

Baobab vruchtvleespoeder (*Adansonia digitata*)

Baobab dried fruit pulp (*Adansonia digitata*)

Tweede beoordeling van de veiligheid voor de consument, volgens de Europese verordening 258/97 betreffende nieuwe voedingsmiddelen en nieuwe voedselingredienten

Second opinion regarding consumer safety, in accordance with European Regulation 258/97 concerning novel foods and novel food ingredients

aan/to:

de Minister van Volksgezondheid, Welzijn en Sport
the Minister of Health, Welfare and Sport

Nr. 2007-05BNV, Den Haag, 27 september 2007
No. 2007-05BNV, The Hague, September 27, 2007

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Beoordeling

Inleiding

Aan de orde is een tweede beoordeling volgens de Europese Verordening 258/97, over het gebruik als nieuw voedselingrediënt van vruchtvlies van de Baobab (*Adansonia digitata*) ook wel apenbroodboom. De aanvraag is ingediend door PhytoTrade Africa, een koepelorganisatie van Afrikaanse bedrijven.

Het nieuwe product komt als vruchtvliespoeder op de markt maar is niet direct beschikbaar voor de consument. Volgens de aanvrager kan het als ingrediënt dienen van bijvoorbeeld dranken op basis van gepureerd fruit (*smoothies*) en graanrepen, maar levensmiddelenfabrikanten kunnen het ook gaan gebruiken in allerlei andere producten.

Voordat op 15 mei 1997 de verordening in werking trad werd er in de EU geen Baobab vruchtvlies toegepast in de voeding. Een veiligheidsbeoordeling als nieuw voedingsmiddel is daarom vereist. In het kader van de desbetreffende Europese toelatingsprocedure is deze tweede beoordeling uitgevoerd door het Bureau Nieuwe Voedingsmiddelen van het College ter Beoordeling van Geneesmiddelen. Het bureau heeft hiervoor de Commissie Veiligheidsbeoordeling Nieuwe Voedingsmiddelen geraadpleegd, hierna genoemd 'de commissie VNV'.

Eerste beoordeling

De eerste beoordeling van de aanvraag voor markttoelating is verricht in het Verenigd Koninkrijk door de *Advisory Committee on Novel Foods and Processes* (ACNFP). De ACNFP heeft geen bezwaar tegen markttoelating.

De veiligheidsbeoordeling is gebaseerd op het traditionele gebruik van Baobab vruchtvlies. Dit wordt in grote delen van Afrika van oudsher als hoofdvoedsel genuttigd.

De ACNFP concludeert dat er geen schadelijk eigenschappen bekend zijn van het nieuwe product. Ook is het onwaarschijnlijk dat het allergische problemen veroorzaakt onder de Europese bevolking. Net als bij andere vruchten is het volgens de ACNFP echter niet uit te sluiten dat individuele consumenten een allergie zouden kunnen ontwikkelen voor de eiwitten in het nieuwe product.

Volgens de ACNFP heeft PhytoTrade Africa voldoende toezicht op de aangesloten bedrijven om een product van constante kwaliteit te leveren. De ACNFP was bezorgd over de mogelijke aanwezigheid van schimmeltaxinen, maar de aanvrager heeft aangetoond dat passende controlemaatregelen er voor zorgen dat gehalten aan in het bijzonder aflatoxines voldoen aan de Europese normen voor gedroogd fruit.

Bevindingen van de commissie VNV

De commissie VNV heeft geen bezwaar tegen de toelating in de EU van Baobab vruchtvliespoeder. Wel plaatst zij een kanttekening in aanvulling op de veiligheidsbeoordeling van de ACNFP. De commissie VNV baseert haar oordeel op de informatie in het dossier¹ (waarvan de samenvatting is opgenomen als bijlage A), aanvullende informatie², en de eerste beoordeling door de ACNFP³ (bijlage B).

Het nieuwe ingrediënt is afkomstig van vruchten van Baobab bomen (*Adansonia digitata*) die in Afrika in het wild groeien. De aanvrager beschouwt het nieuwe ingrediënt als onbewerkt omdat het "productieproces" uitsluitend een eenvoudig mechanische bewerking behelst. Eerst wordt de harde schil (schaal) gekraakt en het binnenste van de vruchten verwijderd. Dit wordt vervolgens gezeefd om zaden en vezelachtige materialen te verwijderen waarna het van nature relatief droog vruchtvlies als een poeder overblijft. Het dossier bevat uitgebreide samenstellingsgegevens van drie partijen die in 2004-2005¹ en in 2006² zijn geproduceerd; de regionale verschillen zijn niet bijzonder groot en acceptabel voor een natuurproduct. De voedingswaarde van Baobab vruchtvlies is vergelijkbaar met dat van andere soorten vruchten.

De positieve beoordeling van de ACNFP is gebaseerd op de uitgebreide onderbouwing van het traditionele gebruik.

- Het dossier bevat wetenschappelijke en andere publicaties waaruit blijkt dat consumptie van Baobab vruchtvlies op grote schaal plaats vond in vele gebieden in Afrika. Het werd direct gegeten of verwerkt in dranken of andere voedingsmiddelen zoals pap.
- Het huidige gebruik is geïnventariseerd aan de hand van vragenlijsten die in de meeste gevallen zijn beantwoord door medewerkers van bij PhytoTrade Africa aangesloten bedrijven. Hieruit blijkt dat er tot op heden een wijd verbreide consumptie is van Baobab vruchtvlies en dat de toepassingen weinig of niet zijn veranderd.
- Uit literatuuronderzoek van de aanvrager blijkt dat in Australië vruchten van een nauw verwante soort (*Adansonia gregorii*) als voedsel worden gebruikt.
- Volgens verschillende deskundigen op het gebied van Afrikaanse voeding en voedselgewassen uit Afrika, Europa en de Verenigde Staten van Amerika is Baobab vruchtvlies een gewoon voedingsmiddel in verschillende delen van Afrika en zijn er geen schadelijke effecten bekend. Dit bevestigt de resultaten van uitgebreid literatuuronderzoek door de aanvrager.

De commissie is het eens met de ACNFP dat de aanvrager het voldoende aannemelijk heeft gemaakt met dit totaal aan gegevens dat er geen schadelijke gezondheidseffecten zijn te verwachten voor de Europese consument. Klassiek toxicologisch onderzoek met het nieuwe product is daarom niet nodig voor de veiligheidsbeoordeling. Volgens de commissie VNV maakt de ACNFP terecht onderscheid tussen Baobab vruchtvlies en andere exotische ingrediënten waarvoor aanvragen voor markttoelating zijn gedaan en waarvoor wel toxicologische onderzoeken zijn vereist. De commissie noemt bijvoorbeeld nonisap. In tegenstelling tot Baobab vruchtvlies worden deze andere producten niet als hoofdvoedsel gebruikt in de landen van herkomst.

De commissie VNV stemt in met de ACNFP dat de kwaliteit van het product gewaarborgd is. De aanvrager toont aan dat in recente partijen van Baobab vruchtvliespoeder de verontreinigingen met bodemmateriaal minimaal zijn². Ook bevatten

de producten maar geringe hoeveelheden aan vruchtmetaal anders dan het vruchtvlies. De commissie VNV vindt de bovengrens van 2 % (w/w) aan vreemd metaal in de huidige productspecificatie onacceptabel hoog. Zij verwijst hiervoor naar de laatste pagina van het beoordelingsrapport van de Engelsen (*foreign material*, bijlage B). De commissie meent dat het totale gehalte aan deze verontreinigingen ten hoogste 0,2 % (w/w) mag zijn voor het te verhandelen Baobab vruchtvliespoeder. Volgens de aanvullende informatie² is deze waarde haalbaar. Bovendien valt de hoeveelheid vreemd metaal van partijen die in 2006 zijn geproduceerd zelfs beduidend lager uit (< 0,03 % w/w). Dit waarborgt voldoende dat er geen ongewenste stoffen, bijvoorbeeld afkomstig uit de zaden, in het product zullen terecht komen.

De ACNFP is tevreden over de microbiologische kwaliteit. De aanvrager heeft op verzoek van de ACNFP aanvullende informatie verstrekt inzake het beheersen van microbiologische risico's en zegt toe dat bij de regelmatige inspecties ook de omvang van gist en schimmelinfecties (en daarmee samenhangend mogelijke besmettingen met schimmeltoxinen) te zullen controleren. Het kwaliteitsbeheersysteem dat de aanvrager hanteert moet garanderen dat de verschillende producenten Baobab vruchtvliespoeder leveren dat voldoet aan de productspecificatie, dat wil zeggen een vochtgehalte van ten hoogste 12 % én afwezigheid van ongewenste chemische en microbiologische verontreinigingen. Volgens de Engelse beoordelaars is de aanvrager in staat om te voldoen aan de algemeen geldende eisen voor voedselveiligheid.

De aanvrager is van plan het product ook in andere vormen te vermarkten om de verwerking in meerdere soorten eindproducten mogelijk te maken. Hiervan zijn twee pectinevrije ingrediënten in meer detail toegelicht^{1,2}. Net als de ACNFP heeft de commissie VNV geen bezwaar tegen dit type bewerking van Baobab vruchtvlies aangezien het gebruik van pectinolytische enzymen al een gangbare techniek is in de vruchtensapindustrie. De aanvrager noemt twee producten waarin de nieuwe ingrediënten zullen worden verwerkt, *smoothies* en graanrepen, die per portie ten hoogste ongeveer 15 g Baobab vruchtvliespoeder zullen bevatten. Daarnaast vermeldt de aanvrager andere soorten (eind)producten als mogelijke toepassing zoals gebak en biscuits, maar een concreet voorstel voor een productassortiment ontbreekt. Ook zijn er geen innamegegevens van producten die met Baobab vruchtvliespoeder bereid zullen worden. De commissie VNV gaat er vanuit dat de aanvrager een brede toepassing beoogt zoals die in de vruchtverwerkende industrie en heeft hier geen bezwaar tegen.

Conclusie

Samenvattend is de commissie VNV het eens met de positieve beoordeling door de ACNFP. De gegevens over traditioneel gebruik van Baobab vruchtvlies onderbouwt de veiligheid voldoende. De commissie verwacht geen nadelige gezondheidseffecten na consumptie van Baobab vruchtvliespoeder. Zij meent dat het gebruik net zo veilig is als dat van andere, tot de basisvoeding behorende vruchten. Wel zou het gehalte aan vreemde bestanddelen, afkomstig van andere vruchtdelen of van de bodem, moeten worden verlaagd in de specificatie van 2 % naar 0,2 % (w/w).

Referenties

1. Het autorisatiedossier van PhytoTrade Africa zonder bijlagen is te vinden op de website van de ACNFP: 'Baobab Dried Fruit Pulp – An application for Novel Foods Approval in the EU as a food ingredient' (<http://www.food.gov.uk/multimedia/pdfs/baobabapplicationfinal.pdf>)
2. Aanvullende informatie van PhytoTrade Africa in antwoord op vragen van de ACNFP is te vinden op de website van de ACNFP:
 - Addendum to Novel Food Application for Baobab Dried Fruit Pulp (<http://www.food.gov.uk/multimedia/pdfs/acnfp825addnf>)
 - Addendum to Novel Food Application for Baobab Dried Fruit Pulp, Appendices (<http://www.food.gov.uk/multimedia/pdfs/acnfp825add>)
3. Initial opinion on an application under the novel foods regulation for Baobab dried fruit pulp as a food ingredient (12 July 2007) (<http://www.food.gov.uk/multimedia/pdfs/baobabinitialopinion.pdf>)

Assessment (English courtesy translation)

Introduction

The subject in question is a second assessment, in accordance with European Regulation 258/97, regarding the use of the pulp of the fruit of the Baobab (*Adansonia digitata*) or “upside down tree”, as a novel food ingredient. The application was submitted by PhytoTrade Africa, an umbrella organisation for various African companies.

The novel product will be marketed as dried fruit pulp, but it will not be directly available to consumers. According to the applicant, it can be used as an ingredient for such products as drinks based on pureed fruit (smoothies) and cereal bars. However, food producers can also use it in a range of other products.

Baobab fruit pulp was not used in foods in the EU prior to 15 May 1997, when the Regulation came into effect. This new application therefore requires a safety assessment as a novel food in the EU. In the framework of the relevant European approval procedure, this second assessment was prepared by the Novel Foods Unit of the Medicines Evaluation Board, after consulting the Committee on the Safety Assessment of Novel Foods (hereafter referred to as “the VNV Committee”).

Initial assessment

The initial assessment of the application for market authorisation was carried out by the Advisory Committee on Novel Foods and Processes (ACNFP), in the United Kingdom. The ACNFP has no objection to Baobab fruit pulp being admitted to the market.

The safety assessment is based on the traditional use of Baobab fruit pulp. This has traditionally been a staple part of the diet in a large geographical area of Africa.

The ACNFP concluded that the novel product is not known to have any harmful properties. It is also unlikely to cause allergy problems for the population of Europe. However, the ACNFP takes the view that, as with other fruit, the possibility cannot be excluded that individual consumers might develop an allergy in response to specific proteins in the novel product.

According to the ACNFP, PhytoTrade Africa monitors its member companies closely enough to ensure that they deliver a product of constant quality. The ACNFP was concerned about the possible presence of mycotoxins, but the applicant has demonstrated that appropriate monitoring measures ensure that the concentrations of aflatoxins in particular comply with European standards for dried fruit.

Findings of the VNV Committee

The VNV Committee has no objection to the authorisation of dried Baobab fruit pulp in the EU. However, it would like to add a supplementary comment to the ACNFP's safety assessment. The VNV Committee bases its views on the information contained in the dossier¹ (the summary of which is contained in Annex A), on additional information², and on the initial assessment by the ACNFP³ (Annex B).

The novel ingredient is derived from the fruit of wild-growing Baobab trees (*Adansonia digitata*) in Africa. The applicant considers the novel ingredient to be unprocessed, since the "production process" involved consists solely of simple mechanical treatment. First the hard shell is cracked open, then the inner part of the fruit is removed. This is then sieved to remove seeds and fibrous materials, leaving fruit pulp (which is naturally rather dry) in the form of a powder. The dossier contains extensive compositional data on three batches that were produced in 2004-2005¹ and in 2006². The regional differences, which are not especially pronounced, are within the range of acceptability for a natural product. The nutritional value of Baobab fruit pulp is comparable to that of other types of fruit.

The ACNFP's favourable assessment is based on the extensive material provided to support the traditional use of this product.

- The dossier contains scientific and other publications which show that Baobab fruit pulp has been consumed on a large scale in many areas of Africa. It is either eaten directly, or incorporated into drinks or other foods, such as porridge.
- Details of its current use have been collected by means of questionnaires, most of which were filled in by the staff of companies affiliated to PhytoTrade Africa. This shows that, to date, Baobab fruit pulp has been widely consumed and that there has been little or no change in the uses to which it is put.
- A literature survey conducted by the applicant revealed that the fruit of a closely related species (*Adansonia gregorii*) is used as a food in Australia.
- According to various experts in the field of African food and food crops from Africa, Europe and the United States of America, Baobab fruit pulp is a familiar food in various parts of Africa. It is not known to have any harmful effects. This confirms the results of extensive literature surveys conducted by the applicant.

The VNV Committee concurs with the ACNFP that the applicant has presented sufficient evidence to support the assumption that no harmful health effects for European consumers are to be expected. Accordingly, classic toxicological testing of the novel product is not required for the purposes of the safety assessment. The VNV Committee takes the view that the ACNFP is correct to distinguish between Baobab fruit pulp and other exotic ingredients for which applications for market authorisation have been submitted, and for which toxicological testing was required. In this connection, the Committee cites the example of noni juice. In contrast to Baobab fruit pulp, these other products are not a staple part of the diet in their countries of origin.

The VNV Committee concurs with the ACNFP that the quality of the product is sufficiently well safeguarded. The applicant has demonstrated that recent batches of dried Baobab fruit pulp exhibit only minimal contamination with soil material². Nor do the products contain more than small amounts of fruit material other than fruit pulp. The VNV Committee

feels that the upper intake level of 2 % (w/w) of foreign material, as cited in the current product specification, is unacceptably high. In this connection, the Committee refers to the final page of the British assessment report (Annex B). The Committee takes the view that the total content of these contaminants must not exceed 0.2 % (w/w) in traded batches of dried Baobab fruit pulp. According to the additional information provided², this is a feasible value. Furthermore, the quantity of foreign material in batches that were produced in 2006 is actually substantially lower than this (< 0.03 % w/w). This provides sufficient safeguards that no undesirable substances, derived from the seeds for example, will be mixed with the product.

The ACNFP is satisfied with regard to microbiological quality. At the ACNFP's request, the applicant has provided additional information on the management of microbiological risks, and has promised to monitor the extent of yeast and mould infections (together with any related incidences of mycotoxin contamination) in the course of regular inspections. The quality management system used by the applicant should guarantee that the various producers supply dried Baobab fruit pulp that meets the product specification. This means a moisture content not exceeding 12 % and the absence of undesirable microbial and chemical contaminants. The British assessors feel that the applicant is able to meet the generally accepted food safety requirements.

The applicant also plans to market other forms of the product, thus enabling it to be incorporated in a wider range of end products. Further details are provided of two such products, both pectin-free ingredients^{1,2}. Like the ACNFP, the VNV Committee has no objection to the application of this type of processing to Baobab fruit pulp, since the use of pectinolytic enzymes is already a commonly used technique within the fruit juice industry. The applicant cites two products into which the novel ingredients will be incorporated: smoothies and cereal bars. These will contain no more than approximately 15 g of dried Baobab fruit pulp per portion. In addition, the applicant indicates other types of products (and end-products) into which such ingredients could potentially be incorporated, such as pastries and biscuits. However, no specific proposals are made concerning a product range. Nor did the applicant provide any intake data for products to be prepared using dried Baobab fruit pulp. The VNV Committee assumes that the applicant has a wide range of applications in mind, such as that in the fruit processing industry, and will have no objection to this.

Conclusion

In summary, the VNV Committee concurs with the favourable assessment by the ACNFP. The data on the traditional use of Baobab fruit pulp adequately supports the safety of this ingredient. The Committee does not believe that the consumption of dried Baobab fruit pulp is liable to have any adverse effect on health. It takes the view that the use of this ingredient is just as safe as that of other fruits that are part of the staple diet. Nevertheless, the level of foreign substances (from the other parts of the fruit or from the soil) cited in the specification must be reduced from 2 % to 0.2 % (w/w).

References

1. The authorisation dossier of PhytoTrade Africa without annexes can be found on the website of the ACNFP: 'Baobab Dried Fruit Pulp – An application for Novel Foods Approval in the EU as a food ingredient' (<http://www.food.gov.uk/multimedia/pdfs/baobabapplicationfinal.pdf>)
2. Additional information from PhytoTrade Africa in reponse to questions by the ACNFP can be found on the website of the ACNFP:
 - Addendum to Novel Food Application for Baobab Dried Fruit Pulp (<http://www.food.gov.uk/multimedia/pdfs/acnfp825addnf>)
 - Addendum to Novel Food Application for Baobab Dried Fruit Pulp, Appendices (<http://www.food.gov.uk/multimedia/pdfs/acnfp825add>)
3. Initial opinion on an application under the novel foods regulation for Baobab dried fruit pulp as a food ingredient (12 July 2007) (<http://www.food.gov.uk/multimedia/pdfs/baobabinitialopinion.pdf>)

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Samenvatting van het dossier / Summary of the dossier

Executive Summary – Novel Foods Approval Summary for use of Baobab Fruit Pulp as a Food ingredient in the EU.

Introduction

- PhytoTrade Africa would like to market a dried fruit pulp derived from the Baobab tree *Adansonia digitata* as a nutritional food ingredient in the EU. Approval for this product is sought under the EC regulation No. 258/97 which is concerned with the introduction of novel foods and ingredients into the EU and ensures that the novel food in question is assessed for its safety prior to its introduction to the general public.
- PhytoTrade Africa has 58 members. Producers that want to export their Baobab fruit pulp are required to be assessed for the capacity to produce the product to appropriate standards.
- 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.

Specification of Baobab Fruit Pulp

- The Baobab tree *Adansonia digitata* is a member of the Bombacaceae family which consists of around 20 genera and around 180 species (Heywood, 1993)
- Also known as the “upside down tree”, on pollination by fruit bats, it produces large green or brownish fruits which are capsules and characteristically indehiscent. The capsules contain a soft whitish powdery pulp and reinform, kidney shaped seeds (Soton, 2001).
- The Baobab tree is found primarily in South Africa, Botswana, Namibia, Mozambique and Zimbabwe (Keith & Palgrave, 2000) but it is also common in America (Rashford, 1994), India, Sri Lanka, Malaysia, China, Jamaica and Holland (Sidibe & Williams, 2002)

Phytochemistry of *Adansonia digitata*

- The seeds are reported to contain 4-demethylsterols (23-42%), tocopherols (10-37%), and hydrocarbons (15-17%). Fatty acids have also been isolated from the seeds, including the identification of cyclopropenoid fatty acids (CPFA's).
- The roots are reported to contain the following flavonol glucosides: fisetin-7-O-alpha-rhamnopyranoside (JS Chauhan et al, 1987), 3,7-dihydroxy-flava-4-one-5-O-beta-D-galactopyranosyl-(1-4)-beta-D-glucopyranoside and quercetin-7-O-beta-D-xylopyranoside (YN Shukla et al, 2001).
- The leaves are reported to contain vitamin A precursors. Alpha carotene, beta-carotene and cryptoxanthin were isolated (Garrett C Smith et al, 1996).
- The bark is reported to contain flavonoids, glycosides, and tannins (Tuani et al, 1994).
- The fruit of *Adansonia digitata* is reported to contain triterpenoids beta-sitosterol, beta-amyrin palmitate, alpha-amyrin palmitate, and ursolic acids

(Al-Qawari et al, 2003). Organic acids including ascorbic acid and tartaric acids are present in high quantities (Airan and Desai, 1954; Nour et al,1980)

Specification of Phytotrade's Product – Baobab dried fruit pulp

- Three batches of Baobab dried fruit pulp from different regions (appendix 2 from the main document) were analysed to determine the variation in allowable limits of the Phytotrade product.
- Consistency of the Phytotrade product and the limits of variation within the parameters chosen are described in table I below.

Table I
Analysis results of the main nutritional components found in PhytoTrade's Baobab dried fruit pulp samples

	Baobab dried fruit pulp
Moisture (loss on drying) (g/100g)	11.1 - 13.7
Protein (g/100g)	2.03 - 3.24
Fat (g/100g)	0.4 - 0.7
Ash (g/100g)	5.5 - 6.6
Total carbohydrate (g/100g)	78.3 - 78.9
Total dietary fibre (g/100g)	45.8 - 53.7
Available carbohydrate (g/100g)	24.6 - 32.8
Energy (kcal/100g)	115 - 149
Energy (kJ/100g)	488 - 631
Total sugars (as glucose) (g/100g)	16.9 - 25.3
Sodium (mg/100g)	7.42 - 12.2
Saturated fats (g/100g)	0.2 - 0.26
Monounsaturated fats (g/100g)	0.1 - 0.23
Polyunsaturated fats (g/100g)	0.04 - 0.2

Effect of production process applied to Baobab dried fruit pulp

- The baobab fruit is wild harvested in a sustainable manner from non-cultivated trees growing wild in southern Africa.
- PhytoTrade Africa use a simple process to obtain the fruit pulp. The material is collected from the trees, and the hard shells are cracked open and the pulp is separated from the seeds and shell. This is milled, separated into course and fine lots (particle size 3-600 μ) and then bagged. During the processing method, the moisture content falls from an already low value of around 13% to a resulting material which is around 10% when packaged.

- To ensure the consistency of the dried fruit pulp from different areas, within a particular region, the dried fruit pulp is blended to give a consistent batch/product (appendix 2 of the main application).
- The stability of the Baobab dried fruit pulp was assessed by comparing samples collected from the three different regions to freshly harvested samples (appendix 5 of the main application). The storage of the product over 12 months showed no significant stability problems.

History of the organism used as the source of Baobab dried fruit pulp

- Phytotrade operates a Pre-Qualified Supplier system which assesses the capacity of individual suppliers to produce the Baobab fruit at the appropriate quality level. This quality assessment covers the harvesting methods of the Baobab fruit, method of transport and storage conditions.

Anticipated Intake of Baobab dried fruit pulp

- PhytoTrade plan to incorporate approximately 6-10g of Baobab dried fruit pulp in 100g smoothies and 10-15g in a 100g fruit bar and other related confectionery and food products. The Leatherhead Food results clearly demonstrate that these values are acceptable for the incorporation of baobab pulp at these levels (LFH, 2003i; LFH, 2003ii).

Traditional uses of Baobab

- The pulp of the Baobab fruit is reported to have numerous uses by the indigenous people of Africa. (Lewicki, 1974).
- Several authors have reported that the fruit pulp is used to make a refreshing drink (Bosch et al 2004; Carr, 1955; Nicol, 1957).
- Bosch et al (2004) reports that Baobab fruit pulp is eaten as a sweet and used to make ice-cream. The fruit pulp is also used as an alternative to 'cream of tartar' in baking.
- The pulp is rich in calcium and this is the main reason that the Baobab fruit is largely consumed by pregnant women and children in Senegal (Diop et al, 1988).
- Use of Baobab fruit pulp compiled in Appendix 7 of the main application shows extensive use in Africa.

History of Use of Baobab in the EU

- Used during World War I as leaven for baking bread (Watt and Breyer-Brandwijk 1962).
- Baobab fruit, also known as 'pain de singe' is sold in areas of Paris where the local population is made up of West and Central African immigrants.
- Baobab fruit supplements have been endorsed by Italian cyclists, a Formula one driver, and AC Milan football players.
- The Baobab fruit company is a major supplier in Europe of Baobab fruit (www.baobabfruitco.com).
- Several tonnes of the pulp were used for the preparation of tea cakes in the UK in the early 1900's (Keraudren, 1963).

- Used during World War I as leaven for baking bread (Watt and Breyer-Brandwijk 1962).

History of Use of Baobab in the Rest of the World

- Its significance in terms of being widely traded in Africa and other parts of the world is its inclusion in the USA dispensaries from 1865- 1947 (Woods et al., 1880, 1907, 1932, 1943).
- In Canada, Baobab is listed as a substance in cosmetics and care products regulated under the Foods and Drug act between January 1, 1987 and September 13, 2001.
- In India, *Adansonia digitata* is widespread and similarly consumed by Indians.
- In Australia, *Adansonia gregorii*, a closely related species to *Adansonia digitata* was considered by the Australian Food Standards agency as 'not novel' and given food status in March 2005.
- More details of the wide spread food use of Baobab fruits around the world have been compiled by PhytoTrade research staff and can be found in Appendix 7 of the main application.

Medicinal Uses of Baobab Fruit : Folklore

- All parts of the baobab tree are believed to have medicinal properties (Haerdi 1964, Kerhero 1974, Kokwaro 1976, Watt and Breyer-Brandwijk 1962).
- Baobab fruit and seeds used to treat dysentery reported by both Kerhero (1974) and Watt/Breyer-Brandwijk (1962).
- Watt/Breyer-Brandwijk (1962) also report that baobab has febrifuge properties.

Scientific Studies

- At the intended level of use, Baobab dried fruit pulp is not expected to exhibit any medicinal effects.
- Dried root of Baobab reported to have trypanocidal activity (Atawodi et al, 2003).
- Baobab fruit pulp had similar *in vitro* anti-oxidant properties to the standard grape seed extract Manfredini et al (2002).
- Water extract of Baobab fruit pulp has anti-inflammatory, analgesic and anti-pyretic activity *in vivo* (Ramadan et al, 1994).
- 'Pain de singe' solution made of Baobab fruit pulp is as effective in treating dehydration caused by diarrhea as standard WHO rehydration treatment (Tal-Dia et al, 1997).
- Baobab root and leaf extracts are reported to have antibiotic and antiviral properties (Hudson et al, 2000a; Hudson et al, 2000b).
- Water extract of Baobab fruit pulp and seeds reported to have hepatoprotective activity *in vivo* (Al-Qawari et al, 2003).

Nutritional aspects of Baobab dried fruit pulp

- Baobab dried fruit pulp contains a number of common nutritional components (appendix 12 of the main application) as shown in table I.
- Ascorbic acid content (appendix 9 of the main application) varies from 74 to 163 mg/100g of Baobab dried fruit pulp depending on the region collected. This 1.6 to 3.5 times the level of ascorbic acid found in oranges.
- Soluble pectin levels (appendix 10 of the main application) range from 23.4 to 33.8 g/100g of Baobab dried fruit pulp. These levels of soluble fibre are 9 to 14 higher than found in oranges.
- Baobab dried fruit pulp provides a good source of essential fatty acids (appendix 11 of the main application).
- Amino acid content (appendix 15 of the main application) Baobab dried fruit pulp consistent between samples from different regions. Some variation noted with aspartic acid (0.2 – 0.34 g/100g) content and glutamic acid (0.29 – 0.39 g/100g) content.
- Trace element content (appendix 13 of the main application) for Baobab dried fruit pulp is given below in table II.

Table II

Analysis results of the main trace elements found in PhytoTrade's Baobab dried fruit pulp samples

Trace Elements	Baobab dried fruit pulp (mg/kg)
P	561-733
Ca	2570-3700
Mg	1260-1790
K	20100-23900
Na	7-31
Fe	39.5-91.3

- Heavy metal content (appendix 14 of the main application), microbiological analysis (appendix 16 of the main application) and pesticide residue analysis (appendix 17 of the main application) of Baobab dried fruit pulp were all within EU safety limits.
- No cyanide was detected (appendix 21 of the main application) within the Baobab dried fruit pulp.
- No alkaloids were detected (appendix 19 of the main application) in the Baobab dried fruit pulp.
- Ochratoxin A levels (appendix 20 of the main application) were within EU safety limits.
- Cyclopropene fatty acid levels (appendix 18 of the main application) were detected at levels well below the limit expected to show any toxic effects in humans.

Safety Profile and Toxicity Studies of Baobab dried fruit pulp

- A 10% dilution of Baobab fruit pulp has been shown to be non irritating when applied to the skin of 25 volunteers, using a modified Draize test (Marzatico, 2001).
- A study conducted on 160 children investigating an aqueous solution of Baobab fruit pulp as an anti diarrhoea agent did not report any adverse reactions (Tal-Dia et al., 1997).
- In toxicity studies in mice, the aqueous pulp extract was found to provide an LD50 value of 8g/kg (Ramadan 1994), suggesting the low toxicity of Baobab fruit pulp.
- Baobab Fruit Company who has been developing Baobab as a food ingredient since 2000 has also found no toxicity reports or adverse reactions for the fruit pulp (Baobab Fruit Company 2005).
- Tuani et al (1994) has shown that various extracts of different parts of the plant display low toxicity in the brine shrimp assay.
- Baobab seed oil (the exact *Adansonia* species appears not to have been properly defined in most of the following references) is known to contain cyclopropene fatty acids (CPFA's) (Ralaimanarivo *et al.*, 1982. 1983). While there has been some toxicity issues with these compounds (Bezard *et al.*, 1996 and references therein), levels of CPFA's detected in the Baobab Dried Fruit Pulp were well the below the level expected to cause toxicity issues in humans (equivalent to consuming 10 to 14 g of CPFA's).
- The presence of an alkaloid adansonin has been detected in the stem bark of Baobab but the exact nature of this alkaloid remains to be established (Watt *et al.*, 1962). Earlier phytochemical studies have proved negative for the presence of alkaloids in Baobab fruit pulp (Ramadan et al, 1994) and are in agreement with our analyses.
- The pulp has been shown to contain hydrocyanic acid, but only 0.0049% per dry weight of fruit (Ghani and Abejule, 1986). Our analyses found no cyanide present at the limit of detection.
- Literature search of the Bombacaceae family to which *Adansonia digitata* belongs and the closely related Malvaceae family did not highlight any apparent toxicity problems. A number of species from these two families are known to be edible including:
 - fruits of the durian tree (Watson, L., and Dallwitz, M.J, 1992)
 - Malabar Chestnut (Purdue, 2005)
 - fruits of *Ceiba pentandra* (Kawanishi et al., 2002; Duke 2005)
 - Bombax malabaricum* (Gunaseka et al., 2003)
 - fruit of *Quararibea cordata* (Purdue, 2005)
 - seeds of *Eriodendron anfractuosum* (Purdue 2005)
 - Hibiscus species used as herbal teas (Heywood 1993)

End use of the product

- According to the literature review and the analyses carried out on the Phytotrade product, at the intended level of use, Baobab dried fruit pulp is not expected to produce any adverse effects..

- PhytoTrade would like to use Baobab dried fruit pulp in a variety of drinks and food products but in the first instance, the material would be used as an ingredient for the manufacture of “smoothies” (drinks based on fruit pulps) using between 6-10 % (w/w) of the dried fruit pulp and in a fruit bar using 10-15 % (w/w) of dried fruit pulp (LFH 2003i).

Conclusion

- With regard to the safety, toxicological and history of use data supplied in the application and the lack of toxic components from extensive literature searches and analytical studies, we submit that Baobab dried fruit pulp is safe to use as a food ingredient at the intended level of use.

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Eerste beoordeling / First assessment

INITIAL OPINION ON AN APPLICATION UNDER THE NOVEL FOODS REGULATION FOR BAOBAB DRIED FRUIT PULP AS A FOOD INGREDIENT

Applicant Phyto Trade Africa

Responsible Person Cyril Lombard

EC Classification 2.2

Introduction

1. An application was submitted by PhytoTrade Africa for the authorisation of baobab dried fruit pulp as a novel food ingredient. The UK Competent Authority accepted the application on 9 August 2006.
2. Baobab dried fruit pulp is derived from the fruit of the baobab tree (*Adansonia digitata*) of the family Bombacaceae. The baobab tree otherwise known as the “upside down tree” produces large green or brownish fruits, which are characteristically iridescent. *A. digitata* grows primarily in South Africa, Botswana, Namibia, Mozambique and Zimbabwe but is also found in India, Sri Lanka, Malaysia, China and Jamaica.
3. PhytoTrade Africa proposes to market baobab dried fruit pulp as a novel food ingredient (NI) for use in a range of food products such as smoothies, cereal bars and other similar food products. The applicant also intends to market a depectinised version of the fruit pulp.
4. PhytoTrade Africa is a trade association that represents individual companies in Africa who would like to export their baobab dried fruit to the EU. PhytoTrade Africa acts as an umbrella organisation and operates a Pre Qualified Supplier (PQS) system which assesses and maintains members' standards to ensure a consistent approach to the production and quality of the product.
5. The information supplied by the applicant highlights that the NI is unprocessed and has a long history of traditional use in Africa. the applicant considers that this history of use provides adequate reassurance about the safety of the product, thereby reducing the need for conventional safety studies which are normally required in a novel food assessment.
6. The application dossier was published on the Agency’s website for public consultation and two comments were received. The first suggested that baobab fruit pulp is not a novel ingredient as it is a source of cream of tartar, which is not the case. The second comment related to yeast /moulds and mycotoxins and this point is covered in sections XII and XIII below.

I Specification of the Novel Ingredient (NI)

Information on this aspect is provided on p.1 6 – 9 and 19-27 of the application dossier

7. Baobab dried fruit pulp is obtained from the fruits of the baobab tree (*Adansonia digitata*). The baobab fruit comprises of a very hard outer shell, whitish powdery pulp and kidney shaped seeds. The shell and the seeds are removed and discarded. The pulp is then sieved and stored in the form of a fine powder.
8. In response to questions from the Committee, the applicant provided further information on the procedures employed for the harvesting and processing of the fruit. The physical nature of the fruit (which resembles a coconut in hardness) provides some reassurance that damage leading to possible environmental and microbiological contamination will be minimal.
9. The applicant also submitted additional data which showed the NI to have minimal contamination with soil and other detritus. The level of acid insoluble ash found in one sample was attributed to inappropriate handling and the use of trial production technology. The applicant proposed that this result, which would fall outside the specification of the NI, should be ignored. Another sample appeared to contain a disproportionately high amount of endogenous material (i.e. material other than pulp, derived from the fruit. . The applicant noted that this sample was one that had been prepared in under laboratory conditions and may therefore have limited relevance to the commercial product. The applicant highlighted that four other samples had consistently lower levels of endogenous material
10. The applicant has provided details on the phytochemistry of compounds found in the seeds, roots, leaves, bark and fruit of *A. digitata* based on literature reports. According to scientific literature various triterpenoids (beta-sitosterol, beta-amyrin palmitate, alpha-amyrin palmitate and ursalic acid) are present in the fruit. Organic acids such as citric, tartaric, malic, succinic and ascorbic acid have also been reported to be present in the fruit pulp.
11. The applicant also intends to market the NI as a powdered, depectinised extract, as the pectin content of the raw pulp may have an undesirable viscosity and cloudiness which can limit product applications. This product is not considered in detail because pectinases (The applicant intends to use Pectinase 714L, Biocatalysts) are permitted treatments in the preparation of fruit juices (Directive 2001/112/EC), indicating that their use should not give any cause for concern in this application.
12. The applicant has provided nutritional data on three batches of the NI. Each batch is from a different region and has been analysed in duplicate. The results indicate that there is little regional difference in composition of the NI.
13. The vitamin C content of the NI is variable and reported values (4 samples, 3 analysed in duplicate) show a range between 74 and 163 mg per 100g fruit pulp. A number of B vitamins are also present in the NI and the content of thiamine and riboflavin varies between 0.05-0.11 and 0.01-0.03 mg/100g respectively. Analysis's of the amino acid content has also demonstrated that the levels are consistent between geographical locations.
14. The pectin content of the NI varies from 23.4-33.8% by weight, which is consistent with values reported in the scientific literature.

15. The NI contains low levels of fatty acids (less than 1%). The fatty acid composition of the NI as determined by gas chromatography is as follows:
- Alpha linoleic acid 17-20%
 - Linoleic acid 13-20%
 - Oleic acid 19-31%
16. The applicant also shown that the trace metals present in the NI are comparable with values reported in scientific literature for baobab fruit. Levels of arsenic, cadmium, lead and mercury were found to be within agreed safety levels.
17. As the NI is harvested in the wild it is not anticipated that pesticides will be present in the final NI. However, a multi-residue screen for pesticide content was carried out on three batches of the NI, which confirmed that no residues were detectable.
18. A detailed specification for the NI is attached at Annex A

Discussion *The Committee was satisfied that the information supplied by the applicant demonstrated that the product was harvested in a manner that ensured that process contamination was kept to a minimum. The Committee also accepted that the data provided by the applicant adequately described the compositional profile of the NI.*

II. Effect of the production process applied to the novel food

Information on this aspect is provided on p.10 of the application dossier

19. A simple, exclusively mechanical, process is used to obtain the fruit pulp. First the fruit is harvested, the hard outer shell of the fruit is cracked and the contents removed. The seeds are then separated from fibrous material and mesocarp. This is screened to remove further unwanted fibrous and flaky material, leaving a fine mesocarp powder, which is stored in clean food grade packaging.
20. The applicant states that during the production process the moisture content falls to around 10 – 13%. Fruit pulp from different areas within a particular region is blended to give a consistent product from one batch to another.
21. In response to a request from the Committee regarding shelf life, the applicant provided additional analytical data to show that the levels of Vitamin C and other key nutrients remained stable over time. The applicant did not indicate a specific shelf life for the products but concluded that these data demonstrate that dried Baobab fruit pulp is stable over the time period examined.
22. Also in response to the Committee's concerns about the rigour of the quality control system, the applicant provided additional clarification as to the extent of the Pre-Qualified Supplier System. The applicant has indicated that regular audits will take place to ensure that the NI produced by their suppliers is within the stated specification (Annex A).

Discussion: *The Committee was satisfied with the applicant's proposed production process and audit procedures.*

III. History of the organism used as the source of the novel food

23. See Section X below.

IX. Anticipated intake/extent of use of the novel ingredient

Information on this aspect is provided on p.13-14 of the application dossier

24. The applicant that Baobab dried fruit pulp and the depectinised pulp should be used in such products as smoothies, at a level of 6-8%, and cereal bars at levels between 5% and 10%. The applicant estimates that intake of the NI would be 6-10g in a 100g smoothie drink, and 10-15g in a 100g cereal bar.
25. The application also refers to potential use in other, unspecified, health food products at levels around 5-10%. The applicant suggests that the pulp could be used in biscuits, confectionery and other (unspecified) related food products.
26. The applicant has not provided any calculations based on dietary survey data and it is therefore not possible to estimate average, and high level intake of the NI arising from consumption of the specified products.

Discussion *The Committee was content that the intended uses of the NI did not give rise to concern and there was no requirement to restrict use. (See also section XIII below)*

X. Information from previous human exposure to the novel ingredient

Information on this aspect is provided p. 14-19 and Appendices 7/7a/7b of the application dossier

27. The applicant has highlighted a number of publications indicating that the fruit pulp has a long and extensive history of consumption amongst indigenous Africans. The pulp can be consumed as such, in drinks or used as an ingredient in other foods.
28. The applicant has also provided information on current use in Africa from two questionnaires. The first was completed by nineteen participants at the PhytoTrade Annual General Meeting in May 2006 and confirms literature reports that the fruit pulp is widely consumed in the areas where it is available.
29. The second questionnaire was completed by fifteen experts (nutritionists and botanists from Africa, the EU and the US with knowledge of African diets and food crops. These provide additional evidence of that baobab pulp is a familiar food in various parts of Africa and that there are no known toxicity issues. There is a possibly not unexpected laxative effect if the product is consumed in excess.
30. The applicant has also presented a literature review indicating that the baobab fruit (*A. digitata*) is also consumed in India and other *Adansonia* species have a history of consumption in Australia (Appendix 7b of the application dossier). There are also references to limited sales in the Europe, for example in ethnic markets and in food supplements. However, the Food Standards Agency is

satisfied that the fruit pulp does not have a significant history of consumption prior to May 1997 and is therefore to be regarded as a novel ingredient.

31. The fruit pulp is sometimes used as a folk remedy and numerous medicinal uses have been reported in the literature. Laboratory studies have indicated that the pulp may have some antipyretic and hepatoprotective effects. Extracts from other parts of the tree (leaves and roots) have antibiotic effects *in vitro*.

Discussion *The Committee accepted that the information supplied indicated that the product has an extensive history of traditional consumption in a significant geographical area of Africa. The Committee did not comment on any perceived health benefits that are attributed to the consumption of the NI as this is outside the scope of a novel food assessment.*

XI Nutritional information on the novel food

Information on this aspect is provided on p.19-28 of the application dossier

32. The applicant highlighted that the NI has a range of potential nutritional benefits due to the high levels of ascorbic acid, pectin, linoleic acid and several B vitamins. Although these nutrients are present in relatively high concentrations compared with other foods, the low level of consumption of the NI means that it is unlikely to have a major impact on the nutrient content of the diet. Further information on the composition/ of the NI is presented in section I above.

33. The presence of anti-nutrients in the NI has also been examined (see Section XIII below).

Discussion *The Committee accepted that the nutritional profile of the NI, which was consistent with other fruits, did not provide any cause for concern*

XII. Microbiological information on the novel food

Information on this aspect is provided on p.26 of the application dossier

34. The applicant has carried out analyses of three separate batches of the NI. These results confirmed that levels of coliforms, *E. coli*, *S. aureus*, faecal *Streptococci*, *Salmonella* are within acceptable safety limits. The Committee sought clarification of discrepancies in the recorded levels of yeast and mould contamination. Additional information provided by the applicant indicated that typical levels of yeast were <100cfu/g and moulds are within the range $10^2 - 1.4 \times 10^4$ CFU/g. The applicant has advised that these figures are well within the recommended limits for yeasts and moulds in Dried Foods (to be cooked), specified by the Institute of Food Science and Technology (IFST).

Discussion *The Committee agreed that the levels of micro-organisms did not give cause for concern. The Committee noted that that whilst the levels of yeast and moulds appeared to be high, the NI complied with recognised limits for this type of*

contamination¹. The Committee was also reassured that the product was analysed for mycotoxins (See XIII below), and that the applicant has undertaken to carry out regular audits that will include an investigation of the extent of yeast and mould contamination.

XIII. Toxicological information on the novel food

Information on this aspect is provided on p.26-35 of the application dossier

Literature survey

35. The survey undertaken by the applicant found no mention of any toxic effects with regard to Baobab fruit pulp.

in vivo studies

36. LD₅₀ test in rodents – the dossier refers to a study from 1994 in which the results of LD₅₀ tests on rodents were reported. The test material was from a different source to PhytoTrade's product and was an aqueous extract of freeze-dried pulp, administered intraperitoneally. The resulting LD₅₀ was 8000mg/kg. The applicant has estimated that this is equivalent to 746-840g of fruit pulp for a 70kg adult.

Natural toxins

37. Cyclopropene fatty acids – Sterculic and malvalic acids are two cyclopropene fatty acids (CPFAs) that been found in a large number of seed oils from plant families of the order Malvales (Sterculiaceae, Malvaceae, Bombaceae and Tiliaceae). CPFA's inhibit fatty acid metabolising enzymes leading to an accumulation of saturated fats. They are present in the seed oil of baobab but there are no reports of them being found in the fruit pulp. The levels of fatty acids, including malvalic and sterculic acids, were determined by GC-MS in 3 batches of the NI. The method used and the results obtained are detailed in appendix 18 and summarised in Table XIV (page 30) of the dossier. The range of values for malvalic acid were 0.03-0.18 mg/g and for sterculic acid 0.01-0.08 mg/g. The applicant estimates that there is a safety factor of 3000 between the intake associated with adverse effects (in rat studies) and the estimated intake in humans and concludes that there is no cause for concern.

38. Erucic acid is undetectable in the NI (detection limit 0.10%).

39. Alkaloids – There are historical reports of the occurrence of an alkaloid, adansonin, in the bark of the baobab tree and in other related species. Studies were commissioned by PhytoTrade to attempt to detect alkaloids in baobab fruit pulp using thin layer chromatography, but none were detected (sensitivity (0.001%)).

¹ Regulation (EC) 2073/2005 defines microbial criteria for foodstuffs, but does not include a specification for levels of yeast and mould. The IFST recommendations are viewed to be a satisfactory alternative and are widely used by industry.

40. Ochratoxin – analysis of the NI for Ochratoxins showed that all samples were below the level of detection. The Committee recommended that the applicant should additionally carry out analyses for aflatoxin, a mycotoxin commonly associated with dried fruit. The applicant carried out the necessary analyses which confirmed that the levels of aflatoxins were within legal limits (see XII above).
41. Cyanide – PhytoTrade baobab fruit pulp samples (hydrolysed and aqueous extracts) were analysed for cyanide content (appendix 21 and Table XVII). All samples analysed were below the limit of detection for the method used (5mg/kg).

Other safety-related data

42. The applicant has presented information from the literature regarding related botanical families, such as the Bombaceae; and no toxicity issues were identified. Questions regarding any known toxicity/safety concerns were also included in questionnaires presented to two separate audiences and none were identified (see paragraph 29 above).

Allergenicity

43. No evidence of any allergenic effects in baobab fruit pulp or other genera of the family Malvaceae was found in the published literature. In addition, a study published in 2001 on the irritant effects of baobab fruit pulp on human volunteers is cited as evidence that the fruit pulp is “non-irritant”.

Discussion Members noted that the information provided by the applicant was not typical of other novel food applications, which generally include a series of classical toxicological analyses. However in this specific case Members were reassured that the NI was a simple fruit preparation that formed an integral part of the traditional diet in a large geographical area of Africa.

Members were reassured that the additional mycotoxin analyses indicated that the NI would not be contaminated by mycotoxins. Members also noted that the hard outer shell would offer protection and ensure that the NI was unlikely to be damaged and contaminated by fungi before harvesting. Members noted that the applicant's PQS system requires that mycotoxin (aflatoxin) analyses are carried out routinely as a check against post-harvest contamination.

Members noted that there were no reports of allergenicity in the family Malvaceae and on the basis of this information agreed that the NI was unlikely to be a major cause of allergenicity and that people with existing food allergies were unlikely to suffer cross-reactions after consuming it. However Members did note that, as with other fruits, there was the potential for individuals develop an allergy to proteins in the NI.

Proposed labelling

44. *The applicant has stated that the NI will be labelled in accordance with EU food labelling legislation thereby ensuring that consumers are informed of its presence in food products.*

Discussion *Members accepted that the product would be labelled appropriately.*

OVERALL DISCUSSION

45. The information supplied by the applicant offers sufficient reassurance that the consumption of the NI does not give rise to any toxicological or allergenic concerns. Members agreed that the absence of extensive toxicological analyses did not give cause for concern because baobab fruit was a staple part of the diet throughout Africa and a retrospective toxicological assessment would have limited value. In coming to this conclusion the Committee wished to draw a distinction between this application and other foods that had previously subject to a novel food assessment that could be viewed to be a regularly consumed outside the EU. In all previous cases there was either a specific safety concern (eg allergenicity or liver toxicity) or the food was of limited palatability and was consumed essentially as a natural remedy rather than as a staple part of the diet.

46. The microbiological analysis highlighted that the novel ingredient contained significant levels of yeast and mould contamination. Whilst the Committee accepted that the levels were within guidelines for similar dried products, the issue of mycotoxin contamination was identified as being of particular concern. The Committee was reassured by the additional analyses carried out by the applicant that indicated that levels of aflatoxins were within EU limits for dried fruit. Members were also reassured that the applicant would carry out routine quality control tests to ensure that the NI contains demonstrably low level of aflatoxins.

CONCLUSION

The Advisory Committee on Novel Foods and Processes is satisfied by the evidence provided by PhytoTrade Africa that the range of uses for Baobab Dried Fruit Pulp is acceptable, subject to the applicant's adherence to the proposed specification and the production parameters described above.

July 2007

Product Specification for *Adansonia digitata* fruit pulp powder

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 than 2%
Loss on drying	not more than 12%
Solubility	Partially soluble in hot and cold water
Ash	[insufficient data – limits will be determined in the light of future production batches]

Heavy metals:

Lead	less than 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 1g
Staphylococcus aureus	Absent in 1g
Salmonella	Absent in 25g