereby contamination of the raw material. The roads should drain well and should be able to be cleaned
Buildings All buildings should be soundly constructed and in good repair, including non-leaking roofs. Use of materials that cannot be adequately cleaned and disinfected, such as wood, should be avoided as they are a potential source of contamination. Construction materials that exude toxic substances, such as plastics, should also be avoided. Layout and design should be such that "dirty" areas, for use in drying or milling, should be isolated from "clean" areas, for use in oil pressing for example. Preferably "dirty", "clean" and storage areas should all be in different buildings.
Additional desirable building characteristics should include:

- Adequate working and storage space for all expected operations
- Facilitate efficient and hygienic operations through enabling a flow through from arrival of raw collected materials to dispatch of final processed materials
- Enable appropriate control of temperature and humidity
- Enable separation of "dirty", "clean" and storage areas
- Permit control of access to different sections as required
- Enable easy and adequate **cleaning and to** facilitate proper supervision of hygiene
- Prevent access by environmental contaminants such as dust and exhaust fumes
- Prevent access and harbouring pests, livestock, domesticated animals and pets
- Prevent access by unauthorized personnel

Plant material handling areas These should all be designed and constructed so as to enable clean hygienic conditions to be maintained at all times as well as for ease of cleaning and disinfecting as necessary:

- **Floors** should be waterproof, non-absorbent, washable, non-slip and constructed from non-toxic materials. Floors should slope sufficiently for liquids to drain away into trapped outlets (the new EWC factory is an excellent example of this
- **Walls** should be covered with waterproof, washable, non-absorbent materials, sealed, free and maintained free of ALL insects. They should be light coloured, smooth and without crevices, as well as being sealed to enable cleaning and disinfecting. The sharp angles between individual walls and each other as well as the joins to the roof and the floor should be gently curved so as to prevent the accumulation of dust as well as easy dust removal
- **Ceilings** should be constructed so as to prevent the accumulation of dirt and to minimise condensation, mould development and flaking - as well as being easy to clean
- **Windows** should be constructed so as to prevent accumulation of dirt and those that open should be screened to prevent insect entry. These screens should be kept clean and in good repair. Internal sills should be sloped to prevent use as shelves
- **Doors** should be smooth, non-absorbent, close fitting and preferably self closing
- **Living quarters, food preparation and eating** areas, **changing** facilities, **toilets and areas where animals are kept** should be completely separate from plant material handling and processing areas and should not open directly onto them.

Water supply An ample supply of water, under appropriate pressure, together with storage facilities, should be available. Potable water for washing and sterilization should also be available.

Effluent and waste disposal Facilities should be designed and constructed so as to be able to handle expected peak loads and be maintained at all times in good repair and order. Contamination of potable water supplies should be prevented.

Changing facilities and toilets These should be adequate for expected employment levels and conveniently located for operations. They should be well lit, easily cleanable and should be kept clean at all times. Hand washing facilities, with hot and cold water availability should be on hand. Along with suitable hand cleaning soaps and methods of drying. These should be located next to the toilets and in such a manner that employees have to pass them on t heir way to the exit. Notices should be posted directing personnel to wash their hands after using the toilet.

Lighting Should be adequate natural or artificial and should not alter colours. Fixtures and bulbs located over processing areas should be protected to prevent contamination in the event of breakage

Ventilation Should be adequate to prevent excessive heat, steam condensation and dust, and ot remove contaminated air. Air should NOT flow from a "dirty" area to a "clean" one.

Storage of waste and unusable materials There should be full provision of containers for storage of waste and unusable materials before they are removed from the premises. Pests should not be able to access these containers. The containers should be clearly marked and emptied daily or more frequently as required.

7. **Personnel**

- All personnel involved in harvest and related procedures should maintain appropriate hygiene and should have received training in respect of their hygiene responsibilities
- Personnel with illnesses, especially those that could be carried through plant material should be excluded from all contact with plant material
- Personnel with open wounds, skin diseases etc and those suffering food borne diseases eg dysentery and diarrhoea should be suspended from working with the plant material until fully recovered
- Personnel should ensure regular washing of hands, especially after going to the toilet
- Smoking and eating in vicinity of collected material should not occur

Annex 1

Sources of contamination to watch out for

The main sources of microbiological contaminants for fruit and eventually pulp are in their collection, handling and storage.

- **Collection** When fruits drop from the tree onto the ground they are immediately vulnerable to picking up a wide variety of pathogens on their surfaces. The ground around the tree will have moisture and this immediately gives rise to the potential for yeasts and moulds to start to form. Human and animal activity under and around the tree will give rise to the presence of e.coli, salmonella and other pathogens.
- **Rotten material** Inclusion of rotten fruit and other material with healthy, dry fruit will lead inevitably to deterioration and rotting of otherwise healthy fruit
- **Handling** Human contact with fruit can be especially hazardous from the viewpoint of contamination, especially in areas where it is not easy to maintain hygienic standards.
- **Fruit cracking** Where processor collection is of fruit, cracking of the fruit and subsequent storage of the pulp on seed should be undertaken in as clean and hygienic conditions as is possible.
- **Collecting bags** Often fruit is collected from the wild and placed in any old container/bag, that may have been used for any number of purposes in the past ranging from, say, storage of chicken food through to storage and transfer of chicken manure. Prior to be used for the harvest of fruit, it may have been slept on by the village dog. All provide significant opportunities for contamination.
- **Storage at collector level** Once bags have been filled with fruit and before they are collected and stored in bulk by the processor further opportunities for contamination are numerous. The bags full of fruit may be stored on damp patches of earth, enabling water to seep through into the bag and cause further moulds to form. Bags may be stored in areas where there is a prevalence of rubbish etc.
- **Bulk storage** Once the bags full of fruit have been collected in from rural areas and are stored at the processor prior to processing, there still remains potential for further contamination. Storage on the floor and/or against walls enables absorption of moisture through condensation with attendant risks of mould formation. Storage in too hot conditions can lead to the rapid multiplication of microbes as well as rotting of seed.

Minimising the risks of microbiological contamination involves much in the way of common sense as well as providing all concerned with the greatest awareness of the needs for hygienic handling of the seed at all times.

Appendix 6 - PhytoTrade Africa searches and report on the history of use of Baobab Fruit Pulp from around the World.

BAOBAB (Adansonia digitata) FRUIT PULP

Combined reviews of Michel Mallet (Paris) and Rosie Abdy Collins (London)

Structure

1. Informal Trade
2. Documented use in Europe
3. Documented use in Africa
4. Documented use in Rest of World
5. Historical use in Africa
6. References/Annexes

1. Informal trade:

- **Paris (Michel Mallet's research)**

The "pain de singe" (seeds with pulp) was only found in some of the African & exotic food shops in very few areas of Paris and suburbs. These areas are those customised (and most often inhabited) by West and Central Africans (and North Africans).

The main area of concentration of these shops is the Barbes – Chateau Rouge – Marcadet Poissonniers area (North of Paris in the 18th arrondissement), particularly in "rue des Poissonniers" and adjacent small streets. Nothing was found in the Belleville area (North-East of Paris at the corner of the 10th, 11th, 19th and 20th arrondissements). Some shops were identified in Montreuil, a close suburb of Paris to the East. Other African shops could probably be found in other areas of Paris *intra muros* and suburbs, but this was not explored further (it is likely that the number of such shops is far less). No baobab fruit or baobab product was found on the weekly street markets (but Devil's Claw in sliced dried form was found once at the Belleville market), nor in 'posh' health and exotic food shops.

Rue des Poissonniers:

There are approximately 20 African & exotic food shops in and around "rue des Poissonniers", which typically sell North, West and Central African food stuffs, as well as Chinese food products. Less than half of them had baobab fruit products. The shop managers of the others said it is because it does not sell much. The shops with baobab mainly sell "pain de singe" (seeds with pulp) in small plastic pockets from around 200g to 500g (price from €1.00 to €2.50). The turnover seems very low considering the few bags displayed (and difficulty to find). Only one shop was selling whole baobab fruits (said to be from DRC?) at €1.00 per kg. All the baobab products on the shelves did not look particularly fresh. In any case, the "pain de singe" is poorly packaged with no label. (One bag with the identification of the shop was purchased and could be pictured).

Typically these shops are small, low-standard and messy, and it is not sure if they would pass a health and hygiene inspection. This might explain the extreme suspicion expressed by the shop managers and reluctance to respond when asked anything specific about the trade in baobab. Furthermore, half of the African & exotic food shops are owned and managed by Chinese, who hardly speak French (except for counting money). Another third are owned and managed by North Africans, the rest of the shops seems to be owned/managed by West Africans, particularly from Ivory Coast (at least 3 shops), and also Togo and Congo.

It seems that most "pain de singe" is occasionally imported from Senegal (and probably Mali) together with typical products such as millet and fonio flours. However, most other sub-Saharan food stuffs seem to be originating from West-Central Coastal Africa (Ivory Coast, Cameroun…), i.e. roots and tubers, tropical fruits, chilis and condiments. It is therefore suspected that there are at least two trade routes for importing baobab fruit pulp into France, one through Senegal (and probably from inland Mali) and another one through Ivory Coast (and probably from neighbouring countries). From the limited information gathered, it also seems that the shops are only involved in retailing, including "pain de singe", and are not directly involved in importing the products. They seem to buy from specialised traders, who could unfortunately not be identified.

Information gathered in these shops (and from other sources) tend to indicate that the trade in "pain de singe" is not new (therefore prior to May 1997) but this could not be substantiated further.

- **Sweets in Germany**

There have been reports of Baobab pulp sweets sold in post-war Germany, however preliminary phone calls to German sweet shops have yielded nothing so far. Jens Gebauer was told of these sweets by his supervisor who had consumed the sweets as a boy. Jens has subsequently searched Berlin for evidence of this but found no proof.

N.B. Jens Gebauer author of:
Okophysiologie und Verwendungsmoglichkeiten der Wildobstarten Adansonia digitata und Tamarindus indica im Sudan.

2. Documented use in Europe:

- Most current imports to Europe are to Italy, through the Baobab Fruit Company.

a) Email from Baobab Fruit Company 21st April, 2005:
"I don't really know how many Baobab Pods are imported anually, but I'm sure that the 90% of baobab Based products that you can see on the market are maded with our *(Baobab Fruit Company)* Raw Materials... Our quality has become a reference for a lot of producers...all over the world.

Here our production:
2001: 300 Tons of Pod - Senegal & Gambia (Very good quality)
2002: 80 Tons of Pod - Mali (Good quality but a lot of Problems due to corruption)
2003: 20 Tons of pod - Mozambique (Very Bad quality, with a lot of insects)
2004: 160 Tons of Pod - Senegal - Tambacounda (Very Good Quality)
2005: 140 Tons of Pod - Senegal - Tambacounda (Very Good Quality)"

b) Vertuani S, B., E, Buzzoni, V, Manfredini, S. (2002)
This Italian study compares the anti-oxidant content of a selection of teas e.g. Green tea pods, Baobab flavoured. The methodology describes how all teas were bought from specialist small shops or supermarkets (presumably in Italy). A subsequent email to Stefano Manfredini (29th October, 2004) confirms that the company producing the pods is D.o.c. S.r.l., Castel San Pietro Terme (BO), Italy and the company supplying the Baobab component is Baobab Fruit Company, Verona, Italy.

Baobab Fruit Company
http://www.baobabfruitco.com/

New Agriculturalist
http://www.new-agri.co.uk/03-6/focuson/focuson3.html

- Historically, Baobab fruit pulp has been lauded as both a medicinal product and a food ingredient. The Encycopaedia Britannica implies that Baobab was imported for medicinal purposes. It was used as an ingredient for the much demanded Terra lemnia (terra lemnia sigillata = the stamped tablet); a pill taken with water to treat poisoning, hemoptysis, dysentery and fever; and used topically to treat festering wounds. The trade was administered from Northern Africa into Italy and was fuelled by the regular caravan routes travelling northwards to Egypt.

Alpini, P. (1592)
Basilerskaia, V. (1969).
Bircher, A. and Bircher, W. (2000)
Encyclopaedia Britannica (1797)
Freller, T. (1998)
Hasluck, F. (1909-1910)
Irvine, F. R. (1961)
Merat, V., Francois, V. and Lens, A. (1829)
Nunez, B. (1995)
Owen, J. (1970)

- As a food ingredient, Baobab fruit pulp, has been used for bread making. During the East Africa Campaign in World War I, the fruit pulp was used as a leaven in making bread (Watt and Breyer-Brandwijk, 1962). Prior to that there were significant exports (several tons) to England, where the pulp was used in the production of tea cakes (Keraudren, 1963 and Mogg, 1950).

- **Food recipes based on baobab fruit pulp (in French):**
  Baobab fruit juice recipes were found on the web.
  One peculiar mention of a baobab fruit pulp ice cream was found in a French Chef menu of Jan. 2002
  http://perso.wanadoo.fr/denis.feldmann/gagnaire.htm

- A news article (Annex 5) 'European Sportsmen: Champions boosted with Baobab' dated 27 Oct. 2004 (by Madieng Seck, Syfia Sénégal) is devoted to the baobab product launch of BFC – Italy & Senegal subsidiary (see full newsbrief in attached document *Additional French Reference on Baobab*). The article mentions the baobab food supplements provided to Italian cyclists, a Formula 1 race driver and AC Milan soccer players.

- Queries have been made at Public Records Office, HM Customs and Excise, UK Trade & Investment, British Library, Kew Gardens, National Statistics, French customs service (DGDDI) "Douane", French Internal Trade Authorities (DGCCRF) but all requests for trade, culinary and medicinal information have returned negative.. Queries have been made at the London Chamber of Commerce but a search into company literature is dependent upon becoming a member (£394.80/an).

- **EINICS Plus/ ELINCS number :** 294-680-8 for Adansonia digitata extract

- **Conclusion:**
  Baobab has been consumed within the EU both in recent times (post and pre- 1997) and historically. The historical literature refers to its use as a medicinal and food product. No claims are made to its historical toxicity. Recent documentation of its trade and usage in EU is sparse, however there is evidence proving that there is an informal trade in Baobâb fruit pulp (France and Italy). There have been no recent adverse reports concerning Baobab despite this informal trade.

3. Documented use in Africa

- **Baobab oil exported from Madagascar in 1926 (104.992 kg)**
  Institut colonial de Marseille (1926) Le commerce et la production des colonies francaises. Marseille, Institut Colonial.

  However no further information available- was it exported to France? What was the oil used for?

- **Baobab pulp consumed in Mali**
  A quantitative food-frequency questionnaire was conducted on 34 women (15- 45yrs) and 36 men (15-45yrs) from 29 households from Ouassala in Western Mali. Discussion groups were organized pre-study to determine the food categories and the types of food that are consumed in the region. Baobab pulp was listed under 'Fruit': other categories were cereals, milk, meat/eggs, fish, legumes, vegetables, green leaves, salt, sweets, edible fats. The results indicate that Baobab pulp is consumed on a regular basis and the category 'fruit' is consumed second to cereals on a daily basis.

- **Countless references to Baobab fruit pulp's widespread African traditional use** as a refreshing and wholesome drink, a nutritional food based on the mineral and protein content and as a traditional medicine. It is even used in Baptismal ceremonies as an ingredient for the traditional dishes. Uses are 'domestic culinary' but also by physicians to treat fevers, diarrhea and other diseases. None of the following references contain any reference to the pulp's toxicity. Most papers on Baobab list subheadings- botanical description, ecology, food value, medicinal uses, indicating that its function as a food source and medicine are major components of its widespread use across the African continent. Use is often singled out to be mostly amongst children and pregnant women.

The Chemist and Druggist (1907)
Ake Assi, L. (1991)
Andy, E. and Eka, O. (1985)
Baobab fruit company www.baobabfruitco.com
Barminas et al (1998)
Basilerskaia, V. (1969)
Berhaut (1974)
Bircher, A. and Bircher, W. (2000)
Booth, F. E. M., Wickens, G.E., (1988)
Bosch, C., Sie, K. and Asafa, B. (2004)
Campbell, A. (1986)
Carr, W. R. (1955)
Carr, W. R. (1958)
Chaumeton, F. (1814)
Christy, T. (1878)
Diop, P. A., Frank, D., Grimm, P., Hasselmann, C., (1988)
Doumbia + Doumbia (2004)
Dweck, A. (1996)
Elujoba, A. A. (1995)
Encyclopaedia Britannica (1797)
Engelter, C., Wehmeyer, A.S., (1970)
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FAO website *Adansonia digitata* www.fao.org.
FAO and USDA (1968)
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Hartwell, J. L. (1968)
Hepper, F. N. (1976)
Hocking, G. (1997)
Imperial Institute (1906)
Imperial Institute (1913)
International Centre for Underutilized Crops (2001)
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Rodin, R. (1985)
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Parr (2002)
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Proll, J., Petzke, K.J., Ezeagu, I.E., Metges, C.C., (1998)
Redwood, T. (1857)
Salami, L. I., Okezie, U.N., (1994).
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Society for the Diffusion of Useful Knowledge (1840)
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Watt, G. (1885)
Watt, J. M. and Breyer- Brandwijk, M. G. (1932)
Watt, J. M. and Breyer- Brandwijk, M. G. (1962)
Wehmeyer, A. S. (1986)
Weiss, E. A. (1979)
Wickens, G. E. (1980)
Wickens, G. E. (1982)
Williamson, J. (1955)
Wittstein, G. (1882)

4. Documented use in rest of world:

- **Canada:**

Baobab oil and extract are listed in the, "Substances in cosmetics and personal care products regulated under the Food and Drugs Act (F&DA) that were in commerce between January 1, 1987 and September 13, 2001"
The document may be accessed from:
www.hc-sc.gc.ca/ear-ree/87_01_no_cas_num_e.pdf
p18 documents Baobab Oil and Baobab Extract

Response from Food Directorate of Health Canada is pending (Monique_Routhier@hc-sc.gc.ca)

- **India:**

Adansonia digitata is widespread in India and is similarly consumed by Indians (Simmonds, 1854).

- **Australia:**

Adansonia gregorii (known as boab) is considered by the Australian Government as 'not novel' and was therefore given 'food' status in March 2005 (Novel Foods Standard of Food Standards Code, 1999). Foods that have previously been consumed by small communities (whether in Australia, New Zealand or abroad) and are now being made available to broader communities are considered on a different basis from other categories of novel foods:

<u>Known potential for adverse effects in humans</u>

> Foods that are non-traditional in Australia or New Zealand may be widely consumed in other countries. In some cases, there are reports in the scientific literature of adverse effects associated with consumption of these foods. Such foods may warrant assessment, particularly as consumption patterns of these foods may be different in other countries and the foods may or may not be accompanied by dietary advice.

Single ingredient foods/whole foods

This category includes foods that have not traditionally formed part of the diet of the broad community in Australia and New Zealand, such as foods from other parts of the world, traditional indigenous foods, or new foods produced from traditional breeding techniques.
While there are many new foods on the market, it is likely that only those where there is some evidence of potential adverse effects would be considered novel. Single ingredient foods may need to be considered under Standard 1.5.1 because of the level of undesirable substances in the product, known potential for adverse effects in humans, and/or the use of traditional preparation and cooking techniques.

www.foodandwinelovers.com.au/features.php?id=92&seriesID=4&episodeID=0 (refer to Melissa Boots emails)
http://www.foodstandards.gov.au/search/index.cfm (search 'boab')
http://www.foodstandards.gov.au/_srcfiles/Novel_Food_Guidelines_March_2005.pdf
http://www.foodstandards.gov.au/_srcfiles/Novel%20Food%20Guidelines%20-%20March%202005.pdf
(guidelines and novel food decision tree)

- **America**

The Dispensatory of the United States of America (combines The British Pharmacopeia, The National Formulary and The United States Pharmacopoeia) lists Adansonia digitata as a medicinal and food source in the following editions:

Edition	Authors	Date	Mention Adansonia
1	Wood + Bache	1833	No
2	Unable to obtain copy		
3	Wood + Bache	1836	No
4	Unable to obtain copy		
5	Wood + Bache	1843	No
6	Wood + Bache	1845	No
7	Unable to obtain copy		
8	Wood + Bache	1849	Yes
9	Unable to obtain copy		
10	Unable to obtain copy		
11	Wood + Bache	1858	Yes
12	Wood + Bache	1865	Yes
13	Unable to obtain copy		
14	Wood + Bache	1877 (1880)	Yes
15	Wood, Remington + Sadtler	1883	Yes
16	Wood, Remington + Sadtler	1891	Yes

17	Wood, Remington + Sadtler	1894	Yes
18	Wood, Remington + Sadtler	1899	Yes
19	Wood + Bache	1907	Yes
20	Remington + Wood	1918	Yes
21	Wood + LaWall	1926	Yes
22	Wood + LaWall	1937	Yes
23	Wood + Osol	1943	Yes
24	Osol + Farrar	1947 (1950)	Yes
25	Osol + Farrar (Vol 1) Wood + Osol (Vol 2)	1955 (1960) 1960 (1950)	No No
26	Osol, Pratt + Altschule	1967	No
27	Osol + Pratt	1973	No

6. Historical use in Africa

Archaeological evidence indicates that current day usage can be extended back in time to stone age man. Based on the reality that the Baobab tree plays a significant part in the day to day life of many communities within Africa today (Hadza, San, Mandeetc.) archaeologists have used the Baobab tree as an indicator of historical settlements across the continent. The debate rings as to whether the Baobab followed humans or vice versa but nonetheless from both sides of the debate the truth that Baobab and human settlement are connected is maintained.

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Not a direct use in Europe but was used in Africa as bread leaven during East Africa Campaign in World War I.

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Annex 4.

Adansonia digitata (Bombacaceae) toxic and anti-nutritional components

Botanical name	Country of origin	Plant part	Type of extract	Type of test	Toxic level	Toxic constituent and method of activity	Type of molecule		Source

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M. Mallet - March 2005

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-> See web pages in file "Baoblog"

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-> See web page www.refi.fr/fichiers/MFI/Sante/975.asp enquête SUVIMAX (Supplémentation en vitamines et minéraux antioxydants) par Serge Hereberg (INSERM) sur 13 000 volontaires adultes sur 8 ans

USAID Senegal '**Augmenter la commercialisation de produits agricoles non traditionnels et des produits naturels'**
-> See web page www.usembassy.state.gov/dakar/wwwhaidst1fr

Repas chez Pierre Gagnaire (page personnelle de Denis Feldmann)
http://perso.wanadoo.fr/denis.feldmann/gagnaire.htm
Menus et cartes de Pierre Gagnaire - Encore un exemple parfait: janvier 2002.
Le grand dessert : fruits d'hiver en salade confite (poires, cédrat, pistaches...); mandarine et **glace au pain de singe (le fruit du baobab)**; macaron aux fraises des bois et framboises; margarita comme un sorbet mousseux; pagode en chocolat.

Jumelage Coopération des villes de Quetigny (France)-Bous
<http://www.jumelagequetigny.org/francais/temoignages.htm>
... bâché" de Youssouf. Je me souviens du "pain de singe", **fruit** du **baobab**, savouré comme confiserie par les enfants.

Suppliers of baobab products (in France & Africa)

BFCS (Baobab Fruit Company SENEGAL sarl): Raw materials & extracts for alimentar, nutritional & cosmetic field since 1999 (sic)
web site under reconstruction - we will be online wednesday 09 march 2005
Contact: Laudana Zorzella (SENEGAL) +221 952 27 52 +221 5647092
laudana@baobabfruitco.com <mailto:laudana@baobabfruitco.com>
<http://codicepro.shinystat.it/cgi- <mailto:webmaster@baobabfruitco.com>

CECODI (Centre International d'Ecodéveloppement Intégré) **Cotonou, Bénin**
cecodibenin.africa-web.org [see web page]
-> Sirop de Baobab, purée de Baobab

CONFEJES (Dakar, Sénégal): Baobab juice, www.confeges.org
-> See web page & illustration "Fabrication et vente de jus à base de produits locaux (pain de singe, ...)

ENTREPRISE INTERCONTINENTALE DE NEGOCE: Toutes entreprises intéressées par les produits dérivés du baobab pouvent nous contacter à l'adresse suivante : Entreprise Intercontinentale de Négoce, 30 avenue Amadou G Sow, Thies – Sénégal, Tel: 221 9517060 Mobile: 221 5738640, Fax: 221 9564092, E mail: internegoce@sunumail.sn

ETHNOGENS: 1 Lb (454 gm) Baobab tree bark US$25.00 (against fever)
www.ethnogens.com [see web page]

FREE WORKS SERVICES ("La maison du consommer sénégalais"): Baobab juice in polyethylene bags, Dakar, Sénégal
-> Mrs Aïsatou Diagne Dème, since 1995; see web page 'B16 Conditionner en sachets polyethylene pré-imprimés'

HEVEA (Labo Hévéa): Huile végétale Baobab sauvage, www.labo-hevea.com
-> Baobab seed oil cold-pressed 60 ml

Podoartisanat.com: fruit du baobab sauvage

sachet de 30 € 12,96
Assistance technique : 06 77 19 16 21

VAGHEGGI COSMETIQUE: Vagheggi Ligne Adansonia, crème contre les vergétures
-> Baobab extract cream [see web page]

Sportifs européens : Des champions dopés au baobab (mercredi 27 octobre 2004)

Une société italienne, en partenariat avec un entrepreneur sénégalais, commercialise de la poudre de fruits de baobab. Un nouveau complément alimentaire très apprécié des champions sportifs européens.
Le secret de la réussite du cycliste Damiano Cunego, vainqueur en mai 2004 du Tour d'Italie ? La poudre de fruit de baobab, qualifiée de "pozione magica" par le quotidien italien Corriere Del Veneto. Des joueurs de foot du Milan A C ainsi qu'un pilote de Formule 1 italien vantent eux aussi les mérites de ce complément alimentaire vendu sous la marque Baobab déposée par la société italienne Baobab Fruit Company (BFC).
Le baobab (Adansonia digitata), dont presque toutes les parties sont utiles et en particulier les fruits appelés pains de singe, procure depuis toujours aux populations d'Afrique tropicale et de Madagascar toutes sortes d'aliments et de remèdes traditionnels. Les feuilles et la pulpe du fruit contiennent du calcium, du phosphore, des vitamines B1 et C aux propriétés anti-oxydantes bien connues. Ces dernières années, les universités africaines et occidentales se sont intéressées aux divers produits de cet arbre spectaculaire. A Dakar, plusieurs thèses de doctorat en pharmacie lui ont été consacrées.
Les produits naturels à la mode
C'est dans cette même capitale sénégalaise qu'il y a deux ans, Mamadou Dia, le jeune directeur d'Intercontinentale de négoce, féru de produits naturels africains, rencontre les responsables de la société italienne BFC. "Depuis, nous avons développé notre partenariat pour exploiter le baobab et d'autres plantes naturelles dans la pharmacopée, la cosmétique et l'alimentation", révèle Mamadou Dia, rencontré en septembre à Dakar lors de la 4ème conférencce internationale sur les produits naturels africains issus des plantes.
En marge de cette conférence, le stand de Baobab Fruit Company (BFC) déclinait toute une gamme de produits à base de baobab : crèmes de beauté, déodorants, tisanes et bien sûr compléments alimentaires présentés dans de magnifiques emballages haut de gamme. "Nos produits sont officiellement reconnus en Italie. Ils sont aussi vendus en pharmacie en Suisse, en Espagne et en Allemagne", précise Mme Laudana Zorziella, gérante de la branche sénégalaise de BFC qui rêve de conquérir le Japon et le reste de l'Europe dès l'année prochaine. La société italienne fournit déjà en produits bruts ou semi-finis des firmes internationales comme Unilever. Le vieux baobab va donc profiter de la mode des produits naturels et des médicaments à base de plantes dont le marché aux Etats-Unis et en Europe a augmenté de 10 % par an ces dix dernières années.
La branche sénégalaise de BFC se charge de collecter et d'acheter les produits du baobab aux producteurs. Son unité de traitement, installée à Thiès (70 km de Dakar), emploie 140 personnes, en majorité des saisonniers. "Depuis le début de notre partenariat nous avons vendu plus de 140 t de fruits de baobab", déclare Mamadou Dia.
Le jeune homme d'affaires traite avec des associations comme Wula Nafaa (l'utilité de la forêt en bambara) dans la région de Tambacounda (470 km au sud de Dakar). Soutenue par l'USAID, la coopération américaine, Wula Nafaa encadre des groupements de femmes pour une exploitation rationnelle du baobab. Les fruits, par exemple, ne peuvent plus être récoltés en dehors d'une période fixée en concertation avec les villageois. Les producteurs qui ont vu leurs prix doubler en cinq ans (entre 60 et 80 Fcfa le kilo de fruit), se réjouissent d'autant que la demande devrait elle aussi doubler en 2005.
Wula Nafaa, Mamadou Dia et Baobab Fruit Company vont élaborer un programme de développement durable qui prévoit de replanter des arbres. Son but : approvisionner le marché européen en fruits sans nuire à l'espèce.
Madieng Seck (Syfia Sénégal)

Appendix 7 – Edited version of Baobab questionnaires

List of Respondents to the "Traditional consumption and safety of baobab (*Adansonia digitata*) fruit" Questionnaire:

1. Professor [redacted] University of Malawi. Malawi.
2. [redacted] UNICEF. Zimbabwe.
3. [redacted] Institut d'Economie Rurale (IER). Mali.
4. [redacted] ILIFA KNOWLEDGE SYSTEMS. RSA and surrounding countries.
5. [redacted] Letloa Trust, Land Livelihoods and Heritage Resource Centre. Botawana.
6. [redacted] Royal Botanical Gardens Kew. UK.
7. [redacted] Self-employed consultant. South Africa.
8. [redacted] PROTA, Wageninge University. The Netherlands.
9. [redacted] SAFIRE. Zimbabwe.
10. [redacted] Department of Health. South Africa.
11. [redacted] University of Ferrara. Italy.
12. [redacted] University of Abomey-Calavi. Republic of Benin.
13. [redacted] The University of Agriculture, Abeokuta. Nigeria.
14. [redacted] University of New Mexico School of Medicine. USA.
15. [redacted] Royal Botanic Gardens, Kew. UK.

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: [redacted] College University of Malawi

Job role: Lecturer, Teaching and Research

Country: Malawi

City/Town/ District: Zomba

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes, the local communities use the fruit as food and or as fruit drink. This is the case across the country.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?
   N/A.

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   The fruit is cracked and the edible white pulp is chewed directly by young and old people countrywide (People in the Rift Valley areas are the most important uses. The edible pulp with the seeds is soaked in water, stirred and the resulting juice drank. Consumption is across the various categories of people, healthy or sick persons. Large quantities are now being sold in urban markets to serve those in cities/towns.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   No.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   Not applicable.

6. Please make any other comments.
   We have determined the quality of oil from the seed kernel. Although the oil is rich in oleic and linoleic acids, it contains some trace amounts of malvalic acid which is toxic. Although the seed kernel is sometimes processed in flour for vegetable seasoning, the toxic associated with the kernel use remains unknown.

Signed: [redacted]. Date: 4th July, 06

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: UNICEF

Job role: Nutritionist

Country: Zimbabwe

City/Town/ District: Harare

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes, it is soaked in water and used as a drink or the water is then used to make sour porridge.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?
   N/A.

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   Baobab is consumed by both young and old. It is widely consumed in Hwange and Binga districts.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   No.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   I have worked with women in the community and particularly to increase the variety and nutrient density of foods for young children.

6. Please make any other comments.
   The leaves are also used as a vegetable and seeds as an energy source.

Signed: [redacted] Date: 05/07/06

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation : Institut d' Economie Rurale (IER)

Job role: Senior research scientist

Country: Mali

City/Town/ District: District of Bamako

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   The pulp of baobab fruit is traditionally dissolved in water or milk and the liquid is used as a drink. It is generally incorporated to cereal as a substitute to milk for young or old people. It is widely consumed in all countries of West Africa, particularly in arid and semi arid zones.
   It is popular in Senegal and largely used in Mauritania, Mali, Upper Volta, Niger, Nigeria, etc... It is manufactured in Mali.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   No.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   Since 1991 I conducted research on baobab fruit. There is significant potential for selecting trees and clones with high vitamin C content. The study indicates that the traditional grouping of baobab on trunk colour is not useful as selection criteria for vitamin C content. Very high vitamin C levels could be found in all major tree types in Mali. The other study indicates that it is possible to store pulp of baobab fruit for a year with a very low rate of vitamin C reduction. All these information can be found in the baobab monograph edited by ICUC ''Fruits for future 4''.

6. Please make any other comments.
   It is a good dink recommended for health according to its mineral and height vitamin C content. Taking into count of the importance of baobab tree in Mali, you can create a transformation unit.

Signed: [redacted] Date: 5th July 2006

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: ILIFA KNOWLEDGE SYSTEMS

Job role: Ethno-botanist

Country: RSA and surrounding countries

City/Town/ District:

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   The mesocarp of the young fruits, along with the soft seeds, are cut up and boiled as a vegetable. Eaten by old and young.
   The powdered mesocarp is mixed with water or milk as a refreshing drink for old and young. The powder is used as a substitute for baking powder. It is also used as a remedy for a running stomach.
   In all the Southern African countries where the Baobab occurs it is used throughout the year, and is sold in formal and informal markets in areas where it is absent.
   It is very popular as a drink and also for the other properties and uses of the fruit. Due to its long shelf life it is used and traded during the whole year.
   The fruit pulp is also sought after by baboons and other animals.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   None.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   For 42 years studied the uses of plants by indigenous people in Africa south of the Sahara, specializing in their edible, poisonous and medicinal properties. For many years gathered the relevant information on national database level.

6. Please make any other comments.
   Sorry to be late, just came back from the Richtersveld and southern Namibia, on medicinal plant project.

Signed: H. Vahrmeijer Date: 5th July 2006

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: Letloa Trust, Land Livelihood and Heritage Resource Centre (Phytotrade member)

Job role: Coordinator

Country: Botswana

City/Town/District: Shakawe, Ngamilanad, North West district

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Growing up north central, Namibia, baobab has always formed part of people's diet. The endocarp would be moistened up in milk/water and drank or consumed depending on its constituency. The pulp can be crushed into a powder form and turn into porridge.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?
   Wherever the baobab tree occurs the fruit pulp has always been consumed and I have never come across any record of poisoning except the icy feelings on your teeth when you chew the seeds.

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   Adansonia digitata is widely distributed in the North West part of north central regions of Namibia. It is consumed by everyone whenever available.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   Traditionally people believed it constitutes some nutritional value although they could not prove what it is.

5. Please provide a brief summary of your experience and expertise relevant to this topic.

6. Please make any other comments.
   It will be very crucial if information on nutritional value of this plant can reach rural dwellers so that their resource could have an ended value and therefore resulting in a wise of resource.

Signed: [redacted] Date: June 2006

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: Royal Botanic Gardens Kew UK

Job role: Head of Sustainable Uses of Plants Group (Economic Botany and Biological Interactions)

Country: UK

City/Town/ District: Surrey

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes: in research on famine foods and on plants being used for medicinal purposes within Africa. Yes the fruit is used as a food in many parts of Africa.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   The fruits and /or extracts of the fruits are given to young children by their parents in areas where the tree is growing. I have seen school children eating the fruits in parts of North Africa. I have also seen it being sold in Ghana, Uganda and Nigeria. I cannot make any comments about how popular/common it is as collecting this type of information has not been our priority.
   Sorry but lack of time prevents me being able to expand on this answer.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   We have done some work on the potential "health" aspects of the fruit as it contains flavonoids also found in other fruits such as passionfruits. This work has not yet been published by us. I am also aware from publications and from talking with local people in Africa (Ghana, Uganda and Tunisia) that it is used and back in the mid 1990's saw it being grown in some house gardens near Sfax for home use.
   We studied the fruit as a source of nutrients and to study its health benefits as it was given to children (high Vit C content but this varied in samples we analysed).

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   I have nearly 30 years experience in looking at the uses of plants made by people and the analysis of the chemistry to support these traditional uses. I have also extensive experience in the role of plant chemistry in the modulation of insect behaviour.

At Kew I manage projects that investigate the potential new uses of plants and have developed methods to chemically fingerprint plants so enable us check the source (botanical) and quality of plant-derived products entering the market.

6. Please make any other comments.
   Baobab is an interesting fruit with potential as a food additive etc but suggest we should know more about the long term use of the species.

Signed: [redacted] Date: 14th July 2006

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: Self-employed Consultant

Job role: Natural Products R&D, product development

Country: South Africa

City/Town/ District: Cape Town

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes, it is widely and commonly used in southern and eastern Africa, eaten directly, mixed into food, and mixed with water as a drink.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   It is consumed by rural children as a snack-food and with water as a beverage, and it is also eaten and taken with water by rural adults. It is commonly consumed by healthy people, while people with fevers and diverse ailments may take it as a medicine.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   No, I have never found any evidence to suggest it may be toxic, and indeed have consumed it myself, and given it in drinks to my children.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   I am a medical doctors and botanist who has spent the last twenty years documenting indigenous African food and medicinal plant use, mainly in southern Africa, but also in Tanzania and Kenya. I have co-authored two books on South African medicinal and useful plants. Baobab pulp is well-known to be commonly consumed by rural folk throughout the natural distribution of the tree, and is a minor item sold for consumption in some urban markets. Most recently I saw it being sold to the public at a market in Dar es Salaam in November 2005.

6. Please make any other comments.
   Baobab pulp is commonly and widely used in Africa as a food, and in beverages, and is generally regarded as entirely safe.

Signed: [redacted] Date: 29 June 2006

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: PROTA (Wageningen University)

Job role: Editor/Researcher

Country: The Netherlands

City/Town/ District: Wageningen

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes there is plenty evidence incl. published, well-documented for traditional use both as food as well as drink.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?
   Not applicable.

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   The fruit contains soft, white, edible and nutritious flesh ('monkey bread'). It is used to curdle milk, it is eaten as a sweet and is used in making gruel and refreshing drinks and ice-cream. In Sudan it is made into a milk-like drink called 'gubdi'. The powdered fruit flesh is added to cold liquid, thus preserving vitamins. An emulsion of the fruit pulp may be used to adulterate milk. The dried pulp is used as a substitute for cream of tartar in baking.
   It is used throughout mainland tropical Africa by young and old.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   No.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   Extensive literature search.
   See: Bosch, C.H. & Sié, K. & Asafa, B.A., 2004. **Adansonia digitata** L. [Internet] Record from Protabase. Grubben, G.J.H. & Denton, O.A. (Editors). PROTA (Plant Resources of Tropical Africa / Ressources végétales de l'Afrique tropicale), Wageningen, Netherlands. <http://database.prota.org/search.htm>. Accessed 12 July 2006.
   Hands on knowledge from Mali and Zimbabwe.

6. Please make any other comments.

Signed: [redacted] Date: 12 July 2006

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: SAFIRE

Job role: Research and Development Section Manager

Country: Zimbabwe

City/Town/ District: Harare

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes the fruit is being consumed as fruit in most dry parts of Zimbabwe in different forms that include porridge, drink when it is mixed with milk, as ice cream when mixed with milk and then put in a freezer. It is also consumed in its natural form. It is usually consumed in high volumes during drought years.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   The fruits are consumed by all sectors of people from the communities the fruit is found in abundance. It is widely consumed because it provides a lot of vitamin C, B vitamin complexes that is vitamin B1 and B2, protein, and as well as fibre. It is popular in the driest parts of Zimbabwe such as Muzarabani, Rushinga, Chipinge and parts of Chimanimani. It is widely consumed because no extra costs are required when preparing the fruit for consumption.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   In relation to white pulp no.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   Research and Development Section within SAFIRE is spearheading the research in all baobab products. Baobab fruits may be used as food for consumption in various ways and this has facilitated its promotion and commercialisation for food security and for income generation. SAFIRE has facilitated the development of a number of community based enterprises that focus on baobab products. This is aimed at improving and diversifying the livelihoods of the rural poor.

6. Please make any other comments.
The major worry is that the resource base of the baobab tree seems to be deteriorating as a result of over exploitation in areas where SAFIRE is carrying out intervention programmes in relation to baobab fruits. This is because the tree is a multi-purpose tree. This calls for sustainable management as well as enhancement of the tree specie to maintain high harvesting levels of the fruit for both consumption and commercialisation. Generally harvesting or the utilisation of the tree should not exceed its capacity to regenerate for sustainable production.

Signed: [redacted] Date: 07/07/06

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: Department of Health

Job role: Nutritionist

Country: South Africa

City/Town/ District: Pretoria

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   It is widely consumed in the rural areas (around Venda, in South Africa) where I come from. Sometimes we would mix it with sugar and water and take it as a drink. There are many ways we consume it. It can also be eaten as it is.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?
   They are widely consumed in rural areas. I've never come cross myths around the baobab fruit. I've never come across any person who has been poisoned by consuming it.

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   It is widely consumed by young and old people. Baobab trees are mainly found in the Venda area of the Limpopo province in South Africa.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   I've never come across any evidence contrary to what I know about the baobab fruit.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   I'm not an expert in this area of baobab fruit. But through my personal experience, people still consume it when available. We also do not discourage people to consume it because there is a belief that it is a rich source of vitamin C (anecdotal evidence). It will be interesting to get more information on the nutritional information of the baobab fruit.

6. Please make any other comments.

Signed: [redacted] Date: 17 July 2006

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: University of Ferrara

Job role: Professor of Pharmaceutical Chemistry and Toxicology

Country: Italy

City/Town/ District: Ferrara

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   As far as I am concerned, I know of traditional use as food ingredients in Senegal. In Italy it is consumed as food supplement particularly in case of bowel disorders, energy supplement, vitamin C supplement, Calcium supplement. In any case by both young and old people with particular benefits in older subjects. Generally for healthy people that whish to maintain their body performance or in case of non-good health (but not sickness).

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   None. We have had evidences of discomfort (in particular bowel) in case of dosages over 20 gr/day.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   We are working on Baobab tree products since 2000. Our interest regards possible application as food supplement, cosmetic ingredient and in pharmaceutical compositions. In particular our expertise regards:
   i. Characterization of composition of Baobab tree parts
   ii. Preparations of extracts from different of Baobab tree parts
   iii. Characterization of antioxidant activity of tree parts and related extracts
   iv. Investigation of tree parts and related extracts as possible ingredients for supplements, cosmetics and pharmaceuticals compositions

v. Investigation of tree parts and related extracts in skin disorders (lenitive, moisturizing, antiaging)
vi. Investigation of tree parts and related extracts in bowel disorders (IBS, constipation)

Publications:
Antioxidant capacity of Adansonia digitata *fruit pulp and leaves*
Silvia Vertuani, Elena Braccioli, Valentina Buzzoni and Stefano Manfredini
Terapeutica Acta 2002, 2, 86-91.

Frutto del Baobab (Adansonia digitata) L'albero farmacista
Stefano Manfredini, Silvia Vertuani, Valentina Buzzoni,
Integratore nutrizionale 2002, 5, 25-29.

Capacita' Antiossidante Di Prodotti Derivanti Dal Frutto Del Baobab (Adansonia Digitata) *In Comparazione Con Altri Frutti Ed Estratti Vegetali*
Stefano Manfredini, Elena Braccioli, Valentina Buzzoni e Silvia Vertuani
Erboristeria Domani, 2003, 267, 52-59.

The Use of Photochemiluminescence for the Measurement of the Integral Antioxidant Capacity of Baobab Products
Elena Besco, Elena Braccioli, Silvia Vertuani, Paola Ziosi, Francesca Brazzo, Renato Bruni, Gianni Sacchetti and Stefano Manfredini
Food Chemistry in Press

6. Please make any other comments.

Signed: [redacted] Date: 03 July 2006

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: Laboratory of Applied Ecology, Faculty of Agronomic Sciences, University of Abomey-Calavi, Benin

Job role: Researcher

Country: Republic of Benin

City/Town/ District: Cotonou

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   In Benin, the pulp of baobab is used in the preparation of drinks, sour dough, gruel and as dessert. An appreciable quantity of pulp is mixed with water and the mixture is further sieved and give a nice drink named « *Kô ba you* » by 'Djerma' and 'Dendi' ethnic groups. This drink is often consumed by farmers during harvest of agricultural products. The "*Mutchoyan*" in 'Otamari', is a sour dough made with baobab pulp and cereals flour. The pulp is also used as a substitute of milk, and is hence added to gruel in '*Dendi*', '*Haoussa*' and '*Djerma*' ethnic groups. In *Dendi* area, this type of gruel is especially given to people during burial ceremonials of old persons (70 to 80 years). It aims to decrease thirst of people from the cemetery. The pulp is also mixed with millet or sorghum flour and the mixture is used to prepare a gruel named « *Kö koumandi* ».

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   I have never heard that baobab pulp have a toxicity risk.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   My Research experience on baobab tree
   - Supervision of six Master of Sciences thesis on baobab tree.
   - Molecular characterization of *Adansonia digitata* (AFLP & SSR markers) for its sustainable management in the traditional parklands agroforestry systems of Benin, West-Africa.

- Research on morphological characters and production of baobab's (*Adansonia digitata* L.) capsules across the bioclimatic zones of Benin.
- Research on ethnobotanical knowledge of rural populations and valorisation of baobab tree (*Adansonia digitata*) in Benin.
- Research on ecological diversity and pulp, seed and kernel production of the baobab (*Adansonia digitata*) in Benin.
- Research on Germination and seedlings survival of baobab tree.
- Research on different uses of baobab tree (*Adansonia digitata*) in Benin with partial analysis of its organs' chemical component.

My Scientific publications related to baobab tree

- **Assogbadjo A.E.**, Kyndt T, Sinsin B, Gheysen G, Van Damme P (2006). Patterns of genetic and morphometric diversity in baobab (*Adansonia digitata* L.) populations across different climatic zones of Benin (West Africa). *Annals of botany* 97: 819-830.
- **Assogbadjo A.E.**, Sinsin B., Codjia J.T.C. and Van Damme P. (2005). Ecological diversity and pulp, seed and kernel production of the baobab (*Adansonia digitata*) in Benin. *Belgian Journal of Botany* 138 (1): 47-56.
- **Assogbadjo A.E.**, Sinsin B. and Van Damme P. (2005). Caractères morphologiques et production des capsules de baobab (*Adansonia digitata* L.) au Bénin. *FRUITS* 60 (5) : 327-340.
- **Assogbadjo A.E.**, De Caluwé E., Sinsin B, Codjia JTC & Van Damme P. (2005). Indigenous knowledge of rural people and importance of baobab tree (*Adansonia digitata* L.) in Benin. In press in *Proceeding ICEB- 2005*.
- Codjia J.T.C, **Assogbadjo A.E**, & Ekué M.R.M.(2003). Diversité et valorisation au niveau local des ressources forestières alimentaires végétales du Bénin. *Cahiers Agriculture,* 12 : 321- 31.
- Codjia J.T.C., Fonton-Kiki B., **Assogbadjo A. E.**, et M.R.M Ekué (2000). Le baobab (*Adansonia digitata*), une espèce à usage multiple au Bénin. CECODI /CBDD/ Veco/ SNV/ FSA. 47p. ISBN 99919-953-0-7

6. Please make any other comments.
   I would like you to extend your activities in West Africa especially in Benin. Baobab pulp is available there and we have experience on baobab and can collaborate without any difficulty with you. There is presently an ongoing research in Benin on bioavailability of micronutrients, preservation and processing of baobab products.

Signed: [redacted] Date: 29/06/2006

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: The University of Agriculture, Abeokuta Nigeria

Job role: Lecturer/Research

Country: Nigeria

City/Town/ District: Abeokuta

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?
   Not Applicable.

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   It is used as an additive in the production of local condiment. The powder made from the seeds is also used as an additive in brewing local drinks.
   It is widely used and popular. It does not have any known health implications or side effects in most parts of Nigeria particularly in the savannah ecological zones.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   No. rather it adds to the shelf life of products by eliminating pathogenic strains of microorganisms.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   Details could be found in my research work published in European Food Research Tech. journal (2005) Vol. 220; 187-190 (Afolabi O. R & Popoola T.O.S).

6. Please make any other comments.
   I strongly support your organisations campaign to promote the use of baobab.

Signed: [redacted] Date: 07 July 2006

Associate Professor of Applied Microbiology
Dept. of Microbiology

Unversity of Agriculture
Abeokuta 110001
Ogun State. NIGERIA

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: University of New Mexico School of Medicine Albuquerque, New Mexico, USA

Job role: Professor, senior researcher

Country: USA

City/Town/ District: Albuquerque

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   Yes, baobab fruit and leaves are widely consumed in West Africa, by rich and poor alike.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?
   N/A.

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   The leaf is consumed by all age groups. It is very popular. Usually it is taken as a soup called miyan kuka in Hausa.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   No.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   I have been doing research on the nutrient content of plant foods in Nigeria and the Republic of Niger for 15 years and have written several dozen papers on the topic.

6. Please make any other comments.
   None.

Signed: [redacted] Date: June 29, 2006

Traditional consumption and safety of baobab (*Adansonia digitata*) fruit

Name of respondent: [redacted]

Organisation: Royal Botanic Gardens, Kew

Job role: Retired Head, Economic and Conservation Section

Country: UK

City/Town/ District: London

Note: By "baobab fruit" we refer to the white / cream powdery material (the mesocarp) found within the hard shell (the epicarp), and ***exclude*** *the shell, stalk (peduncle) the seed and its oil.*

1. In your research or experience, have you ever come across any evidence or data to suggest that baobab fruit is traditionally consumed as a food or drink?
   I have worked in Nigeria, Zambia, Zimbabwe and the Sudan and observed the fruit being eaten. I have even eaten myself.
   My research has shown that it is eaten throughout its natural distribution range apart from Yemen and Oman; it is also eaten in the West Indies.

2. If not, do you know, or could you speculate, why baobab fruit might not be traditionally consumed?
   It is not eaten in Yemen or Oman probably because the trees are so rare although the fruits are used medicinally in Oman. In India the baobabs are sacred trees and venerated but the fruits are not eaten.
   It is often not eaten in African countries where it has been introduced, probably because there is no tradition for its use as food.

3. If yes, could you briefly provide any details of this consumption? For example, is it consumed by young or old people, the health or the infirm? Is it widely consumed and popular? If so, where?
   The fruits are eaten by all age classes, including the infirm. It is widely consumed and a popular food.

4. In your research or experience, have you ever come across evidence or data to suggest baobab fruit might constitute a food safety or toxicity risk?
   It is alleged that excessive eating of the fruit, especially by the young, is fattening but there is no clinical evidence to confirm this.

5. Please provide a brief summary of your experience and expertise relevant to this topic.
   I lived in Nigeria, Zambia, Zimbabwe and the Sudan from 1952 to 1965. From 1967 until my retirement from Kew I maintained my interest in the baobab and published several papers. For the past five years I have been writing a book, which will be published later this year, on all eight species of Adansonia.

6. Please make any other comments.

Signed: [redacted] Date: 11 July 2006

Pages 129-132 removed under exemption b(4).

Appendix 9 - Determination of the Trace Elements in Baobab Dried Fruit Pulp by Inductively Coupled Plasma Atomic Emission Spectroscopy

Method

Organic matter in duplicate samples from all the batches of Baobab dried fruit pulp, was destroyed by prolonged boiling with nitric acid and hydrochloric acid.

The concentration of each element was determined by Inductively Coupled Plasma (ICP) with optical emission spectroscopy (OES).

Reference: in-hose method accredited to ISO 17025 (UKAS)

Results

Sample	Ca (mg/kg)	Fe (mg/kg)	Mg (mg/kg)	K (mg/kg)	P (mg/kg)	Na (mg/kg)
Baobab dried fruit pulp – 1	3300	90.2	1430	20100	611	8.2
Baobab dried fruit pulp – 2	3380	91.3	1460	20300	621	12.1

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Appendix 10 - Determination of the Amino Acid Content in Baobab Dried Fruit Pulp by High Pressure Liquid Chromatography

Method

Samples from all the batches of Baobab dried fruit pulp were treated with 6M hydrochloric acid in sealed bottles at 110 °C for 22 hours to hydrolyse the protein chains.
For analysis of cystine and methionine, the Baobab dried fruit pulp samples were oxidised with performic acid at 2-8 °C for 16 hours prior to acid hydrolysis.
The resulting hydrosylate was diluted and filtered.
An aliquot was adjusted to pH 2.2, and a known quantity of norleucine was added as an internal standard.
The extracted amino acids were derivatised with 6-aminoquinolyl-N-hydroxysuccinimide carbamate prior to determination by gradient HPLC with fluorescence detection.

Based on UKAS accredited method (AM/C/206).

Determination of Total Tryptophan in Food by High Pressure Liquid Chromatography

Method

Samples from all the batches of Baobab dried fruit pulp were hydrolysed under alkaline conditions with barium hydroxide. The tryptophan in the extract was determined by HPLC with fluorescence detection.

Based on UKAS accredited method (AM/C/228); adapted from Office Journal of the European Communities, directive 2000/45/EC

Results

Amino acid (total)	Baobab dried fruit pulp – 1	Baobab dried fruit pulp – 2
Tryptophan (g/100g)	0.03	0.03
Aspartic acid (g/100g)	0.2	0.2
Serine (g/100g)	0.23	0.28
Glutamic acid (g/100g)	0.29	0.29
Glycine(g/100g)	0.13	0.14
Histidine (g/100g)	0.06	0.07
Arginine (g/100g)	0.1	0.1
Threonine	0.12	0.13

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Amino acid (total)	Baobab dried fruit pulp – 1	Baobab dried fruit pulp – 2
(g/100g)		
Alanine (g/100g)	0.13	0.14
Proline (g/100g)	0.17	0.16
Cystine (g/100g)	0.05	0.05
Tyrosine (g/100g)	0.07	0.08
Valine (g/100g)	0.09	0.1
Methionine (g/100g)	0.02	0.03
Lysine (g/100g)	0.1	0.1
Iso-leucine (g/100g)	0.07	0.07
Leucine (g/100g)	0.13	0.14
Phenylalanine (g/100g)	0.12	0.12

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Appendix 11 - Determination of the organic acid content of Baobab Dried Fruit Pulp

Method

Carboxylic acids in fruit pulp samples were extracted into water (solid/liquid extraction). The extract was analysed directly by HPLC with UV detection against appropriate calibration standards.

Results

Sample	Citric acid (mg/kg)	Malic acid (mg/kg)	Succinic acid (mg/kg)	Tartaric acid (mg/kg)	Oxalic acid (mg/kg)
Baobab dried fruit pulp – 1	29000	1400	< 400	< 400	< 400
Baobab dried fruit pulp – 2	27000	1100	< 400	< 400	< 400
Baobab dried fruit pulp – 3	32000	1200	< 400	< 400	< 400

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Appendix 12 - Determination of the presence of β-sitosterol in Baobab Dried Fruit Pulp and generate a fingerprint by quantitative thin layer chromatography

Method

Baobab fruit pulp samples in the form of a yellow free flowing powder from Phytotrade, were tested for the presence of the plant sterol, β-sitosterol, by a quantitative thin layer chromatography method.

Three batches of the baobab powder, Baobab dried fruit pulp – 1, Baobab dried fruit pulp – 2, and Baobab dried fruit pulp – 3 were all tested in duplicate. Each sample was extracted with solvent, filtered, and then spotted onto plates by micro pipettes prior to development and visualisation via an anisaldehyde reagent. All samples tested in this experiment were found to contain β-sitosterol by this TLC method.

Materials

Baobab fruit pulp samples	Baobab dried fruit pulp – 1	Phytotrade
	Baobab dried fruit pulp – 2	Phytotrade
	Baobab dried fruit pulp – 3	Phytotrade
β-sitosterol	20338	Apin Chemicals
ethyl acetate	1147399 / 21105376	Fluka
hexane	02957DD-425	Sigma-Aldrich
graduated micro pipette (1-5μl)	3415010	Hirschmann
Alumgram Silica Plates	405 / 139	Macherey-Nagel
anisaldehyde	651522	BDH Chemicals
glacial acetic acid	0434160	Fisher Scientific
methanol	S/D/440/27 no.45	Hayman Ltd
concentrated sulphuric acid	1100307 / 43204037	Fluka

Extraction of Samples

Two samples of Baobab dried fruit pulp – 2 weighing 2.00g each, were transferred to glass vials containing a magnetic stirring bar. To each glass vial was added 6ml of solvent (70:30 hexane:ethyl acetate). These two samples were labelled as HSI 300/2/1/1 and HSI 300/2/1/2.

Two samples of Baobab dried fruit pulp – 1 weighing 1.00g each and two samples of Baobab dried fruit pulp – 3 weighing 1.00g each were carefully transferred to glass vials containing magnetic stirring bars (the reason that only 1.00g of sample was used here was due to the amount of Baobab dried fruit pulp – 1 and Baobab dried fruit pulp – 3 available for testing). To each of the glass vials was added 3 ml of solvent (70:30 hexane:ethyl acetate). These samples were labelled as HSI 300/3/1/1, HSI 300/3/1/2, HSI 300/3/3/1, and HSI 300/3/3/2.

All of the samples were stirred for one hour at room temperature. Each of the solutions were able to stir freely, but at no time did the fruit pulp appear to dissolve into the solvent.

After one hour, each of the samples was filtered through a Whatman 40 Ash less qualitative filter paper directly into a clean 10ml Volac (class B) measuring cylinder. The volume of each of the collected filtrates was made up to a minimum 1ml by washing the fruit pulp with fresh solvent (70:30 hexane:ethyl acetate).

HSI 300/3/1 filtrate was observed to be a very pale yellow colour

HSI 300/3/2	filtrate was noticeable pale yellow in colour
HSI 300/3/3	filtrate had hardly any colour; hint of yellow colour detected

Final volume of all filtrate samples was 1.2ml

TLC Plates

The β-sitosterol standard was made up as follows:

10 mg of β-sitosterol (Apin Chemicals) was carefully weighed into a glass vial. To this, 5ml of solvent (70:30 hexane:ethyl acetate) was added. The white solid β-sitosterol dissolved immediately to leave a clear solution.

The visualisation reagent was prepared as follows:

The reagents were added to clean glass storage jar in the following order
0.5ml anisaldehyde, 10 ml glacial acetic acid, 85ml methanol, and 5ml concentrated sulphuric acid.
(from Plant Drug Analysis: A Thin Layer Chromatography Atlas by H. Wagner and S Bladt, 2nd edition Springer Verlag 1996)
This reagent was sprayed onto the developed TLC plates and then heated with a hot air blower on the highest setting for two minutes until the spots could be visualised in a quantitative way. Sterols appear as a violet-blue spot on the TLC plate.

The TLC plates were prepared in the following way. Three spots were placed onto each plate per sample; this gave six plates in total. The first was β-sitosterol standard (1μl), the second was 5μl of extract, and the third spot was 10μl of extract. This was done to ensure that there was sufficient extract on the TLC plate and allow the β-sitosterol in the samples to be clearly identified as a strong spot once the plate had been developed.

The TLC solvent used to develop the plates was 70:30 hexane:ethyl acetate. Each plate was developed twice in the solvent before visualisation by the anisaldehyde reagent.

Results

HSI 300/3/1/1			
β-sitosterol		Rf=0.59	
5μl extract	Rf=0.41 (weak)	Rf=0.59	Rf=0.92 (strong as standard)
10μl extract	Rf=0.41 (weak)	Rf=0.59	Rf=0.92 (strong as standard)
HSI 300/3/1/2			
β-sitosterol		Rf=0.54	
5μl extract	Rf=0.27 (weak)	Rf=0.54	Rf=0.95
10μl extract	Rf=0.27 (weak)	Rf=0.54	Rf=0.95

(β-sitosterol spot in 10μl extract stronger than 5μl extract)

HSI 300/3/2/1			
β-sitosterol		Rf=0.56	
5μl extract	Rf=0.49	Rf=0.56	Rf=0.93
10μl extract	Rf=0.49	Rf=0.56	Rf=0.93

HSI 300/3/2/2

β-sitosterol		Rf=0.60	
5μl extract	Rf=0.43	Rf=0.60	Rf=0.92
10μl extract	Rf=0.43	Rf=0.60	Rf=0.92

(spots at Rf=0.92 in both the 5μl and 10μl extract spots were much stronger than the β-sitosterol standard)

HSI 300/3/3/1

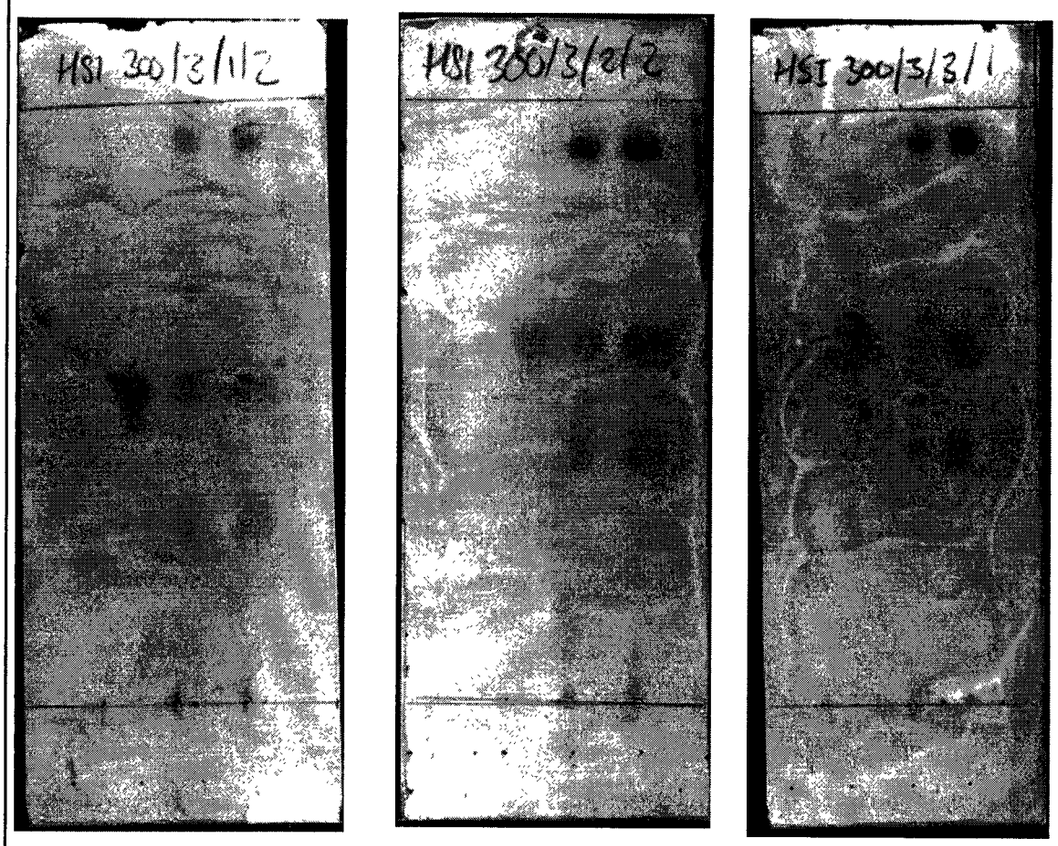
β-sitosterol		Rf=0.62	
5μl extract	Rf=0.42	Rf=0.62	Rf=0.96
10μl extract	Rf=0.42	Rf=0.62	Rf=0.96

(spots at Rf=0.96 were very strong; similar intensity to β-sitosterol)

HSI 300/3/3/2

β-sitosterol		Rf=0.53	
5μl extract	Rf=0.37	Rf=0.53	Rf=0.89
10μl extract	Rf=0.37	Rf=0.53	Rf=0.89

(spots at Rf=0.89 were very strong; similar intensity to β-sitosterol)



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Conclusion

All the Baobab dried fruit pulp samples, Baobab dried fruit pulp – 1, Baobab dried fruit pulp – 2, and Baobab dried fruit pulp – 3, showed the presence of β-sitosterol by this TLC method.

Appendix 13 – Determination of acid insoluble ash (silica) and foreign matter content of Baobab dried fruit pulp

Method – Acid Insoluble Ash (Silica)

Duplicate samples from the batches of Baobab dried fruit pulp were heated in a muffle furnace at 550°C until all the organic matter was burnt off.
Ash was dissolved in diluted hydrochloric acid and the insoluble material that remained was analyzed for silica content.

UKAS accredited method

Results

Sample	Acid Insoluble Ash (per 100g)
Baobab dried fruit pulp – 1	0.1
Baobab dried fruit pulp – 2	0.1
Baobab dried fruit pulp – 3	0.1

Method – Detection of Foreign Matter in Baobab dried fruit pulp

Foreign matter at 2.5x magnification

100g of Baobab dried fruit pulp was weighed in a container. A sub-sample (10 – 20g) of this powder was spread out as a thin layer on a smooth white surface, and examined under a 2.5x magnification lens, with occasional 'turning-over' (mixing) of the powder to ensure all material was adequately examined. Obvious visible particles of foreign matter were removed with forceps, and placed into a pre-weighed vial. These processes were repeated on further sub-samples (the collected foreign matter being pooled) until the entire sample had been examined.

Vials containing the foreign matter were weighed, and the amount of such material determined by the difference between the original (empty) and final (full) weights, determined to an accuracy of 1mg. For the purposes of this trial two types of foreign matter were determined separately – endogenous material of obvious Baobab origin, though not pulp (e.g. clearly identifiable fruit fibers and seed coats fragments) and material of either obviously foreign or indeterminate origin ('possible extraneous material'). These individual values were summated where necessary.

The results of this analysis are reported in Table 1.

Foreign matter at 6x magnification

Baobab dried fruit pulp shows a tendency to loosely clump, and is not easy to quantitatively examine under any degree of magnification without some form of pre-treatment. A 30mg aliquot

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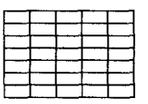
of Baobab dried fruit pulp was thoroughly mixed with 0.7g olive oil, which served to disperse the powder aggregates. Immediately after mixing, i.e. when particles were still in suspension, a known weight of oil/Baobab dried fruit pulp mix (typically 0.05g) was removed and placed onto a glass slide. The material was then examined under a 6x magnification lens, and all visible foreign matter (distinguished by differences in color and translucence compared to the powdered pulp) present in the aliquot was counted. The total number of foreign particles in the original Baobab Dried Fruit Pulp sample was then calculated.

This procedure is replicated 3 times for each Baobab dried fruit pulp sample.

Diagram 1
Example of background grid used to count small particles in Baobab Dried Fruit Pulp



For the counting of the foreign particles in the oil/Baobab dried fruit pulp mix, it was found convenient to place the glass slide on top of a printed grid (2 x 4 mm rectangles is convenient – see Diagram 1), and the oil spread out thinly over the slide until 20 – 30 grid squares were covered. The presence of an underlying grid provides a structuring mechanism that allows the systematic counting of the particles in the mix (e.g. count those in the top left square first, those in the next square along second, and so on), but its dimensions are not crucial to the method.

Results

Table 1
The content of foreign matter in Baobab Dried Fruit Pulp samples at 2.5x magnification.

sample	Endogenous material (g per 100g)	Extraneous material (g per 100g)
Baobab dried fruit pulp – 1	0.019	0.0025
Baobab dried fruit pulp – 2	0.013	0.006
Baobab dried fruit pulp – 3	0.025	0.003

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Appendix 14 - Determination of the Microbiological Contamination of Baobab Dried Fruit Pulp

Method

Total Viable Count

Duplicate samples from all three batches of Baobab dried pulp and a diluent were mixed together. 1ml of this solution transferred to sterile petri dish and 18Ml of plate count agar was added. Once solidfied, this was incubated at 30°C +/- 1°C for 48 +/- 4 hours. All colonies were then counted.
Reference: BS EN ISO 4833:2003

Presumptive Coliforms

Duplicate samples from all three batches of Baobab dried pulp and a diluent were mixed together. These were homogenised before 1ml of this solution transferred to sterile petri dish. 15-20 ml violet red bile lactose sugar was added and allowed to solidfy. This was then incubated at 37°C +/- 1°C for 22-26 hours. All pinkish-red colonies with diameter > 0.5mm were counted. This was the presumptive coliform count.
References: BS 5763-2:1991; BS 4763-3:1987; Marks and Spencer Manual of Microbiological Methods, method 2.3

Presumptive *E. coli*

Duplicate samples from all three batches of Baobab dried pulp and a diluent were mixed together. These were homogenised for 30 seconds before 1ml of this solution transferred to sterile petri dish. 18ml TBX agar was added and allowed to solidfy. This was then incubated for 44 +/- 1°C for 24 +/- 4 hours. All blue colonies were counted and reported as presumptive *E. coli.*
Reference: The Manual, 8th edition, Oxoid Ltd

Staphylococcus Aureus
Duplicate samples from all three batches of Baobab dried pulp and a diluent were mixed together. These were homogenised for 30 seconds before 0.5ml was transferred onto Baird-Parker agar. This was incubated at 37 +/- 1°C for 48 +/- 4 hours. Typical and atypical colonies were counted, and at least five colonies are confirmed using Oxoid Staphytect Plus kit (positive test reported as *Staphylococcus aureus*).
Reference: BS EN ISO 6888 Part 2:1999

Faecal *Streptococci*

Duplicate samples from all three batches of Baobab dried pulp and a diluent were mixed together. These were homogenised for 30 seconds before 0.5ml was transferred onto the surface of a surface-dried KAA agar plate and spread evenly. The plates were incubated at 37 +/- 1°C for 24 +/- 4 hours. Typical colonies were counted and reported as faecal *streptococci.*
Reference: The Manual, 8th edition, Oxoid Ltd

Yeasts and Moulds

Duplicate samples from all three batches of Baobab dried pulp and a diluent were mixed together. These were homogenised for 30 seconds before 0.5ml was transferred onto the surface of RBCA plate. Plates were incubated at 25 +/- 1°C for 5 days +/- 5 hours. Yeasts and moulds were counted separately.

Salmonella sp.

Duplicate samples from all three batches of Baobab dried pulp weighing 25g and 225ml of buffered peptone water pre-enrichment were incubated at 37 +/- 1°C for 16-20 hours. 0.1ml of buffered peptone water enrichment broth was inoculated into 10ml RV broth and incubated at 42 +/- 0.5°C for 21 +/- 3 hours. A 1-2ml aliquot of RV broth was steamed for 20 +/- 2 minutes and allowed to cool. An an ELISA test was performed using Diffchamb Test Kit. Subculture the RV broth onto XLD and Brilliant Green Agar, before incubating at 37 +/- 1°C for 18-24 hours. Confirm 5 colonies from each plate.
References: BS EN ISO 6579:2002; Diffchamb ELISA method

Results

Microbiological test	**Baobab dried fruit pulp – 1 (cfu/g)**	**Baobab dried fruit pulp – 2 (cfu/g)**
Total viable count (cfu/g)	3.90×10^4	2.50×10^4
Coliforms (presumptive) (cfu/g)	< 10	< 10
E.coli (presumptive) (cfu/g)	< 10	< 10
Staphylococcus aureus (cfu/g)	< 20	< 20
Faecal *streptococci* (cfu/g)	< 20	< 20
Yeasts (cfu/g)	< 20	< 20
Moulds (cfu/g)	1.60×10^4	7.80×10^3
Salmonella sp. (per 25g)	Not detected	Not detected

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Appendix 15 - Determination of the Pesticide Residues in Baobab Dried Fruit Pulp

Method

Samples from all the batches of Baobab dried fruit pulp were blended together and then extracted with ethyl acetate.
This extract was cleaned with a pre-packed florisil column before an aliquot was taken and analysed by gas chromatography with mass selective detection and flame photometric detection.
References are based on the following:

Panel on Determination of Residues of Organophosphorus Pesticides in Fruits and Vegetables, Analyst, 102, 858-868 (1977)
Watts et al JAOAC 1969, 52, 522
Statutory Instrument 2005 No. 3286 Section 7
Quality Control Procedures for Pesticide Residues Analysis, EU Document SANCO/10232/2006

Results

Class of pesticide	Residue detected (mg/kg)
organophosphorous	< 0.05 mg/kg
organochlorine	< 0.02 mg/kg
organonitrogen	< 0.05 mg/kg
dicarboximides	< 0.05 mg/kg
strobilurin	< 0.05 mg/kg
triazine	< 0.05 mg/kg
pyrethoids	< 0.05 mg/kg

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Organophosphorus	LOD mg/kg	Organochlorine	LOD mg/kg	Organonitrogen
Acephate	0.02	Aldrin	0.01	Benalaxyl
Azinphos-ethyl	0.05	Chlordane	0 02	Bupirimate
Azinphos-methyl	0.05	DDT	0 02	Buprofezin
Bromophos-ethyl	0 05	Dieldrin	0.01	Carbofuran (parent molecule)
Bromophos	0.05	Endosulfan	0.02	Carbosulfan
Cadusafos	0.05	Endrin	0.01	Chlorpropham
Carbophenothion	0 05	Heptachlor	0.01	Cyproconazole
Chlorfenvinphos	0.05	Hexachlorobenzene (HCB)	0.01	Difenoconazole
Chlorpyrifos	0.05	Hexachlorocyclohexane-alpha	0.02	Diphenylamine
Chlorpyrifos-methyl	0.05	Hexachlorocyclohexane-beta	0 02	Etridiazole
Diazinon	0.02	Hexachlorocyclohexane-delta	0.02	Fenarimol
Dichlorvos	0.05	Hexachlorocyclohexane-gamma	0.01	Fluazifop-P-butyl
Dimethoate	0.02	Quintozene	0.01	Hexaconazole
Ethion	0.05	Tecnazene	0.02	Imazalil
Ethoprophos	0.05			Metalaxyl
Etrimfos	0.05	**Pyrethroids**		Metribuzin
Fenchlorphos	0.01	Bifenthrin	0 02	Oxadixyl
Fenitrothion	0.05	Cyfluthrin	0.02	Penconazole
Fenthion	0.05	lambda cyhalothrin	0.02	Pirimicarb
Fonofos	0.05	Cypermethrin	0.05	Propachlor
Heptenophos	0.05	Deltamethrin	0.05	Propham
Iodofenphos	0.05	Fenvalerate	0.02	Propiconazole
Malathion	0.05	Flucythrinate	0.05	Propyzamide
Methacrifos	0.05	Permethrin	0.05	Tebuconazole
Methamidophos	0.01	Tefluthrin	0.05	Thiabendazole
Methidathion	0.02			Tolyfluanid
Mevinphos	0.05	**Triazines**		Triadimefon
Omethoate	0.05	Atrazine	0.05	Triadimenol
Parathion	0.05	Cyanazine	0.05	Trifluralin
Parathion-methyl	0 05	Desmetryn	0.05	Buprofezin
Phosalone	0.05	Prometryn	0.05	
Phosmet	0 05	Simazine	0.05	**Others**
Phosphamidon	0.05	Terbuthylazine	0.05	Azoxystrobin
Pirimiphos-methyl	0.05	Terbutryn	0.05	Chlorothalonil
Quinalphos	0.05			Chlorthal-dimethyl
Sulfotep	0.05	**Dicarboximides**		Chlorthion
Tolclofos-methyl	0.05	Iprodione	0.02	Dichlofluanid
Triazophos	0.02	Procymidone	0.02	Dicofol
		Vinclozolin (parent molecule)	0 05	Kresoxim-methyl
				Methoxychlor
				Pendimethalin
				Pentachloroaniline (PCA)

Appendix 16 - Determination of Heavy Metals content in Baobab Dried Fruit Pulp

Method

The preparation of duplicate samples for the detection of **lead** and **cadmium**, from the batches of Baobab dried fruit pulp, required the samples to be destroyed by boiling with nitric acid and hydrochloric acid over a long period of time.
The samples were then analysed by Perkin Elmer SIMA6000 Graphite Furnace Atomic Absorption Spectrometer.

The preparation of duplicate samples for the detection of **arsenic**, from the batches of Baobab dried fruit pulp, required ashing with magnesium nitrate due to the volatile nature of arsenic.
The resulting samples were analysed using a PS Analytical Excalibur atomic fluorescence analyser, which detects the fluorescence of arsenic hydride.

The preparation of duplicate samples for the detection of **mercury**, from the batches of Baobab dried fruit pulp, required ashing at high temperature and trapping the mercury vapour on a gold amalgam. The mercury was then purged and quantified by atomic absorption spectroscopy.

Reference: all heavy metal methods accredited to ISO 17025 (UKAS)

Results

sample	Arsenic (mg/kg)	Cadmium (mg/kg)	Lead (mg/kg)	Mercury (mg/kg)
Baobab dried fruit pulp – 1	< 0.10	< 0.010	0.09	< 0.004
Baobab dried fruit pulp – 2	< 0.10	< 0.010	0.08	<0.004

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Appendix 17 - Determination of the Aflatoxins and Ochratoxin A content of Baobab Dried Fruit Pulp

Method for the determination of Aflatoxins content

Fruit pulp was extracted into aqueous acetonitrile.
The extract was diluted with PBS and cleaned-up using an immunoaffinity column.
The aflatoxins were quantified by HPLC with post column derivatisation using PBPB with fluorescence detection.

UKAS accredited method

Results

Sample	Aflatoxin B1 (µg/kg)	Aflatoxin B2 (µg/kg)	Aflatoxin G1 (µg/kg)	Aflatoxin G2 (µg/kg)	Total Aflatoxins (µg/kg)
Baobab dried fruit pulp – 1	< 0.09	< 0.09	< 0.09	< 0.09	< 0.36
Baobab dried fruit pulp – 2	< 0.09	< 0.09	< 0.09	< 0.09	< 0.36
Baobab dried fruit pulp – 3	< 0.09	< 0.09	< 0.09	< 0.09	< 0.36

Method for the determination of Ochratoxin A content

Duplicate samples from all three batches of Baobab dried pulp were extracted with bicarbonate solution.
Each of the bicarbonate sample solutions were then centifuged.
The ochratoxin was separated using an immunoaffinity column, eluting with acidified methanol.
Ochratoxin was determined by reverse phase HPLC with fluoresence detection.

Results

Sample	Ochratoxin A (µg/kg)
Baobab dried fruit pulp – 1	< 0.1
Baobab dried fruit pulp – 2	< 0.1

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Appendix 18 - Determination of the Cyanide Content in Baobab Dried Fruit Pulp

Method

An aqueous extract was made from samples of the Baobab dried fruit pulp.
The cyanide levels were determined by using a Merck test strip kit.

Separate hydrolysis extracts was made from the batches of Baobab dried fruit pulp.
The acid hydrolysis was carried on each extract out to release any hydrocyanic acid from cyanogenic glucosides contained in within the dried fruit pulp.
The cyanide levels were determined by using a Merck test strip kit.

Results

Sample	Aqueous extract of fruit pulp (mg/kg)	Hydrolysis mixture of fruit pulp (mg/kg)
Baobab dried fruit pulp – 1	< 5	< 5
Baobab dried fruit pulp – 2	< 5	< 5
Baobab dried fruit pulp – 3	< 5	< 5

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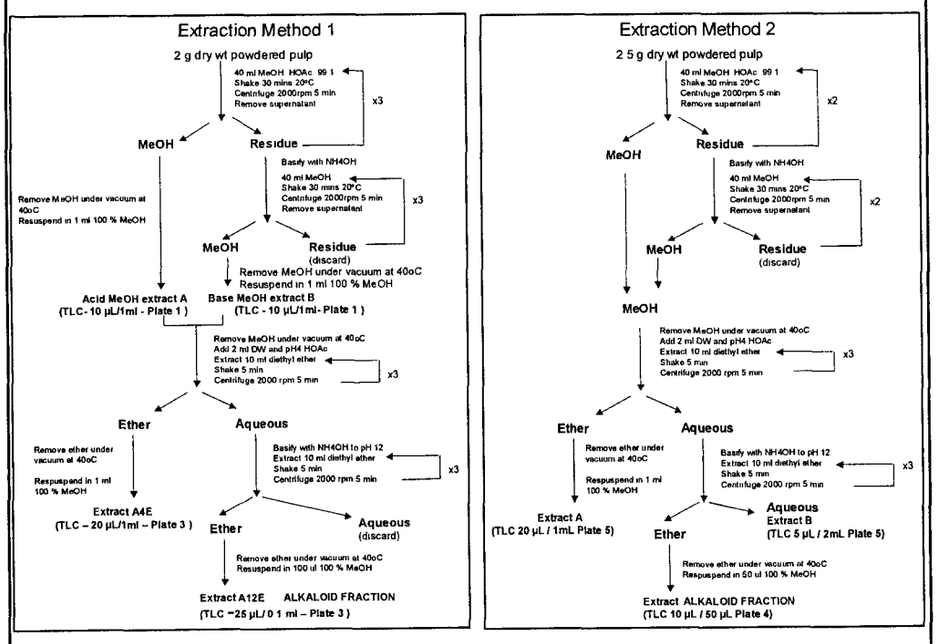
Appendix 19 - Determination of the Alkaloid content in Baobab Dried Fruit Pulp

Method

The following experiments were undertaken to detect the presence of alkaloids in the fruit pulp. These were using standard phytochemical extractions to extract the alkaloids; there detection by thin layer chromatography (tlc) compared to a variety of known alkaloids and also by visualisation of the tlc plate using spray reagents that specifically detect the presence of alkaloids. The extraction methodology is shown below.



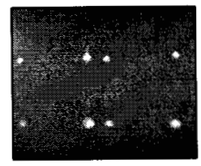
Based on standard alkaloid extraction methods of
Wagner H et al, Plant Drug analysis a thin layer chromatography atlas, Springer Verlag, Berlin 1984.
Harborne J B Phytochemical Methods· Chapman and Hall,1999

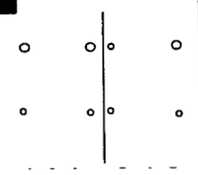
As can be seen from the above schemes non alkaloids extractions were also tested for alkaloids for the sake of completion.

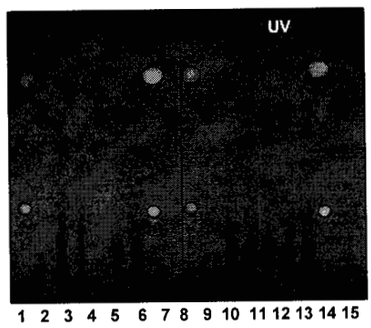
The following thin layer chromatography experiments were conducted on different batches of Baobab Fruit Pulp.

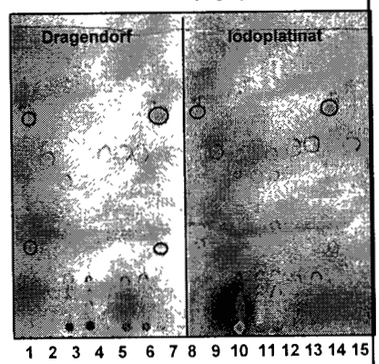
E303 Plate 1
Silica gel G
254 nm
$CHCl_3$: MeOH
(85:15)

1 – reserpine	2 µg
2 – caffeine	2 µg
3 – sample A	300/3/2
4 – samples A	300/3/3
5 – caffeine	5 µg
6 – sample B	300/3/3
7 – sample B	300/3/2
8 – reserpine	10 µg
9 – caffeine	10 µg
10 - reserpine	2 µg
11 – caffeine	2 µg





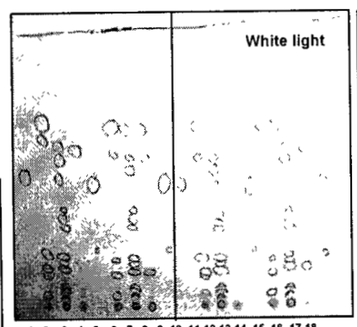


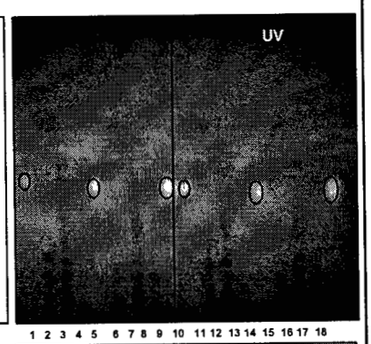


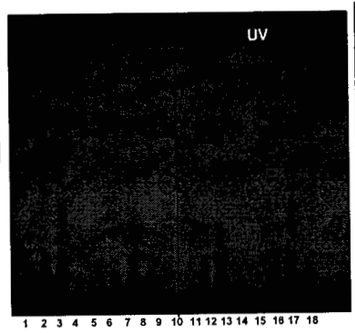
E303 Plate 3
Silica gel G
254 nm
$CHCl_3$: MeOH
(85:15)

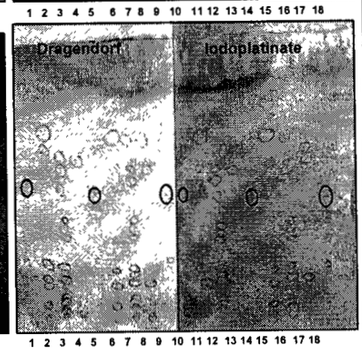
1 - galanthamine
2 µg
2.- sample 300/3/2 B
3 - sample 300/3/2 A4E
4 - sample 300/3/2 A12E
5.- galanthanine
5 µg
6 - sample 300/3/3 B
7.- sample 300/3/3 A4E
8.- sample 300/3/3 A12E
9.- galanthamine
10 µg

10 - galanthamine
2 µg
11 - sample 300/3/2 B
12 - sample 300/3/2 A4E









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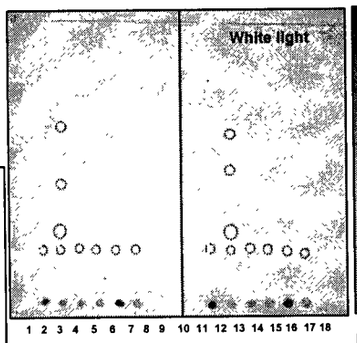
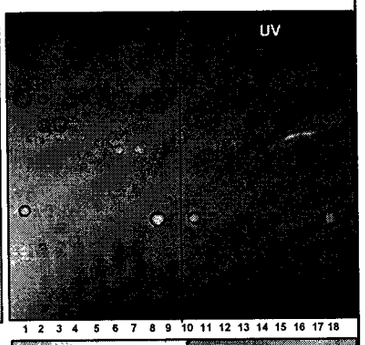
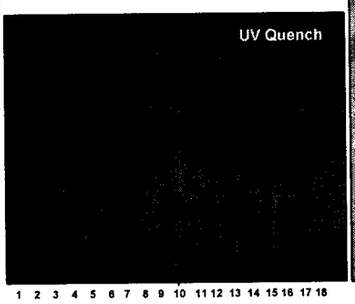
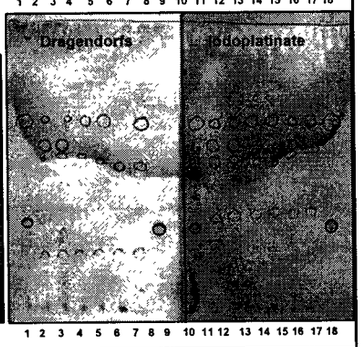
E303 Plate 4
Silica gel G
254 nm
$CHCl_3$: MeOH
(85:15)

1 - galanthamine + caffeine 5 µg
2.- sample 300/3/1 R1 ALK
3 - sample 300/3/1 R2 ALK
4 - sample 300/3/2 R1 ALK
5.- sample 300/3/2 R2 ALk
6 - sample 300/3/3 R1 ALK
7.- sample 300/3/3 R2 ALK
8 - galanthamine + caffeine 10 µg
9 -
10 - galanthamine + caffeine 5 µg
11.- sample 300/3/1 R1 ALK
12 - sample 300/3/1 R2 ALK



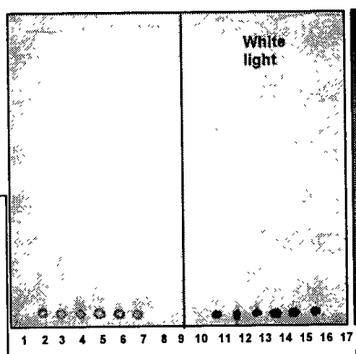


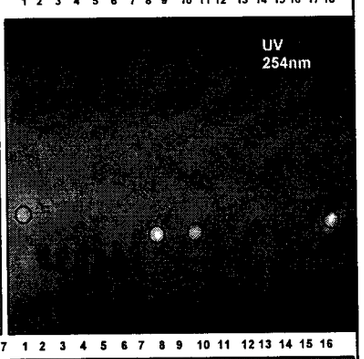


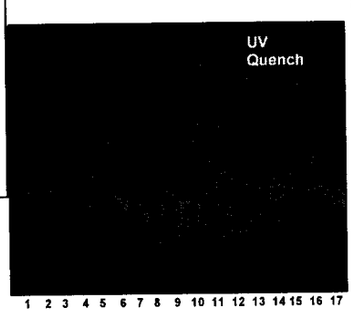


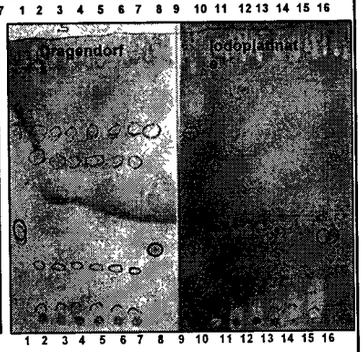
E303 Plate 5
Silica gel G
254 nm
$CHCl_3$: MeOH
(85:15)

1 - galanthamine + caffeine 5 µg 2.- sample 300/3/1 R1 A
3.- sample 300/3/1 R2 A
4 - sample 300/3/2 R1 A
5.- sample 300/3/2 R2 A
6 - sample 300/3/3 R1 A
7 - sample 300/3/3 R2 A
8.- galanthamine + caffeine 10 µg
9 –
10 - galanthamine + caffeine 5 µg
11 - sample 300/3/1 R1 B
12 - sample 300/3/1 R2 B
13.- sample 300/3/2 R1 B
14 - sample 300/3/2 R2 B
15 - sample 300/3/3 R1 B
16 - sample 300/3/3 R2 B
17.- galanthamine + caffeine









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Conclusions

Plate 1

Alkaloids were not detected with either Dragendorf or iodoplaninate reagents in either acidic methanol (A) or basic methanol (B) extracts (method 1) of the 2 samples tested (at a detection limit of 5 ug / 20 mg – 0.025% dry wt)

(Note: A compound with similar chromatographic properties to caffeine (a methylated purine alkaloid not sensitive to Dragendorf or Iodoplantinate reagents) was detected in the basic extracts.

Plate 3

Alkaloids were not detected with either Dragendorf or iodoplaninate reagents in the alkaloid enriched fractions (A12E) (method 1) of the 2 samples tested following acid/base extraction
(at a detection limit of 5ug / 0.5g – 0.001% dry wt)

Plate 4

Alkaloids were not detected with either Dragendorf or iodoplaninate reagents in the alkaloid enriched fractions (ALK) (method 2) of the 3 replicated samples tested following acid/base extraction
(at a detection limit of 5ug / 0.5g – 0.001% dry wt).

Plate 5

Alkaloids were also not detected in the two residue fractions (A and B) (method 2) with either Dragendorf or iodoplaninate reagents (at a detection limit of 5 ug in 50 mg – 0.01% (dry wt A) and 5 ug/6.25mg 0.08% dry wt (B)

(Note1: the 'caffeine like' compound was mainly extracted into the acidic ether fraction A, (but not completely cf plate 4)

(Note 2: sample 300/3/1 also contained much larger amounts of a second compound marked * than samples 300/3/2 and 300/3/3)

(note 3: Some of the spots when conducted in duplicate showed varying amounts of material on the baseline, even thought they were from the same sample. This is because the ether extraction may contain small amounts of the aqueous phase and that the Ph was adjusted with indicator paper. This could effect the amount of material being extracted. Despite this however, this would not be expected to change the amount of alkaloids that could have been present in the ether / alkaloid extracts within the pH range used (4.0 – 4.5).

NB: detection limits of alkaloids in the samples were calculated on the basis of a minimum detection limit of 5ug with Dragendorf or iodoplatinate reagent for any alkaloid present on the TLC plates.

NB: Even though some of the plates showed a basline colour reaction with Dragendorf's reaction, this was due to overloading on the plate. If there any alkaloids present in these baseline spots they would be present in less than 0.003 % of the plant material. Also a further experiment using more polar solvents, did move the baseline material and there was no colour reaction on the plate indicting that the presence of alkaloids is extremely unlikely.

Appendix 20 - Determination of the Cyclopropene Fatty Acid Content in Baobab Dried Fruit Pulp by Gas Chromatography

Method

The lipids from samples of all three dried baobab fruit pulp batches were extracted using chloroform:methanol (2:1) and washed with ¼ the volume of 0.88% potassium chloride solution.

This is an adaptation of the method described by Folch et al (1957) (Folch J, Lees M, Stanley GHS, *Journal of Biological Chemistry* **226** pp 497-509)

All the fatty acids were converted to fatty acid methyl esters by sodium methoxide-catalysed tranesterification.

The fatty acid methyl esters were analysed by gas chromatography.
All samples were compared to standard fish methyl esters and sterculia africana seed oil.

Results

Fatty Acid	Baobab dried fruit pulp – 1 (mg/g fruit pulp)	Baobab dried fruit pulp – 2 (mg/g fruit pulp)
16:0 palmitic	0.90	0.89
16:1 hexadecenoic	0.02	0.02
17:0 heptadecenoic	0.02	0.02
16:3 hexadecatrienoic	0.03	0.03
malvalic	0.09	0.09
18:0 stearic	0.10	0.11
18:1 oleic	0.84	0.83
18:2 linoleic	0.67	0.67
sterculic	0.02	0.02
18:3 α-linolenic	0.51	0.52
20:0 icosanoic	0.04	0.05
22:0	0.06	0.02
Total	3.30	3.27

Analysis carried out by GC-MS and compared to known standards

Oil content of fruit pulp 0.8%

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SUBMISSION END

AM

Bonnette, Richard

From: Cyril Lombard [cyril@phytotradeafrica.com]
Sent: Monday, February 16, 2009 7:16 AM
To: Bonnette, Richard
Cc: katie@phytotradeafrica.com
Subject: FW: Baobab dried fruit GRAS submission

Dear Richard,

Thanks you for your e-mail of Friday 13th February.

We can confirm that the inconsistencies as noted by the review team of GRN 273 (Baobab fruit pulp) were made in error and that the interpretations by the FDA are correct. The interpretations as highlighted by the FDA are confirmed in bold in the bullet points below.

- Table 18 on page 38 should be titled; "Analysis data of the **alkaloid** content in Baobab dried fruit pulp samples".
- Table 22 is placed on page 47 and the sentence on page 46 should read; "The data in Table 22 (**page 47**) shows the results of a multi-pesticide residue scan on the Baobab dried fruit pulp (Appendix 15)".
- The reference to the study by Ramadan *et al.*, 1994, on page 15 should refer to mice rather than rats and the sentence should read; "This group carried out an LD50 experiment in **mice** which were administered an aqueous extract of Baobab fruit pulp via intraperitoneal administration. This experiment produced an LD50 value in **mice** of 8,000 mg/kg".

Please let me know if we can clarify anything further,

With good wishes,

Cyril

Cyril Lombard
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From: Cyril Lombard [mailto:cyril@phytotradeafrica.com]
Sent: 16 February 2009 10:20
To: 'Katie Beckett'
Subject: FW: Baobab dried fruit GRAS submission

From: Bonnette, Richard [mailto:richard.bonnette@fda.hhs.gov]
Sent: 13 February 2009 19:37
To: Cyril@phytotradeafrica.com
Subject: Baobab dried fruit GRAS submission

Mr. Lombard,
Our review of GRN 273 (baobab dried fruit) is progressing well. As part of the review, our review team noted a

few very minor inconsistencies or typos in the text of your submission. According to our typical procedure, I would like to quickly confirm the correct interpretation in the cases I've noted below.

- Table 18 on page 38 notes that it describes the cyanide content of baobab dried fruit, though the table seems to describe alkaloid data. I assume the table title should have read alkaloid rather than cyanide.
- On page 46, at the beginning of the last paragraph, the sentence refers the reader to Table 22 on page 35. Table 22 is located on page 47. I assume that you intended to refer the reader to table 22 on page 47.
- The last paragraph on page 15 (and the first paragraph on page 16) notes that the Ramadan et al. LD50 was performed in rats. The paper notes that while rats were used in other aspects of the study, mice were used in the LD50 acute toxicity test. I assume the text intended to refer to mice as the model in the LD50 test reported.

These confirmations are intended for our administrative record alone and do not affect our overall evaluation of your submission. Please confirm that our understanding is correct.

Best regards,
Richard

Richard E Bonnette, MS
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AM

Bonnette, Richard

From: Cyril Lombard [cyril@phytotradeafrica.com]
Sent: Tuesday, June 30, 2009 1:35 PM
To: Bonnette, Richard
Subject: RE: Baobab dried fruit GRAS submission - question regarding HCN

Hello Mr. Bonnette,

I apologise for my slow response. It has proved more difficult than expected to have the cyanide analyses carried out in South Africa than expected. We will now have them carried out here in the UK – at least initially.

Also, instead of putting cyanide onto the Technical Data Sheet (which is only reviewed around once a year) we now plan to first carry out cyanide analyses on a range of samples and then, if any concerns are raised, to list cyanide as a test criteria on the Certificate of Analyses. The COA analyses are carried out on every batch for export. This could be between 3 and 30 batches over the next 12 months. Samples from batches are made up by collecting samples from the square root of the number of bags in the batch, plus 1. The bags are 25kg each, so in a 1,000kg batch at least 7 bags will be sampled.

The range of samples we are going to analyse first include:

- Baobab dried fruit pulp from the 2007 season
- Baobab dried fruit pulp from the 2008 season
- Baobab dried fruit pulp from the 2009 season
- Baobab fruit depectinised extracts from the 2008 season
- Baobab fruit depectinised extracts from the 2009 season

We will prepare samples so that they are representative of each year's production. We would be happy to share the results of these analyses with FDA. We are currently organising the samples shipment and the contract laboratory. It could be another month before we have the results.

We are concerned that this is holding up progress with FDA's consideration of our notification. I would be grateful if you could comment on whether this process adequately addresses your concerns.

With good wishes,

Cyril

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From: Bonnette, Richard [mailto:Richard.Bonnette@fda.hhs.gov]
Sent: 23 June 2009 19:23
To: cyril@phytotradeafrica.com