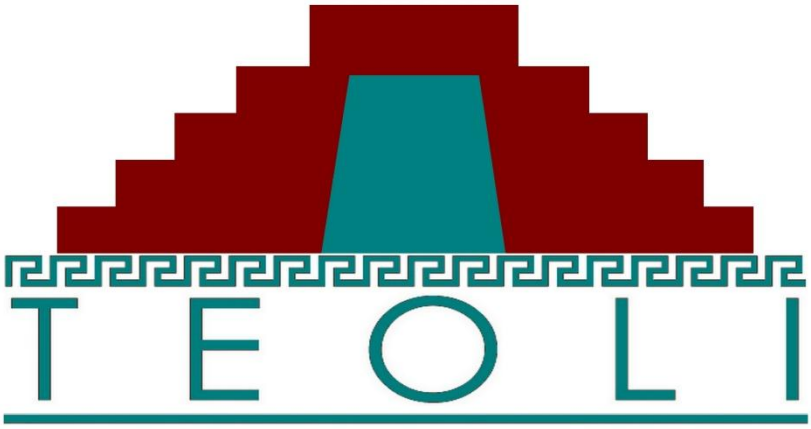

Request for Scientific Evaluation of Substantial Equivalence for the Approval and Extended Use of Chia Seeds (*Salvia hispanica* L.)

23 February 2015

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Nutra Earth Functional foods, S.A. de C.V trading as Teoli Mexican Speciality Foods Ltd. ("Teoli") seeks to obtain a scientific evaluation of substantial equivalence for the approval and use of Chia seeds (*Salvia hispanica* L.). A decision is sought on the equivalence of the Chia seed produced by Teoli Ltd. ("Mexican Chia seed") and the approved Chia seed produced and imported into the European Union by The Chia Company (hereinafter, "TCC Chia"). This approval is pursuant to Article 5 of Regulation (EC) nº 258/97 on novel
foods and novel food ingredients (hereinafter, the "Novel Food Regulation").

INTENDED USES

- Use in bread at 5%
- Baked goods - not more than 10%
- Breakfast cereal – not more than 10%
- Fruit, nut, and seed mixes – not more than 10%
- 100% Packaged Chia seed – not more than 15 g per day

These uses have been approved by the European Commission pursuant to Decision 2009/827/EC on January 20, 2013 and notified under document C (2013) 123. Teoli Chia seed is intended to be consumed in a manner identical to that of the TCC Chia.

This report follows the "ACNFP guidelines for the presentation of data to demonstrate substantial equivalence between a novel food or food ingredient and an existing counterpart". The Teoli Grain Chia seed has been independently analysed and we present evidence to confirm that the product is substantially equivalent in composition and level of undesirable substances to that of the TCC Chia.

2 ADMINISTRATIVE INFORMATION

Applicant:

Teoli Mexican Speciality Foods Ltd.
Townsend Farmhouse
2 High Street
Rode
Somerset
BA11 6NZ

Telephone: +44 1373830863
Email: info@nutra-Earth.com
Web: www.nutra-earth.com

Contact:
Richard Feather
Teoli Mexican Speciality Foods Ltd.
Telephone: +44 (0)1373830863
Email: rf@specialitysupply.co.uk

Name of novel food ingredient:
CHIA SEED (SALVIA HISPANICA L.)

Date of application:
23/02/2015

3 COMPOSITION

3.1. INFORMATION ON THE SOURCE ORGANISM

Chia (*Salvia hispanica* L.) is a summer annual herbaceous plant belonging to the Labiatae family. The Chia plant grows approximately 1-1.2 meters tall, growing from a seeding to then develop lush, green foliage before it produces long flowers similar to lavender which are either purple or white. These flowers then develop into seed pods which contain the Chia seeds themselves.
The Chia seed is naturally grown and contains all components of the dicot: the seed coat, cotyledons and the embryo. Chia seed contains high percentages of fibre, protein, and Omega-3 essential fatty acids, providing a nutritious and healthy food and food ingredient.

3.2. PRODUCTION PROCESS

Teoli Chia seeds are grown in Mexico on our own farms and on behalf of Teoli by contracted producers. The farms are located in areas that provide the perfect climactic conditions for Chia to thrive. Teoli seed is cleaned mechanically and by air to remove contaminants prior to its final use as a food ingredient. The Chia is planted mechanically into prepared soil, with no chemicals at all used during the planting process. The Chia is not irrigated, and so receives water through natural precipitation. During the growing process the fields are visited at least weekly in order to evaluate the growth of the Chia plants. The Chia seeds are then harvested 100% mechanically, using machinery similar to that used for soy or wheat. Prior to entry into the field, the harvesting machines are cleaned in order to avoid introducing foreign elements to the harvested Chia. Following harvest, the Chia is then placed into brand new 1000 kg bags and then sealed and numbered to identify the specific field in order to maintain purity and traceability.

Post-harvest the Chia seeds are mechanically cleaned and classified, using absolutely no chemicals. The cleaning process removes the flowers, leaves, stems, and other undesired parts of the plants. Following cleaning and classification, the Chia seeds are generally packed into 25kg polypropylene bags. These bags are either then sent to warehouses for storage or directly to customers.

3.1. COMPOSITION OF PRODUCT

Three separate batches of Teoli Mexican Speciality seeds have been analysed by independent laboratories (see Appendix) and the results are presented in the tables below. As can be seen, the relative ratios of micronutrients found in the Teoli seed and the TCC Chia are *"substantially equivalent".*

Table 1 Comparative Nutrient Table

NUTRIENT	TEOLI (%)	TCC CHIA (%)
Dry Matter	92.0-94.0	95.0-96.8
Protein	18.7-21.8	17.4-22.4
Fat	29.4-31.8	28.5-34.7
Carbohydrates	34.7-42.1	37.1-42.6
Dietary Fibre	34.3-39.1	32.8-40.2
Ash	4.9-5.0	4.5-5.6

Table 2 Fatty Acid Composition

FATTY ACID PROFILE	TEOLI (g/100g)	TCC CHIA (g/100g)
Total Fat	29.4-31.8	28.5-34.7
Saturated Fat	3.1-3.4	2.8-4.1
Mono-unsaturated Fat	2.3-2.6	2.0-3.0
Polyunsaturated Fat	23.4-26.0	17.8-27.8
(Of Which C18:3 ω3 Linolenic Acid)	61.4-63.7% of total fatty acids	57.4% of total fatty acids

Table 3 Mineral Content

MINERALS mg/100g	TEOLI	TCC CHIA
Sodium	2.6-10	<0.1-6
Potassium	586-702	510-710
Calcium	633-918	500-640
Iron	4.1-5.8	5.7-15
Phosphorous	650-820	600-870
Magnesium	307-460	310-430

Table 4 Vitamin Content

VITAMIN	TEOLI	TCC CHIA
Vitamin A (Retinol)	<20 IU	16 IU
Vitamin C (Ascorbic Acid)	4.0-4.2 mg/100g	<1-6 mg/100g
Vitamin E (α-tocopherol)	<0.34 mg/100g	<0.1-0.3 mg/100g

4 NUTRITIONAL VALUES

As shown in the tables , the Teoli 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 their weight, a significant percentage of which is alpha-linolenic fatty acid (an essential Omega-3 fatty acid). The Teoli Chia seeds are also a source of vitamins A, C, and E, calcium, phosphorous, potassium and zinc, and contain natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides).

4.1. GENERAL DESCRIPTION

Chia (*Salvia Hispanica* L.) is an estival growing annual species belonging to the family Labiatae that is indigenous to Mexico and Central America.

Chia seeds were first used as food as early as 3500 BC and were one of the main components of the Aztec and the Mayan diets. Chia seeds 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. Chia was extremely important to these pre-Columbian societies, and in terms of significance, only corn and beans outweighed it. Although Chia was originally part of the indigenous peoples' diet, this changed with colonization and modernization. Chia has only recently been "rediscovered" and it's nutritional and health benefits more widely publicised.

5 METABOLISM

The composition of Teoli Chia seeds does not differ significantly from the TCC Chia. As reference, the following studies describe the bioavailability and stability of Chia seeds in general.

5.1. BIOAVAILABILITY

Chia Seed (Salvia hispanica L.) as an ω-3 Fatty Acid Source for Broilers: Influence on Fatty Acid Composition, Cholesterol and Fat Content of White and Dark Meats, Growth Performance, and Sensory Characteristics *R.Ayerza,* W. Coates,*,1 and M. Lauria†*

Five thousand four hundred, 1-d-old, male, Ross 308, broiler chicks were fed for 49 d to compare diets containing 10 and 20% chia (*Salvia hispanica* L.) seed to a control diet. Cholesterol content, total fat content, and fatty acid composition of white and dark meats were determined at the end of the trial. A taste panel assessed meat flavour and preference. Cholesterol content was not significantly different among treatments; however, the 10% chia diet produced a lower fat content in the dark meat than did the control diet. Palmitic fatty acid content was less in both meat types when chia was fed, with differences being significant (P <0.05), except for the white meat and the 20% chia diet. *Alpha*-Linolenic fatty acid was significantly higher (P <0.05) in the white and dark meats with the chia diets. Chia significantly lowered the saturated fatty acid content as well as the saturated: polyunsaturated fatty acid and ω-6: ω-3 ratios of the white and dark meats compared to the control diet. No significant differences in flavour or preference ratings were detected among diets. Body weight and feed conversion were significantly lower with the chia diets than with the control, with weight reductions up to 6.2% recorded with the 20% chia diet.

AYERZA R and COATES W (2000). Dietary levels of Chia: influence on yolk cholesterol, lipid content and fattyacid composition for two strains of hens. Poult. Sci. 79: 724-739.

Four hundred fifty H&N laying hens, half white and half brown, were fed for 90 days to compare a control diet to diets containing 7, 14, 21, and 28% Chia (*Salvia hispanica L.*) seed. Cholesterol content, total fat content, and fatty acid composition of the yolks were determined 30, 43, 58, 72, and 90 days from the start of the trial. Significantly less cholesterol was found in egg yolks produced by the hens fed the diets with 14, 21, and 28% chia compared to control, except at day 90. Palmitic fatty acid content and total saturated fatty acid content decreased as chia percentage increased and as the trial progressed. Total omega-3 fatty acid content was significantly greater ($P<0.05$) than from the control diet. Generally, total PUFA content tended to be highest in the yolks of the white hens.

Dietary chia seed (Salvia hispanica L.) rich in *α*-linolenic acid improves adiposity and normalises hypertriacylglycerolaemia and insulin resistance in dyslipaemic rats *Adriana G. Chicco, Maria E. D'Alessandro,Gustavo J. Hein, Maria E. Oliva and Yolanda B. Lombardo**

The study investigates the benefits of the dietary intake of chia seed (Salvia hispanica L.) rich in alinolenic acid and fibre upon dyslipidaemia and insulin resistance (IR), induced by intake of a sucrose-rich (62·5%) diet (SRD). To achieve these goals two sets of experiments were designed: (i) to study the prevention of onset of dyslipidaemia and IR in Wistar rats fed during 3 weeks with a SRD in which chia seed was the dietary source of fat; (ii) to analyse the effectiveness of chia seed in improving or reversing the metabolic abnormalities described above. Rats were fed a SRD during 3 months; by the end of this period, stable dyslipidaemia and IR were present in the animals.
From months 3–5, half the animals continued with the SRD and the other half were fed a SRD in which the source of fat was substituted by chia seed (SRD þ chia). The control group received a diet in which sucrose was replaced by maize starch. The results showed that: (i) dietary chia seed prevented the onset of dyslipidaemia and IR in the rats fed the SRD for 3 weeks – glycaemia did not change; (ii) dyslipidaemia and IR in the long-term SRD-fed rats were normalised without changes in insulinaemia when chia seed provided the dietary fat during the last 2 months of the feeding period. Dietary chia seed reduced the visceral adiposity present in the SRD rats.
The present study provides new data regarding the beneficial effect of chia seed upon lipid and glucose homeostasis in an experimental model of dislipidaemia and IR.

Nuts and seeds in health and disease prevention, By Victor R. Preedy, Ronald Ross Watson, Vinood B. Patel

A 28 day preliminary trial was conducted with 16 subjects (Coates & Ayerza 2002 unpublished) in which half received 28g of chia seed each day, the others receiving a placebo. Serum cholesterol, HDL, LDL and triglyceride levels were measured the day before the trial began, and at the end of the trial. Results were inconclusive. Significant differences in cholesterol, HDL, LDL and triglyceride levels between groups were not detected; however, an analysis of covariance showed HDL and triglyceride levels to differ between groups, with the difference favouring consumption of chia. Vuksan and colleagues (2007) divided 20 adults with type 2 diabetes into two groups, providing one with 37g of chia daily and the other with wheat bran, for 12 weeks. Chia significantly reduced ($P<0.05$) systolic blood pressure, diastolic blood pressure, high sensitivity C-reactive protein, and vonWillerbrand factor. Total LDL and HDL cholesterol levels all decreased, but not significantly. Triglycerides increased, but not significantly.

Nieman and Colleagues (2009) divided 90 subjects into two groups, one ingesting 25g of chia seed twice daily, the other a placebo. At the end of 12 weeks, body mass and composition showed no differences between two groups. Although plasma ALA increased significantly ($P<0.05$) in the chia group, no significant differences in EPA and DHA were detected. No significant differences in disease risk factors including serum CRP, plasma cytokines, blood lipoproteins and blood pressure were detected.

5.2. STABILITY OF THE PRODUCT

The Chia seed is a small oval shaped seed with an outer shell that encapsulates the Omega-3 content. Most oilseeds have a tip on the end that can become the route for oxidation and rancidity. This is caused through the cleaning and packing process as the tip is prone to break off. As Chia seeds don't have this tip it allows them to be perfectly sealed. As Chia seeds have naturally occurring antioxidants, the oxidation process is prevented significantly. The following studies support this:

Dietary fibre content and antioxidant activity of phenolic compounds present in Mexican chia (*Salvia hispanica *L.) seeds E. Reyes-Caudillo, A. Tecante, M.A. Valdivia-López

Chia seeds from two different regions in the states of Jalisco and Sinaloa were analyzed for soluble and insoluble fibre and antioxidant activity of phenolic compounds. The soluble and insoluble fibre content of the Sinaloa and Jalisco seeds was similar. The major compounds identified in hydrolyzed and crude extracts were quercetin and kaempferol, while caffeic and chlorogenic acids were present in low concentrations. Screening of antioxidant activity using 2,2'-azino-bis-3-ethylbenzothiazoline-6-sulphonic acid radical action ($ABTS_{+}$), β-carotene linoleic acid model system (β-CLAMS) and *in vitro* liposome peroxidation system assays, showed that the crude extract of the Jalisco seed has an antioxidant activity comparable to the commercial antioxidant Trolox used as a reference. Different concentrations of the hydrolyzed and crude extracts of the seeds from both regions showed antioxidant effect when tested in a model water-in-oil food emulsion.

Nuts and seeds in health and disease prevention, By Victor R. Preedy, Ronald Ross Watson, Vinood B. Patel

The main anti-oxidants in chia are chlorogenic and caffeic acids, as well as myricetin, quercetin and kaempferol flavanols (Taga at el., 1984 Castro Martinez et al 1986). Caffeic and chlorogenic acids have been shown to inhibit lipid peroxidation, and are significantly stronger than common antioxidants such as Vitamin C and Vitamin E (Kweon et al 2001). Quercetin can prevent oxidation of lipids and proteins and it's antioxidants properties are significantly more effective than those of some flavanol compounds (Makris & Rossiter 2001). Chia seeds are also stable because these seeds exhibit a special source of anti-oxidants that function to protect the nutrients and components of Chia. Antioxidants are a group of vitamins, minerals, natural colourings, and other vegetable compounds and enzymes (substances of our own organisms that intervene in multiple metabolic processes), which block the harmful effect of the so-called free radicals. The majority of the antioxidants are found in vegetable foods which is why including fruits, legumes, seeds, vegetables, and whole grains in our diet, is so beneficial.

6 INTENDED USE

Teoli Chia seeds are intended to be used under the European Commission Implementing Decision 2013/50/EU authorising an extension of use of Chia seed (*Salvia hispanica* L.) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.
The labelling on the foodstuff containing Chia seeds will be 'Chia (Salvia hispanica) seeds'.
Additional labelling of pre-packaged chia seed will be done to inform the consumer that the daily intake should be no more than 15g.

The intended use of Teoli Chia seeds is as follows:

PRODUCT	USE
Bread products	maximum 5%
Baked products	maximum 10%
Breakfast cereals	maximum 10%
Fruit, nut and seed mixes	maximum 10%
Pre-packaged Chia seed	maximum 15g per day

7 LEVEL OF UNDESIRABLE SUBSTANCES

Three separate batches of Teoli Mexican Speciality Grain Chia seed have been tested for undesirable substances (see Appendix for lab analysis results). Teoli Mexican Speciality production process ensures that the levels of undesirable substances are well below the specified limits and equivalent to the TCC Chia.

7.1. CHEMICAL CONTAMINANTS & HEAVY METALS

CONTAMINANT	TEOLI	TCC CHIA
HEAVY METALS – mg/kg (ppm)		
Arsenic	<0.1	<0.1
Cadmium	<0.1	<0.1
Lead	<0.2	<0.5-1.0
Mercury	<0.01	<0.01-0.02
MYCOTOXINS – ug/kg (ppb)		
Aflatoxin B1	<0.2	<1
Aflatoxin B2	<0.2	<1
Aflatoxin G1	<0.2	<1
Aflatoxin G2	<0.2	<1
Ochratoxin A	<0.5	<1

7.2. MICROBIOLOGICAL CONTENT

CONTAMINANT (CFU/g)	TEOLI	TCC CHIA
Yeasts & Moulds	<10 CFU/g	<200 CFU/g
Staphylococcus aureus	<100 CFU/g	<100 – 200 CFU/g
Coliforms	<10 CFU/g	Unknown
Salmonella	Absence/25g	Absence/25g
Enterobacteriaceae	<10	Unknown
Bacillus cereus	<100	<100

8 RELEVANT DATA

Proposal for labelling: Chia seed (*Salvia hispanica* L). Where sold to the final consumer, additional labelling will state that the recommended daily intake is 15g.

9 CONCLUSION

From the above nutritional, compositional, bioavailability and toxicological information and considering the history of use, it can be concluded that Teoli Chia seeds is substantially equivalent to the TCC Chia and we request approval to be able to sell the product under its approved uses in the European Union.

Appendix A. **LAB ANALYSIS REPORTS**