Application for the authorization of Chia Seed from Salvia hispanica L. for consumption as a food and as an ingredient in additional food groups.

Submitted pursuant to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27th January 1997 concerning novel foods and novel food ingredients

For all correspondence regarding this dossier please refer to:

23 March 2011

Contents

List of Appendices

List of Tables and Figures

Executive Summary

Chia (Salvia hispanica L.) is a summer annual herbaceous plant belonging to the Labiatae family. The Chia seed is a naturally grown grain containing all components of the dicot; the seed coat, cotyledons and the embryo. Chia seed contains high percentages of fibre, protein, and Omega-3 and Omega-6 ALA essential fatty acids, providing a nutritious and healthy food and food ingredient.

Chia seed was considered a Novel Food under EU Novel Foods regulation No 258/97 due to a lack of history of consumption within the Community prior to 1997. The status of Chia seed altered in 2009 to become recognised and approved as a novel ingredient that could be sold and consumed within the EU. Commission Decision 2009/827/EC on 13 October 2009 and posted in the Official Journal of the European Community approved Chia seed and grounded Chia for inclusion in bread at a maximum of five percent (5%) (European Commission 2009).

As stated in the Commission Decision 2009/827/EC (European Commission 2009) the initial application for Chia seed was made by R. Craig & Sons on 30 June 2003. This application was then taken over by Columbus Paradigm Institute S.A on 30 September 2006. This was the application that was approved by the Commission in 2009. On December 22nd 2009 The Chia Company (TCC) submitted a substantial equivalent dossier to demonstrate that the company's Australian Grown Chia Seed was equivalent to the 'approved chia' of Colombus Paradigm 2009 (EC)258/97 in 2009 (decision 2009/827/EC). On July 1, 2010, The Food Standards Agency (FSA) the UK Competent Authority for all novel food issues, advised that The ACNFP (Advisory Committee on Novel Foods and Processes) concluded that TCC had 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.

TCC is requesting an "extension of use" for Chia seed within the EU for the following food product categories:

- 100% Packaged Chia seed
- Baked goods (muffins, cookies, crackers, biscuits)
- Breakfast cereal
- Fruit, nut, and seed mixes

The production process of TCC Chia Seed has been audited and accredited by SAI Global as meeting the SQF 2000 food safety standard. The production process for the initial Application from R. Craig and Sons was reviewed and approved by EFSA. The production process for the Subsequent Equivalent Application from TCC was reviewed and approved by ACNFP. The ACNFP stated that "production process of the NF as described by the applicant does not raise concern (ACNFP 2004)". Chia seed is not Genetically Modified nor are the foods derived from Chia seed obtained from GM.

An estimate at the anticipated intake of Chia seed has been derived from UK NDNS data and the proposed inclusion % that have been obtained through product formulation research performed by TCC and various third party food research institutes. Table 3 below provides a potential daily intake of Chia seed for the average adult UK consumer. 13.4g of Chia seed is the estimated average intake of Chia seed through consumption of a wide variety of products containing Chia seed. However, it should be considered highly unlikely that a consumer will select a product from each category containing Chia seed to the vast range of products now available in each food category. It should also be identified that EFSA approved the initial Application by R. Craig and Sons after acknowledging that the average Bulgarian bread consumer could consumer up to 15.1g of Chia seed through 5% inclusion in bread (Table 8, Page 15, EFSA 2009).

Table 3: Potential Intake of Chia seed as calculated from UK NDNS for Bread, Breakfast Cereals, Baked Goods, Nuts, Savoury Snacks, and Confectionary Food Categories

All Respondents	Mean Consumption - (grams per day)							
Product Categories	Age Groups							
	19-24	25-34	34-49	50-64	All Consumers	% All Consumers	Chia % Inclusion	Grams of Chia Consumed / Day
Bread	94.3	102.7	101.6	101.4	100.9	99%	5%	5.0
Breakfast Cereal	16.4	26.4	28.1	37.6	29.0	67%	10%	2.9
Biscuits, buns, cakes, pastries & fruit pies	19.3	28.7	33.6	41.9	33.0	84%	10%	3.3
Nuts	0.9	2.3	2.3	2.1	2.1	20%	10%	0.2
Savoury snacks	12.4	9.9	7.0	3.6	7.4	56%	10%	0.7
Confectionary	15.9	12.3	12.3	8.6	11.7	62%	10%	1.2
SUM	159.1	182.3	184.9	195.1	184.1	65%		13.4

Source: Table 2.1.a, 2.1.b, 2.1.c of The National Diet & Nutrition Survey: adults aged 19 to 64 years, Summary Report Volume 5 (2004)

Chia seed has had increasing human exposure over recent years. Chia seed has been approved for consumption as a food in N. America, Australasia, Argentina, and Asia. Mintel GNPD reported over 277 products released in the last 12 months globally containing Chia seed. 100% whole packaged Chia seed is being sold in 340 chemists and natural food stores throughout Australia as well as in an ingredient in various products and breads in over 700 retail sites nationwide. TCC conducted research into potential reports of allergic reactions to Chia in countries where Chia is widely available as an ingredient in products and as a nutritious whole food. Despite the wide availability and proliferation of products containing Chia seed, there have been no reported incidents of an allergic reaction to Chia seed.

Chia seed is a highly nutritious addition to the European diet. 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 its weight, about 80 % of which is _ -linolenic acid, making this ingredient a source of n-3 fatty acids. The seeds alone possess about 5 % soluble fibre. The TCC seeds are also a source of vitamins B, calcium, phosphorous, potassium, zinc, and copper, and contain natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides). Consumption of the nutrients that occur naturally in Chia, dietary fibre, protein and Omega 3 ALA are generally recognised for improved health. EFSA Panel concluded that "Chia seeds are unlikely to be nutritionally disadvantageous to the consumer under the proposed conditions (EFSA 2009)".

The ACNFP opinion on the initial Application was that they "were content with the microbiological information supplied (ACNFP 2004)" especially after a further requested review of the HACCP schema demonstrated that quality measures were in place to control and monitor moisture level during long bulk storage and transportation. ACNFP stated in their opinion that "The Committee was satisfied with the toxicological data supplied by the applicant (ACNFP 2004)". Heavy metal and chemical analysis of the Chia seed all complied with EU regulations. TCC conducted a survey of food allergy associations and food safety regulatory complaint authorities. Despite the proliferation of Chia seed as an ingredient and consumption of whole Chia seed, as demonstrated in Section X of this Application, no reports of allergic reaction to Chia seed has been reported and recorded.

1.0 Administrative Details

Name and Contact Details for Correspondence

The dossier is submitted by The Chia Company, the grower, marketing body and seller of Chia Seed and Chia Seed products.

Address of the applicant as follows

2.0 General Introduction

Novel classification

Chia (Salvia hispanica L.) is a summer annual herbaceous plant belonging to the Labiatae family. The Chia seed is a naturally grown grain containing all components of the dicot; the seed coat, cotyledons and the embryo. Chia seed contains high percentages of fibre, protein, and Omega-3 and Omega-6 ALA essential fatty acids, providing a nutritious and healthy food and food ingredient.

Chia seed was considered a novel food under EU Novel Foods regulation No 258/97 due to a lack of history of consumption within the Community prior to 1997. The status of Chia seed altered in 2009 to become recognised and approved as a novel ingredient that could be sold and consumed within the EU. Commission Decision 2009/827/EC on 13 October 2009 and posted in the Official Journal of the European Community approved Chia seed and grounded Chia for inclusion in bread at a maximum of five percent (5%) (European Commission 2009).

Previous Novel Food Applications for Chia Seed

As stated in the Commission Decision 2009/827/EC (European Commission 2009) the initial application for Chia seed was made by R. Craig & Sons on 30 June 2003. This application was then taken over by Columbus Paradigm Institute S.A on 30 September 2006. This was the application that was approved by the Commission in 2009.

On December 22nd 2009 The Chia Company (TCC) submitted a substantial equivalent dossier to demonstrate that the company's Australian Grown Chia Seed was equivalent to the 'approved chia' of Colombus Paradigm 2009 (EC)258/97 in 2009 (decision 2009/827/EC).

On July 1, 2010, The Food Standards Agency (FSA) the UK Competent Authority for all novel food issues, advised that The ACNFP (Advisory Committee on Novel Foods and Processes) concluded that TCC had 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.

Purpose of Proposal / Dossier: Application for Extension of Use

TCC Chia Seed has been classified as safe for consumption within the EU, specific to use in bread at a maximum of 5%. In light of supporting evidence from N. America, Asia, and Australasia national food safety authority approvals for Chia consumption as well as increasing consumption with no reported incidents of allergic reactions, TCC now seeks approval under EU Novel Foods regulation No 258/97 to sell their packaged Chia within the EU and to expand the approved use of Chia as an ingredient in other food categories that commonly contain grains and seeds.

TCC is requesting an "extension of use" for Chia seed within the EU for the following food product categories:

- 100% Packaged Chia seed
- Baked goods (muffins, cookies, crackers, biscuits)
- Breakfast cereal
- Fruit, nut, and seed mixes

Dossier Requirements

In accordance with the EU guidelines, the requirements for the submission of a dossier for this class of Novel Food are as follows:

I. Specification of the Novel Food
II. Effect of the Production Process Applied to the Novel Food
III. History of Source Organism
IX. Anticipated Intake/Extent of Use
X. Information on Previous Human Exposure
XI. Nutritional Information
XII. Microbiological Information
XIII. Toxicological Information

We present our submission in the required format below to extend the use of Chia Seed beyond the currently approved European Commission decision of 5% inclusion in bread.

I Specification of the Novel Food

Based on Commission Recommendation 97/618/EC decision trees the following questions must be addressed pertaining to the specifications of the novel food (European Commission 1997):

- "Depending on the derivation and composition of the Novel Food, is appropriate analytical information available on potentially toxic inherent constituents, external contaminants and nutrients?"
- "Is the information representative of the novel food when produced on a commercial scale?"
- "Is there an appropriate specification (including species, taxon, etc for living organisms) to ensure that the novel food marketed is the same as that evaluated?"

In accordance with the Commission Decision 2009/827/EC the approved specification of Chia seed for the initial R. Craig and Sons application and the ACNFP approved substantial equivalent application from TCC is as follows:

Description

Chia (*Salvia hispanica*) is a summer annual herbaceous plant belonging to the *Labiatae* family. Post-harvest the seeds are cleaned mechanically. Flowers, leaves and other parts of the plant are removed. Whole ground Chia is produced by passing the whole seeds through a variable speed hammer mill.

Composition of Chia Seed

Table 1: Composition of Chia Seed

Dry Matter	91-96%
Protein	20-22%
Fat	30-35%
Carbohydrate	25-41%
Crude Fibre (*)	18-30%

Ash	4-6%
*Crude fibre is the part of the fibre made mainly part from indigestible cellulose, pentosans, and lignin	

Source: European Commission (2009). Authorising the placing on the market of Chia seed (Salvia hispanica) as novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. (notified under document C(2009) 7645) (European Commission 2009)

To view further detailed Chia Seed specifications please see the EFSA Scientific Opinion on Chia seeds, page 7 onwards (EFSA 2009).

Potentially toxic inherent constituents, external contaminants and nutrients

The initial application for R. Craig and Sons and the substantial equivalent application from TCC were both reviewed for potential toxic inherent constituents, external contaminants and nutrients. Proximate parameters were found to be in accordance with the samples provided (pg 7, EFSA 2009); heavy metals were found to comply with the maximum levels of set in EU Regulation 466/2001/EC (pg 10, EFSA 2009). The ACNFP were "satisfied with the specification of the Novel Food (ACNFP 2004)". Chia seed in both instances were found to comply with EU standards not found to present any danger to human health. The EFSA Opinion on the Safety of Chia seeds advised that the toxicological information provided in the initial proposal's was limited, but that the "experience gained from previous and current use of Chia seeds for food purposes in non-EU countries can be regarded as supportive evidence of the safety of Chia seeds and ground whole Chia seeds" (EFSA 2009).

Samples and specification representative of commercial scale and traceable

Samples and specifications reviewed by ACNFP during the substantial equivalent application were commercial samples of product currently sold on the N. American and Australasian market. In order to ensure Chia seed quality complies with specifications and traceability TCC has put in place a Quality Management System based on the Codex Hazard Analysis Critical Control Point (HACCP) method developed by the *Codex Alimentarius*. This system describes agreed methods and specifications to maintain effective control, thereby ensuring a high standard of food safety throughout the production process.

The Quality Management System of TCC has been designed to meet the requirements of the SFQ (Safe Quality Food) 2000 Code, a HACCP-based international standard focusing on risk assessment and prevention of food recalls and food safety incidents. A certificate of compliance with the HACCP system is attached in Appendix 7.

II Effects of the Production Process Applied to the Novel Food

Based on Commission Recommendation 97/618/EC decision trees the following questions must be addressed regarding the production process of the Novel Food (European Commission 1997):

- "Does the novel food undergo a production process?"
- "Is there a history of use of the production process for the food?" If no, "does the process result in significant change in the composition or structure of the novel food compared to its traditional counterpart?"
- "Is information available to enable identification of the possible toxicological, nutritional and microbiological hazards arising from use of the process?"
- "Are the means identified for controlling the process to ensure that the Novel Food complies with its specification?"
- "Has the process the potential to alter the levels in the Novel Food of substances with an adverse affect on public health?"
- "After processing is the novel food likely to contain microorganisms of adverse public health significance?"

The production process applied to Chia seed have been reviewed by EFSA for the initial "Application for Approval of Whole Chia (*Salvia hispanica L*) Seed and Ground Whole Chia as Novel Food Ingredients" from R. Craig and Sons (taken over by Columbus Paradigm Institute S.A on 30 September 2006) and by the ACNFP for the "Request for Scientific Evaluation of Substantial Equivalence Application for the Approval of Chia seeds (*Salvia Hispanica* L.) from The Chia Company for use in bread" in 2009. In the EFSA Journal 2009 the Panel on Dietetic Products, Nutrition, and Allergies state that:

"The production process of the NF as described by the applicant does not raise concern. It should be ensured that any residues or contaminants derived from apparatus and equipment or from chemical, physical or biological aids are controlled. According to the ACNFP assessment the seeds are monitored during the transport and storage on the basis of a HACCP plan that describes measures to be put in place to control temperature and humidity during storage and transport. Providing the above monitoring is implemented, the Panel considers it is not likely that the process would induce changes in the food that might have an impact on essential nutritional, toxicological and microbiological parameters of the final product. (EFSA 2009)".

Below is a further description of the production process outlined in The initial Application from R. Craig and Sons and the Subsequent Equivalent Application from TCC.

The production process of TCC Chia Seed has been audited and accredited by SAI Global as meeting the SQF 2000 food safety standard. A copy of the certification is provided in Appendix 7.

Chia is planted with precision planters into a prepared soil bed to ensure accurate seeding depth and optimal plant density.

It is then fertilised with Superphosphate, potassium and nitrogen along with additional trace elements as required maximising crop vigour to produce ideal levels of biomass. Plant tissue tests are taken during the growth stage to ensure the correct nutrition levels are obtained to guarantee the oil yield, Omega 3:6 ratio and levels of protein, fibre, antioxidants, vitamins and minerals.

During crop growth the biomass of the crop is measured with satellite technology imagery to indicate areas of higher or lower biomass levels to allow management to apply corrective nutrition applications. The Chia crop is watered with a gravity fed irrigation system which provides perfect soil moisture levels to guarantee the optimal yield and nutritional profile. Soil moisture data logger probes are positioned in the crop to ensure the soil moisture level is accurately monitored. Once the Chia seed has developed in the seed head it is mechanically swathed to ensure even ripening and consistent oil yield in the seed and to prevent seed loss through shedding onto the ground.

At harvest, each paddock is harvested and recorded individually and entered into TCC electronic inventory system. The seed from each paddock, farmer and variety has its identity preserved throughout the cleaning, packing and storage process to ensure complete supply chain traceability.

After harvest, a sample from each lot is collected and tested for a full array of nutritional and residue tests. The seed is tested at the National Measurement Institute (NMI), the foremost "Australian measurement body responsible for biological, chemical, legal, physical and trade measurement (NMI 2010)". NMI is accredited by the National Association of Testing Authorities (NATA) ensuring it complies with national and international measurement and calibration standards and regulations. The seeds are directly sent to the receival point for collation before freighting, temporarily stored on the farm prior to forwarding to the receival point, or transferred to a separate facility for processing in case of breeding stock.

After receival and collation, the seeds are loaded onto road transport and brought to a seed cleaning facility. There, they are transferred to silos for fumigation, cleaned, packed off as finished products and dispatched.

They are fumigated with carbon dioxide (CO_2), a substance which has been authorized as a fumigant as per Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (European Commission 1991).

As finished products, the seeds may be sent directly to warehouses for storage, directly to customers, or directly for further processing. They may also go to warehouses prior to being sent to customers or to undergo further processing. A detailed diagram of TCC production method is included in Appendix 9.

TCC Australian grown Chia seed is of the exact same botanical origins as the South American variety. The Chia Seed had been imported into Australia as a health food product sold directly to consumers in health food retail outlets. No botanical variations have been made.

TCC Australian grown Chia Seed is grown in the Ord River farming region in Kununurra, in the Kimberley's in Western Australia. The region has the ideal climatic and geographic

conditions for growing Chia Seed.

Kununurra is exactly 15 degrees south of the equator, which is the same latitude as where Chia Seed is grown in parts of South America. This means that the region has the specific climatic and geographic conditions required to grow Chia Seed. The correct latitude is essential for growing Chia because it affects day length and exposure to sunlight for Chia to develop.

Kununurra has a very distinct dry season from March to August where there is no rain. This is ideal for growing Chia because once the seed pod has formed rain can cause crop failure due to the fibrous nature of Chia. South American Chia is rain fed where as Australian Grown Chia is irrigated.

The water source for irrigation is Lake Argyle. Lake Argyle is the largest water source in the southern hemisphere. TCC farms are watered utilising gravity fed irrigation which is a natural and sustainable watering method. Water is applied through hand administered channel irrigation. Soil moisture is monitored with soil moisture sensors to indicate achieve best water use efficiency. Irrigation means that there is greater consistency in the Chia Crop. During the time that an oil seed is filling with Oil it requires a significant amount of water; irrigation allows control of the amount of water that is administered.

TCC harvest Chia in August which is the driest month of the year ensuring pure clean and dry seed. At point of ripening the Chia crop is swathed using a mechanical swather to windrow the crop and prevent seed loss. This differs to South American Chia where the method is to apply chemical desiccant such as Parquat to induce even ripening. The Chia Co uses mechanical methods rather than chemical to avoid chemical residues on the crop close to harvest.

Post harvest TCC applies CO2 as an organic certified fumigant to prevent insect contamination. We have complete traceability of each batch back to the paddock in which it was grown. Each batch after harvest is analysed in NATA certified laboratories to ensure that it meets our high standards for purity and nutrition.

III History of the Source Organism

Based on the Commission Recommendation 97/618/EC decision trees the following questions must be addressed pertaining to the history of the source organism (European Commission 1997):

- "Is the Novel Food obtained from a biological source, i.e. a plant, animal or microorganism?"
- "Has the organism used as the source of the Novel Food been derived using GM?"
- "Is the source organism characterised?"
- "Is there information to show that the source organism and/or food obtained from it are not detrimental to human health?"

Chia seed Source, GM Status, and Taxonomy

The History of the Chia seed has been reviewed and approved by EFSA for the initial "Application for Approval of Whole Chia (*Salvia hispanica L*) Seed and Ground Whole Chia

as Novel Food Ingredients" from R. Craig and Sons (taken over by Columbus Paradigm Institute S.A on 30 September 2006) and by the ACNFP for the "Request for Scientific Evaluation of Substantial Equivalence Application for the Approval of Chia seeds (*Salvia Hispanica* L.) from The Chia Company for use in bread" in 2009.

Chia seed is not Genetically Modified nor are the foods derived from Chia seed obtained from GM. Chia (Salvia hispanica L.) is a summer annual herbaceous plant belonging to the Labiatae family. It grows approximately 1-1.2 meters tall. It grows from a seeding to develop lush, green foliage before it produces long flowers similar to lavender which are either purple or, less commonly, white. These flowers develop into seed pods to produce Chia seeds. Chia seeds were first used as food as early as 3500 BC and were one of the main dietary components of the Aztecs and the Mayans. They were eaten as a grain, drunk as a beverage when mixed with water, ground into flour, included in medicines, pressed for oil and used as a base for face and body paints.

In the 1990s, a research initiative was launched between a North American non profit organisation and a group of South American farmers with the goal of increasing and diversifying commercial production in the region. Chia was selected as part of the cropping program and growing trials proved successful. In the years that followed small scale, commercial production of Chia began. Today, Chia seed is grown commercially in several Latin American countries and in Australia by TCC. TCC is now the largest producer of Chia in the world.

Information on Detrimental Health Effects

During the initial "Application for Approval of Whole Chia (*Salvia hispanica L*) Seed and Ground Whole Chia as Novel Food Ingredients" from R. Craig and Sons (taken over by Columbus Paradigm Institute S.A on 30 September 2006) and the "Request for Scientific Evaluation of Substantial Equivalence Application for the Approval of Chia seeds (*Salvia Hispanica* L.) from The Chia Company for use in bread" in 2009 various human and animal medical trials were presented to demonstrate the absence of detrimental human effects. The applications were approved based on the information provided.

Further evidence supporting the absence of detrimental health effects can be drawn from the food safety regulatory approvals in N. America, Asia, and Australasia as well as the proliferation of consumer products containing Chia seed that are now being consumed globally with no negative consumer health impacts reported. Documentation of recent consumption can be found in Section X "Information on Previous Human Exposure" of this application.

IX Anticipated Intake / Extent of Use

Based on Commission Recommendation 97/618/EC decision trees the following questions must be addressed regarding to intake/extent of use of the Novel Food (European Commission 1997):

- "Is there information of the anticipated uses of the Novel Food based on its properties?"
- "Is there information to show anticipated intakes for groups predicted to be at risk?"
- "Will introduction of the novel food be restricted geographically?"

- "Will the Novel Food replace other foods in the diet?"

Intended Uses

TCC is proposing to extend the current restricted permitted use of Chia seed in baked bread to other baked goods and categories that currently commonly contain seeds. These anticipated uses are seen as a reasonable extension from the current limited use of Chia seeds in bread.

Current Position

Due to the lack of seed consumption data as an individual product included within the UK National Diet and Nutrition Survey (NDNS) or other reputable consumption data resources on seed consumption, we were unable to draw comparisons between Chia seed consumption/intake levels and other seed consumption/intake levels within the UK or EU.

The approved Application by R. Craig and Sons and the approved Substantial Equivalent Dossier from TCC both outlines anticipated intake levels at 5% inclusion in bread.

The EFSA Scientific Opinion on the safety of Chia seed, on which the R. Craig and Son and application was approved, and the ACNFP opinion on which TCC Subsequent Equivalent application was approved, concluded that at 5% inclusion in bread that Chia seed is unlikely to have "an adverse effect on public health (EFSA 2009)". EFSA developed this opinion based on the average EU consumption of bread, which would deliver approximately 9g / person / day (Page 21, EFSA 2009). In Table 8 of the EFSA Scientific Opinion on the safety of Chia seed (Page 15, EFSA 2009), it was identified that Chia seed would be consumed at different average consumption rates across the 17 Member States for which data was provided. The lowest average consumption of Chia seed through 5% inclusion in bread would be 7.0g / person / day in the UK and that the highest average consumption of Chia seed would be in Bulgaria at 15.1g / person / day. It can therefore be derived that the EFSA did not anticipate consumption of Chia seed at 15.1g / person / day or over to be a risk to public health.

The above data is provided on an average level consumption of bread and not on high level consumption of bread (97.5th percentile) as was performed during the ACNFP's "Opinion on Application Under the Novel Foods Regulation for Chia" (ACNFP 2004). ACNFP assessed UK high level bread consumers as having a potential consumption level of Chia seed at 11.6g / day / person with 5% Chia seed inclusion in bread. The ACNFP did not present concern for human health with consumption of Chia seed at this level.

TCC is proposing a Recommended Daily Intake or serving size of 15g on 100% Packaged Chia seed products, and recommending but not restricted, inclusion levels of Chia seed in all other product categories at up to 10%. The RDI of 15g / day was developed in line with the Australian Heart Foundation recommended adult intake of two grams of Omega 3 ALA per day (Australian Heart Foundation) and approved by Food Safety Australia and New Zealand (Appendix 1).

Table 2 below outlines the proposed average level of inclusion of Chia seed within each of the proposed product categories that TCC is seeking extension of approval for inclusion of

Chia seed. The inclusion % is based on product formulations performed by Dairy Innovation Australia, Food Science Australia, Baking Research Institute, DTS Food Laboratories, and private formulation by TCC and corporate customers. All formulations were designed to meet sensory and nutritional requirements for consumers and to comply with regulatory food safety laws in the N. American and Australasian markets. Additionally, TCC has analysed product containing Chia seed that are already sold and distributed within N. America and Australasia markets. Recommended Daily Intake levels and % inclusion of Chia seed in products varies between product categories, different countries, as well as similar products within the same category. The recommended inclusion % in Table 2 are comparable to the current % of Chia included in products sold on the market and comparable to the "Recommended Daily Intake" advice for 100% Chia seed products sold on the market.

Table 2: Proposed Chia seed inclusion % in each new product category

Proposed Category	**% Inclusion and Recommended Daily Intake**	**Chia seed Consumption per Product Category**
100% Packaged Chia Seed	15g Recommended daily intake (RDI)	15g Chia Seed
Baked products (muffins, cookies, crackers and biscuits)	10%, 10g Chia per 100g total mix 'flour weight'	- Muffin 95g with 9.5g of Chia Seed - Cookies 40g with 4g Chia Seed - Cracker 40g with 4g Chia Seed - Biscuit 40g with 4g Chia Seed
Breakfast cereal	10%, 10g per 100g total mix	Cereal 45g serve with 4.5g Chia Seed
Fruit, nut and seed mixes (sprinkles)	10%, 10g per 100g total mix	Fruit/Nut/Seed Mix 45g serve with 4.5g Chia Seed

Anticipated Intake

UK NDNS provides consumption data for the average UK consumers, including between the ages of 19-64 (Hoare, Henderson et al. 2004). In order to assess the average potential intake of Chia seed for a UK/EU consumer, Table 3 isolates the product categories for which we are seeking the "Extension of Use" for Chia seed. Table 4 provides the data for high potential consumer of Chia seed, the 97.5th percentile consumer of Chia seed. By calculating the daily consumption of each product category by the average adult consumer, then multiplying this by the proposed inclusion % of Chia seed as provided in Table 2 above, we provide an estimate of the potential consumption of Chia seed by the average and 97.5percentile UK/EU consumer.

Table 3: Average potential Intake of Chia seed as calculated from UK NDNS for Bread, Breakfast Cereals, Baked Goods, Nuts, Savoury Snacks, and Confectionary Food Categories

All Respondents	Mean Consumption - (grams per day)							
Product Categories	Age Groups							
	19-24	25-34	34-49	50-64	All Consumers	% All Consumers	Chia % Inclusion	Grams of Chia Consumed / Day
Bread	94.3	102.7	101.6	101.4	100.9	99%	5%	5.0
Breakfast Cereal	16.4	26.4	28.1	37.6	29.0	67%	10%	2.9
Biscuits, buns, cakes, pastries & fruit pies	19.3	28.7	33.6	41.9	33.0	84%	10%	3.3
Nuts	0.9	2.3	2.3	2.1	2.1	20%	10%	0.2
Savoury snacks	12.4	9.9	7.0	3.6	7.4	56%	10%	0.7
Confectionary	15.9	12.3	12.3	8.6	11.7	62%	10%	1.2
SUM	159.1	182.3	184.9	195.1	184.1	65%		13.4

Source: Table 2.1.a, 2.1.b, 2.1.c of The National Diet & Nutrition Survey: adults aged 19 to 64 years, Summary Report Volume 5 (2004)

From the analysis of the UK NDNS data and applying Chia seed inclusion % it is possible that an average adult UK/EU consumer could have a daily intake of 13.4g of Chia seed per day if all product varieties contained Chia seed.

Table 4: Potential Intake of Chia seed as calculated from UK NDNS for Bread, Breakfast Cereals, Baked Goods, Nuts, Savoury Snacks, and Confectionary Food Categories for a 97.5 percentile consumer

All Respondents	Mean Consumption - (grams per day)							
Product Categories	Age Groups							
	19-24	25-34	34-49	50-64	All Consumers	97.5th Percentile	Chia % Inclusion	Grams of Chia Consumed / Day
Bread	188.6	205.4	203.1	202.9	201.7	Upper 2.5%	5%	10.1
Breakfast Cereal	32.9	52.9	56.3	75.1	58.0	Upper 2.5%	10%	5.8
Biscuits, buns, cakes, pastries & fruit pies	38.6	57.4	67.1	83.7	66.0	Upper 2.5%	10%	6.6
Nuts	1.7	4.6	4.6	4.3	4.3	Upper 2.5%	10%	0.4
Savoury snacks	24.9	19.7	14.0	7.1	14.9	Upper 2.5%	10%	1.5
Confectionary	31.7	24.6	24.6	17.1	23.4	Upper 2.5%	10%	2.3
SUM	318.3	364.6	369.7	390.3	368.3	Upper 2.5%		26.7

Source: Table 2.1.a, 2.1.b, 2.1.c of The National Diet & Nutrition Survey: adults aged 19 to 64 years, Summary Report Volume 5 (2004)

Based on current marketing Chia seed is likely to only be included in a minority of brands within each product category. For example, within the Australian market, there are approximately 67 product options to choose from in the muesli bar/cereal bar category, 85 bread options, and 178 breakfast cereal options (Woolworths Ltd. 2010). Chia seeds are seen to compliment all of these categories very well. But currently, only five (5) of the 330 choices currently contains Chia seeds; less than 2%. Therefore, due to the availability of

product choices within each product category, the level of consumption of Chia seed as an ingredient, which is demonstrated in Table 3, is unlikely to be achieved by the majority of consumers due to the wide product selection available in each category.

Not all consumers consume a product from each category every day, and sometimes consumers do not consume certain categories at all, as represented by the NDNS data and the "% All Consumers" column in Table 3 below (Hoare, Henderson et al. 2004). Therefore the statistical representation in Table 3 of a potential Chia seed consumer has a very low probability of actually occurring. For example, according to UK NDNS data from Volume 5 Summary Report, Table 2.1.(c), 99% of surveyed consumers ate bread, but only 67% ate cereal, and 20% ate nuts (Hoare, Henderson et al. 2004). A consumer would only achieve a Chia consumption rate of 13.4g / day, as displayed in Table 3 above, if they consumed the RDI of each product from each category containing the maximum recommended inclusion rate of Chia seed. This is a highly unlikely scenario, therefore whilst the purpose of the statistical analysis of Table 3 was an attempt to provide an average consumer's intake of Chia seed; this analysis probably represents a minority of consumers.

Table 3 is describes an average consumer consumption potential for Chia seed under the extension of use conditions. TCC has also calculated the potential Chia seed consumption of a 97.5^{th} percentile consumer for all categories. In order to estimate the 97.5^{th} percentile consumption levels for each category we have made the reasonable assumption in line with Hoare, Henderson et al. 2004, that the 97.5^{th} percentile is twice the mean consumption level. Again it should be acknowledged that this situation is highly unlikely due to the small percentage of consumers that would purchase and heavily consume an item from each category containing Chia seed daily. The result of the calculation is a potential daily consumption of Chia seed of 26.7g / consumer / day.

<u>100% Chia seed as a Consumer Product</u>

TCC has included within the extension of use proposal for Chia seed, the permission to sell 100% Chia seed as a consumer product as is widely done in other markets. The intended use for this product is to permit consumers to add Chia seed to their muesli or home baking recipes for bread and cookies. This will permit consumers to have the option to add Chia seed to their choice of muesli and home baked products in the recommended % as stated in Table 2. Clear labelling on the product can be used to provide recommended daily intake of Chia seed and recommended inclusion % in recipes.. Clear labelling of "seed" will also allow consumers who are allergic to other seeds to avoid consumption, this is coherent with the strategy applied in other markets and intended for use within the EU.

<u>Intake for Groups Predicted to be at Risk</u>

The EFSA approved Application by R. Craig and Sons and the ACNFP approved Substantial Equivalent Dossier from TCC, both provide reviewed and approved information regarding other toxicological information of the Chia seed. Please refer to the EFSA decision on inclusion of Chia seed in bread (EFSA 2009).

TCC conducted a survey of food allergy associations and food safety regulatory complaint authorities. Despite the proliferation of Chia seed as an ingredient and consumption of whole Chia seed, no reports of allergic reaction to Chia seed has been reported and recorded as of

today. For further information please see the Section XIII on Toxicological Information of Chia Seed.

Geographic restriction of Chia seed Release

TCC do not believe that the release of Chia seeds into the EU should be in anyway restricted due to the product delivering nutritional benefits to consumers and to date having no reported incidence of allergic reaction from a consumer in markets where Chia is consumed widely.

Will Chia seed replace other foods in the diet?

Chia seed will not replace other foods in the diet. Chia seed will most likely accompany flax seed and walnuts as a good source of omega-3 polyunsaturated fatty acids and protein in the EU consumers' balanced and diverse diet. Consumption of polyunsaturated fatty acids has been widely viewed as beneficial for human health with consumption levels needing to increase in the western diet. Chia seed inclusion in these categories will increase the occasions for consumers to supplement their intake of omega-3 polyunsaturated fatty acids.

Labelling

TCC will label Chia seed products in accordance with the EU regulatory decisions on Chia seed use as a novel food and ingredient and the EU guidelines for labelling and nutrition. This is in accordance with the EFSA previous decision on labelling of Chia seed for inclusion in bread (EFSA 2009).

X Information on Previous Human Exposure

Based on Commission Recommendation 97/618/EC decision trees the following questions must be addressed regarding the previous human exposure to the Novel Food (European Commission 1997):

- "Is there previous information from previous direct, indirect, intended, or unintended human exposure to the Novel Food or its source which is relevant to the Community situation with respect to production, preparation, population, lifestyles, and intakes?"
- "Is there information to demonstrate that exposure to the Novel Food is unlikely to give rise to nutritional, microbiological, toxicological and/or allergenicity problems?"

Recent Human Exposure to Chia seed

The approved Application by R. Craig and Sons and the approved Substantial Equivalent Dossier from TCC both provides information on previous human exposure to Chia seed. Both applications have information on pre-colonial consumption to Chia seed by Central and Southern American indigenous populations. As acknowledged in the EFSA Opinion on the Safety of Chia seed, the Panel regarded the current use of Chia seed in non-EU countries as supportive evidence of the safety of Chia seed (pg 21, EFSA 2009). This section expands on this subject and demonstrates that recently, Chia seed has been welcomed into the modern western diet as a highly nutritional food supplement and as a food ingredient.

- Mintel GNPD lists 272 new products containing Chia seeds that have been launched into the global market from October 2009 through November 2010.
- In January 2010 the largest Australian fresh bread bakery franchise, with 700 stores serving 2.5 million customers a week, successfully launched Chia bread into the market (Baker's Delight 2009; The Chia Company 2010).
- Global multi-national food manufacturers Kellogg's and Fonterra have followed suit by launching cereal bars containing Chia seed and yoghurt containing Chia seed respectively (Be Natural 2010; Mintel 2010).
- TCC branded packaged Chia Seed (100%) is currently sold in over 190 Health and Wellbeing retailers across Australia and 150 Terry White Chemists with a Recommended Daily Intake of 15g/person/day.
- The equivalent of over 30g of Chia seed was consumed by each Australian citizen during the last financial year (Australian Bureau of Statistics 2010; The Chia Company 2010).
- Despite actively requesting consumer feedback and providing contact details on every consumer pack sold, engaging with food allergy associations globally, and performing research, TCC has not received or located information to suggest that there have been any instances of an allergic reaction to Chia seed.

Consumption Recent History

Chia seed products have been introduced to the market at an increasing pace and variety. Categories that Chia seed is now involved includes health supplements, dairy, bread, baked goods, hot cereals, cold cereals, energy and cereal bars, chips and other extruded savoury snacks, cosmetics and beauty products, and pure 100% Chia seed and 100% Chia Oil. In order to demonstrate this proliferation of products we have used personal data collected from the market and Mintel Global New Product Database (GNPD).

Mintel is the world leader in market intelligence for food, beverage, and FMCG products. Mintel's GNPD collects and records information on many new product releases, allowing companies to identify how many products are being created in their category globally. Through this tool we can identify new Chia seed products in the market and keep track of market growth. Please note, GNPD is directed at new products only, if the Chia product has been on the market for over 12 months, which many Chia products have, the product will no longer be recorded in the GNPD. Therefore this is merely a representation of products and not a complete list of all available Chia products globally.

Australia and New Zealand:
Mintel GNPD identifies 33 individual products containing Chia seed have been launched into the Australian and New Zealand market. Of the 33 products over 13 were from the cereal, baked goods, and pure Chia seed categories. Additionally, Chia seed bread is served daily in over 700 fresh bread bakeries across Australia and New Zealand under the Baker's Delight franchises(Baker's Delight 2009).

Canada & USA:
Mintel GNPD identifies 39 individual products containing Chia seed that have launched into the Canadian market. Of these 39 products, at least 17 products were from the cereal, baked goods, and pure Chia seed categories.
Chia has now become so main-stream in Canada that the company Ruth's Hemp Foods commands a centre shelf position in the cereal aisle with the "Chia Goodness" branded cereal

product. A cereal, using Chia seed as the primary ingredient, has four (4) varieties of "Chia Goodness" cereal and commands six (6) product facings in prime product position on the shelf (Ruth Hemp Foods 2010).

Figure 1: Image of Chia cereals in holding 6 facings of prime shelf position

Mintel GNPD identifies 134 individual products containing Chia seed that have launched into the USA market. Of the 134 products, over 40 products were from the cereal, baked goods, and pure Chia seed categories.

Asia:
Mintel GNPD lists 11 individual products containing Chia seed that have been launched in Japan and South Korea. Of the 11 products, 6 products were from the cereal, baked goods, and pure Chia seed categories.

Argentina:
Mintel GNPD lists 42 individual products containing Chia seed that have been launched in Argentina. Of the 42 products, 23 products were from the cereal, baked goods, and pure Chia seed categories.

Table 5 below provides a brief summary of some of the Chia seed products sold in N. America, S. America, Australasia, Asia, and Europe. This table is meant to highlight the variety of products already available to the global consumer base, the difference in Recommended Daily Intake and inclusion %, and the proliferation of highly nutritious products already available providing opportunities for cross consumption of Chia seed on a daily basis.

Table 5: Summary table of a small representative sample of Chia products from Mintel GNPD (viewed 7 December 2010)

Market	**Product**	**Chia content in Product**	**Picture**

Global Regulatory Approvals for Chia Seed

Australia and New Zealand:
Chia seed has been recognized as non-traditional, non-novel food by the Novel Food Reference Group of the Food Standards Australia New Zealand (hereinafter, the "FSANZ"). An excerpt of the FSANZ approval document is provided in Appendix 1.

As confirmed in the initial Application by R. Craig and Sons, the USA and Canada have concluded "that Salvia hispanica can be used as a food, without prior regulatory notification or approval (R. Craig and Sons Ltd 2006)".

Investigation into Allergic Reactions to Chia

TCC conducted research into actual or potential allergic reactions to consumption or contact with Chia seed in markets where Chia seed and Chia seed products have a recent history of sale. Responses from allergy associations and food safety regulator consumer complaint resources were as follows:

- Anaphylaxis Australia, the leading not-for-profit allergy association in Australia has stated that there have been no reported cases of an allergic reaction to Chia seed and that "there is currently no reason to think that those allergic to peanut, tree nuts or seeds like sesame seed are at any higher risk of allergic reactions by consuming them (Chia seeds) (Anaphylaxis Australia Inc. 2010)" (Please see Appendix 3).
- The Food Allergy and Anaphylaxis Network (FAAN) in the USA stated that "FAAN has no record of a reaction from that product (Chia seed) (The Food Allergy and Anaphylaxis Network 2010)" (Please see Appendix 5)
- The Allergy Bureau of Australia reported that it "is not aware of any reports of allergic reactions to chia seeds in Australia (The Allergy Bureau 2010)" (Please see Appendix 4).
- The Asthma and Allergy Foundation of America reported that "we have not received any complaints regarding chia seed (The Asthma and Allergy Foundation of America 2010)" (Please see Appendix 8)

Conclusion on Previous Human Exposure

Chia seed is now a widely available product and ingredient in N. America, S. America, Australasia, and Asia. As demonstrated in Section IX that despite there being numerous occasions for cross consumption, the chance of a consumer having Chia seed included in each of their food groups is not likely. With a minority of consumers there is a possibility for cross consumption in the above listed markets allowing for a high daily consumption of Chia seed by some consumers. Most populations in N. America and Australasia have European heritage and similar eating, diet, and nutritional consumption habits to modern EU citizens (Australian Bureau of Statistics 2006). From TCC's personal research to date, no allergic reactions to Chia seed have been recorded in markets where Chia seed is widely sold and consumed.

Nutritional, Microbiological, and Toxicological Information related to Chia seed Exposure

Sections XI, XII, and XIII below discuss the nutritional, microbiological, and toxicological issues with regards to human exposure to Chia seed

XI Chia Nutritional Profile

Based on Commission Recommendation 97/618/EC decision trees the following questions must be addressed regarding the nutritional profile of the Novel Food (European Commission 1997):

- "Is there information to show that the Novel Food is nutritionally equivalent to existing foods that it might replace in the diet?"
- "Is there information to show that the Novel Food does not affect the bioavailability of nutrients from the diet or have adverse physiological effects?"
- "Is there information to allow an assessment to be made of the nutritional impact of the introduction of the Novel Food?"

Statement of Nutritional Profile

The approved Application by R. Craig and Sons and the approved Substantial Equivalent Dossier from TCC provide EFSA and ACNFP reviewed and approved information regarding the nutritional profile of Chia seed.

EFSA Panel concluded that "Chia seeds are unlikely to be nutritionally disadvantageous to the consumer under the proposed conditions (EFSA 2009)".

The below nutritional profile (Table 6) has been taken from TCC Chia seed samples that were analysed at the Australian Government National Measurement Institute in February 2009. Please see Appendix 2 for original Certificates of Analysis.

Table 6: Nutritional Profile of Chia seed

Nutrient	**Percentage %**
Dry matter	95 - 96.8
Protein	17.4 - 22.4
Fat	28.5 - 34.7
Carbohydrate	37.1 - 42.6
Fiber	32.8 - 40.2
Ash	4.5 - 5.6

Mineral	**Result (mg / 100g)**
Sodium	<0.1 – 6
Potassium	510 - 710
Calcium	500 – 640
Iron	5,7 – 15
Magnesium	310 - 430
Phosphorus	600 – 870

Vitamin	**Result (mg / 100g)**
Retinol (Vit. A)	16 IU
Thiamin (Vit. B1)	0.79 - 0,81
Riboflavin (Vit. B2)	0,05
Niacin (Vit. B3)	7.8 – 9.4
Cobalamin (Vit B12)	90 – 110 ng
Ascorbic acid (Vitamin C)	<1 – 6

Alpha-tocopherol (Vit. E)	<0.1 – 0.3

Aminoacids	**Results (% of proteins)**
Isoleucine	3.05 – 3.53
Leucine	5.47 – 6.34
Lysine	3.87 – 4.42
Methionine	1.00 – 1.14
Phenylalanine	4.19 – 4.71
Threonine	2.90 – 3.42
Tryptophan	0.89 – 1.04
Valine	3.86 – 4.56

Fatty Acids	**Results %**
Total fat	28.5 - 34.7
Saturated fat	2.8 - 4.1
Mono-unsaturated Fats	2 – 3 (g/100g)
Poly-unsaturated Fats	17.8 – 27.8 (g/100g)
Trans fats	<0.1 - 0,1 (g/100g)
C06:0 Caproic	< 0.1
C08:0 Caprilic	< 0.1
C12:0 Lauric	< 0.1
C14:0 Myristic	< 0.1
C15:0 Pentadecanoic	< 0.1
C16:0 Palmitic	7.1
C18:0 Stearic	3.7
C20:0 Arachidic	0.3
C14:1 Miristoleic	< 0.1
C16:1 Palmitoleic	0.3
C17:1 Heptadecanoic	< 0.1
C18:1w9 Oleic	8.7
C20:1w9 Eicosaenoic	< 0.1
C18:2w6 Linoleic	22.0
C18:3w3 Linolenic	57.4
C18:3w6 Linolenic	< 0.1
C20:2w6 Eicosadienoic	< 0.1
C20:3w3 Eicosatrienoic	< 0.1
C20:5w3 Eicosapentaenoic	< 0.1
C22:4 Docosatetraenoic	< 0.1
C22:5w3 Docosapentaenoic	< 0.1
C22:6w3 Docosahexaenoic	< 0.1
C24 Lignoceric	0.1

Source: Australia Government National Measurement Institute, Certificate of Analysis, Job Number: CHIA01/090219, Date Sampled 18 February 2009 (See Appendix 2)

Chia seed Nutritional Equivalence to Food it Might Replace

The Chia seed is not predicted to replace any existing food in the diet.

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 its weight, about 80 % of which is _ -linolenic acid, making this ingredient a source of n-3 fatty acids. The seeds alone possess about 5 % soluble fibre. The TCC seeds are also a source of vitamins B, calcium, phosphorous, potassium, zinc, and copper, and contain natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides).

Consumption of the nutrients that occur naturally in Chia, dietary fibre, protein and Omega 3 ALA are generally recognised for improved health. In particular EFSA has conclude that "evidence in adults shows there are health benefits associated with higher intakes of dietary fibre e.g. reduced risk of heart disease, type 2 diabetes and weight maintenance. (EFSA 2010)"

Bioavailability of Nutrients and Nutritional Impact of Chia seed

EFSA Panel concluded that "Chia seeds are unlikely to be nutritionally disadvantageous to the consumer under the proposed conditions (EFSA 2009)".

Human and animals tests on the bioavailability of nutrients from Chia seeds were discussed within the approved Application by R. Craig and Sons and the approved Substantial Equivalent Dossier from TCC..

Heavy Metals and Chemical Contaminants

The EFSA approved Application by R. Craig and Sons and the ACNFP approved Substantial Equivalent Dossier from TCC, both provide reviewed and approved information regarding analysis of heavy metals and chemical contaminants in Chia seed. The heavy metal and chemical contaminant content was found to comply with EU regulations (EFSA 2009).

Table 7: Analytical data on heavy metals in Chia seed

Heavy Metals	Result (ppm)
Arsenic	<0.1 (Detection limit: 0.1)
Cadmium	<0.1 (Detection limit: 0.1)
Mercury	<0.01 - <0.02 (Detection limit: 0.02)
Lead	<0.5 - <1 (Detection limit: 1)

Source: Substantial Equivalent Dossier from The Chia Company

XII Microbiological Information of the Chia Seed

Based on Commission Recommendation 97/618/EC decision trees the following questions must be addressed regarding the microbiological information of the Novel Food (European Commission 1997):

- "Is the presence of any microorganisms or their metabolites due to the novelty of the product/process?"

The ACNFP opinion on the initial Application was that they "were content with the microbiological information supplied (ACNFP 2004)" especially after a further requested review of the HACCP schema demonstrated that quality measures were in place to control and monitor moisture level during long bulk storage and transportation.

The EFSA approved Application by R. Craig and Sons and the ACNFP approved Substantial Equivalent Dossier from TCC both provide reviewed and approved information regarding

analysis of microbiological contamination in Chia seed. The results of microbiological contamination analysis found that Chia seed samples complied with EU regulations.

Table 8: Analytical data on Mycotoxins

Mycotoxins	Results (ppb)
Ochratoxine A	<1
Aflatoxine B1	<1
Aflatoxine B2	<1
Aflatoxine G1	<1
Aflatoxine G2	<1
Sum of afl. B1 + B2+ G1+ G2	<5
Toxine T-2	<100
Toxine HT-2	<100
Fumonisine B1	<250
Fumonisine B2	<250
Deoxynivalenol	<250
Zearalenone	<25

Mycotoxins	Results
Yeasts/g	<200 CFU/g
Accredited moulds/g	<200 CFU/g
Coagulase Positive Staphylococci / g	<100 CFU/g – 200 CFU/g
Bacillus cereus/g	<100 CFU/g – 200 CFU/g
Salmonella/25 g	Not Detected/25 g
E. Coli (CFU)	<10 CFU/g – 20 CFU/g
Listeria monocytogenes	Not Detected/25 g
Clostridium perfringens	<100 CFU/g – <200 CFU/g

Source: Substantial Equivalent Dossier from The Chia Company

XIII Toxicological Information of the Chia Seed

Based on Commission Recommendation 97/618/EC decision trees the following questions must be addressed regarding the toxicological information of the Novel Food (European Commission 1997):

- "Is there a traditional counterpart to the Novel Food that can be used as a baseline to facilitate the toxicological assessment?" If no, "is there information from a range of toxicological studies appropriate to the Novel Food to show that the Novel Food is safe under anticipated conditions of preparation and use?"
- "Is there information which suggests that the Novel Food might pose an allergic risk to humans?"

The EFSA approved Application by R. Craig and Sons and the ACNFP approved Substantial Equivalent Dossier from TCC, both provide reviewed and approved information regarding other toxicological studies on animals and humans for safe consumption of Chia seed at various levels. ACNFP stated in their opinion that "The Committee was satisfied with the toxicological data supplied by the applicant (ACNFP 2004)". The EFSA Opinion on the Safety of Chia seeds advised that the toxicological information provided in the initial proposal's was limited, but that the "experience gained from previous and current use of Chia

seeds for food purposes in non-EU countries can be regarded as supportive evidence of the safety of Chia seeds and ground whole Chia seeds" (EFSA 2009).

The safety of Chia seeds has been further investigated by Fernandez, Vidueiros, Ayerza, Coates, and Pallaro (Fernandez, Vidueiros et al. 2008). This study was performed to analyse the effect of Chia on some aspects of the immune system such as the thymus and serum IgE concentration. Weanling male Wistar rats (23 d of age) from the Department of Nutrition at the School of Pharmacy and Biochemistry of the University of Buenos Aires, were divided in three groups (6 rats each) that received for one month (g/kg diet): 150 ground Chia seed (T1); 50 Chia oil (T2); no Chia (T3; control group). Diets T1 and T2 were formulated to provide equal quantities of alpha-linolenic acid from the chia. All the experimental diets were iso-energetic, contained (g/kg) 200 protein and 70 oil, and were prepared according to the American Institute of Nutrition guidelines. No significant differences were observed in food intake, body weight, thymus weight, total thymocyte number and IgE levels when Chia was added to experimental diets as seeds (T1) or as oil (T2) when compared with the control (T3). Moreover, no symptoms such as dermatitis, diarrhoea and abnormal animal growth and behaviour were observed. Adding Chia seeds or oil to experimental diets did not produce any of the problems associated with other n-3 fatty acid sources such as flaxseed or marine products, e.g. fishy flavour, weight loss, digestive problems, diarrhoea and allergies.

As outlined in section Appendix 1, the Novel Food Reference Group for Food Standards Australia and New Zealand (FSANZ) ruled in 2007 that no safety risks were present in Chia Seed.

The EFSA Panel has noted that "it is not possible to predict the potential allergenicity of Chia using methodologies available to date (EFSA 2009)".

TCC again sought clarification regarding the potential to provide an "allergen warning" on the product label advising customers that Chia seed might be an allergen and to avoid if you had an allergen to other food types. The response provided by the Food Allergy Brand of the UK FSA was that:

"There is no requirement for any general warning that an ingredient may cause an allergic reaction. Whilst people may have a reaction to a food not on the current EU allergen list, clear ingredients listings should allow anyone allergic to a food not on the EU list to avoid that food (Food Allergy Branch: UK FSA 2010)." (Please see Appendix 6)

<u>Allergy</u>

To minimise the exposure of individuals to Chia seed that might have a possible allergy, TCC has chosen to restrict the extension of use to categories in which nuts and seeds are already readily included. This strategy makes the reasonable assumption that consumers who have an allergy to another nut or seed will be prepared for seed and nut content in these categories, and therefore avoid consumption of Chia seed. This will reduce the risk of cross reaction.

In order to try and provide further information regarding the potential allergenicity of Chia seed, TCC conducted a survey of food allergy associations and food safety regulatory

complaint authorities in countries where Chia seed was widely available. Despite the proliferation of Chia seed as an ingredient and consumption of whole Chia seed in consumer products, as explained in Section X of this Application, there were no reports of allergic reaction to Chia seed that these organisations were aware of. The responses were as follows:
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- Anaphylaxis Australia, the leading not-for-profit allergy association in Australia has stated that there have been no reported cases of an allergic reaction to Chia seed and that "there is currently no reason to think that those allergic to peanut, tree nuts or seeds like sesame seed are at any higher risk of allergic reactions by consuming them (Chia seeds) (Anaphylaxis Australia Inc. 2010)" (Please see Appendix 3).
- The Food Allergy and Anaphylaxis Network (FAAN) in the USA stated that "FAAN has no record of a reaction from that product (Chia seed) (The Food Allergy and Anaphylaxis Network 2010)" (Please see Appendix 5)
- The Allergy Bureau of Australia reported that it "is not aware of any reports of allergic reactions to chia seeds in Australia (The Allergy Bureau 2010)" (Please see Appendix 4).
- The Asthma and Allergy Foundation of America reported that "we have not received any complaints regarding chia seed (The Asthma and Allergy Foundation of America 2010)" (Please see Appendix 8)

The lack of reported allergic reactions to Chia seed to date might be due to several factors. One possible reason that is relevant to this application is that the majority of Chia seed is sold as 100% whole Chia seed or as an ingredient in bread, cereal, or baked goods as represented by the Mintel data in Section X of this extension of use dossier. Clear labelling of the product as a "seed" and limiting its inclusion to products that generally contain seeds and nuts, would have prevented many consumers at risk to cross reaction from consuming the Chia seed. Consumers with allergies to seeds or nuts can continue to use their normal risk management plan to prevent consumption of a potential allergen.

The fact that consumption patterns of bread, biscuits, cereals, nut and seed mixes, and other products is generally similar between the EU and markets where Chia seed is already widely consumed such as Australia and the USA. These general consumption pattern similarities in combination with the strategy of only adding Chia seed to products that currently contain nut and seed allergens provides a risk mitigation strategy to exposing a potentially allergic consumer to Chia seed.

Conclusions

Chia seed is a nutritious ingredient that can contribute positively to the modern EU diet. Tests for microbiological, chemical, and heavy metal contaminants have demonstrated compliance with EU food safety regulations as advised in the EFSA Opinion on Safety of Chia seed page 10 and 11 (EFSA 2009). TCC has demonstrated a dedicated commitment to supplying high quality and safe non-GM Chia seed through their accredited HACCP QMS system SQF 2000. TCC's tightly controlled production process produces a high quality, safe, and traceable product which has lead to achieving global supplier accreditation to some of the world's largest multinational food companies. Chia seed has been approved for unregulated use as a food in N. America, Australasia, Argentina, and some countries in Asia. Chia seed is being consumed in an ever increasing number of products across N. America, Australasia,

S. America, and Asia as a food ingredient and as a whole Chia seed product. Despite wide proliferation of Chia seed, there have been no reports of an allergic reaction to Chia seed to date. TCC is seeking an extension of use into other food categories that commonly contain seeds and have demonstrated using UK NDNS data that the average composite consumption of Chia seed in all of these product categories is not likely to exceed 13.4g per person per day (Table 3). 13.4g of Chia seed consumption is less than the current estimated average consumption of Chia seed through 5% inclusion in bread for an average Bulgarian citizen which has already been approved by the EFSA (Table 8, Page 15, EFSA 2009).

TCC propose for an extension of use of Chia seed to 10% inclusion % in other baked goods and categories that commonly contain seed and 15g Recommended Daily Intake for 100% whole packaged Chia seed.

Glossary of Abbreviations

ACNFP	Advisory Committee to the Novel Food Process
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAAN	The Food Allergy and Anaphylaxis Network
FSANZ	Food Safety Australia New Zealand
GM	Genetically Modified, Genetic Modification
GMO	Genetically Modified Organism
GNPD	Mintel Global New Product Database
HACCP	Hazard Analysis Critical Control Points
NATA	National Association of Testing Authorities
NDNS	National Dietary and Nutrition Survey (UK)
NF	Novel Food
TCC	The Chia Company
UK FSA	UK Food Standards Agency

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