Meeting

Bambara Groundnut (Vigna Subterranea (L.) Verdc) - Discussion Paper

Committee Paper for Discussion - ACNFP/171/03

Advisory Committee For Novel Foods and Processes

Application for authorisation for Bambara Groundnut (Vigna Subterranea (L.) Verdc) as a traditional food from a third country.

WHATIF F&I PTE LTD., Application Number - RP2272

Issue

A notification for a traditional food from a third country has been received under article 15 of assimilated regulation 2015/2283, for Bambara groundnut (*Vigna subterranea* (L.) verdc.).

The Committee is asked to advise whether there are safety concerns with the proposed use of this traditional food for the GB market. The information from the Committee will provide the basis for risk management decisions made by the FSA/FSS.

Members are also asked whether, in using this notification as a case study, there is specific advice for applicants that the Committee wish to put forward. The Secretariat aims to use this to develop wider advice to support traditional food notifications in future.

Background

1. On the 10th October 2024 the FSA and FSS received a notification for Bambara Groundnut (*Vigna subterranea* (L.) verdc.) from WhatIF F&I Pte Ltd. (Singapore). The notification proposes to market the product as a dried whole 'groundnut' seeds and groundnut flour (processed from cooked groundnut seeds). Specific use categories with maximum use levels have not been proposed but it is expected to be consumed similarly to or a lesser extent than, other dried legumes (for cooking), and legume type flours.

2. Bambara groundnut is native to Africa (widespread across northeast, west central and west regions). The applicant indicates that it is also grown and consumed more widely across Asia, Australasia, Caribbean and countries of the Indian Ocean.

3. The FSA and FSS have four months from the date of receipt of a valid notification dossier, to provide reasoned safety objections to the Traditional Foods sale in GB. If authorised, the updated authorisation will be open to any company subject to the specifications and conditions of use and additional uses detailed in the dossier. Advice on the safety of this traditional food is requested to inform this process.

4. The notification dossier is attached as Annex A. The request for further information letters (with responses) are attached as Annex B. All supporting documents for all sections of the application, which have been updated following the request for further information, can be found in Annex C. All annexes contain confidential information.

5. For information, in the EU, this application was authorised under Commission Implementing Regulation (EU) 2024/2047 of 29 July 2024, which is not extended to the UK, following EU exit. This was authorised in the EU without reasoned safety objections by Member States or EFSA.

6. EFSA published a Technical Report in January 2024 summarising their view [Annex D], that did not raise safety concerns and contains their review and outcome of a further literature review. This information was provided by the applicant to support an authorisation in GB.

7. It is noted that allergenicity considerations were made by EFSA. They also raised points on the cooking/soaking requirements of the whole seeds. It is also noted that the EU adopted lowered total plate count and yeast and mould specifications for the traditional food, as recommended by EFSA, which has not been extended to the application submitted to FSA/FSS.

This application

Identification

8. The traditional food, Bambara groundnut (*Vigna subterranea* (L.) verdc) is a tropical legume that grows underground, comprising of the edible cream coloured mature seed, also known as the 'Bambara bean' or referred to as the raw groundnut. The applicant stated that there is no formal cultivar used. The applicant provided taxonomic classification and verification of the Bambara seeds identity (Annex A; p 10-11 of dossier). Information on the location where the traditional food is grown, harvested and sourced from in Africa is provided in Annex C [Annex 1]).

Production Process

9. The applicant has stated that production is carried out according to Global Food Safety Initiative (GFSI) standards (Annex B; question 1, c., of initial response letter].

10. A flow chart can be found in Annex C [Annex 1; p11] which identifies the chosen Critical Control Points. Following a request for further information on food safety management, a HACCP is provided (Annex C [files 'HACCP Plan Summary' and 'Hazard Analysis Worksheet for Process Steps – BGN Flour']. This has identified the hazards and risks being managed and measures in place with information on Critical Control Points. The HACCP plan also states compliance with GMP. Further justification for all food safety management measures was requested thereafter and the applicant response can be found in Annex B; question 1, b., of response letter dated 7th March 2025.

11. Following an initial FSA request for further information, regarding process controls the applicant had stated that changes to the production processing parameters and storage conditions had been made since the initial submission to FSA/FSS (Annex B; question 1, d., of initial response letter]. Further details were requested thereafter and the response from the applicant is provided in Annex B; question 1, c., of response letter dated 7th March 2025.

12. A detailed confidential description is provided on these processes describing cultivation to end product in Annex C [Annex 1]. Briefly, in line with traditional practices, the production process is a manual process starting with sourced sun dried, hulled and deshelled Bambara groundnut mature seeds which are manually

sorted in a central warehouse and stored until shipping. These are shipped to a processing location where washing of the seeds takes place and, for the flour product, further steps include cooking in water, drying and milling. Cooking in water takes place at 75-80°C until the food consists of a ‘slurry’. This is then dried in a rotary vacuum dryer until the desired water content is met. The cooking and processing steps for the flour product is described in Annex C [Annex 1; page 10].

13. Information on storage, transport, drying conditions and packaging is provided in Annex C [Annex 1].

14. A certificate is provided in Annex C [Annex 1; p 15] to confirm absence of pest infestation.

15. The applicant has stated that there are no uses of chemicals or pesticides during cultivation or harvest [Annex B; question 1, b., of response letter dated 7th March 2025]. Further information on pest control management can be found in Annex C [Annex 1; p 13-14 and Annex B; question 1, b., of response letter dated 7 th March 2025.

16. Pesticide residues were tested in the compositional analyses on both raw dried whole seeds prior to processing and on the end product flour. The results for all pesticide residues were below the limit of quantification. All batches of dried whole Bambara groundnut seeds are screened for pesticides and the flour is analysed every 3 batches.

17. Analyses are conducted on whole seeds to ensure they comply with the intended specifications before flour processing is conducted.

18. Details on raw materials are provided in Annex C [Annex 1; p 16-2 and the corresponding files].

19. The processed flour product is stored in double sealed HDPE hermetic bags and information on temperature and humidity is provided.

Composition

20. Information on composition can be found in Annex A; p 13 – 28 of dossier, where the data is presented throughout this section of the dossier. Validated methods are used for the analyses and laboratory accreditations are provided in Annex C [Annex 4; p2, 33-39, 40-68]. Further justification for the certificates provided is in Annex B; question 2, a., of initial response letter.

21. Batch data is provided for 2-7 independent batches of the dried whole groundnut seeds and 5-6 independent batches of groundnut flour in line with guidance for a whole foods classification. Further batch data is provided by the applicant for 2 batches of groundnut flour following a request for information on stated changes made to the production process to allow for further assessment to be made with regards to control of mycotoxin and microbial levels (Annex B; question 2, a., of response letter dated 7th March 2025). All certificates of analyses can be found in Annex C.

22. Parameters included a proximate analysis and macronutrients, other nutritionally relevant constituents (minerals, vitamins, amino acids, fatty acids), antinutrients, heavy metals, pesticides, mycotoxins, pyrrolizidine alkaloids, microbial contaminants, Polychlorinated biphenyls, polycyclic aromatic hydrocarbons. Following a request for further information, data on ash levels in groundnut flour and the mass balance calculations for dried groundnut seeds and groundnut flour was also provided (Annex B; question 2, b., of the initial response letter).

23. A literature search has been performed, and a report is provided in Annex C [Annex 7]. This was produced to inform the compositional testing of Bambara groundnut.

24. Further information on the variability of mycotoxin and microbial levels, the sources of variation and controls and monitoring was requested. It was noted that for Aflatoxin B1, the level in one batch of the flour was close to the threshold limit and a greater level of variability across batches was observed for total plate count and yeast and moulds for both the raw groundnut seed and the flour; one batch was discarded due to high levels across these parameters (Annex A; p16 and 18 of dossier). The applicant response can be found in Annex B: question 2., d, of initial response letter. Additional data for 2 batches of groundnut flour is provided as described above. The applicant also refers to their food safety management in their response.

Stability

25. Information on stability was provided in Annex A; p 29 of dossier and Annex C [Annex 8]. However, this has been updated following a request for further information where full stability reports were subsequently provided alongside all certificates of analyses (found in Annex C).

26. The applicant has provided a range of analytical data investigating stability under normal and accelerated conditions. The applicant investigated the stability of 1 batch of Bambara groundnut flour in a beverage formulation under normal conditions for 12 months. The applicant also investigated the stability of 2 batches of dried groundnut seeds, 3 batches of groundnut flour and 3 batches of a Bambara groundnut beverage under accelerated storage conditions (40 °C, 75% relative humidity) over a period of 120 days. The data is provided to support a shelf life of 12 months.

27. Stability data covering the intended storage duration for the dried groundnut seeds at the central warehouse was queried with the applicant. However, it is understood that dried groundnut seeds are tested on receipt and prior to further processing as part of food safety management and in line with product specifications. Stability data is therefore provided on dried groundnut seeds following compliance with this product testing.

Specifications

28. The specification parameters for dried Bambara groundnut seeds and Bambara groundnut flour, were assessed using internationally recognised methods. Information on specifications can be found in Annex A; p 30-31 of dossier.

29. In a request for further information (Annex B; question 3.a., of initial response letter), the rational for total plate count and yeast and mould limits were queried. The applicant has not extended lowered total plate count and yeast and mould specifications for the traditional food, as recommended by EFSA in their application submitted to FSA/FSS. The justification provided by the applicant was to allow for a full assessment by the FSA/FSS of the original submission data. The applicant state that at EU level, they are working towards the recommendations from EFSA and continually monitoring these levels and sources of contamination to meet the EFSA specification recommendations.

Experience of continued food use in the third country

30. The applicant has provided information supporting an extensive history of continued use beyond 25 years predominantly in regions and countries across Africa (Annex A; p 32-65 of dossier). A systemic literature review has been conducted. A scientific expert opinion is also provided in Annex C [Annex 9].

31. Traditional uses evidenced in this section relate to roasting and cooking of the legume. Preparation, handling and extent of use and target population exposure matches the proposed application.

32. A known precaution is cooking to reduce antinutrients and microbial contaminants.

Proposed uses and use levels

33. The applicant stated that the traditional food is intended to be used by the general population marketed in two forms of use: dried whole groundnut seeds and Bambara groundnut flour.

34. Specific use categories and maximum use levels have not been proposed.

35. The intended role in diet is expected to be similarly to, or a lesser extent than, other dried legumes (cooking required), and legume type flours.

36. It is noted that the dried whole seeds are intended to be cooked and an analysis of antinutrients present in the traditional food can be found in the composition section.

Allergenicity

37. It is noted that Bambara groundnut is of the legume family and allergenicity implications similarly for those individuals sensitive to peanuts, soy or pea is a consideration. An allergenicity literature review for Bambara groundnut and discussion on this can be found in Annex A; p 57-58 of dossier which indicates insufficient data to reach a conclusion.

38. A caution for those with known legume allergies is highlighted by the applicant. However, the applicant does not specify precautionary labelling or restrictions of use with their application.

39. An ELISA test was conducted by the applicant that did not detect Bet v 1 allergen or homologous proteins and cross allergens thereof (birch pollen allergen) above the levels of detection (Annex C [Annex 6]). An analysis was made with consideration for possible birch pollen allergenic proteins in the traditional food. An ELISA test was conducted that did not detect Bet v 1 allergen or homologous proteins and cross allergens thereof above the levels of detection (Annex C [Annex 6]). The Committee has previously considered this type of data is useful for identification of potential cross contamination but does not contribute

to the allergenicity assessment of the food itself.

Advice to applicants – Bambara as a case study

40. Members are aware that the Committee has reviewed and provided advice to the FSA and FSS on a number of traditional foods in the form of third country notifications. FSA/FSS expect, as trading relationships further develop, there may be increased interest in making use of this route to market through the novel food regulations. To support this, Members advice is sought on how to improve how the process operates. In particular, what applicants could do to have the best chance of smooth consideration through this process in the UK.

Members are asked:

- What key advice for applicants is needed to make the retained EFSA technical guidance for traditional food applications more comprehensive to support GB applications?
- What aspects of traditional food applications are typically lacking that make a conclusion on safety difficult?
- What recommendations would members have to the FSA to improve the process to support applicants and assessors?

Committee Action Required

- Members are asked whether there are safety concerns that need to be managed with this traditional food from third countries.
- Members are asked what additional advice to applicants would be most effective in supporting better quality and more complete dossiers from applicants in future.

ACNFP Secretariat

March 2025

Annexes

Annex A – Dossier [Confidential]

Annex B – Request for information with applicant’s responses [Confidential]

Annex C – Supporting documents with annexes, references and appendices [Confidential]

Annex D – EFSA 2024 technical report on the notification of dried seeds and flour thereof of *Vigna subterranea* (L.) Verdc.