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FOOD STANDARDS AGENCY

Mr Andreas Klepsch
European Commission
By email

12 July 2007 Reference: NFU 621

Dear Mr Klepsch,

INITIAL OPINION: BAOBAB DRIED FRUIT PULP

On 9 August 2006, the UK Competent Authority accepted an application from PhytoTrade Africa for Baobab Fruit Pulp as a novel food ingredient, in accordance with Article 4 of regulation (EC) 258/97. The Advisory Committee on Novel Foods and Processes (ACNFP) reviewed this application and their opinion is attached. I apologise for the delay in submitting this opinion as the ACNFP's evaluation was extended while we obtained additional information from the applicant.

In view of the ACNFP's opinion, the UK Competent Authority considers that Baobab Fruit Pulp meets the criteria for acceptance of a novel food defined in Article 3(1) of regulation 258/97.

I am copying this letter and the ACNFP's opinion to the applicant.

Yours sincerely,

(By e-mail only)

Dr Chris Jones
For the UK Competent Authority

INVESTOR IN PEOPLE

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POSITIVE ABOUT DISABLED PEOPLE

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 disproportionably 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 triterpernoids (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 exampling 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 – $1.4x10^4$ 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*

contamination[1]*. 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. LD_{50} test in rodents – the dossier refers to a study from 1994 in which the results of LD_{50} 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_{50} 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 be 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

ANNEX A

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