ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON SUBSTANTIAL EQUIVALENCE OF SOUTH AMERICAN CHIA SEED PRODUCED FOR BETTERBODY CONSIDERED UNDER ARTICLE 3(4) OF THE NOVEL FOODS REGULATION 258/97

Applicant	**BetterBody Foods, Ltd** **1762 West 20 South Unit #5** **Lindon** **UT 84042** **United States**
Responsible person	**Mark Gilbert**

Introduction

1. In April 2017 an application from Betterbody Foods Ltd was accepted by the UK Competent Authority for an opinion on the equivalence of their chia seeds grown in South America, compared with the existing chia seeds marketed in the EU by The Chia Company.

2. Chia (*Salvia hispanica* L) is a summer annual herbaceous plant belonging to the Labiatae family. It grows from a seedling to develop lush green foliage before it produces long flowers which are either purple or, less commonly white. These flowers develop into seed pods that contain chia seeds. Today, Chia is grown commercially in several South American countries and Australia but they have not been consumed to a significant degree in Europe prior to 1997.

3. In 2003 an application was submitted to the UK for the use of chia seeds in certain types of bread but, following a positive UK initial opinion, a number of questions were raised by other EU Member States regarding the safety of the seeds. The applicant provided additional data that were scrutinised by the European Food Safety Authority (EFSA) before the seeds were authorised in 2009[1].

[1] Commission Decision 2009/827/EC
(http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:294:0014:0015:EN:PDF)

4. An application from The Chia Company, to authorise the use of the seeds in a wider range of products, including baked goods and breakfast cereals, was authorised in January 2013 following a positive opinion from the UK[2]. A further application from Wow Foods and Drinks Ltd. to extend the use of the seeds in fruit juice and fruit juice blends, was authorised in September 2015 following a positive opinion from the Irish Competent Authority[3].

5. Novel food authorisations are granted on an applicant-specific basis until January 2018, so other companies seeking to market the same ingredient must gain separate approval.

6. Regulation (EC) 258/97 makes provision for novel foods or ingredients that are substantially equivalent to an existing product to be placed on the market once the applicant has notified the Commission. In most cases, the Commission requires that the applicant first obtain an opinion on equivalence from a Member State. BetterBody Foods Ltd is requesting such an opinion from the UK Competent Authority.

7. According to Article 3(4) of (EC) 258/97, the notification procedure applies to "foods or food ingredients…which on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies…are substantially equivalent to existing foods or food ingredients as regards to their:

    - Composition
    - Nutritional value
    - Metabolism
    - Intended use, and
    - level of undesirable substances contained therein."

8. BetterBody Foods Ltd has provided information to support the claim that their chia seeds, grown in Ecuador and Peru, are equivalent to an authorised source of chia seeds by The Chia Company. BetterBody Foods Ltd seek equivalence to use chia seeds in baked good and other products as listed in Commission Implementing Decision 2009/827/EC and Commission Implementing Decision 2013/50/EU, as authorised for supply by The Chia Company.

[2] Commission Decision 2013/50/EU (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:021:0034:0035:EN:PDF)

[3] http://ec.europa.eu/food/safety/docs/novel-food_authorisation_2015_chia-seeds_2nd-extension_authorisation-letter_en.pdf

Evaluation

a) Composition

9. The dossier by BetterBody Foods Ltd states that chia seeds are grown and harvested in South America and are not processed in any way prior to use as a food ingredient. During the growing process, the fields are visited at least weekly in order to evaluate the growth of the chia plants. The chia seeds are harvested mechanically, using machinery similar to that used for soya or wheat. Prior to entry into the field, the harvesting machines are cleaned thoroughly. Following harvest, the seeds are placed into new 800 kg bags, sealed and numbered to identify the specific field in order to maintain purity and traceability.

10. Post-harvest the chia seeds are mechanically cleaned and classified. No chemicals are used. The cleaning process removes flowers, leaves, stems, and other undesired parts of the plants. Following cleaning and classification, the chia seeds are generally placed into new 25 kg bags or 1000kg super sacks, sealed and numbered to identify the specific field in order to maintain purity and traceability.

11. The applicant has compared the published composition of the approved chia seed with three separate batches of their chia seeds from South America. This is summarised in the table below. Small variations can be seen, but the applicant does not regard these as significant.

Nutrient (%)	Better Body	The Chia Company
Dry matter	93.6 - 94.3	95.0 – 96.8
Protein	16.7 - 20.8	17.4 – 22.4
Fat	26.2 - 29.1	28.5 – 34.7
Carbohydrate	40.3 - 46.6	37.1 – 42.6
Fibre	35.8 - 44.0	32.8 – 40.2
Ash	3.5 - 4.8	4.5– 5.6

12. The applicant has also compared the fatty acid, vitamin and mineral concentrations of their chia seed with the approved chia. The mineral concentrations are summarised in the table below. Small variations can be seen, but the applicant does not regard these as significant. This pragmatic approach is in line with a previous request for an opinion on equivalence between two sources of chia seed[4].

Minerals Mg/100g	Better Body	The Chia Company
Sodium	19.2 - 78.5	<0.1 - 6
Potassium	735.4 -1046.0	510.0 - 710.0
Calcium	677.5 - 716.4	500.0 - 640.0
Iron	6.7 - 7.2	5.7 - 15.0
Phosphorus	681.8 – 982.0	600.0 - 870.0
Magnesium	345.1 – 535.0	310.0 - 430.0

Discussion: *The Committee was not concerned that minor differences were observed between the chia seeds from BetterBody compared to those of The Chia Company. They also noted that while the sodium levels were higher, this was because of differences in the soils on which the crops were grown. The Committee agreed that the data were sufficient to conclude that the BetterBody chia seeds and the comparator's chia seeds have an equivalent composition.*

b) Nutritional Value and Metabolism

13. The applicant has compared the nutritional profile of its seeds with authorised chia (three separate batches) and found no significant nutritional differences between its chia seeds and those from The Chia Company.

14. The applicant's chia seed contains about 16-20% protein. Chia seeds have an oil content of approximately one third of their weight, a significant percentage of which is alpha-linolenic fatty acid (an essential omega-3 fatty

[4] http://www.food.gov.uk/multimedia/pdfs/chiacompdraftopinion.pdf

acid). The applicant states that the BetterBody Foods chia seeds are also a source of vitamins A, C, and E, calcium, phosphorus, potassium and zinc, and contain natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides).

Discussion: *The Committee was content with information provided on the nutritional value of the chia seed, compared with the existing products. The Committee requested additional data on the Vitamin A content of BetterBody's chia seeds and were satisfied with the additional information from the applicant.*

c) Intended Use

15. The applicant intends to incorporate chia seeds into a range of foods (baked products (10%), breakfast cereal (10%), fruit, nut and seed mixes (10%) and bread(5%) in addition to marketing 100% packaged chia seeds as authorised for supply by The Chia Company. BetterBody Foods have declared that they do not intend to use chia in fruit juices or fruit juice blend and are therefore not seeking equivalence for this use.

Discussion: *The Committee was content that the intended uses of the chia seed are consistent with those permitted for the existing products.*

d) Level of undesirable substances
Chemical and Microbial Content

Chemical Contamination

16. The applicant provided results of heavy metal analyses (arsenic, cadmium and lead) for three separate batches of its seeds and has compared these with data obtained for authorised chia by the Chia Company. The applicant also provided data relating to mycotoxins (Aflatoxin B1, B2, G1, G2 and Ochratoxin A) for three separate batches of its chia seeds. All results are comparable to those obtained by The Chia Company.

Microbial Contamination

17. The applicant presented microbiological data for the analyses of three separate batches of its seeds and compared these to relevant data for authorised chia seeds. Data relating to yeasts and moulds, *E.coli*, *Salmonella*, coagulase positive Staphylococci, *Bacillus cereus,* Coliforms and Enterobacteriaceae were presented. No concerns were identified with the results of the chia seeds grown in South America by BetterBody Foods Ltd which are comparable to those obtained by The Chia Company.

Discussion: *The Committee was in agreement that the applicant's chia seeds are comparable to the comparator's seeds with respect to the levels of undesirable chemical contaminants and microorganisms, and no concerns were raised.*

Conclusion

CONCLUSION

The Committee is content that the applicant's approach to demonstrating the equivalence of their Chia seeds with existing Chia seeds is consistent with the criteria set out in Article 3(4) of the Novel Food Regulation (EC) 258/97.

Therefore the Chia seeds proposed for marketing by BetterBody Foods Ltd can be considered to be substantially equivalent to the existing Chia seeds marketed by The Chia Company.