#### ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

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

**Applicant** The Chia Company

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Responsible person April Helliwell

#### Introduction

- In January 2010 a request was submitted by The Chia Company to the UK Competent Authority for an opinion on the equivalence of their chia seed grown in Western Australia, compared with the existing chia seed cultivated in South America, and marketed in the EU by the Columbus Paradigm Institute S.A.
- 2. Chia (*Salvia hispanica*) 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 to produce chia seeds.
- 3. A novel food application for whole and ground chia seeds was submitted by R. Craig & Sons to the UK in 2003. Following a number of concerns raised by Member States, regarding the safety of chia seed, responsibility for the dossier was transferred to the Columbus Paradigm Institute S.A. in 2006. The new applicant provided additional information to address these concerns and, following a favourable opinion from the European Food Safety Authority (EFSA) in 2009, authorisation to market chia seed as a novel food ingredient at a level of up to 5% in bread products was issued on 13 October 2009 (Commission Decision 2009/827/EC).
- 4. 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

- 5. The applicant sows chia into prepared soil beds where it grows until the desired biomass is reached. Plant tissue tests are carried out throughout the growth stage to ensure the correct nutrition levels are obtained.
- 6. Post-harvest, the seed head is mechanically swathed to ensure even ripening and consistent oil yield and to prevent seed loss through shedding onto the ground. The seeds are then transported to a seed cleaning facility where they are transferred to silos for fumigation with carbon dioxide before cleaning and packaging.
- 7. The applicant has compared the published composition of the approved chia seed in the EFSA opinion in 2009 with their own chia seed. See table below.

Nutrient (%)		TCC Seed	Approved Chia
Dry matter		95.0 – 96.8	91 – 96
Protein		17.4 – 22.4	20 – 22
Fat		28.5 – 34.7	30 – 35
Carbohydrate		37.1 – 42.6	25 – 41
Fibre	Soluble	5.3 – 7.1	NA
	Insoluble	30.9 – 33.0	18 – 30
Ash		4.5 – 5.6	4 – 6

NA: Not available

8. The applicant has also compared the mineral content of their chia seed with the approved chia seed. This is summarised in the table below.

Mineral (mg/100g)	TCC Seed	Approved Chia
Sodium	<0.1 – 6	0.94 – 12
Potassium	510 – 710	660 – 809
Calcium	500 – 640	557 – 770
Iron	5.7 – 15	6.3 – 9.9
Magnesium	310 – 430	325 – 390
Phosphorus	600 – 870	751 – 780

9. The applicant has included a comparison of the amino acid content of their chia seed with the approved chia. This is summarised in the table below.

Amino acid (% of protein)	TCC Seed	Approved Chia
Isoleucine	3.05 – 3.53	3.21 – 3.98

Leucine	5.47 – 6.34	5.89 – 7.30
Lysine	3.87 – 4.42	3.60 - 5.50
Methionine	1.00 – 1.14	0.36 - 0.45
Phenylalanine	4.19 – 4.71	4.73 – 5.86
Threonine	2.90 - 3.42	3.23 – 4.25
Tryptophan	0.89 – 1.04	NA
Valine	3.86 – 4.56	5.10 – 6.32

NA: Not available

10. The applicant also compared the fatty acid profile of their chia seed with the approved chia. Although they acknowledge that there are small but measurable differences, the applicant does not view this to be a cause of concern.

Discussion: The Committee was satisfied that the data comparing the Australian chia seed and the existing chia seed show that they have an equivalent composition. The Committee requested information on the botanical origins of the Australian chia seed to determine whether there were any differences when compared to seeds produced in South America. The applicant confirmed that the original source of the chia seed grown in Australia was seed stock from Mexico and Bolivia and that they had not carried out any programme of plant breeding. The Committee also sought information on the conditions in which chia seed is grown in Australia. The applicant advised that the Australian chia seed is grown under very similar climatic conditions to the South American variety at a latitude of 15 degrees south of the equator. The applicant also stated that unlike chia grown in South America, which is harvested using a chemical desiccant, they employ mechanical harvesting techniques. The Committee considered that the additional information regarding the seed stock and growing conditions provided sufficient reassurance that there were no significant differences between the two seeds.

## b) c) Nutritional Value and Metabolism

11. The applicant states that chia seed contains around 20% protein and an oil content of approximately one third by weight, of which about 80% of which is α-linolenic acid. The seeds possess about 5% soluble fibre and measurable quantities of vitamin B, minerals and antioxidants. These figures are consistent with those for the existing product.

**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 will limit the use of chia seed to bread products at a maximum level of 5%, in accordance with the authorisation given to Columbus Paradigm in 2009.

**Discussion:** The Committee was content that the intended use of the chia seed in bread products at a maximum level of 5% is consistent with the existing product.

## e) Level of undesirable substances

#### **Chemical Contamination**

13. The applicant is of the view that the production process ensures that the levels of undesirable substances are equivalent to the approved chia. The applicant has provided data from four separate batches for the heavy metal screen. See table below.

Heavy metal	TCC Seed (ppm)	Approved Chia (ppm)
Arsenic	<0.1	<0.1 - <0.2
Cadmium	<0.1	0.018 - <0.2
Mercury	<0.01 - <0.02	<0.01 - <0.03
Lead	>0.5 - <1	<0.004 - <0.12

## Microbial Contamination

14. The chia seeds have been tested for microbiological contamination as part of the applicant's HACCP quality control system at accredited laboratories in Australia. Analyses include detection of yeasts and moulds, *E.coli*, *Salmonella*, *Listeria* and *Clostridium perfringens*.

**Discussion:** The Committee was content that the applicant had quality control procedures in place to minimise the risk of contamination of the chia seed.

## f) Additional information

15. The applicant states that they have in place a Quality Management System based on the Codex Hazard Analysis Critical Control Point (HACCP) system. The applicant also states that their Quality Management System has been designed to meet the requirements of the Safe Quality Food (SQF) 2000 code. The applicant provided a certificate of compliance with the HACCP system.

- 16. The applicant included a number of bioavailability studies relating to the uptake and metabolism of chia in rats, hens and cows. Two of the studies describe an increase in blood levels of  $\alpha$ -linoleic acid after introducing chia through controlled feeding studies in rats and cows.
- 17. In order to demonstrate the stability of the seed, the applicant re-tested their 2006 harvest in 2009 and found that the nutritional content did not change over this 3 year period and no deterioration in taste or smell was evident. The microbial status remained constant throughout this period of time

#### Conclusion

- 18. The Committee concluded that The Chia Company 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.
- 19. The Committee therefore concluded that the chia seed produced by The Chia Company can be considered to be substantially equivalent to the existing chia seed produced by Columbus Paradigm Institute S.A.
- 20. This opinion applies solely to the use of chia seed as an ingredient in bread products at a maximum level of 5%.

**DRAFT May 2010**