

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

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

Applicant **Crescendo Organics and Natural Products BV.**
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Introduction

In February 2015 a request was submitted by Crescendo Organics and Natural Products BV 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.

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.

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.

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.

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>)

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

Crescendo Organics and Natural Products chia seeds are grown and harvested in Argentina. The chia seeds are cleaned mechanically post-harvest. Flowers, leaves and other parts of the chia plant are removed. The seeds are then categorised by size and passed to a table separator which separates them by size and density from undesirable foreign materials. The whole seeds are then packed for despatch without any further processing.

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. 3)

| Nutrient (%) | Crescendo Organics and Natural Products BV | The Chia Company |
|--------------|--|------------------|
| Dry matter | 93.8 - 94.0 | 95.0 – 96.8 |
| Protein | 23.2 – 23.4. | 17.4 – 22.4 |
| Fat | 33.3 – 34.1 | 28.5 – 34.7 |
| Carbohydrate | 32.4 – 33.4 | 37.1 – 42.6 |
| Fibre | 40.2 – 41.6 | 32.8 – 40.2 |
| Ash | 3.9 – 4.1 | 4.5– 5.6 |

The applicant has also compared the fatty acids, vitamins and mineral content of their chia seed with the approved chia and this is summarised in the table below. (Dossier, pg. 4) Small variations can be seen, but the applicant does not regard these to be a cause for concern. In all of these 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>

| Minerals Mg/100g | Crescendo Organics and Natural Products BV | The Chia Company |
|---------------------|---|---------------------|
| Sodium | <0.1 - <0.2 | <0.1-6 |
| Potassium | 661 – 693 | 510-710 |
| Calcium | 530 – 559 | 500-640 |
| Iron | 6.2 -6.5 | 5.7-15 |
| Phosphorous | 699 -716 | 600-870 |
| Magnesium | 282 -297 | 310-430 |

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 the Crescendo Organics and Natural Products chia seed from Argentina and the Chia Company's chia seed from Australia have an equivalent composition.

b) Nutritional Value and Metabolism

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.

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 Crescendo Organics and Natural Products chia seeds are also a source of vitamins A, C, and E, calcium, phosphorous, potassium and contain natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides).

Discussion: The Committee was satisfied that minor differences in nutrient content between the seeds were likely to be due to differing growing conditions and was content with information provided on the nutritional value of the chia seed, compared with the existing product.

c) Intended Use

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

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

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 in terms of chemical contaminants and microorganisms and no concerns were raised.

Conclusion

The Committee concluded that Crescendo Organics and Natural Products 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.

The Committee therefore concluded that the chia seed produced by Crescendo Organics and Natural Products can be considered to be substantially equivalent to the existing chia seed produced by The Chia Company.

**Secretariat
January 2016**