

5. The current request addresses substantial equivalence according to the five criteria set out in Article 3(4) of Regulation (EC) 258/97: composition, nutritional value, metabolism, intended use and the level of undesirable substances.

Evaluation

a) Composition

6. Advantage Health Matters Inc. chia seeds are grown and harvested in Mexico 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 950 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 (Dossier, pg. 6)

Nutrient (%)	Advantage Health Matters	The Chia Company
Dry matter	92.7-94.34	95.0 – 96.8
Protein	17.93-21.43	17.4 – 22.4
Fat	25.67-31.51	28.5 – 34.7
Carbohydrate	38.2-42.6	37.1 – 42.6
Fibre	27.7-33.7	32.8 – 40.2
Ash	4.66-5.01	4.5– 5.6

9. The applicant has also compared the mineral content of their chia seed with the approved chia and this is summarised in the table below (Dossier, pg. 7). Small variations can be seen, but the applicant does not regard these to be a cause for concern. In all of the 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. The applicant has also provided information on additional minerals analysed for their chia seed that was not carried out in the original application.

Minerals Mg/100g	Advantage Health Matters	The Chia Company
Sodium	<0.1-1.09	<0.1-6
Potassium	660-812	510-710
Calcium	623-715	500-640
Iron	5.81-7.6	5.7-15
Phosphorous	761-845	600-870
Magnesium	324-346	310-430
Copper	1.38-1.87	-
Manganese	2.87-4.18	-
Selenium	0.01-0.07	-
Zinc	5.33-6.34	-

***Discussion:** The initial data provided indicated an error within the analysis. The company then checked their data and submitted a corrected report. 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 the Advantage Health Matters chia seed and the Australian chia seed have an equivalent composition*

b) 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.

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

11. The applicant's chia seed contains about 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 acid). The applicant states that the Advantage Health Matters chia seeds 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). The applicant comments that the Vitamin A content in their seeds is <50IU/100g of the seeds which is higher than that of the TCC seeds, but this does not pose a risk to the health of the consumer.

Discussion: The Committee was content with information provided on the nutritional value of the chia seed, compared with the existing product. The Committee was satisfied that the differences observed between vitamin A levels of the seeds were likely to be due to differing growing conditions and agreed that the vitamin levels of the applicant's seeds while higher were consistent with other authorised chia seeds.

c) Intended Use

12. 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. 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.

d) 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 their 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 Advantage Health Matters Inc. 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 Advantage Health Matters Inc. can be considered to be substantially equivalent to the existing chia seed produced by The Chia Company.

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