COMMITTEE PAPER FOR DISCUSSION **ACNFP/96/4**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

CHIA SEED (*Salivia hispanica* L.)

Issue

The Committee is asked to consider the information provided for the approval of chia seeds (*Salvia hispanica* L.) for use in bread products. The Chia Company requests the opinion of the UK Competent Authority (CA) that their chia seeds should be considered substantially equivalent to an existing product.

Background

1. Chia 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. Today, Chia is grown commercially in several Latin American countries and Australia, but they have not been consumed to a significant degree in Europe.
2. A novel food application for whole and ground chia seeds was submitted by R. Craig & Sons to the UK in 2003. The UK issued a positive opinion in 2004, and following a number of objections from Member States the application was referred to the European Food and Safety Authority (EFSA) for further evaluation and assessment. EFSA concluded that the safety of chia could not be established on the basis of the available data and additional studies were therefore required. EFSA issued a negative opinion in 2005.
3. In 2006, responsibility for the dossier was transferred to the Columbus Paradigm Institute S.A. who were able to provide additional information to satisfy EFSA. EFSA issued a positive opinion in 2009 (**Annex B**) and on 13 October 2009 authorisation was given to Columbus Paradigm Institute S.A. for the use of chia seed as a novel food ingredient in bread products with a maximum content of 5 % chia seeds (Commission Decision 2009/827/EC).
4. 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. The Chia Company is requesting such an opinion from the UK Competent Authority.

5. According to Article 3(4) of (EC) 258/97, the notification procedures 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 their:

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

6. The Chia Company is requesting an opinion from the UK Competent Authority on equivalence of its chia seed, grown in Australia, compared with the Columbus Paradigm chia seed which is grown in South America. The application dossier and appendices are attached at **Annex A**. The Chia Company notes that the 2009 EFSA opinion stated that the compositional data which had been provided by Columbus Paradigm on Australian chia seeds showed little difference to chia seeds sourced from the South Americans countries. (See **Annex B**, p 6).

7. The Committee will wish to note that the application dossier will be published on the Agency's website for a 21-day public consultation. Any comments received will be forwarded to the Committee.

Evaluation

a) Composition

Annex A, p. 5 – 9 and Appendices 1 and 2

8. The chia seed is not processed in any way prior to use as a food ingredient. The chia is planted into prepared soil beds and grown until the desired biomass is reached. This is achieved with the help of satellite imagery to indicate areas of higher and lower biomass levels and allow corrective nutrition applications. Plant tissue tests are carried out during the growth stage to ensure the correct nutrition levels are obtained.

9. Post-harvest, the seed head is mechanically swathed to ensure even ripening and consistent oil yield in the seed and to prevent seed loss through shedding onto the ground. The seeds are transported to a seed cleaning facility where they are transferred to silos for fumigation with carbon dioxide, cleaned and packed as finished products. (See **Annex A**, Appendix 1).

10. The applicant notes that use of carbon dioxide as a fumigant is permitted in the EU and they state that they use the gas in accordance with Council Directive 91/414/EC concerning the placing of plant protection products on the market.

11. The applicant has compared the published composition of the approved chia seed with 3 batches of their seed. (**Annex A**, p 6 and Appendix 2). This is summarised in the table below. The Secretariat notes that some of the components analysed fall slightly outside of the range of the approved chia seed.

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

12. The applicant has also compared the mineral content of their chia seed with the approved chia as published in the EFSA opinion in 2009 (**Annex B**, Table 2, p 8). (**Annex A**, Table 2, p 7 and Appendix 2).

Mineral (mg/100g)	TCC Seed	Approved Chia
Sodium	<0.1 – 6	0.94 – 12.15
Potassium	510 – 710	660 – 809.15
Calcium	500 – 640	557 – 770
Iron	5.7 – 15	6.3 – 9.9
Magnesium	310 – 430	325 – 390
Phosphorus	600 – 870	751 – 780

13. The applicant has included a comparison of the amino acid content of their chia seed with the approved chia. Small differences are noted in the range of values in the majority of the amino acids analysed. (**Annex A**, Table 4, p 8 and Appendix 2).

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

14. The applicant has also included a comparison of the fatty acid profile of their chia seed with the approved chia. (**Annex A**, Table 5, p8). Small differences in some of the fatty acids were seen but the applicant does not view this to be a cause for concern.

15. In all of the above analyses, it should be noted that the applicant's data are being compared with published data on the approved product. It is therefore possible that the reported differences could be due to different method of analysis.

b), c) Nutritional Value and Metabolism

Annex A, p. 10 - 14

16. The applicant states that chia seed contains about 20% protein, a level greater than other nutritional grains such as wheat (14%), corn (14%), rice (8%) and oats (15%). The applicant also states that chia seeds have an oil content of approximately one third of its weight, about 80% of which is α-linolenic acid, making this ingredient a source of n-3 fatty acids. The seeds possess about 5% soluble fibre and are a good source of vitamin B, minerals and antioxidants. These figures are similar to the existing product.

d) Intended Use

Annex A, p. 14

17. The applicant will limit the use of chia seed to bread products at a maximum level of 5%. This is consistent with the authorisation given to Columbus Paradigm.

e) Levels of Undesirable Substances

Annex A, p. 14 - 17

<u>Chemical Contamination</u>

18. The applicant is of the view that the production process ensures that the levels of undesirable substances are well below the specified limits and equivalent to the approved chia. The applicant has provided data from four separate batches for the heavy metal screen and one sample for the mycotoxins screen to support this statement. (**Annex A**, Tables 7 and 8, p15-16 and Appendices 5 and 6). The

Secretariat notes that the applicant has presented the analyses of four batches in table 7, however only three certificates of analysis are presented in Appendix 5.

Microbial Contamination

19. Chia seeds have been tested for microbiological contamination as part of the applicant's HACCP quality control system at accredited laboratories in Australia. The applicant states that it has looked at samples from the period 2006 to 2009. (**Annex A**, Table 9, p17). Analyses include detection of yeasts and moulds, *E.coli*, *Salmonella*, *Listeria* and *Clostridium perfringens*. The applicant has included test reports in **Annex A**, Appendices 7 and 8. The Secretariat notes that Appendix 8 does not contain certificates of analysis for the years 2006 and 2007.

Toxicity and Safety Studies

20. The applicant is of the view the safety of chia seeds when used in bread at a maximum of 5% has been confirmed by EFSA. EFSA's 2009 opinion took into consideration a number of trials to assess the nutritional quality of chia as a feed ingredient, its effect on selected markers of coagulation and immune function in humans, and its potential allergenicity.

g) Additional Information

Annex A, p. 18 and Appendix 9

21. The applicant states that they have in place a stringent 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. A certificate of compliance with the HACCP system is included in **Annex A**, Appendix 9.

22. The applicant has 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 α-linoleic acid after introducing chia through controlled feeding studies in rats and cows.

23. In order to demonstrate the stability of the seed, the applicant conducted a re-test of their 2006 harvest in 2009. The applicant states that the nutritional content has not changed over this 3 year period and no deterioration in taste or smell was evident. The applicant also claims the microbial status remained constant throughout this period of time. (**Annex A**, Appendix 3).

Committee Action Required

24. The Committee is asked if it has any objections or comments to raise and whether it agrees that substantial equivalence has been established between The Chia Company's chia seed and an existing product, from Columbus Paradigm Institute S.A., in accordance with Article 3(4) of Regulation (EC) 258/97.

25. If so, the Secretariat proposes to draft an opinion incorporating the ACNFP's comments on this application which will be discussed at the next Committee meeting in April.

26. If not, the Committee is asked what additional information the applicant should supply in order to demonstrate equivalence.

Secretariat
January 2010

Annex attached:

Annex A: Application dossier and appendices

Annex B EFSA Scientific Opinion on Chia 2009

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Application dossier for Chia Seeds (*Salivia Hispanica* L.)

Secretariat
January 2010

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

EFSA 2009 opinion on the safety of chia seeds (*Salvia hispanica* L.) and ground whole chia seeds as a food ingredient

Secretariat
January 2010