Meeting

# Tetradenia Riparia Committee Paper for Discussion

### Committee Paper for Discussion - ACNFP/152/04

### Advisory Committee For Novel Foods and Processes

### Traditional Food Notification Number RP1086 – Bambara groundnut

## Issue

1. A notification has been received under the traditional food from third countries authorisation process (EC Regulation 2015/2283 as retained in UK law) for powdered Tetradenia Riparia from Super Bio Boost Ltd.

2. The Committee is asked whether there are safety concerns with the proposed use of this traditional food in the UK market. The information from the Committee will provide the basis for risk management decisions made by the UK.

## Background

3. On the 31st March 2022, the FSA (Food Standards Agency) received the submission for Tetradenia Riparia (Iboza) from Super Bio Boost Ltd. The product concerned is manufactured through drying and grinding of the Tetradenia Riparia leaf material. The food is intended to be used as a complimentary dietary supplement, which can be added to drinks and food, or used to make infusions. The product is intended for use in foodstuffs for the general population, with no restriction on population groups.

4. The Governments of the nations of the UK have four months to provide reasoned safety objections to the Traditional Foods sale in the UK. If authorised, the authorisation will be open to any company subject to the specification and conditions of use detailed in the notification. An assessment of the safety of this

traditional food is requested to inform this process.

5. The complete notification dossier is attached as Annex A. Relevant supporting information is attached as Annexes B, C, D, E and F.

# Identification

6. The plant, Tetradenia Riparia, from which the traditional food seeking authorisation is derived, originates from middle and southern African countries where it grows wild as well as being farmed for local consumption. The applicant provides information on the taxonomy of the plant, stating that it lies within the Lamiaceae family of flowering plants along with Mints, Sages and other commonly used herbs.

7. Visual and organoleptic descriptions of the plant have been provided within the dossier. The applicant also states that the parts of the plant which are traditionally used as a food are the leaves and roots, which are typically dried before chewing or subsequently grinding into a powder and consuming as a cold or hot water infusion, or mixed into foods.

# Production Process

8. Historically in Africa, the crop is grown and harvested for local consumption as a herbal remedy. The production methods described in this application are traditional and small scale, currently performed in Uganda. However, the applicant also describes the modernised methods which will be used to grind the dried leaves within the UK. This is the production process for which a HACCP plan has been provided in Annex C.

9. The proposed method of production is through traditional cultivation, harvesting, and drying within the southern African countries from which the Tetradenia Riparia plant originates. The dried whole leaves of the plant are then to be shipped to the UK for further processing; grinding into a fine, free-flowing powder, and subsequently packaged for sale. Details can be found in pages 45 of Annex B and pages 1-4 of Annex D.

10. The applicant states that no pesticides are used during cultivation due to the Tetradenia Riparia plants not being targeted by pests. A HACCP plan for the production process can be found in Annex C. The applicant draws particular attention to potential contamination of the product by other parts of the plant

(such as stems). They also highlight that drying of the harvested leaves provides an opportunity for fungal growth and subsequent mycotoxin production if conditions are not optimum. The conditions for drying are simply stated to be ambient (18-28°C and 70-80% humidity), with daily agitation of leaves over a period of 5-10 days. The process is stated to be carried out inside a secured building out of direct sunlight.

## Composition

11. The applicant provides an overview of the general nutrient composition of the Tetradenia Riparia plant matter as seen below.

| **Nutrient** | **Typical values (100g)** |
|---|---|
| Energy Kcal | 256 |
| kJ | 1058 |
| Protein | 17.5g |
| Fat | 5.6g |
| -of which saturates | 3.5g |
| Available Carbohydrates | 12.7g |
| -of which sugars | 0.4g |
| Fibre | 42.2g |
| Sodium | 22mg |
| -expressed as salt | 0.06g |

| | |
|---|---|
| Moisture | 8.8g |
| Ash | 13.2g |

12. The applicant also provides literature data on the composition of the essential oils (terpenes) found within the leaves of the plant. Other literature sources are provided here which aim to characterise the plant and its composition. Please note that the applicant does not provide any robust analytical data to evidence the microbiological or chemical compositions of their product, although it is later stated that analyses will be conducted at a UKAS accredited laboratory using accredited test methods. The compositional data provided by the applicant can be found in Annex B pages 6-9.

13. The applicant provides a consideration of toxic or harmful components of Tetradenia Riparia, including chemical and microbiological contaminants. The applicant states that risk from chemical contaminants within the product is reduced due to the traditional methods used to process the raw materials – which do not include any chemical treatment. The applicant does highlight that there is a potential risk from mycotoxin production, although they comment this is mitigated through the drying process.

14. With regards to the microbiological contaminants, the applicant highlights that the leaves are dried to below 0.6aw (test results are 0.415aw and 0.460aw), which should effectively inhibit the growth of pathogens. The results of the water activity test can be found in Annex F; no method information or evidence of accreditation has been provided.

# Stability

15. The applicant provides a basic consideration of the stability of the finished product. It is stated again that the powdered finished product has a water activity level of <0.6aw, thus is not prone to microbiological spoilage. It is stated that the powdered finished product is stable under ambient conditions and the proposed shelf life is 12 months from the date of packaging. The applicant has not provided any relevant supporting evidence for the stability of their own product.

# Specification

16. The applicant provides a range of specifications relating to the product seeking authorisation (‘Iboza’ - powdered Tetradenia Riparia). The physical properties of the product have been specified, along with the nutrient composition and both chemical and microbiological properties based on the literature as permitted in the guidance. The applicant has not provided any analytical evidence in support of their application but they do state that the regular testing once in production will be carried out by a UKAS accredited laboratory using accredited methods. Specification tables can be found attached as Annex D.

## Data from experience of continued use

17. The applicant has provided a description of the traditional use and extent of use of Tetradenia Riparia, including also a characterisation of the population groups of consumers. Literature sources have been provided as evidence along with some other forms of media. The evidence provided by the applicant can be found attached as Annex E.

18. The applicant draws attention to the fact that historically the use for Tetradenia Riparia is medicinal or remedial. However, no defined medical effect has been identified and the applicant likens its use to camomile.

19. Please note that the applicant brings forward two recorded cases of adult poisoning by the plant, although it is stated that the administration was not traditional and the administration nor the doses consumed do not represent normal use.

## Proposed conditions of use

20. The proposed use of the product seeking authorisation is as a powdered food supplement, sold as either a pre-dosed powder in a capsule, pure powder, or as a blended powdered drink mix. The food is not intended to replace any other dietary component. A table of proposed uses and use levels can be found in Annex B page 17.

21. The applicant has proposed unrestricted use by the general population. However, the applicant suggest that it should not be used by infants and young children as a precaution.

22. The applicant draws particular attention to the historic use as a medicinal or herbal remedy product and ensures that this would not be the intention of this particular product. No claims will be made regarding the products perceived medicinal benefits.

## Committee Action Required

- Members are asked whether there are safety concerns that need to be managed with this traditional food from third countries.

- The Committee’s advice will form the basis for the UK’s formal response to the Commission and whether reasoned safety objections are submitted.

## Annexes (Confidential)

Annex A – Technical dossier

Annex B – HACCP Plan

Annex C – Specification tables

Annex D – Evidence of experience gained through continued use

Annex E – Literature references

Annex F – Water activity test results