

Request for Scientific Evaluation of Substantial  
Equivalence for the approval and extended use of  
Chia seeds (*Salvia hispanica* L.) from The Chia  
Company

 **INFOCORE LTD<sup>®</sup>**

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## 1. Summary

Infods Ltd seeks to obtain a scientific evaluation of substantial equivalence for the approval and extended use of Chia seeds (*Salvia hispanica* L.) from The Chia Company who are based in Australia. Infods Ltd is a U.K company owned by two directors who have over the years focused greatly to outsource the best nutritional food ingredients to create a healthy range of food products for general public consumption.

The production process for Infods Ltd has been assessed by the Soil Association to meet the organic standard, CQS to meet the ISO 9001:2008 standard and vegan society approved.

In May 2011: Application from The Chia Company (Australia), to extend the use of Chia seeds (*Salvia hispanica* L) under the Novel Food Regulation (EC) 258/97 under the following food product categories:

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

The Chia Company has previously claimed equivalence to the authorised chia seeds and can currently market its seeds at levels of up to 5% in bread products. This application is to extend the approval to enable their chia seeds in a number of additional food categories (baked goods, breakfast cereals and fruit nut and seed mixes).

Infods Ltd Chia seed's level of undesirable substances is also similar, and considered safe for human consumption. It is intended to be consumed in a manner identical to the TCC Chia.

Before any new food product can be introduced on the European market, it must be rigorously assessed for safety. In the UK, the assessment of novel foods is carried out by an independent committee of scientists appointed by the Food Standards Agency, the Advisory Committee on Novel Foods and Processes (ACNFP).

Substantial equivalence is sought between Infods Ltd Chia Seeds and The Chia Company (hereinafter, the "**TCC seed**")

This notification dossier follows the "*ACNFP guidelines for the presentation of data to demonstrate substantial equivalence between a novel food or food ingredient and an existing counterpart*" and provides evidence to confirm that the Infods Ltd seed is substantially equivalent to the TCC Chia.

## 2. Administrative Information

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### **Name of novel food ingredient:**

CHIA SEED (SALVIA HISPANICA L.)

### **Date of application:**

14/02/2013

### **3. Composition**

#### **a) Information on source of organism**

Chia (*Salvia hispanica* L.) is a subtropical crop with an aestival cycle. It is a herbaceous plant belonging to the Labiatae family. Chia is a highly nutritious source seed which contains essential fatty acids Omega-3 ALA, Omega-6 LA as well as high quality protein, Anti-oxidants, Fibre plus Vitamins & Minerals.

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.

We refer to Chia as Nature's complete superfood because it is very high in nutrition essential for healthy diet since "Chia" by definition means "oily" exhibiting essential omega 3 fatty acids and further supported via the nutritional table in Section 4

The 16th century Codex Mendoza provides evidence that it was cultivated by the Aztec in pre-Columbian times; it has been said that it was an important crop.

It is still used in Mexico and Guatemala, with the seeds sometimes ground, while whole seeds are used for nutritious drinks and as a food source.

#### **b) Production process**

Chia seeds are grown and harvested contractually on behalf of Infoods Ltd in South America as the Chia plant requires a specific climate and sub-tropical areas to grow.

The seeds do not undergo further processes or modifications upon receiving keeping the whole seeds intact. During the agricultural process natural forms of fertilizer treatments are utilized avoiding harsh chemicals or pesticides. Post-harvest the seeds are cleaned with the removal of flowers, leaves and other parts of the plant.

The Chia seeds are developed in a system that involves traceability verifying and recording the source of chia throughout the farming process. In order to keep the chia seeds within a natural habitat environment an irrigation system is carefully put in place that prevents any soil erosion of nutrients to leach out of the plantation.

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

### c) Final composition of product

The analysis has been carried out on the following batch numbers by a UKAS accredited lab:

Z84 997

Z85 150

X20 201

The relative ratios of micro nutrients found in the Infoods Ltd Chia seed and the TCC seed are significantly equivalent as it can show in the following comparative tables.

**Table 1 Comparative Nutrient Tables between Infoods Chia seeds and TCC Chia seeds**

NUTRIENT	INFOODS LTD CHIA SEEDS (%)*	TCC CHIA SEEDS (%)
<b>Dry Matter</b>	91.7 - 93.4	95 - 96.8
<b>Protein</b>	21.2 - 24.3	17.4 - 22.4
<b>Fat</b>	27.4 - 31.1	28.5 - 34.7
<b>Carbohydrate</b>	36.1 - 38.5	37.1 - 42.6
<b>Dietary Fibre</b>	35.3 – 41.7	32.8 - 40.2
<b>Ash</b>	4.6	4.5 - 5.6

\*Certificates of analysis are provided in appendix 1

**Table 2 Fatty Acid Composition for Infoods Ltd Chia seeds and TCC Chia seeds**

Composition of Total Fatty Acids		
	Type of Seed	
Fatty Acid Profile g/100g	Infoods Chia Seed*	TCC Chia Seed
<b>Total Fat</b>	27.4 - 31.1	28.5 - 34.7
<b>Saturated Fat</b>	2.72 - 2.96	2.8 - 4.1
<b>Mono-unsaturated Fat</b>	1.89 - 2.14	2-3
<b>Polyunsaturated Fat</b>	21.57 – 22.78	17.8-27.8
<b>C16:0; Palmitic Acid</b>	6.39 - 6.68	7.1
<b>C18:0; Stearic Acid</b>	2.57 - 3.33	3.7
<b>C18:1 n-9; Oleic Acid</b>	6.03 - 7.25	8.7

<b>C18:2 n-6; Linoleic Acid</b>	17.67 - 18.8	22.0
<b>C18:3 n-3; Alpha Linolenic Acid</b>	58.66 - 60.77	57.4
<b>C18:3 n-6; Gamma Linolenic Acid</b>	<0.2	<0.1
<b>C20.0 Arachidic Acid</b>	<0.3	<0.1
<b>C20.1 Gadoleic Acid</b>	<0.2	<0.1
<b>C20.3 (n-3) Eicosatrienoic Acid</b>	<0.1	<0.1
<b>C20.4 (n-6) Arachidonic Acid</b>	<0.1	<0.1
<b>C20.5 Eicosapentaenoic Acid</b>	<0.1	<0.1
<b>C22.6 Docosahexaenoic Acid</b>	<0.1	<0.1

\*Certificates of analysis are provided in appendix 1

**Table 3 Mineral Content**

<b>Minerals mg/100g</b>	<b>Infoods Chia Seeds*</b>	<b>TCC Chia Seeds</b>
<b>Sodium</b>	2.48 - 5.17	<0.1 – 6
<b>Potassium</b>	693 - 750	510 - 710
<b>Calcium</b>	510 - 581	500 – 640
<b>Iron</b>	5.91 - 7.37	5,7 – 15
<b>Phosphorus</b>	817 - 925	600 – 870
<b>Magnesium</b>	298 - 360	310 - 430

\*Certificates of analysis are provided in appendix 1

**Table 4 Vitamins Content**

<b>Vitamins</b>	<b>Infoods Ltd Chia seeds*</b>	<b>TCC Chia Seeds (mg/100g)</b>
<b>Vitamin A (Retinol)</b>	<60.0 µg/100g	16 I.U
<b>Vitamin C (as Ascorbic Acid)</b>	1.09mg/100g - 2.15mg/100g	<1-6
<b>Vitamin E (as alpha tocoopherol acetate)</b>	0.22mg/100g - 0.34 mg/100g	<0.1-0.3

\*Certificates of analysis are provided in appendix 1

In addition, see appendix 1 for a pesticide screen analysis test certificate.

## 4. Nutritional Values

### a) General Description

Infoods Ltd Chia seeds explain in Table 1 the overall nutrition where the values are similar to the TCC seed. Infoods Ltd Chia seeds have protein and fat values that are in the upper range of the TCC seed.

Table 2 shows Infoods Ltd Chia seeds fatty acid profile values that are similar and in the range of the TCC seed.

In Table 3 the Potassium and Phosphorus values are slightly higher. However this isn't a cause for concern and is expected.



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

Chia seed contains 20-23% protein. This is higher than wheat 14.7% and corn 14%. The lysine content is quite high and methionine plus cysteine compares favourably with other oil seeds; consequently chia has no limiting factors in the adult diet from an amino acid standpoint (Weber et al 1991). This means chia can be incorporated into human diets as a balanced protein source.

The lipid, protein, fibre and anti-oxidant contents of chia are significantly higher than in many other crops. Although chia seed serves mainly as a source of omega-3 fatty acids, it also contains a number of other components that are important for human nutrition. The oil content of chia seed ranges between 30 and 34% and it contains one of the highest percentages of alpha linolenic acid known (62-64%).

Tests by independent laboratories of seed coming from numerous sources (Coates 2009 unpublished) showed total fatty acid contents ranging from a low of 22.9% to a high of 31.7% with alpha linolenic acid contents ranging from 14.1 to 20.47 g/100g (wet basis). Regarding percentage of fatty acid, values ranged from 55 to 65.8%

### **b) History of use**

Historically, Chia seeds were a staple food for many Pacific coast groups including the Salinan, Costanoan and Chumash as well as inland tribes such as the Paiute, Maidu, and Kawaiisu. Chia is one of the first plants obtained by humans in Kawaiisu mythology (Zigmond 1981). Chia was regularly cultivated along with corn in the fields of the Nahua peoples of ancient Mexico.

Chia is an important resource that was often managed by native peoples. The Chumash and Cahuilla were among those groups who would increase the following year's harvest by periodically burning stands of Chia plants (Timbrook et al. 1982; Bean & Saubel 1972). It is still used in Mexico and Guatemala, with the seeds sometimes ground, while whole seeds are used for nutritious drinks and as a food source.

The Diegueño took Chia seeds on journeys where a few seeds kept in the mouth and periodically chewed, would keep up their strength (Hedges & Beresford 1986).

Chia seeds are now consumed worldwide in several countries. Currently, there have not been any records of adverse effects such as allergenicity, anti-nutritional or toxic effects.

Table 5 Worldwide consumption

<b>North America and Canada</b>				
<b>Company name</b>	<b>Website</b>	<b>Monthly Consumption (metric tonnes)</b>	<b>History (starting year)</b>	<b>Applications</b>
<b>Nutraceuticals Holding LLC</b>	<a href="http://www.omega3chia.com">www.omega3chia.com</a> <a href="http://www.researchedproducts.com">www.researchedproducts.com</a>	1	2007	Nutritional Supplement Industry: Chia seeds and Chia oil soft gel caps
<b>Valensa International LLC</b>	<a href="http://www.valensa.com">www.valensa.com</a>	10	2002	Nutritional Supplement Industry: Chia seeds Food Industry: Chia oil (Tresalbio TM)
<b>Greensplus</b>	<a href="http://www.greensplus.com">www.greensplus.com</a>	17	2007	Nutritional Supplement Industry: Chia seeds Food. Industry: Chia Bars
<b>Nature's Path</b>	<a href="http://www.naturespath.com">www.naturespath.com</a>	1	2007	Food Industry: Chia Bars: Dr. Weil TM Chia Razz TM Pure Fruit and Nut Bar INGREDIENTS: including organic Chia seeds
<b>Salba</b>	<a href="http://www.sourcealba.com/products.php">http://www.sourcealba.com/products.php</a>	300	2002	Food Industry: cookies, cereal bars, chips, and seeds (all white Chia seed)
<b>South America</b>				
<b>Fuentenatura, Mexico</b>	<a href="http://www.fuentenatura.cl">www.fuentenatura.cl</a>	0.5	2006	Nutritional Supplement Industry: Chia seeds and Chia oil
<b>FPT SA. Chile</b>	<a href="http://www.benexia.com">www.benexia.com</a>	2	2005	Nutritional Supplement Industry: Chia seeds and Chia oil soft gel caps
<b>Empresas Carozzi SA. Chile</b>	<a href="http://www.carozzi.cl">www.carozzi.cl</a>	3	2007	Pastas (Chia oil) Cereals Breakfast (Chia seeds)
<b>Others.Chile</b>	<a href="http://www.chiachile.cl">www.chiachile.cl</a> <a href="http://www.supernatural.cl">www.supernatural.cl</a>	0.5	2007	Nutritional Supplement Industry: Chia seeds
<b>Australia and New Zealand</b>				
<b>The Chia Company, AU</b>	<a href="http://www.thechiaco.com.au">www.thechiaco.com.au</a>	100	2000	Nutritional Supplement Industry: Chia seeds Food Industry in General
<b>Dovedale bread, NZ</b>	<a href="http://www.dovedalebread.co.nz/index.html">http://www.dovedalebread.co.nz/index.html</a>	2	2005	Bakery Industry: Bread with Chia
<b>Slim Secrets</b>	<a href="http://www.slimsecrets.com.au/cookie_trail_mix.asp">http://www.slimsecrets.com.au/cookie_trail_mix.asp</a>	0.02	2009	Cookie snack with Chia
<b>Fonterra</b>	<a href="http://www.fonterra.com">http://www.fonterra.com</a>	0.5	2009	Yoghurt (dairy)

<b>Centenary Bakery</b>	<a href="http://www.madebybikini.com/">http://www.madebybikini.com/</a>	2	2009	Bread
<b>Asia</b>				
<b>Latina Inc. Japan</b>	<a href="http://www.latina.inc.com">http://www.latina.inc.com</a>	2	2005	Nutritional Supplement
<b>K-Squares, Korea</b>	<a href="http://www.ksquares.com">http://www.ksquares.com</a>	0.5	2006	Nutritional Supplement
<b>European Union</b>				
<b>Naturkost Übelhör GmbH &amp; Co KG.DE</b>	<a href="http://www.sachia.de/home.html">http://www.sachia.de/home.html</a>	Unavailable	2005	Nutritional Supplement Industry
<b>Original Chia</b>	<a href="http://www.originalchia.dk">http://www.originalchia.dk</a>	30	2008	Nutritional Supplement Industry
<b>Infods Ltd</b>	<a href="http://www.infodsltd.co.uk">www.infodsltd.co.uk</a>	20	2009	Nutritional Supplement Industry: Chia seeds Food Industry in General. Bread

## 5. Metabolism

The composition of Infods Ltd Chia seeds does not differ significantly from its existing counterpart the TCC seed. Nevertheless the following relevant studies show that the Chia seeds are stable.

### a) Bioavailability

***Chia Seed (Salvia hispanica L.) as an  $\omega$ -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,\*<sup>1</sup> and M. Lauriat<sup>†</sup>

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  $\omega$ -

6:  $\omega$ -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 fatty acid 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  $\alpha$ -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 present study investigates the benefits of the dietary intake of chia seed (*Salvia hispanica L.*) rich in  $\alpha$ -linolenic 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  $\beta$  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 vonWillebrand 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.

### **b) 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 journals are used to 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 cation (ABTS<sup>•+</sup>),  $\beta$ -carotene linoleic acid model system ( $\beta$ -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<sup>®</sup> 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 et al., 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 its 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.

Infoods Ltd archives samples for 4 months. Every batch of seed is tested for its group 2 nutritional, microbiological and mycotoxins analysis at a UKAS accredited lab. The data is checked to ensure the undesirables, such as Aflatoxin B1, do not reach the upper limits for oilseeds set out by the EU Regulation No. 574/2011. It is also used to compare crop analysis and determine which harvest has provided the best nutritional make up of Chia seed. This is also an ideal time to investigate the nutritional values to see if the crop harvest has been consistent.

As part of its quality standard, the chia seeds are subject to an annual pesticide screen test. See appendix 1 for the certificate of analysis.

## 6. Intended Use

Infoods Ltd Chia seeds are intended to be used under the European Commission Implementing Decision 2013/50/EU authorising an extension of use of Chia ( *Salvia hispanica* ) seed as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

The labeling on the foodstuffs containing Chia seeds will be 'Chia (*Salvia hispanica*) seeds'.

Additional labelling of pre-packaged Chia (*Salvia hispanica*) seed will be done to inform the consumer that the daily intake is no more than 15g.

The intended uses of Infoods Ltd Chia (*Salvia hispanica*) seed will be:

Baked products	not more than 10 %
Breakfast cereals	not more than 10 %
Fruit, nut and seed mixes	not more than 10 %
Pre-packaged Chia seed as such	not more than 15 g per day

## 7. Level of undesirable substances

Infoods Ltd production process ensures that the levels of undesirable substances are well below the specified limits and equivalent to the TCC Seed.

### a) Chemical contaminants & Heavy Metals

The food standard agency has specified maximum level of metals to be traced in food sources:

- i. Cadmium <0.5 mg/kg

- ii. Lead <1.0 mg/kg
- iii. Mercury < 0.2 mg/kg
- iv. Arsenic <0.1 mg/kg

Table 6 demonstrates that Infoods Ltd Chia seeds are within the acceptable limits, confirming it's pure and good safety profile.

**Table 6 Contaminants**

	<b>Infoods Ltd Chia*</b>	<b>TCC Chia</b>
<b>Contaminants</b>	<b>Results</b>	<b>Results</b>
<b>Heavy Metals</b>		
<b>Arsenic</b>	<0.1 mg/kg	<0.1 ppm
<b>Cadmium</b>	<0.1 mg/kg	<0.1 ppm
<b>Lead</b>	<0.1 mg/kg	<0.5 - <1 ppm
<b>Mercury</b>	<0.1 mg/kg	<0.01 - <0.02 ppm
<b>Mycotoxins</b>		
<b>Aflatoxin B1</b>	<0.5µg/kg	<1 ppb
<b>Aflatoxin B2</b>	<0.5 µg/kg	<1 ppb
<b>Aflatoxin G1</b>	<0.5 µg/kg	<1 ppb
<b>Aflatoxin G2</b>	<0.5 µg/kg	<1 ppb
<b>Ochratoxin A</b>	<0.2 µg/kg	<1 ppb

\*Certificates of analysis are provided in appendix 1

## **b) Microbiological Content**

**Table 7 Microbiological**

	<b>Infoods Ltd Chia*</b>	<b>TCC Chia</b>
<b>Microbial Content</b>	<b>Results (cfu/g)</b>	<b>Results (cfu/g)</b>
<b>Yeasts</b>	<20	<200
<b>Moulds</b>	<20	<200
<b>Staphylococcus aureus</b>	<20	<100
<b>Coliforms</b>	<10	Unknown
<b>Salmonella</b>	Absence/25g	Absence/25g
<b>Enterobacteriaceae</b>	<10	Unknown
<b>Bacillus cereus</b>	<20	<100

\*Certificates of analysis are provided in appendix 1

## **c) Toxicity and safety studies**

The safety of Chia seeds when used in bread at a maximum of 5% has been confirmed by the EFSA in its opinion adopted on March 13, 2009 (EFSA, 2009).

In addition to this, the safety has been further confirmed with the approval of the extended use by the EC, in its authorisation on the 22<sup>nd</sup> January 2013 under regulation (EC) No 258/97 when used in



baked products not more than 10%, breakfast cereals not more than 10%, fruit, nut and seed mixes not more than 10%, pre-packaged Chia seed as such not more than 15g per day.

The safety of Chia seeds has been previously investigated by FERNANDEZ I, VIDUEIROS SM, AYERZA R, COATES W and PALLARO A (FERNANDEZ I and 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.

No safety concerns were identified by the Novel Food Reference Group of the FSANZ.

The labeling on the foodstuffs containing Chia seeds will be 'Chia (*Salvia hispanica*) seeds'. 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.

Additional labelling of pre-packaged Chia (*Salvia hispanica*) seed will be done to inform the consumer that the daily intake is no more than 15g.

## 8. Relevant Data

### a) Quality Certificates

#### **ISO: 9001 2008 Quality Management Systems**

This orientates our corporative activities, towards the achievement of customer satisfaction through consistent products and services, and by applying continuous improvement logic.

#### **Soil Association certified**

Infods Ltd has been inspected and satisfies the requirements of the Soil Association organic standards, and has been issued an organic certificate on the basis of Article 29(1) of Regulation (EC) No 834/2007 and of Regulation (EC) No 889/2008. This shows that our activities are under control, and meets the requirements laid down in the named Regulations. This certificate is valid for marketing organic products when accompanied by the current trading schedule.

#### **Kosher Certified**

Kosher (also kashrut, kashrus) signifies food that meets with Jewish dietary law.

#### **Vegan society certified**

The Vegan Society Trademark is the gold standard when it comes to veganism. It lets vegans know that a product is vegan and it helps to build confidence in that product.

## Conclusion

From the above nutritional, safety, bioavailability and toxicological information and considering the history of use presented in Section 4b, it can be concluded that (i) Infods Ltd seed is substantially equivalent to the TCC seed in the sense of Article 5 of Regulation 258/97 and; (ii) no adverse effects would be expected for consumers who regularly ingest up to 10% of Chia seeds in; bread products; breakfast cereals; fruit, nut and seed mixes and with pre-packaged Chia seed as such not more than 15g per day in the short or long term.

## References

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## Appendices

Appendix 1 UKAS accredited lab Test certificate of analysis for batch numbers Z84 997, Z85 150, X20 201

Appendix 2 ISO:9001 2008 certificate

Appendix 3 Soil Association certificate

Appendix 4 Kosher Certificate for Chia Seeds

Appendix 5 Vegan society certificate of registration



Appendix 6 Taxonomic Classification System for Chia Seeds (*Salvia hispanica* L.)

The taxonomy of the plant source of Chia seed is as follows:

Kingdom	<i>Plantae</i> - Plants
Subkingdom	<i>Tracheobionta</i> - Vascular plants
Superdivision	<i>Spermatophyta</i> - Seed plants
Division	<i>Magnoliophyta</i> - Flowering plants
Class	<i>Magnoliopsida</i> - Dicotyledons
Subclass	<i>Asteridae</i>
Order	<i>Lamiales</i>
Family	<i>Lamiaceae</i> - Mint family
Genus	<i>Salvia</i> L. - sage
Species	<i>Salvia hispanica</i> L. - chia