

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

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

Applicant	ANDEAN GRAIN PRODUCTS LTD. International House 124 Cromwell Road London SW7 4ET United Kingdom
Responsible person	Thomas Spillane

Introduction

1. In April 2014 a request was submitted by Andean Grain Products Ltd to the UK Competent Authority for an opinion on the equivalence of their chia seed grown in South America, compared with the existing chia seed cultivated in Australia and 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.
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 2009¹.
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 UK². Novel food authorisations are granted on an applicant-specific basis, so other companies seeking to market the same ingredient must gain separate approval.
5. The current request proposes that the applicant's seeds and those from the Chia Company are substantially equivalent according to the five criteria set out in

¹ Commission Decision 2009/827/EC

(<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:294:0014:0015:EN:PDF>)

² Commission Decision 2013/50/EU

(<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:021:0034:0035:EN:PDF>)

Article 3(4) of Regulation (EC) 258/97: composition, nutritional value, metabolism, intended use and the level of undesirable substances.

Evaluation

a) Composition

6. The dossier 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 soy 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.
7. 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 packed into 25kg polypropylene bags. These bags are either then sent to warehouses for storage or directly to customers.
8. The applicant has compared the published composition of the approved chia seed with three separate batches of their seed. This is summarised in the table below.

Nutrient (%)	Andean Grain Products	The Chia Company
Dry matter	92.1 – 92.7	95.0 – 96.8
Protein	18.9 – 20.2	17.4 – 22.4
Fat	31.4 – 33.8	28.5 – 34.7
Carbohydrate	32.8 – 34.8	37.1 – 42.6
Fibre	31.0 – 34.1	32.8 – 40.2
Ash	4.8 – 5.1	4.5 – 5.6

9. The applicant has also compared the fatty acids, vitamins and minerals content of their chia seed with the approved chia. Small variations can be seen, but the applicant does not regard these to be a cause for concern. In all of the above analyses, the applicant's data have been compared with published data on the approved product. This pragmatic approach is in line with a previous request for an opinion on equivalence between two sources of chia seed³.

³ <http://www.food.gov.uk/multimedia/pdfs/chiacompdraftopinion.pdf>

Discussion: The Committee was satisfied that minor differences observed between the seeds were likely to be due to differing growing conditions and agreed that the data were sufficient to conclude that Andean Grain Products' seed and the Australian chia seed have an equivalent composition. The applicant had provided data relating to fatty acids analyses in the appendix to the dossier but the data were not included in the main body of the dossier. At the Committee's request, the applicant has updated the dossier to include these data.

b) c) Nutritional Value and Metabolism

10. The applicant has compared the nutritional profile of its seeds with authorised chia (three separate batches were analysed) and found no significant nutritional differences between its chia seeds and those from the Chia Company.
11. The applicant has also provided details of metabolism and stability studies for chia seeds in general. The applicant's chia seed contains about 20% protein, a level greater than other nutritional grains such as wheat (14%), corn (14%), rice (8%), oats (15%), barley (9%), and amaranth (14%). 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 acid). The Andean Grain chiseeds are also a source of vitamins A, C, and E, calcium, phosphorous, 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 product.

d) Intended Use

12. The applicant intends to incorporate chia seeds into a range of foods (bread products, breakfast cereal, fruit, nut and seed mixes and bread) in addition to marketing 100% packaged chia seeds. These uses and use-levels are consistent with the authorisation given to the Chia Company in 2013.

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

e) Level of undesirable substances

Chemical and Microbial Content

Chemical Contamination

13. The applicant provided results of heavy metals 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

14. 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 and the results 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 Chia Company's seeds relating to the levels of undesirable substances and no concerns were raised.

Conclusion

15. The Committee concluded that Andean Grain Products Ltd has demonstrated the equivalence of their chia seed with the existing chia seed according to the criteria set out in Article 3(4) of the Novel Foods Regulation (EC) 258/97.
16. The Committee therefore concluded that the chia seed produced by Andean Grain Products Ltd can be considered to be substantially equivalent to the existing chia seed produced by The Chia Company.

Draft for publication – July 2014