

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

BAOBAB DRIED FRUIT PULP

**Issue**

An application has been submitted to the UK Competent Authority for authorisation of Baobab dried fruit pulp under the Novel Foods Regulation (EC) 258/97. The Committee is asked to advise whether the available data provides an adequate basis for a safety assessment, and if it recommends authorisation of this novel ingredient.

**Background**

1. PhytoTrade Africa has submitted an application for the authorisation of Baobab dried fruit pulp as a novel food ingredient. The UK Competent Authority accepted the application on 9 August 2006. In accordance with Article 6(3) of Regulation (EC) No 258/97, the UK has 3 months to prepare an initial assessment report on the above application. The European Commission will then circulate this initial assessment to the Competent Authorities in the other Member States for comment. The application dossier is attached as Annex A.
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. The applicant proposes to market their 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. The applicant, PhytoTrade Africa is a trade association representing a number of 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 throughout the process. PhytoTrade Africa currently has 58 members, which are listed in Appendix 1 of Annex A.

5. The present application for authorisation of the NI was prepared pursuant to Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients. The NI has been classified as a complex novel food from a non-GM source (class 2.2). The requirements for a submission for this class are as follows:

I	<b>Specification of the NF</b>	X	VIII	Ability to survive in and colonise the human gut	-
II	<b>Effect of the production process applied to the NF</b>	X	IX	<b>Anticipated intake/extent of use of the NF</b>	X
III	<b>History of the organism used as the source of the NF</b>	X	X	<b>Information from previous human exposure to the NF or its source</b>	X
IV	Effect of the genetic modification on the properties of the host organism	-	XI	<b>Nutritional information on the NF</b>	X
V	Genetic stability of the GMO	-	XII	<b>Microbiological information on the NF</b>	X
VI	Specificity of expression of novel genetic material	-	XIII	<b>Toxicological information on the NF</b>	X
VII	Transfer of genetic material from GM microorganisms	-			

6. The information presented in the dossier is structured accordingly and is considered below. The NI is unprocessed and has a long history of traditional use in Africa. The applicant is of the view that this history of use provides significant reassurance about the safety of the product, reducing the need for conventional safety studies
7. The Committee will wish to note that the application dossier was published on the Agency's website for public consultation, on 11 August. Two comments were received during this period. 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 moulds and mycotoxins and is mentioned in sections XII and XIII below.

## **I Specification of the Novel Ingredient (NI)**

Annex A p.1 6 – 9 and 19-27

8. Baobab dried fruit pulp is obtained from the fruits of the baobab tree (*Adansonia digitata*). The baobab fruit (otherwise known as capsules) contain a whitish powdery pulp and kidney shape seeds.
9. 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 ursolic 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.

10. 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. All data provided by the applicant relate to the unprocessed dried pulp, and the applicant does not provide any details as to how the pectin will be removed or the composition of the NI in this form.
11. 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. Table 1 of Annex A provides comparative compositional data, which shows the variation and specification of the NI and highlights that there is little regional difference in composition of the NI.
12. The vitamin C content ranges between 74 and 163 mg/100g and consumption of the NI at the anticipated level of 10-15 g/day would provide between 2 -4% of the RDA for vitamin C (see Section IX below).
13. The pectin content of the NI varies from 23.4-33.8% by weight, which is consistent with values reported in the scientific literature.
14. The fatty acid composition of the NI has been determined by gas chromatography and is explained in detail in Annex A, Appendix 3. The total fatty acid content is less than 1% and the principal fatty acids are:
  - Alpha linoleic acid 17-20%
  - Linoleic acid 13-20%
  - Oleic acid 19-31%
15. A range of B vitamins are also present in the NI and analytical data demonstrates that thiamine and riboflavin content varies between 0.05-0.11 and 0.01-0.03 mg/100g respectively. Analysis's of the NI's amino acid content has also demonstrated that the levels are consistent between geographical locations (Table XI).
16. The applicant has provided a comparison of trace metals present with scientific literature, which shows that the levels present in the NI are comparable with the published data. The NI has also been analysed for arsenic, cadmium, lead and mercury and these are well within the acceptable safety standards.
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.

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

Annex A p. 10

18. 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.
19. The applicant states that during the production process the moisture content falls to around 10 – 13%.

20. Fruit pulp from different areas within a particular region is blended to give a consistent product from one batch to another. Further information is given in appendix 2 of the dossier.
21. The applicant has not indicated the shelf life of the NI, but information on the stability of the product is presented in Appendix 5 of Annex A. In total, 6 samples of Baobab were analysed in duplicate. One of these samples was collected in 2004, two in 2005 and 3 fresh samples were collected in July 2006. The analysis highlights relatively large differences in the yeast and mould content of the fresh and old samples (See Section XII). Levels of vitamin C were on average 40% lower in the older samples (108 mg/100g) than in the fresh samples (183 mg/100g). Moisture content was higher in the older samples as the dried fruit pulp absorbs moisture over time (average 12.4% compared with 10.8%). 4-Demethylsterols were present in both the fresh and old samples, and no alkaloids were detected. Levels of cyclopropene fatty acids (CPFAs) were found to be low in all the samples. The applicant is of the view that these data demonstrate that dried Baobab fruit pulp is stable over the time period examined.
22. PhytoTrade have a basic quality control system that is described on pages 11-13. This does not require that any compositional, natural toxicant or microbiological analyses be carried out.

### **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**

Annex A, p. 13-14

24. PhytoTrade plan to use Baobab dried fruit pulp and the depectinised pulp 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%. Additionally, the pulp could be used in biscuits, confectionery and other (unspecified) related food products.
26. The applicant has not provided any 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.

### **X. Information from previous human exposure to the novel ingredient**

Annex A p. 14-19 and Appendices 7/7a/7b

27. The dossier highlights a number of publications indicating that the fruit pulp has a long history of consumption by the indigenous people of Africa. The pulp can be consumed as such and it is also made into drinks or used as an ingredient in other foods.

28. The applicant has also provided information on current use from two questionnaires. The first was completed by 19 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 (Appendix 7).
29. The second questionnaire was completed by fifteen experts (nutritionists and botanists) with knowledge of African diets and food crops. The individual responses are presented in Appendix 7a. 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, other than 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). There are also references to limited sales in the Europe, for exempling 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 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*.

## XI Nutritional information on the NF

Annex A p. 19-28

32. The applicant highlights that the NI has a range of nutritional benefits including high ascorbic acid content, high pectin content, linoleic acid and several B vitamins. However these are all based on values per 100g of the NI which is significantly higher than the proposed levels of consumption. Further information concerning the composition/ of the NI is detailed in the specification section.
33. The presence of anti-nutrients in the NI have also been examined (see Section XIII below):

## XII. Microbiological information on the novel food

Annex A p.26

34. The applicant has provided the following microbial analyses on three batches of the NI:

Microbiological test	H.S.I 300/3/1	H.S.I 300/3/2	H.S.I 300/3/3
Total viable count (cfu/g)	$3.77 \times 10^3$	250	$3.20 \times 10^4$
Coliforms (presumptive) (cfu/g)	< 10	< 10	< 10
<i>E.coli</i> (presumptive) (cfu/g)	< 10	< 10	< 10
<i>Staphylococcus aureus</i> (cfu/g)	< 20	< 20	< 20
Faecal <i>Streptococci</i> (cfu/g)	< 20	< 20	< 20

Microbiological test	H.S.I 300/3/1	H.S.I 300/3/2	H.S.I 300/3/3
Yeast (cfu/g)	< 20	< 20	< 20
Moulds (cfu/g)	3.49 x 10 <sup>3</sup>	570	1.19 x 10 <sup>4</sup>
<i>Salmonella sp.</i> (/25g)	Not detected	Not detected	Not detected

35. Analysis has confirmed that the levels of coliforms, *E.coli*, *S.aureus*, faecal *Streptococci*, yeast and *Salmonella* are well within acceptable safety limits. However the Secretariat notes that additional results are given in Appendix 5, Table 3 indicating that some samples contain higher levels of yeast (>3.00x10<sup>7</sup> CFU/g) and moulds (1.4x10<sup>5</sup> CFU/g).

36. The following comment was received from a member of the public in relation to the microbiological analysis:

“I notice that for the microbiological examination the fungi are simply presented as total moulds. Identification to genus or (better) species would be much more informative.”

### **XIII. Toxicological information on the novel food**

Annex A p. 28-34 (section 8) and Appendix 7b

#### Literature survey

37. No mention of any toxic effects was found in the literature with regard to Baobab fruit pulp.

#### in vivo studies

38. LD<sub>50</sub> test in rodents – the dossier refers to a study from 1994 in which the results of LD<sub>50</sub> 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 LD<sub>50</sub> was 8000mg/kg. The applicant has estimated that this is equivalent to 746-840g of fruit pulp for a 70kg adult.

#### Natural toxins

39. 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 itself. The levels of fatty acids, including malvalic and sterculic acids were determined in 3 batches of PhytoTrade’s baobab fruit pulp by GC-MS. The method used and the results obtained are detailed in appendix 18 and summarised in Table XIV (page 30). 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.

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

41. Alkaloids – information on the reported occurrence of an alkaloid, adansonin, in the bark of the baobab tree and in other related species is quoted from the literature. Studies were commissioned by PhytoTrade to attempt to detect alkaloids in baobab fruit pulp using thin layer chromatography (appendix 19), but none were detected at the level of sensitivity attained (0.001%).
42. Ochratoxin – analysis of PhytoTrade baobab fruit pulp samples for ochratoxins showed that all samples were below the level of sensitivity of the test method used (Appendix 20 and Table XVI) which is below the EU limit for this mycotoxin.
43. The following comment was received from a member of the public:

“The product will have to be below the limits for the mycotoxin patulin presumably as it is a fruit. Why was ochratoxin A considered in preference to patulin?”

The applicant has commented in the dossier that “No other mycotoxins, such as aflatoxin, were tested for ... since these toxins are not generally expected to be found in dried fruit pulp” (page 33 of Annex A). Patulin-producing organisms are associated with mouldy apples, pears and some vegetables. EU legislation<sup>1</sup> sets an upper limit of 0.05 mg/kg for patulin in fruit juices and in cider or other alcoholic drinks made from apples, but this limit would not apply to drinks containing the NI. Lower limits of 0.025 and 0.010 mg/kg have been established for patulin in other apple-based products and in baby foods. The Secretariat is in dialogue with colleagues in the Agency who have expertise in mycotoxin contamination of fruit in order to determine whether the applicant’s argument is appropriate in relation to pre- and/or post-harvest contamination. Members will be updated on this issue at the meeting.

44. 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

45. Information is presented from the literature regarding related botanical families, such as the Bombacaceae; no toxicity issues were identified. Questions regarding any known toxicity/safety concerns were also included in questionnaires presented to two separate audiences (appendices 7 and 7a) and none were identified.

#### Conclusion

46. The applicant concludes from all the above data that there is no evidence that proposed levels of consumption of baobab fruit pulp would have any harmful effects.

#### **Allergenicity**

Annex A p. 29 (section 8); p35 (section 9)

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<sup>1</sup> Regulation (EC) No 466/2001 (as amended)

47. No evidence of any allergenic effects of baobab fruit pulp was found in the published literature. In addition, a study published in 2001 on the irritant effects of baobab fruit pulp on human volunteers (referred to on p29, section 8) is cited as evidence that the fruit pulp is “non-irritant”.

**Committee action sought**

48. The Committee is asked to consider whether the available data are adequate to determine whether the NI complies with the criteria for acceptance under the novel food regulation, namely:

- It does not present a danger to the consumer
- It does not mislead the consumer
- It is not nutritionally disadvantageous compared with foods which it might replace.

49. If so, the Committee is asked whether it is content to recommend approval for the NI to be used in the proposed food products.

50. If not, the Committee is invited to identify what further data should be provided.

**Secretariat  
January 2007**

**Annex attached:**

Annex A – Application dossier

**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**

**APPLICATION DOSSIER FOR AUTHORISATION OF BAOBAB DRIED FRUIT  
PULP AS A NOVEL FOOD INGREDIENT**

This document has been published on the Food Standards Agency web-site at:  
<http://www.acnfp.gov.uk/assess/fullapplics/baobab>

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