Consultation

Consideration by the ACNFP of Iboza (Tetradenia Riparia) as a Traditional Food

Background

At the 153rd meeting of the Advisory Committee on Novel Foods and Processes (ACNFP), the notification for Iboza (*Tetradenia riparia*) as a traditional food from a third country was considered. *Tetradenia riparia* is an herbaceous plant from southern Africa, from which the leaves are harvested, dried, and ground before being consumed as hot or cold beverage infusions or mixed into foods.

The applicant requested authorisation within the GB market for *Tetradenia riparia* to be sold as a free-flowing powder and capsules for food supplement use, as well as ingredient use in flavoured drink blends.

The Committee’s discussion

The advice of the Committee to the Food Standards Agency is summarised below. The Committee did not consider any potential health benefits from consuming the food, as the focus of the novel food assessment is to ensure the food is safe, not misleading and not putting consumers at a nutritional disadvantage.

The Committee concluded that insufficient information was provided to make an adequate assessment, and the areas where further information would be needed to assess whether there are food safety risks are detailed in the relevant section.

Identity of the Traditional Food

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. It is a member of the *Lamiaceae* family of flowering plants along with mints, sages and other

commonly used herbs.

The committee was concerned about the characterisation of *Tetradenia riparia*. The Committee noted that the majority of the information provided from the literature related to the dried leaves of the *Tetradenia riparia* plant. Although information from the literature on a consumer product is important for safety assessments, on its own it does not prove that the final consumer product itself is safe.

Insufficient information on the product to be marketed was provided to adequately characterise the source material of the product for which authorisation is sought. Specifically, information on the composition of nutrients and other constituents was limited and no analytical evidence was provided for the product to be sold. The main concern was that the specification was not specific enough to identify this plant versus other similar plants, which could have different hazards.

Production Process

Powdered *Tetradenia riparia* is produced from dried leaves harvested from the plant by grinding into a fine, free-flowing powder.

The Committee commented there was a lack of information surrounding the cultivation of the plant material, the grinding process used, and the production standards and checks made to manage any food safety risks.

There is also a significant lack of information on the use of pesticides during cultivation. All foods in GB must comply with general food safety limits, including pesticides. However, there are claims that no pesticides are used by the local farmers and no analytical evidence was provided to confirm there are no pesticides within the final product.

The Committee identified a particular hazard in relation to the conditions and controls in place during air-drying of the *Tetradenia riparia* leaves, which are critical in mitigating mycotoxin production. As this product is air-dried under ambient conditions, it is considered to be at high risk of supporting microbial growth and therefore being prone to contamination with mycotoxins. Without analyses for mycotoxins and appropriate critical control points being managed in the production process, there is a hazard for consumers from mycotoxins that could not be fully assessed.

The HACCP plan was lacking the detail needed to assess the magnitude and impact of any production risks. Omitting information on how the production and processing alter the source materials meant that hazards in the final product and how they were mitigated was unclear. It was noted that there is insufficient information provided to be able to carry out a risk assessment of the hazards associated with the production process.

Composition

The Committee reviewed the literature on the composition of *Tetradenia riparia* and considered there was no suitable information or data for assessment. Without adequate compositional analyses of the product, it is difficult to understand exactly which substances are being consumed and at what levels, and whether these would pose a food safety risk. Concerns were also raised regarding the variability in composition of the final product and how this related to the risks from consuming undesirable substances in the product.

The Committee stated that analyses of more batches of the applicant's product would need to be provided, along with relevant certificates of analysis and accreditations for proximate analysis, composition for nutrients and non-nutrients, and contaminants.

Toxicology

Some information had been provided on the potential toxicological profile and this was reviewed. The main concern were the multiple reports in the open literature of poisoning in adults and subsequent fatalities associated with consumption of *Tetradenia riparia*. While it was noted that the applicant considers these cases were not as a result of normal use, this was not evidenced. No human data had been provided for this product and there was also no information or data on the levels which are safe to consume. All the data provided from in-vitro studies did not clearly support the safety of the product.

This lack of evidence along with the suggestion of medicinal uses of the *Tetradenia riparia* plant in southern Africa raised further questions on the toxicology that could not be explored with the data provided.

Proposed Conditions of Use for the GB Market

The Committee raised a question on whether the use of the product was consistent with the operation of the traditional food route in the UK. They suggested that the proposed uses for the product as a food supplement do not appear to be consistent with how the *Tetradenia riparia* was used traditionally. There appeared to be some inconsistency in the information on whether there were medicinal uses for the product that is intended to be sold.

Allergenicity

The Committee highlighted that there is no consideration of allergenicity provided in the notification, despite the proposed product containing high levels of protein. Without this information no assessment could be made of the potential for cross reactivity or de novo sensitisation within the new target population.

10-day Consultation

The Secretariat posted the draft summary online for a 10-day consultation to allow members of the public to review the advice. The Secretariat received no comments from the public during the consultation period. Therefore, no further additional information to inform the ACNFP risk assessment was provided, and the advice remained as drafted.

Conclusion

The Committee identified significant evidence gaps in the provision of information in several key areas of the dossier. From the information there are potential hazards identified and the relevance to the product and to what extent these could be risks is not well detailed. These include the risk associated with the potential for mycotoxin production and the lack of information on the composition of the product. Of particular concern were the adverse effects identified in the cases of poisoning and to what extent these could occur with normal consumption. On this basis the Committee could not conclude that the product was safe under the proposed conditions of use and that there were significant areas of concern that required addressing.