COMPAÑÍA INVERSORA AGROPECUARIA S.R.L.
&
SalbaChiaUK Ltd

A request for an opinion on equivalence for Chia seeds in accordance with Article 3(4) of regulation number (EC)258/97

COMPAÑÍA INVERSORA AGROPECUARIA S.R.L.

Application submitted by **Luis Munoz**

25/03/2013

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SUMMARY

This notification dossier is submitted by Luis Munoz on behalf of COMPAÑÍA INVERSORA AGROPECUARIA S.R.L. pursuant to Article 5 of Regulation (EC) nº 258/97 on novel foods and novel food ingredients (hereinafter, the "Novel Food Regulation")

It seeks to obtain a scientific evaluation of substantial equivalence for the approval of Chia seeds (Salvia hispanica L.) from COMPAÑÍA INVERSORA AGROPECUARIA S.R.L. Said substantial equivalence is sought between the Chia seed produced by COMPAÑÍA INVERSORA AGROPECUARIA S.R.L. (hereinafter, the "CIA seed") and the Chia seed produced and imported into the E.U. by The Chia Company (TCC) (hereinafter, the "approved Chia") for

INTENDED USE

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

The CIA seed is intended to be used in bread products at a maximum of 5% (this use has been approved by the European Commission pursuant to Decision 2009/827/EC) and to sell packaged Chia within the EU and to use our Chia seed in other baked goods and to sell the use of Chia as an ingredient in other food categories that commonly contain grains and seeds, as approved. (this use has been approved by the European Commission pursuant to Decision 2009/827/EC) on January 20, 2013 and notified under document C (2013) 123. (Commission Implementing Decision included as attachment 9)

COMPAÑÍA INVERSORA AGROPECUARIA S.R.L. is an Argentine company owned by two directors who have combined over 30 years agronomic experience in producing food for human consumption including wheat, soybeans, corn, sunflower and chia. COMPAÑÍA INVERSORA AGROPECUARIA S.R.L is in the Chia business since the year 2002, being the number 1 exporter to and seller of this product in the United States. Our product (available in the US since 2006) the Salba Chia can be found in big retailers such as Wholefoods Market, small health stores and online at www.salbasmart.com . In the Appendix 12 you can find a list of our products sold in the USA and Canada.

COMPAÑÍA INVERSORA AGROPECUARIA S.R.L.'s plantations of Chia seed can be found in the North of Argentina and in Bolivia. At the present time we are cultivating 1,000's of Hectares of Chia in Argentina and 1,000's of Hectares of Chia in Bolivia. Chia seeds are harvested, stored and packaged in both countries.

The Chia seed and manufacturing process of the CIA seed is similar to that of the Approved Chia. The CIA 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 Approved Chia.

In addition, the EUROPEAN FOOD SAFETY AUTHORITY (hereinafter, the "EFSA") stated that the compositional data which had been provided on Latin American Chia seeds in the framework of the safety assessment of the Approved Chia showed little variety to Chia seeds from the South American countries from which the Approved Chia originates (EFSA, 2009).

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 CIA seed is substantially equivalent to the Approved Chia.

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 CIA 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. 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.

ADMINISTRATIVE INFORMATION

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Name of Novel Food Ingredient

The Salba Chia seed of **COMPAÑÍA INVERSORA AGROPECUARIA S.R.L**

Date of Application

March 20, 2013

COMPOSITION

Information on the source organism

Chia (*Salvia hispanica* L.) is a summer annual herbaceous plant belonging to the Liberate 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 is grown commercially in several Latin American countries and in Australia.

Production process

The Chia seed from COMPAÑÍA INVERSORA AGROPECUARIA S.R.L. is not processed in any way prior to the use as a food ingredient.

Whole Chia seeds are not processed in any way prior to their use as a food ingredient. Current agronomic practice regarding Chia seed production is detailed below, it should be noted however, that the seeds are grown contractually for SALBA UK Ltd. who have the right to specify what herbicide/pesticide treatments are used in order to comply fully with EU legislation.

The Chia seed is sown mechanically at a seeding rate of three to five kg/hectare. The seed is not treated chemically in any way prior to sowing. No insecticide is applied. At sowing, the fertilizer consisting of diamonic phosphate is applied mechanically, localized in rows. Between thirty and forty five days following sowing, 150 kg/hectare of urea is applied, also mechanically and localized in rows.

The crop is allowed to ripen naturally. However, should there be a requirement to speed up the ripening process, Paraquat is used at a rate of one litre/hectare. Yield can vary between growing locations but is generally within the range 500 to 800 kg/hectare. The seed is mechanically harvested using a modified grain combine harvester.

A multi-residue screen for pesticide and herbicide residues was carried out on a composite sample form the four consignments of Chia seed received to date by SALBA UK Ltd. No compounds were detected in the screen test.

Post-harvest, the seed is cleaned mechanically and not subjected to any chemical treatments. The seeds are stored in sacks within a fully enclosed warehouse facility in preparation for shipment.

In the production of whole ground Chia, the whole seeds are passed through a variable speed Christy Briton hammer mill. Manufactured by Christy Hunt Ltd, Foxhill Industrial Estate, Scunthorpe.

1.1. Composition of the final product

The relative ratios of micronutrients found in the CIA seed and in the Approved Chia are *"substantially equivalent"*, as it can be shown in the following comparative tables.

Table 1. Composition of the CIA seed and the Approved Chia

NUTRIENT	CIA SEED		APPROVED CHIA
	Results %	Samples date	Results %
Dry matter*(**)	94.06	08/15/2011	95 – 96.8
Protein*	21.49	08/15/2011	17.4 – 22.4
Fat*	33.56	08/15/2011	28.5 – 34.7
Carbohydrate*(***)	34.10	08/15/2011	37.1 – 42.6
Fiber Soluble*	3.25	08/15/2011	-
Fiber Insoluble*	26.20	08/15/2011	32.8 – 40.2
Ash *	4.75	08/15/2011	4.5 – 5.6

*** Certificates of analysis are hereby provided as Appendix 1- page 1 SENASA**
**** 100% - water (5.94%)**
***** Certificates of analysis are hereby provided as Appendix 3- EUROFINS**

Table 2. Mineral content of the CIA seed and the Approved Chia*

NUTRIENT	CIA SEED	CIA SEED		APPROVED CHIA
	Results Mg/Kg	Conversion Mg/100gg	Samples date	Results Mg/100gg
Potassium	6,200 mg/kg g	=620mg/100gg	10/19/2007	510 – 710
Calcium	6,300 mg/kg	=630mg/100gg	10/19/2007	500 - 640
Iron	59 mg/kg	=5.9mg/100gg	10/19/2007	5.7– 15
Magnesium	3,100 mg/kg	=310mg/100gg	10/19/2007	310- 430

Laboratory AgriQuality – Appendix 4

Table 2 a. Mineral content of the CIA seed and the Approved Chia*

NUTRIENT	CIA SEED		APPROVED CHIA
	Results Mg/100g	Samples date	Results Mg/100g
Sodium	(13mcg/g) = 1.3 ****	09/11/2007	<0.1 – 6
Potassium	680	09/11/2007	510 – 710
Calcium	650	09/11/2007	500 - 640
Iron	7.7	09/11/2007	5.7– 15
Magnesium	320	09/11/2007	310- 430
Phosphorus	9550	09/11/2007	600-870

GELDA SCIENTIFIC – Appendix 2

(****) Windsor Research Laboratories Appendix 5

Table 3. Vitamins in the CIA seed and the Approved Chia

NUTRIENT	CIA SEED		APPROVED CHIA
	Results (mg/100g)	Samples date	Results (mg/100g)
Retinol * (Vit. A)	43 IU*	05/15/02	16 IU
Riboflavin ** (Vit. B2)	(1.8 ug/g) = 0.18 mg/100g	05/15/02	0.05
Niacin ** (Vit. B3)	(71.5ug/g)= 7.15 mg/100g	05/15/02	7.8 - 9.4
Cobalamin (Vit B12)	Unknown	05/15/02	90 – 110 ng
Ascorbic acid *** (Vitamin C)	<0.80	02/08/06	<1 - 6
Alphatocopherol * (Vit. E)	(30ug/g)=3 mg/100 g	05/15/02	<0.1 - 0.3

***Certificates of analysis are hereby provided as Appendix 7 Food and Dairy Chemistry**
**** Certificates of analysis are hereby provided as Appendix 3 Food Microbiology Laboratory Services**
***** Certificates of analysis are hereby provided as Appendix 2 GELDA SCIENTIFIC**

Table 4. Aminoacids in the CIA seed and the Approved Chia*

AMINOACIDS		CIA SEED		APPROVED CHIA
	Result Mg/kg	Conversion Mg/Kg/21.49/100*	Samples date	Result % of protein
Isoleucine	7828	3.64 %	08/15/2011	3.05 - 3.53
Leucine	14400	6.70 %	08/15/2011	5.47 – 6.34
Lysine	11450	5.33 %	08/15/2011	3.87 – 4.42
Methionine	6476	3.01 %	08/15/2011	1.00 – 1.14
Phenylalanine	10790	5.02 %	08/15/2011	4.19 – 4.71
Threonine	8676	4.03 %	08/15/2011	2.90 – 3.42
Tryptophan	2843	1.32 %	08/15/2011	0.89 – 1.04
Valine	10080	4.69 %	08/15/2011	3.86 – 4.56

Certificates of analysis are hereby provided as Appendix 1- page 2 SENASA
(*) 21.49 being the percentage of total protein as in table 1, page 8 (Composition of the CIA seed and the Approved Chia)

Table 5. Fatty acid profile in the CIA seed and the Approved Chia

FATTY ACID	CIA SEED	APPROVED CHIA	
	Result %	Samples	Result (range) %
Total fat	31.5 – 33.56	various	28.5 – 34.7
Saturated fat	3.4	07/04/07	2.8 – 4.1
Mono-unsaturated Fats	2.33(g/100g)	07/04/07	2 – 3 (g/100g)
Poly-unsaturated Fats	26.6 (g/100g)	07/04/07	17.8-27.8 (g/100g)
Trans fats	0.217(g/100g)	07/04/07	< 0.1 – 0.10 (g/100g)
C14:0 Myristic*	0.08 %	08/15/2011	< 0.1
C15:0 Pentadecanoic			< 0.1
C16:0 Palmitic*	8.41	08/15/2011	7.1
C18:0 Stearic*	4.42	08/15/2011	3.7
C20:0 Arachidic*	0.30	08/15/2011	0.3
C14:1 Miristoleic*	0.00	08/15/2011	< 0.1
C16:1 Palmitoleic*	0.26	08/15/2011	0.3
C17:1 Heptadecanoic*	0.18	08/15/2011	< 0.1
C18:1w9 Oleic**	6.29	08/15/2011	8.7
C20:1w9 Eicosaenoic*	0.12	08/15/2011	< 0.1
C18:2w6 Linoleic*	16.40	08/15/2011	22
C18:3w3 Linolenic*	63.46	08/15/2011	57.4
C20:2w6 Eicosadienoic**	< 0.1	11/13/2007	< 0.1
C20:3w3 Eicosatrienoic**	< 0.1	11/13/2007	< 0.1
C20:5w3 Eicosapentaenoic**	< 0.1	11/13/2007	< 0.1
C22:4 Docosatetraenoic**	< 0.1	11/13/2007	< 0.1
C22:5w3 Docosapentaenoic**	< 0.1	11/13/2007	< 0.1
C22:6w3 Docosahexaenoic**	< 0.1	11/13/2007	< 0.1
C24 Lignoceric**	< 0.1	11/13/2007	0.1

Certificates of analysis are hereby provided as Appendix 2 –GELDA SCIENTIFIC

*Certificates of analysis are hereby provided as Appendix 1 –page 3 SENASA
**Certificates of analysis are hereby provided as Appendix 4 AgriQuality

4. General description of Chia seeds

Chia (*Salvia Hispanica* L.) is an estival growing annual species belonging to the family Labiata that is indigenous to Central and South America, particularly the Rocky Mountains area extending from the Mexican western central area towards northern Guatemala.

Pre-Columbian civilizations, mainly Aztecs, used chia as a raw material for a number of applications, such as in a variety of medicinal and nutritional compounds, and in substances such as paints. Chia was extremely important to Pre-Columbian societies. From the point of view of significance, only corn and beans outweighed it.

Although Chia was originally part of the South and Central American and U.S. Southwest indigenous diet, this changed with colonization and modernization. Today,

Mexican Indian descendants still grow Chia on a small scale using rudimentary technological methods, for preparing a popular beverage called “Chia fresca”.

4.a History of use

Salvia hispanica L. is commonly consumed in several countries, including the USA, Canada and Australia, all of which have now a “history of safe use”. This “history of safe use” is based on the absence of records of adverse effects, including allergenicity, anti-nutritional or toxic effects for Chia seeds and ground whole Chia intake in the listed countries.

5. 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.

6. Anticipated Intake / Extent of Use

CIA 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 Bread up to a 5% and in all other product categories at up to 10%.

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
Bread	Up to 5 %	

7. 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.

8. Labeling

CIA 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 labeling and nutrition. Additional labeling of pre-packed Chia seed will inform the customer that the daily intake is no more than 15 g per day. This is in accordance with the EFSA previous decision on labeling of Chia seed for inclusion in bread (EFSA 2009).

9. 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.

10. NUTRITIONAL VALUE

As shown in Table 1 above, the CIA 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 fiber.

The CIA 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).

10.a. Comparison between Robert Craig & Sons Chia seed (approved by the European Commission pursuant to Decision 2009/827/EC), TCC Chia seed (Approved Chia) and CIA Chia seed (Chia Seed results are the average of 4 different batches).

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, compared to CIA Chia seed.
The below nutritional profile (Table 6) has been taken from General (average) Chia seed samples.

Table 6: Nutritional Profile of Chia seed

	Robert Craig & Sons	TCC	CIA
Nutrient	%	%	%
Dry matter	91 -96	**95 - 96.8**	94.06
Protein	20 - 22	**17.4 - 22.4**	21.49 – 23.81
Fat	30 - 35	**28.5 - 34.7**	31.5 – 33.56
Carbohydrate	25 - 41	**37.1 - 42.6**	34.10
Fiber		**32.8 - 40.2**	32.97
Ash	4 - 6	**4.5 - 5.6**	4.24 - 4.75
Mineral	**Result (mg / 100g)**	**Result (mg / 100g)**	**Result (mg / 100g)**
Sodium	0.94 – 12.15	**<0.1 – 6**	(13mcg/g) = 1.3 ****
Potassium	660 – 809.15	**510 - 710**	620 - 680
Calcium	557 - 770	**500 – 640**	630 -650
Iron	6.3 – 9.9	**5,7 – 15**	7.7
Magnesium	325 - 390	**310 - 430**	320
Phosphorus	751 - 780	**600 – 870**	649
Vitamin	**Result (mg / 100g)**	**Result (mg / 100g)**	**Result (mg / 100g)**
Retinol (Vit. A)	44IU	**16 IU**	**43 IU***
Thiamin (Vit. B1)	0.7 – 0.18	**0.79 - 0,81**	Unknown
Riboflavin (Vit. B2)	0.04 – 0.2	**0,05**	**1.8 ****
Niacin (Vit. B3)	6.13 – 7.2	**7.8 – 9.4**	**(71.5 ug/g) = 7.15 ****
Cobalamin (Vit B12)	Unknown	**90 – 110 ng**	Unknown
Ascorbic acid (Vitamin C)	<3 – 5.4	**<1 – 6**	**0.8 ********
Alpha-tocopherol (Vit. E)	0.74	**<0.1 – 0.3**	**.30***

(*) Certificates of analysis are hereby provided as Appendix 7 – **Food and Dairy Chemistry**

(**) Certificates of analysis are hereby provided as Appendix 7 – **Food Microbiology Laboratory Services**

(***) Certificates of analysis are hereby provided as Appendix 5 – **Windsor Research Laboratories Inc.**

(****) Certificates of analysis are hereby provided as Appendix 3 – **GELDA SCIENTIFIC**

	Robert Craig & Sons	TCC	CIA
Aminoacids	**Results (% of proteins)**	**Results (% of proteins)**	**Results (% of proteins)**
Isoleucine	3.21 – 3.98	**3.05 – 3.53**	3.557 *
Leucine	5.89 – 7.30	**5.47 – 6.34**	7.455 *
Lysine	3.60 – 5.50	**3.87 – 4.42**	5.579 *
Methionine	0.36 – 0.45	**1.00 – 1.14**	1.397 *
Phenylalanine	4.73 – 5.86	**4.19 – 4.71**	5.417 *
Threonine	3.23 – 4.25	**2.90 – 3.42**	4.190 *
Tryptophan	Unknown	**0.89 – 1.04**	(2843 mg/kg *) = 1.36
Valine	5.10 – 6.32	**3.86 – 4.56**	4.989 *
Fatty Acids	**Results %**	**Results %**	**Results %**
Total fat	30 – 35	**28.5 - 34.7**	33.56 *
Saturated fat	Unknown	**2.8 - 4.1**	3.40
Mono-unsaturated Fats	Unknown	**2 – 3 (g/100g)**	2.33 (g/100g)
Poly-unsaturated Fats	Unknown	**17.8 – 27.8 (g/100g)**	26.6 (g/100g)
Trans fats	Unknown	**<0.1 - 0,1 (g/100g)**	0.217 (g/100g)
C14:0 Myristic	<0.1 – 0.10	**< 0.1**	0.08 *
C16:0 Palmitic	6.64 – 6.73	**7.1**	8.41 *
C20:0 Arachidic	<0.01 – 0.3	**0.3**	0.30 *
C14:1 Miristoleic	<0.01	**< 0.1**	0.00 *
C16:1 Palmitoleic	0.1 – 0.15	**0.3**	0.26 *
C18:1w9 Oleic	6.61 – 7.51	**8.7**	6.29 *
C20:1w9 Eicosaenoic	<0.01 – 0.1	**< 0.1**	0.12 *
C18:2w6 Linoleic	18.64 – 19.6	**22.0**	16.40 *
C18:3w3 Linolenic	18.7 – 73.8	**57.4**	63.46 *
C20:2w6 Eicosadienoic	<0.01 – 0.1	**< 0.1**	< 0.1 **
C20:3w3 Eicosatrienoic	0.1	**< 0.1**	< 0.1 **
C20:5w3 Eicosapentaenoic	<0.01	**< 0.1**	< 0.1 **
C22:4 Docosatetraenoic	0.1	**< 0.1**	< 0.1 **
C22:5w3 Docosapentaenoic	<0.01 - <0.1	**< 0.1**	< 0.1 **
C22:6w3 Docosahexaenoic	<0.01	**< 0.1**	< 0.1 **
C24 Lignoceric	<0.1 – 0.2	**0.1**	0.00

Certificates of analysis are hereby provided as Appendix 2 –GELDA SCIENTIFIC

***Certificates of analysis are hereby provided as Appendix 1 –page 3 SENASA**
****Certificates of analysis are hereby provided as Appendix 4 AgriQuality**

11. 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 CIA 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)"

12. 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..

13. LEVEL OF UNDESIRABLE SUBSTANCES

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).

13.1. Heavy metals and Chemical contaminants

Table 7: Analytical data on heavy metals in Chia seed

Heavy Metals	Robert Craig & Sons	TCC SEED (Approved Chia)	CIA SEED	
	Result (ppm)	Result (ppm)	Result (ppm)	date
Arsenic	<0.1 - <0.2	<0.1 (Detection limit: 0.1)	<0.2 ppm	August 2007
Cadmium	0.018 - <0.2	<0.1 (Detection limit: 0.1)	<0.05 ppm	August 2007
Mercury	<0.01 - <0.03	<0.01 - <0.02 (Detection limit: 0.02)	<0.05 ppm	August 2007
Lead	<0.004 - <0.12	<0.5 - <1 (Detection limit: 1)	<0.05 ppm	August 2007

Advanced Laboratories Inc (Appendix 6)

14. 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: Microbiological analytical data.

	Robert Craig & Sons	TCC (approved Chia)	CIA seed
Yeasts/g	<10 – 1100	**<200 CFU/g**	**10 CFU/g ***
Accredited moulds/g	<10 – 1100	**<200 CFU/g**	**10 CFU/g ***
Coagulase positive Staphylococci/g	<100	**<100 CFU/g – 200 CFU/g**	**Absent ***
Salmonella/25 g	Absent	**Not Detected/25 g**	**Not detected ***
E. Coli (CFU)	Unknown	**<10 CFU/g – 20 CFU/g**	**<10 CFU/g ***

(*) Certificates of analysis are hereby provided as Appendix 10 –Sillicker Canada Co.

(**)Certificates of analysis are hereby provided as Appendix 11 –Windsor Research Laboratories

External Contaminants

Foodborne illness usually arises from improper handling, preparation, or food storage. Good hygiene practices before, during, and after food preparation can reduce the chances of contracting an illness. The action of monitoring food to ensure that it will not cause foodborne illness is known as **food safety**. Foodborne disease can also be caused by a large variety of toxins that affect the environment. Foodborne illness can also be caused by pesticides or medicines in food. Our production is clean of all external contaminants, in 7 years selling to the US and Canada not one incident has been reported.

a. **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).

EFSA's opinion took into consideration a number of trials to assess the nutritional quality of Chia as a feed ingredient, its effects on selected markers of coagulation and immune function in humans, and its potential allergenicity.

The safety of Chia seeds has been further 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, diarrhea 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.

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 our tests during the substantial equivalent application are commercial samples of product currently sold on the N. American market. In order to ensure Chia seed quality complies with specifications and traceability CIA has put in place a Quality Management System. 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 CIA 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.

15. Allergy

To minimise the exposure of individuals to Chia seed that might have a possible allergy, CIA 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, CIA 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 there were no reports of allergic reaction to Chia seed that these organisations were aware of.

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.

16. CONCLUSION

From the above nutritional, safety, bioavailability and toxicological information and considering the history of use presented in Section 4.2 *supra*, it can be concluded that the CIA seed is substantially equivalent to the Approved Chia in the sense of Article 5 of Regulation 258/97

17. OTHER RELEVANT DATA

. Bioavailability

The following studies have investigated the bioavailability of Chia seeds:

AYERZA R. and COATES W. (2005). Ground Chia seed and Chia oil effects on plasma lipids and fatty acids in rats. Nutrition Research. 25:995-1003.

This study was performed to assess the effect of Chia seed on plasma total cholesterol, high density lipoprotein (HDL), low-density lipoprotein, triacylglycerol content, and fatty acid profile when fed to rats. Twenty-four male Wistar rats were fed ad libitum 3 diets containing equal energy levels derived from corn oil (T1), Chia seed (T2), or Chia oil (T3) for four weeks. At the end of the feeding period, 6 rats from each treatment were used for blood analyses. Blood samples were analyzed for total cholesterol, HDL, low-density lipoprotein, triacylglycerol content, and fatty acid composition. Rats fed Chia showed a significant decrease in serum triacylglycerol content, 3 and 2.5 times lower than the control for T2 and T3, respectively. There was a significant increase in serum HDL cholesterol content, 21.8% and 51% for T2 and T3, respectively, with the increase between chia diets being significant ($P < 0.05$). Total cholesterol was significantly lower for the T2 diet compared with the T3 diet. Serum fatty acid composition showed a significantly higher a–linolenic acid content and an improved ratio of T-6/T-3 fatty acids forT2 and T3 compared with T1. In sum, the chia diets dramatically decreased triacylglycerol levels and increased HDL cholesterol and T-3 fatty acid contents in rat

serum.

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 satured 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.

AYERZA R. and COATES W. (2002). Dietary levels of Chia: influence on hen weight, egg production and sensory quality, for two strains of hens. Br. Poult. Sci. 43: 283-290.

Four hundred fifty H&N laying hens, half white and half brown, were fed for 90 days to compare a control diet with diets containing 70, 140, 210 and 280 g/kg chia (*Salvia hispanica* L.) seed. Although hen weight was not significantly affected by diet, manure production was less for the hens fed on Chia. Egg weight and production, yolk weight, and yolk percentage were determined at day 0, 30, 43, 58, 72 and 90. A sensory evaluation was conducted on eggs produced during the last week of the trial. No significant differences in egg production were found among treatments for the brown hens. With the 280 g/kg Chia diet, the white hens produced fewer and lighter eggs than did the hens fed on the control diet. No significant differences were detected in yolk weight until day 90. On this date, the yolks produced by the white hens fed on the 70 g/kg Chia diet were significantly lighter in weight, whereas the brown hens produced significantly heavier yolks, compared with the hens fed on the control diet. Yolk weight as a percentage of egg weight was lower for white hens throughout the trial except on day 58 with the 140 g/kg Chia diet. Significant differences, however, were detected only with the 70 g/ kg Chia diet on day 90 and with the 210 g/kg Chia die on day 58, 72 and 90. No significant differences in taste preference or flavour were found among any of the Chia treatments and the control.

AYERZA R. and COATES W. (2006). Influence of Chia on total fat, cholesterol, and fatty acid profile of Holstein cow's milk. Revista Cientifica de la Universidad de Cynics Empresariales y Sociales, Volumen X - No. 2 - Primavera 2006:40-49.

This feeding trial was conducted with multiparous lactating Holstein cows to determine the effect that feeding Chia (*Salvia hispanica* L.) would have on milk. Total fat, cholesterol, and fatty acid profile were compared between two groups of cows fed a chia supplement, and a control supplement, over a period of 94 days. Milk production was not significantly different (P<0,05) between the two groups of cows. Cholesterol and total fat contents were lower in the milk obtained from the cows fed the Chia diet. However, no significant differences were detected. Oleic, linoleic and linolenic fatty acids were significantly higher with the Chia diet than with the control diet, as was total polyunsaturated fatty acid. No significant differences in satured fatty acids were detected between treatments. Significantly (P<0,05) lower SFA:PUFA and SFA:n-3 ratios in the milk were found as compared to those of the control diet.

Stability of the product

The Chia seed is a small round seed with an outer shell that perfectly encapsulates the

Omega 3 content. Other oil seeds have a tip on the end which throughout the cleaning and packing process the tip can break off and cause oxidation and rancidity. Chia does not have this tip, so each round seed stays intact and stable.

As part of their hygiene system, COMPAÑÍA INVERSORA AGROPECUARIA S.R.L. keeps samples from each crop batch.

In March 2009, COMPAÑÍA INVERSORA AGROPECUARIA S.R.L. conducted a routine re-test of the 2006 crop. This three year comparison demonstrates that the nutritional content of the seed has not changed over a three year period. There has been no deterioration in taste or smell and the microbial status remained constant.

18. REFERENCES

ACNFP (Advisory Committee for Novel Foods and Processes), 2004. Opinion on an application under the Novel Foods Regulation for Chia (Salvia hispanica L.). Food Standards Agency. London.

AYERZA R and COATES W (1999). An omega-3 fatty acid enriched Chia diet: influence on egg fatty acid composition, cholesterol and oil content. Can. J. of Anim. Sc. 79: 53-58.

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.

AYERZA R and COATES W (2002). Dietary levels of Chia: influence on hen weight, egg production and sensory quality, for two strains of hens. Br. Poult. Sci. 43: 283-290.

AYERZA R, COATES W, LAURIA M (2002). 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. Poult. Sci. 81: 826- 837.

AYERZA R and COATES W (2005). Ground Chia seed and Chia oil effects on plasma lipids and fatty acids in rats. Nutrition Research. 25:995-1003.

AYERZA R and W COATES (2006). Influence of Chia on total fat, cholesterol, and fatty acid profile of Holstein cow's milk. Revista Cientifica de la Universidad de Cynics Empresariales y Sociales, Vol. X - No. 2 - Primavera 2006:40-49.

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EFSA, 2005. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the safety of Chia (Salvia hispanica L.) seed and ground whole Chia seed as a novel food ingredient intended for use in bread (Request N° EFSA-Q-2005-059) (adopted on 5 October 2005). The EFSA Journal 278: 1-12.

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a request from the European Commission on the safety of Chia seed (Salvia hispanica) and ground whole Chia seed (The EFSA Journal (2009) 996, 15-26).

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HENDERSON L, GREGORY J, SWAN G, 2002. The National Diet and Nutrition Survey: adults aged 19 to 64 years. Types and quantities of foods consumed. Her Majesty's Stationery Office. ISBN: 0116215666. London. England.

SCF (Scientific Committee for Food), 1997. Recommendations concerning the scientific aspects of information necessary to support applications for placing on the market of novel foods and novel food ingredients.

http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_39.pdf

19. APPENDIX

Explanation

All analysis presented hereby were done by order of CIA with CIA Chia seeds presented under our trade mark “Salba” as clearly indicated in each laboratory analysis, either under our own request or by request of one of our customers, in the US or Canada.

All of the analysis certificates presented hereby indicate that the batch (sample) received is of “**Salba**” which is our trademark (**Salba Chia**). As an example on Appendix 6 Certificate of Analysis done by **ADVANCED LABORATORIES, Inc** and under **SAMPLE DESCRIPTION** it clearly indicates that the sample received is CIA’s chia seed (**SALBA**) and that this sample is **Salvia hispanica L.**

When ranges are indicated is because we presented the lowest and the highest figures from different analysis measuring the same element. As an example in Table 6, page 13 the Range for **Protein** in the CIA is 21.49% (SENASA, Appendix 1 page 3) -23.81% (Eurofins, Appendix 3); the range for **Fat** is 31.50% (Eurofins, Appendix 3) – 33.56% (SENASA, Appendix 1, page 3); and the range for **Ash** is 4.24% (Eurofins, Appendix3) to 4.75% (SENASA, Appendix 1, page 3).

Appendix 1: Laboratory SENASA

ANALYSIS CERTIFICATE
Protocol Nº Z159801
SENASA Habilitation LA0028

17/10/2011

1.*Sample:*

Received on: 15/08/2011
Solicitor: **COMPAÑÍA INVERSORA AGROPECUARIA S.R.L..**
Quantity of samples: 1
Type of samples: ***Salba Seeds***
Sample number: *1S2009110720 SALVA SEEDS (SALVIA HISPANICA L)*

2.*Analytical Methodology:*

Fatty Acids Profile:

Fatty Acid	Results	Methodology	Detection limit
Miristic	0.08%	AOAC Ce 2-66/ch 2-91	< 0.05%
Miristoleic	0.00%		< 0.05%
Palmitic	8.41%		< 0.05%
Palmitoleic	0.26%		< 0.05%
17:0	0.12%		< 0.05%
17:1	0.18%		< 0.05%
Estearic	4.42%		< 0.05%
Oleic	6.29%		< 0.05%
Linoleic	16.40%		< 0.05%
Linolenic	63.46%		< 0.05%
Araquidic	0.30%		< 0.1%
Eicosenoic	0.12%		< 0.1%
Behenic	0.00%		< 0.1%
Erucic	0.00%		< 0.1%
Lignseric	0.00%		< 0.1%

Values informed as 0.00% corresponds to values minor than the detection limit

ANALYSIS CERTIFICATE
Protocol Nº Z159801
SENASA Habilitation LA0028

17/10/2011

1. Sample:

Received on:	15/08/2011
Solicitor:	COMPAÑÍA INVERSORA AGROPECUARIA S.R.L..
Quantity of samples:	1
Type of samples:	**Salba Seeds**
Sample number:	1S2009110720 SALVA SEEDS (SALVIA HISPANICA L)

Amino Acids Profile:

AminoAcid	Results (mg/Kg)	Methodology	Detection limit
Aspartic acid asparagine	20560	Pretreatment: alkaline and acid hydrolysis of the sample to release amino acids from their protein binding. Detection and quantification: High performance liquid chromatography (HPLC). The equipment used is a Hewlett Packard 1100 Series equipped with diode array detector (DAD) and fluorescence detector (FLD). AOAC.994.12 AOAC Official Method 16 th. Ed	20 mg/Kg
Glutamic acid + glutamine	41130		
Glycine	12010		
Serine	11180		
Threonine	8676		
Histidine	7378		
Tyrosine	5744		
Arginine	24903		
Alanine	10630		
Methionine	6476		
Valine	10080		
Tryptophan	2843		
Phenylalanine	10790		
Isoleucine	7828		
Leucine	14400		
Lysine,	11450		
Proline,	858		
Hydroxyproline	203		
Ornithine	Not detected		
Taurine	Not detected		
Cystine + Cysteine (as cysteic acid)	1319		

Values informed as not detected corresponds to values minor than the detection limit

ANALYSIS CERTIFICATE
Protocol Nº Z159801
SENASA Habilitation LA0028

17/10/2011

1. Sample:

Received on: 15/08/2011
Solicitor: COMPAÑÍA INVERSORA AGROPECUARIA S.R.L..
Quantity of samples: 1
Type of samples: **Salba Seeds**
Sample number: 1S2009110720 SALVA SEEDS (SALVIA HISPANICA L)

Assay	Methodology	Results
Protein	AOAC 981-10	21.49 %
Dietary Fiber	AOAC 985.29/991.43	29.72%
Soluble Dietary Fiber	AOAC	3.25 %
Insoluble Dietary Fiber	AOAC	26.20 %
Carbohydrates	Centesimal difference	4.54 %
Water	AOAC	5.94 %
Fat	AOAC	33.56 %
Ash	AOAC	4.75 %
Total plate count	AOAC	< 10 UFC/g
E. Coli	AOAC	< 10 UFC/g
Coliforms	AOAC	< 10 UFC/g
Yeast and Molds	ICMSF	20 UFC/g

Appendix 2: Gelda Scientific

GELDA SCIENTIFIC
Tel: (905) 673-9320 Fax: (905) 673-8114 Email: mail@gelda.com

ISO 17025: Food & Water;
MOE: Water;
Lic.#100410-A:
Pharmaceuticals
& Neutraceuticals

116625

LABORATORY ANALYSIS REPORT
SOURCE SALBA INC.

REPORT NO.:	**1.0**	**DATE FAXED:**	4-Jul-07
DATE RECEIVED:	6-Jun-07	ANALYSIS DT.:	6-Jun-07
CODE FROM:	1	REPORT TO:	**MARK COUBTY**
CODE TO:	1	FAX:	416-849-0538
# OF SAMPLES:	1	TEL:	416-728-4932
DATE REPORTED:	4-Jul-07	ADDRESS:	600 Bay Street
Lab Trk#:	922		Toronto ON-M5G 1M6

Product: SO-1 SALBA Seeds

SEQ #		PARAMETER		Nutritional Information Units	Result	
		RESULTS OF ANALYSIS OF FOOD				
1		KJ		/100g	2214	
2		Ash		g/100g	4.3	
3		Calories		/100g	529	
4		Protein		g/100g	22.04	
5		Fat (GC/FID)		g/100g	34.0	
6		Saturated Fatty Acids		g/100g	3.40	
7		cis-Monosaturated Fatty Acids		g/100g	2.33	
8		cis-Polysaturated Fatty Acids		g/100g	26.6	
9		Trans-Fatty Acids		g/100g	0.217	
10		Omega-3 Polysaturated Fatty Acids		g/100g	20.7	
11		Omega-6 Polysaturated Fatty Acids		g/100g	5.90	
12		Carbohydrates		g/100g	33.7	
13		Total Dietary Fibre		g/100g	30.8	
14		Total Sugars		g/100g	0.4	
15		Glucose		g/100g	ND	
16		Fructose		g/100g	ND	
17		Lactose		g/100g	ND	
18		Sucrose		g/100g	0.4	
19		Maltose		g/100g	ND	
20		Cholesterol		mg/100g	<1	
21		Moisture		g/100g	5.9	
22		Vitamin A		IU/100g	ND	
23		Vitamin A		RE/100g	ND	
24		Retinol		ug/100g	ND	
25		Beta Carotene		ug/100g	ND	
26		Vitamin C		mg/100g	0.8	

Authorized By: ( )Arvind Gelda, (✓)Damien Boyd, ( )Dr.Sumona Guha

GELDA

GELDA SCIENTIFIC

Tel: (905) 673-9320 Fax: (905) 673·8114 Email: mall@gelda.com

ISO 17025: Food & Water;
MOE: Water;
Llc.#1004111-A:
Pharmaceuticals
11GGIS & Neutraceutlcals

LABORATORY ANALYSIS REPORT
SOURCE SALSA INC.

Pg.2/2

REPORT NO.:	1.0	DATE FAXED:	4-Jul-07
DATE RECEIVED:	6-Jun-07	ANALYSIS DT.:	6-Jun-07
CODE FROM:		REPORT TO:	MARKCOUBTY
CODE TO:		FAX;	416-849-0538
# OF SAMPLES:		TEL:	416-728-4932
DATE REPORTED:	4-Jul-07	ADDRESS:	600 Bay Street
Lab Trk#:	922		Toronto ON-M5G lM6

Product: SO-l **SALBASeeds** — Nutritional Information

SEQ#		PARAMETER		Units	Result	
		ELEMENTS BY ATOMIC SPECTROSCOPY (FOOD)				
27		Calcium (Ca)		mg/IOOg	650	
28		Iron (Fe)		mg!IOOg	7.7	
29		Magnesium (Mg)		mg/IOOg	320	
30		Manganese (Mn)		mg/IOOg	2.9	
31		Potassium (K)		mg/IOOg	680	
32		Sodium (Na)		mg/IOOg	NO	

Analysis Performed by Maxxam Analytics Inc.• Mississauga. NO-Not detected

Analysis	Method Reference
Total Metals Analysis in Food by ICP	EPA 6010
Ash	AOAC923.03
Beta-Carotene	AOAC 922.04, 922.06
Calories	Calculation
Carbohydrates	Calculation
Cholesterol	AOAC 976.26/994.1
Fatty Acid Profile by GC/FID	AOAC996.06
KJ	Calculation
Moisture	AOAC methodology
Protein	AOAC 992.15
Retinol	AOAC 992.04 992.06
Sugar Profile	AOAC980.!3
Total Dietary Fibre	AOAC991.43
Vitamin A lUIIOOg	AOAC 992.04, 992.06
Vitamin A RE!IOOg	AOAC 992.04, 992.06
Vitamin C (Ascorbic Acid)	CFIA/QFCL-001-01 mod

Authonzed By: ( )Arvlnd Gelda. ('1Ciamien Boyd, ( )Or.Sumona Guha

Appendix 3: eurofins

Eurofins Scientific Inc., Des Moines
3507 Delaware
Des Moines, IA 50313

Tel.+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2006-02080344
Sample Description: **Salba Seed**
Client Sample Code: 4685-5766
PO Number: 00654
Client Code: QD0001778

Reporting Date:02/22/2006
Entry Date:02/08/2006

ChromaDex, Inc
attn: Raf
2952 South Daimler Street
Santa Ana, CA 92705

ChromaDex, Inc
attn: Raf
2952 South Daimler Street
Santa Ana, CA 92705

REPORT OF ANALYSIS

AR-06-QD-017000-01

Test	Result
Protein	23.81 %
Ash	4.24 %
Calories Calculated	515 kcal/100 g
Carbohydrates, Calculated	34.10 %
Fructose	< 0.20 %
Glucose	< 0.20 %
Lactose	< 0.20 %
Maltose	< 0.20 %
Sucrose	0.70 %
Total sugars	0.70 %
ß-carotene	< 200 IU/lb
Retinol	< 200 IU/lb
Total Vitamin A	< 200 IU/lb
Vitamin C - Ascorbic Acid	< 2.00 mg/lb
Calcium	0.94 %
Iron	0.033 %
Sodium	0.016 %
Cholesterol	<1.0 mg/100 g
Total Saturated Fatty Acids	3.54 %
Total Fat	31.50 %
Moisture By Vacuum Oven	6.35 %
Total Dietary Fiber	36.9 %

Respectfully Submitted,
Eurofins Scientific Inc.

David Gross, Mgr of Support Svcs.

Appendix 4: AgriQuality

LabNetwork - Auckland
131 Boundary Road
Blockhouse Bay
PO Box 41
Auckland
New Zealand

Phone: +64 9 626 8000
Fax: +64 9 626 8282
email: vlabauckland@agriquality.com

Submitted By Aztec Foods (NZ) Ltd
Job Type Routine
Date/Time Received 19 Oct 2007 09:45

13 Nov 2007

Aztec Foods (NZ) Ltd
PO Box 67-116
Mt Eden
Auckland

Attention: **Philip Kuek**

Final LABORATORY REPORT - Job Number 806800

Comments
The fatty acids are calculated assuming the fat contains 100% triacylglycerides. Results for fatty acids reported as a percentage of the sample.

Lab Ref	Sample Description	Dates	Test	Test Result
806800-1	**SALBA**		Omega 3 fatty acids %m/m	19.8
	S100		Omega 6 fatty acids %m/m	5.8
			Fat %m/m	32.8
			Iron mg/kg	59
			Calcium mg/kg	6300
			Potassium mg/kg	6200
			Magnesium mg/kg	3100
			Octadecenoic C18:1n-6 %m/m	<0.1
			Linoleic C18:2n-6 %m/m	5.7
			Alpha Linolenic C18:3n-3 %m/m	19.8
			Gamma Linolenic C18:3n-6 (GLA) %m/m	0.1
			Steridonic C18:4n-3 %m/m	<0.1
			Eicosadienoic C20:2n-6 %m/m	<0.1
			Eicosatrienoic C20:3n-3 %m/m	<0.1
			Dihomo-gamma-linoleic C20:3n-6 %m/m	<0.1
			Eicosatetraenoic C20:4n-3 %m/m	<0.1
			Arachidonic C20:4n-6 %m/m	<0.1
			Eicosapentanaeoic C20:5n-3 (EPA) %m/m	<0.1
			Heneicosapentaenoic acid C21:5n-3 %m/m	<0.1
			Docosatetraenoic C22:4n-6 %m/m	<0.1
			Docosapentaenoic C22:5n-3 %m/m	<0.1
			Docosapentaenoic C22:5n-6 %m/m	<0.1
			Docosahexaenoic C22:6n-3 (DHA) %m/m	<0.1
			Protein %m/m	22.4
			Cholesterol mg/100g	<1
			Dietary Fibre %m/m	35.3

Method Reference			
	Fat		Based on AOAC 922.06, 950.54, 948.15, 954.02
	Iron	*i*	Acid Digest, ICP OES
	Calcium	*i*	Acid Digest, ICP OES
	Potassium	*i*	Acid Digest, ICP OES
	Magnesium	*i*	Wet oxidation ICP-OES
	Octadecenoic C18:1n-6	*i*	In-house based on JAOCS, 62(1985)

i **Indicates an IANZ accredited test IANZ Reg Nos. 175,278,445,777,891**

MAF Reg No. L1903
Tests not indicated as accredited are outside the scope of the laboratory's accreditation.
The tests were performed on the samples as received, as they were not sampled by AgriQuality Ltd staff.
This report must not be reproduced except in full, without the written approval of the laboratory.

Integrity • Trust

AgriQuality is the leading supplier of testing, analysis, verification, training and quality assurance systems to the food and agribusiness sectors.

	Linoleic C18:2n-6	*i* In-house based on JAOCS, 62(1985) *i*
	Alpha Linolenic C18:3n-3	In-house based on JAOCS, 62(1985) *i*
	Gamma Linolenic C18:3n-6 (GLA)	In-house based on JAOCS, 62(1985) *i*
	Steridonic C18:4n-3	In-house based on JAOCS, 62(1985) *i*
	Eicosadienoic C20:2n-6	In-house based on JAOCS, 62(1985) *i*
	Eicosatrienoic C20:3n-3	In-house based on JAOCS, 62(1985) *i*
	Dihomo-gamma-linoleic C20:3n-6	In-house based on JAOCS, 62(1985) *i*
	Eicosatetraenoic C20:4n-3	In-house based on JAOCS, 62(1985) *i*
	Arachidonic C20:4n-6	In-house based on JAOCS, 62(1985) *i*
	Eicosapentanaeoic C20:5n-3 (EPA)	In-house based on JAOCS, 62(1985) *i*
	Heneicosapentaenoic acid C21:5n-3	In-house based on JAOCS, 62(1985) *i*
	Docosatetraenoic C22:4n-6	In-house based on JAOCS, 62(1985) *i*
	Docosapentaenoic C22:5n-3	In-house based on JAOCS, 62(1985) *i*
	Docosapentaenoic C22:5n-6	In-house based on JAOCS, 62(1985) *i*
	Omega 6 fatty acids	Calculation from fatty acid profile.
	Omega 3 fatty acids	*i* Calculation from fatty acid profile.
	Docosahexaenoic C22:6n-3 (DHA)	*i* In-house based on JAOCS, 62(1985)
	Protein	AOAC 922.87
	Cholesterol	*i* Based on AOAC 933.08, 970.50, 970.51
	Dietary Fibre	AOAC 985.29

Shakeel Ali
Lab Supervisor - Chemistry

Heena Patel
Supervisor - General Chemistry

Lawrence Pickston
Scientific Analyst - Chemistry

Peter Thomas
Scientific Analyst Chemistry

i **Indicates an IANZ accredited test IANZ Reg Nos. 175,278,445,777,891**

MAF Reg No. L1903
Tests not indicated as accredited are outside the scope of the laboratory's accreditation.
The tests were performed on the samples as received, as they were not sampled by AgriQuality Ltd staff.

Appendix 5: Windsor Research Laboratories Inc.

Windsor Research Laboratories Inc.

Certificate of Analysis

Material - Salba Seed
Lot: 032006

	Parameter	Method	Result
Physical	Appearance	01.04.01	Seed
	Colour	01.04.01	Light tan
	Odour	Organoleptic	Characteristic
Nutrients	Energy	USP	531 Cal/100g
	Protein	USP	22.2g/100g
	Fat	USP	34.5 g/100g
	Oleic acid (Omega-9 18:1w9c)	01.02.41	5.50%
	Gamma linoleic acid (Omega-6 18:2w6c)	01.02.41	18.40%
	Alpha linolenic acid (Omega-3 18:3w3)	01.02.41	66.30%
	Carbohydrates	USP	32.9 g/100g
	Cholesterol	USP	<25 mg/100g
General	Arsenic		<2 mcg/g
	Barium		3.42 mcg/g
	Boron		10.1 mcg/g
	Cadmium		<2 mcg/g (detection limit)
	Calcium		4290 mcg/g
	Copper		17 mcg/g
	Iron		47 mcg/g
	Lead		< 4 mcg/g (detection limit)
	Magnesium		6490 mcg/g
	Manganese		18.7 mcg/g
	Mercury		<0.05 mcg/g (detection limit)
	Phosphorous		6490 mcg/g
	Potassium		5210 mcg/g
	Sodium		13 mcg/g
	Strontium		23.6 mcg/g
	Zinc		44 mcg/g

Date Feb. 23/2006

Gary Leong
VP, Scientific and Technical Affairs
Windsor Research Laboratories
(Division of Jamieson Laboratories Ltd)

Results contained in this report refer to the testing samples as submitted

Windsor Research Laboratories Inc.
4025 Rhodes Drive, Windsor, Ontario N8W 5B5 • Tel.: (519) 974-8482 • Fax: (519) 974-4742

Appendix 6: Advances Laboratories, Inc.

Advanced Laboratories, Inc.

309 South 4th Street, Smithfield, NC 27577
Phone: 919-989-7793 Fax 919-989-9226

Test Certificate

Sample Description: **Salba Seed (Salvia Hispanica L)**
Sample ID: EPOHOYQ
Sample Lot No: Exp. 08/10
Location:
Received Date: 8/16/07 10:05
Completed Date: 9/11/2007
PO No: -Check-

Client Name and Address: Mitch Propster
Core Naturals, LLC
5703 Red Bug Lake Rd.
Suite 190
Winter Springs, FL 32708

Lab No: 10563-01

Analysis	Result	Per Unit	Method
Aluminum	0.83	ppm	ICP
Antimony	<0.2	ppm	ICP
Arsenic (As)	<0.2	ppm	ICP
Barium	0.082	ppm	ICP
Beryllium	<0.02	ppm	ICP
Bismuth	<0.05	ppm	ICP
Boron	0.117	ppm	ICP
Calcium	2,440	ppm	ICP
Cadmium (Cd)	<0.05	ppm	ICP
Chromium	5.48	ppm	ICP
Cobalt	0.26	ppm	ICP
Copper	0.42	ppm	ICP
Iron	131	ppm	ICP
Lanthanum	<0.2	ppm	ICP
Lead (Pb)	<0.05	ppm	ICP
Lithium	<0.05	ppm	ICP
Magnesium	4,310	ppm	ICP
Manganese	16.9	ppm	ICP
Mercury (Hg)	<0.05	ppm	ICP
Molybdenum	<0.05	ppm	ICP
Nickel	15.4	ppm	ICP
Niobium	<0.2	ppm	ICP
Phosphorus	9,550	ppm	ICP
Potassium	7,800	ppm	ICP
Selenium	0.42	ppm	ICP
Silicon	40.7	ppm	ICP
Silver	<0.05	ppm	ICP
Sodium	110	ppm	ICP
Strontium	14.6	ppm	ICP
Sulfur	28,700	ppm	ICP

Advanced Laboratories, Inc.

309 South 4th Street, Smithfield, NC 27577
Phone: 919-989-7793 Fax 919-989-9226

Tellurium	<0.05	ppm	ICP
Thallium	0.67	ppm	ICP
Thorium	<0.2	ppm	ICP
Tin	<0.2	ppm	ICP
Titanium	0.117	ppm	ICP
Tungsten	<0.2	ppm	ICP
Vanadium	<0.05	ppm	ICP
Yttrium	<0.05	ppm	ICP
Zinc	64.1	ppm	ICP
Zirconium	<0.2	ppm	ICP
Color	Light Tan/Beige		Visual
Appearance	2x1 mm Small Seed		Visual
Odor	Characteristic		Organoleptic
Omega-6 Fatty acids	18.40	%	HPLC
Omega-3 Fatty acids	65.67	%	HPLC
Omega-9 Fatty acids	5.51	%	HPLC
Calories	472.31	Cal/per 100 g	AOAC
Total Fat	34.2	g/100g	AOAC
Saturated Fat	7.49	g/100g	AOAC
Protein	23.0	g/100g	AOAC
Carbohydrates	35.02	g/100g	AOAC
Sugars	0.31	g/100g	AOAC
Fiber	28.23	g/100g	AOAC
Cholesterol	<2	mg	AOAC
Vitamin A	443.42	IU	AOAC
Vitamin C	0.61	mg	AOAC

THESE RESULTS ARE ASSIGNED ONLY TO THE SAMPLE SUBMITTED NOT TO THE PRODUCT IT WAS TAKEN FROM.

Results Approved By: Robert A. Freeze Dated: 9/11/2007

Bobby Freeze

Appendix 7: Food and Dairy Chemistry

: RFMC-St.Hopital.Toronto FAX NO. : 4168577442
SEP-10-2002 TUE 10:16 AM

July 29, 2002

The following are the results for sample of seeds (submitter ID 001) submitted to our laboratory for Vitamin B analysis:

Riboflavin	1.8ug/g
Niacin	71.5 ug/g
Pyridoxine/Pyridoxal	0.45 ug/g
Biotin	14.4 ug/g
Folic Acid	36.4ug/g
Cyanocobalamin	0 mcg/g
Pantothenic Acid	5.6 ug/g

Food MicrobiologyLaboratory Services
DivisionUniversity of Guelph(519) 767-6307

APPENDIX 8: Food and Dairy Chemistry

/19/1995 07:17

: RFMC-St.Hospital,Toronto FAX NO. : 4168677442 Apr. 09 2003 08:41PM P11
LOIL LAB SERVICES 002

PARTIAL RESULTS

Client: St. Michael's Hospital
Address: 61 Queen Street E.
Toronto, Ont. M5C 2T2
Tel. 416-867-7450
Fax: 416-867-7442
Attn: Dr. Vladimir Vuksan

Sample received: May 15, 2002
Reported: June 19 ,2002

Salvia Hispanica seeds

Client Sample ID	S. Hispanica
LSD #	02-0020946
α- Tocopherol (ug/100g)	30
γ-Tocopherol (ug/100g)	1940
δ-Tocopherol (ug/100g)	160
Vitamin D (IU/100g)	ND
Vitamin A (IU/100g)	43

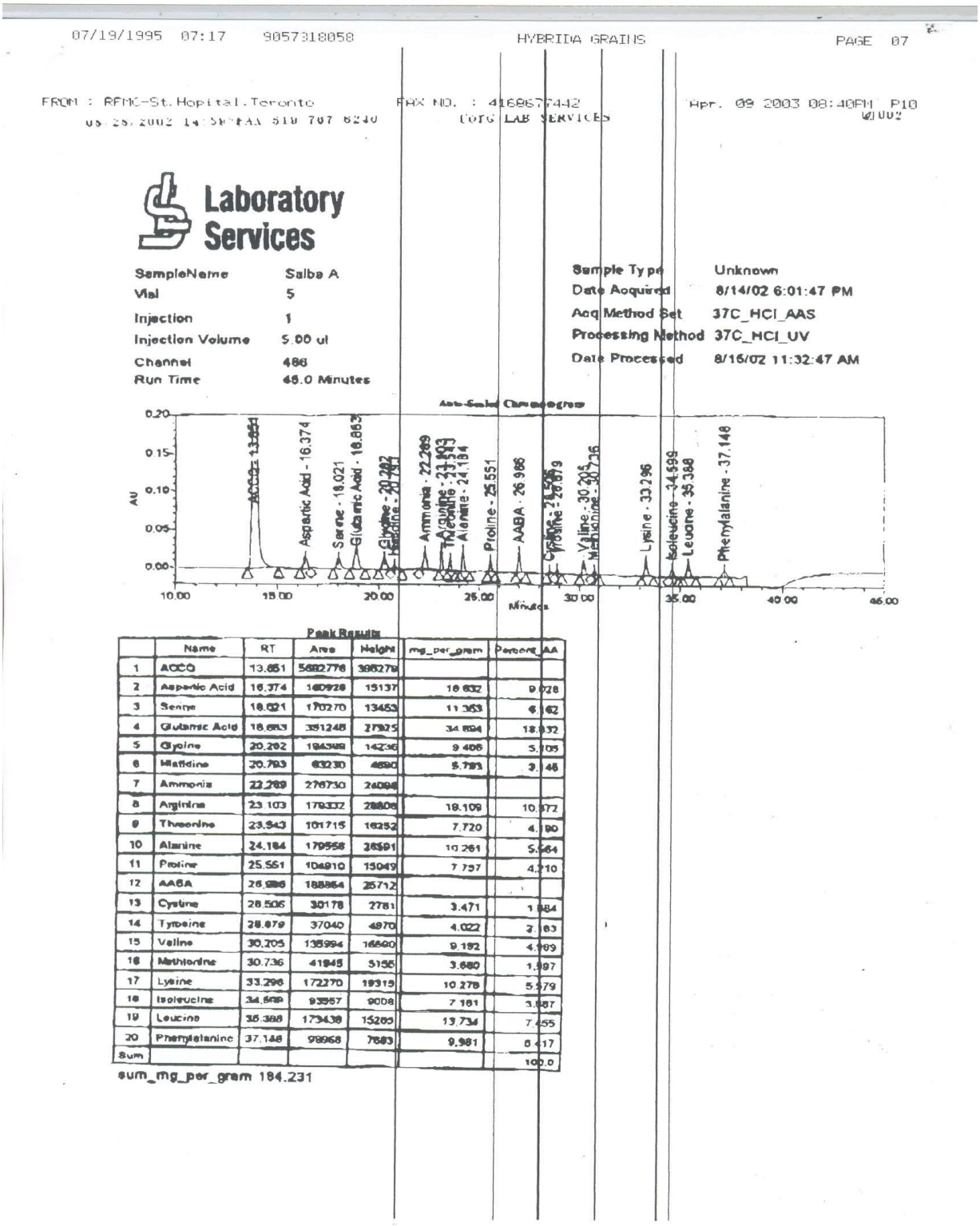
(ND = not detected)

Should you have any questions regarding these results, do not hesitate to call. As always, your business is greatly appreciated!

Results approved by: Dr. Harold Faulkner

Contact:

Dr. Herold Faulkner
Supervisor
Food and Dairy Chemistry
Tel: 519-767-6236
Fax:519-767-6240
e-mail: hfaulkne@lsd.uoguelph.ca



07/19/1995 07:17 9057318058 HYBRIDA GRAINS PAGE 07

FROM : RFMC-St.Hopital,Toronto FAX NO. : 4168677442 Apr. 09 2003 08:40PM P10
05/25/2002 14:58 FAX 519 767 6240 LOTG LAB SERVICES 002

Laboratory Services

SampleName	Salba A
Vial	5
Injection	1
Injection Volume	5.00 ul
Channel	486
Run Time	45.0 Minutes

Sample Type	Unknown
Date Acquired	8/14/02 6:01:47 PM
Acq Method Set	37C_HCl_AAS
Processing Method	37C_HCl_UV
Date Processed	8/16/02 11:32:47 AM

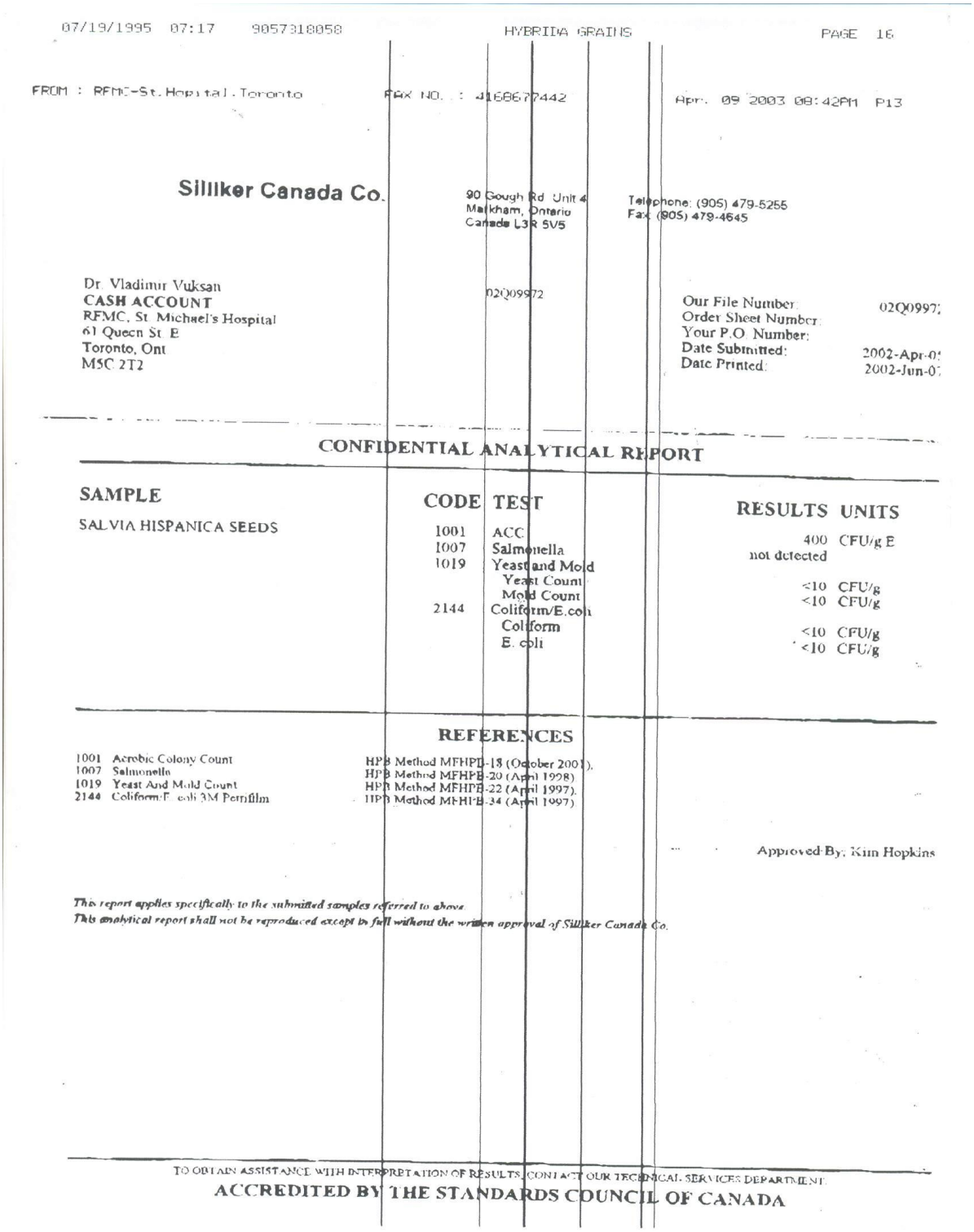
Auto-Scaled Chromatogram

Peak Results

	Name	RT	Area	Height	mg_per_gram	Percent_AA
1	ACCO	13.851	5682776	386276		
2	Aspartic Acid	16.374	180928	15137	18.632	9.078
3	Serine	18.021	170270	13453	11.353	6.162
4	Glutamic Acid	18.683	351248	27925	34.694	18.832
5	Glycine	20.282	194348	14236	9.406	5.105
6	Histidine	20.703	63230	4690	5.783	3.140
7	Ammonia	22.289	276730	24098		
8	Arginine	23.103	178332	28806	18.109	10.972
9	Threonine	23.543	101715	16252	7.720	4.190
10	Alanine	24.184	179558	26591	10.261	5.564
11	Proline	25.551	104910	15049	7.757	4.210
12	AABA	26.986	188864	25712		
13	Cystine	28.506	30178	2781	3.471	1.884
14	Tyrosine	28.879	37040	4970	4.022	2.183
15	Valine	30.205	135994	16690	9.192	4.989
16	Methionine	30.736	41845	5155	3.680	1.997
17	Lysine	33.296	172270	19319	10.278	5.579
18	Isoleucine	34.599	93557	9008	7.181	3.897
19	Leucine	35.388	173438	15265	13.734	7.455
20	Phenylalanine	37.146	99968	7683	9.981	5.417
Sum						100.0

sum_mg_per_gram 184.231

Appendix 10: Silliker Canada Co



07/19/1995 07:17 9057318058 HYBRIDA GRAINS PAGE 16

FROM : RFMC-St. Hospital, Toronto FAX NO. : 4168677442 Apr. 09 2003 08:42PM P13

Silliker Canada Co.

90 Gough Rd Unit 4
Markham, Ontario
Canada L3R 5V5

Telephone: (905) 479-5255
Fax: (905) 479-4645

Dr. Vladimir Vuksan
CASH ACCOUNT
RFMC, St. Michael's Hospital
61 Queen St E
Toronto, Ont
M5C 2T2

02Q09972

Our File Number: 02Q0997
Order Sheet Number:
Your P.O. Number:
Date Submitted: 2002-Apr-0
Date Printed: 2002-Jun-0

CONFIDENTIAL ANALYTICAL REPORT

SAMPLE	CODE	TEST	RESULTS	UNITS
SALVIA HISPANICA SEEDS	1001	ACC	400	CFU/g E
	1007	Salmonella	not detected	
	1019	Yeast and Mold		
		Yeast Count	<10	CFU/g
		Mold Count	<10	CFU/g
	2144	Coliform/E.coli		
		Coliform	<10	CFU/g
		E. coli	<10	CFU/g

REFERENCES

1001 Aerobic Colony Count — HPB Method MFHPB-18 (October 2001).
1007 Salmonella — HPB Method MFHPB-20 (April 1998)
1019 Yeast And Mold Count — HPB Method MFHPB-22 (April 1997).
2144 Coliform/E. coli 3M Petrifilm — HPB Method MFHPB-34 (April 1997)

Approved By: Kim Hopkins

This report applies specifically to the submitted samples referred to above.
This analytical report shall not be reproduced except in full without the written approval of Silliker Canada Co.

TO OBTAIN ASSISTANCE WITH INTERPRETATION OF RESULTS, CONTACT OUR TECHNICAL SERVICES DEPARTMENT.
ACCREDITED BY THE STANDARDS COUNCIL OF CANADA

Appendix 11 Windsor Research Laboratories Inc

Windsor Research Laboratories Inc.

Certificate of Analysis

Material - Salba Oil
Lot: Omega Nutrition

Parameter	Method	Result
Appearance	01.04.01	**Oil**
Colour	01.04.01	**Yellow**
Odour	Organoleptic	**Characteristic**
Oleic acid (Omega-9 18:1w9c)	01.02.41	**5.4%**
Gamma linoleic acid (Omega-6 18:2w6c)	01.02.41	**17.4%**
Alpha linolenic acid (Omega-3 18:3w3)	01.02.41	**65.4%**
Peroxide Value	current USP	**0.1**
Acid Value	current USP	**1.1**
Water	Karl Fisher	**0.10%**
Lead	current USP	**<0.25ppm**
Arsenic	current USP	**<1.25%**
Iron	01.04.702	**0.3 -0.6 ppm**
Phosphorus	01.04.702	**4.6-5.8 ppm**
Heavy metals	current USP	**<20 ppm**
:al Total Aerobic Microbial Count*	current USP	**< 10 cfu/mL**
Combined Yeast & Mold*	current USP	**<10 cfu/mL**
E. Coli	current USP	**Absent**
Salmonella	current USP	**Absent**
Staphylococcus aureus	current USP	**Absent**
Pseudomonas aeruginosa	current USP	**Absent**

Date Feb. 24/2006

Technical Affairs
Laboratories
on Laboratories Ltd)

APPENDIX 12: OUR PRODUCTS SOLD IN THE US

APPENDIX 13: CONVERSION TABLES

CONVERSION TABLE 4 AMINOACIDS			
AMINOACID	mg/Kg		%
Aspartic acid asparagine	20560	0.098629	9.8629
Glutamic acid + glutamine	41130	0.197306	19.7306
Glycine	12010	0.057614	5.7614
Serine	11180	0.053632	5.3632
Threonine	8676	0.04162	4.1620
Histidine	7378	0.035393	3.5393
Tyrosine	5744	0.027555	2.7555
Arginine	24903	0.119463	11.9463
Alanine	10630	0.050993	5.0993
Methionine	6476	0.031066	3.1066
Valine	10080	0.048355	4.8355
Tryptophan	2843	0.013638	1.3638
Phenylalanine	10790	0.051761	5.1761
Isoleucine	7828	0.037552	3.7552
Leucine	14400	0.069079	6.9079
Lysine	11450	0.054927	5.4927
Proline	858	0.004116	0.4116
Hydroxyproline	203	0.000974	0.0974
Ornithine			
Taurine			
Cystine + Cysteine (as cysteic acid)	1319	0.006327	0.6327
TOTAL	208458	1	100.00

CONVERSION VITAMINS

	ug/g	mg/g	mg/100g
Niacin * (Vit. B3)	71.5	0.0715	7.15
Alphatocopherol * (Vit. E)	30	0.03	3
Riboflavin	1.8	0.0018	0.18

Appendix 14: Opinion on an Application under the Novel Foods Regulation for Chia (Salvia hispanica L) by the Advisory Committee for Novel Foods and Processes (April 2004)

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

OPINION ON AN APPLICATION UNDER THE NOVEL FOODS REGULATION FOR CHIA (*Salvia hispanica* L)

Applicant	**Robert Craig and Sons**
Responsible Person	**David Armstrong**
EC Classification	**2.2**

Introduction

1. An application was submitted by R Craig & Sons [M] Ltd. to the UK Competent Authority for authorisation of whole Chia (*Salvia hispanica* L) seed and ground whole Chia as a novel food ingredient in soft grain bread.

2. Chia (*Salvia hispanica* L) is a summer annual herbaceous plant belonging to the mint family (Labiatae). The seed of the Chia plant has a long history of consumption in South America and was a major part of the diet in pre-Columbian civilisations, mainly in the Aztec population. If approved in Europe, Chia seeds would provide consumers with an alternative source of the n-3 polyunsaturated fatty acid, alpha-linolenic acid. A number of studies carried out by one South American company suggest that incorporating Chia seeds into hens' diets results in eggs with an increased content of n-3 fatty acids, thereby providing another potential source of these fatty acids in the diet.

3. The applicant will import whole Chia seeds that are mechanically harvested from conventionally-grown crops in two locations: Peru and Argentina. The whole ground Chia to be marketed in the EU will be produced in the UK by milling the imported whole seeds.

I. Specification of the novel food
pp 5 – 9 of the application dossier

4. Chia (*Salvia hispanica* L) is a summer annual herbaceous plant belonging to the Labiatae family.

5. Detailed compositional analyses of Chia seed are given in the application dossier for these analyses the applicant has tested four samples from four consignments of Chia from Peru, for proximate analysis, fatty acid composition and heavy metal content. Whilst details of the methods employed in the proximate analysis and heavy metal analysis are not given, fatty acid profiling was carried out to accredited procedures. Mineral, vitamin and carbohydrate analyses were also carried out on seed in Argentina. Although details of the methods of analysis are

not given, the applicant states that the analytical laboratory in Buenos Aires which carried out the analyses is a member of the Union of International Independent Laboratories and is approved by the UK Grain and Feed Trade Association to issue certificates of analysis for feed ingredients.

Discussion *The Committee was satisfied with the specification of the Novel Food.*

II. Effect of the production process applied to the novel food
pp 10 – 11 of the application dossier

6. Whole Chia seeds are not processed in any way prior to their use as a food ingredient. The seeds are grown in Argentina and Peru under contract for the applicant who states that agronomic practices will be carried out to fully comply with EC legislation. Details of the cultivation conditions are given in the application.

7. Post-harvest, the seed is cleaned mechanically and not subjected to any chemical treatments. The seed is stored in sacks within a fully enclosed warehouse facility in preparation for shipment. Although the information on the storage and transport conditions is limited, following a request from the Committee concerning proposed conditions of handling, storage and shipment, the applicant submitted a proposed HACCP procedure the use of which would minimise batch to batch variation. The seeds are monitored during transport and storage whilst the proposed HACCP plan describes measures to be put in place to control temperature and humidity during storage and transport. The applicant has also provided data in respect of potential microbial contamination of Chia seed.

   Discussion *The Committee was satisfied that the proposed method of production is controlled, and that the in-transport and in-process monitoring steps are appropriate to ensure a safe and consistent product. The Committee accepted the proposed HACCP procedures offered sufficient reassurance that the applicant would be able to ensure the quality of the product.*

III. History of the organism used as a source of the novel food
pp 12 – 13 of the application dossier

8. Chia (*Salvia hispanica* L) seeds have a history of use as a food and a medicine, mainly by the Aztecs up until colonisation by the Europeans. Historically, Chia seeds were roasted and ground to form a meal called 'pinole', then mixed with water to form a porridge or made into cakes. Although grown only on a very small scale, and with rudimentary technological methods, Mexican Indian descendants are still producing this grain. Chia seeds are also used in a Mexican beverage 'chia fresca' in which the seeds are soaked in water and then flavoured with fruit juice and consumed as a drink.

9. An extensive research and development programme on Chia has been undertaken in South America to determine the feasibility of growing this crop on a commercial scale. This has resulted in the development of new production areas

acids since raised intakes are associated with reduced risks of coronary heart disease. The main sources of n-3 fatty acids in the Western diet are oily fish, green vegetables and certain vegetable oils.

15. Alpha-linolenic acid is a significant contributor to the intake of n-3 polyunsaturated fatty acids (PUFA) and can be elongated and desaturated *in vivo* to its long-chain derivatives, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). However, in man the extent and regulation of this conversion is unclear[1].

16. Chia seed contains natural antioxidants (chlorogenic acid, caffeic acid and flavanol glycosides) which confer a distinct technological advantage over alternative alpha-linolenic acid sources such as flaxseed, in terms of product stability and flavour quality.

17. Since Chia is intended to be used as a nutritional ingredient, any claims made on the food due to the inclusion of the seed or milled whole seed must comply with the general criteria for making nutrient content claims. Final products will need to be labelled with the ingredient name and the prescribed nutritional labelling according to Directive (79/112/EEC as amended).

Discussion *The Committee did not raise any concerns regarding the nutritional properties of the novel food.*

XII. Microbiological information on the novel food
p 20 of the application dossier

18. Samples were taken from four consignments of Chia seeds for microbiological analysis. No pathogenic organisms were detected. No substances inhibitory to BHK21 (C-13) cells were detected in a cytotoxicity assay.

19. No mycotoxins were detected in the screen carried out on a composite sample from the four Chia consignments (the applicant describes this analysis under scheme XIII).

Discussion *The Committee were content with the microbiological information supplied, but requested further information on the control of storage and transport, which would minimise the potential for foodborne spoilage microorganisms to develop. The applicant was able to supply this information and the Committee agreed that the proposed HACCP schema described sufficient measures that would control and monitor levels of moisture within the seeds during bulk storage and transport.*

[1] In 2002, the Food Standards Agency convened a group of expert scientists to review current research investigating whether n-3 PUFA from plant oils (alpha-linolenic acid) were as beneficial to cardiovascular health as the n-3 PUFA from marine oils (EPA and DHA). The group concluded that dietary intake of ALNA has been associated with a beneficial effect on coronary heart disease; however, the results from studies investigating the effects of ALNA supplementation on CHD risk factors have proved equivocal.

XIII. Toxicological information on the novel food
pp 21-27 of the application dossier

20. A number of human clinical studies were carried out to assess the safety of this product, including an allergenicity study, a 4-week dietary intervention study and a 12-week randomised, single blind crossover feeding trial.

21. The applicant has also provided details of two 8-week trials in laying hens and one 28-day study in broiler chickens which investigated the effects of Chia on hens' egg yolk composition and chicken breast and thigh muscle.

Discussion *The Committee was satisfied with the toxicological data supplied by the applicant.*

Allergenicity
p 21 - 22 of the application dossier

22. An investigation into potential allergenicity of Chia was carried out at BIBRA International Ltd., Surrey, Southampton University and King's College London. The study described in the report was carried out to internationally accepted standards of Good Laboratory Practice but was not subject to any Quality Assurance inspection programme. The study is summarised below and more detailed information can be found in the application dossier.

23. No allergy-associated properties of Chia seed have been reported in the literature to date and no verifiable cases of patients with allergies to common UK food plants with any botanical relationship to Chia have been found. Chia belongs to the Labiatae, or Laminiaceae, family. The plants of this family include mint, sage, thyme, basil, pennyroyal, lavender, lemon balm, bergamot, oregano and savory. An allergic response to oregano and thyme is cited in the report, however this is related to the leaf of the plant rather than the seed. Consequently the investigation was targeted at the peanut and tree nut allergens as the most likely source of cross-reactivity.

24. An initial IgE binding screen was carried out against a panel of 30 individuals by Multiple Allergy Screening Test (MAST), selected on the basis of their reactivity to peanut. Sera from peanut allergic subjects showed low levels of serological binding to Chia protein in immunoblots, although this binding varied considerably between different serum samples. Inhibition studies indicated that IgE binding to Chia was specific. However, it was considered that the binding of IgE to Chia protein did not necessarily imply that there would be coincidental clinical reaction to Chia.

25. IgE binding of Chia was further analysed using sera from five double-blind placebo-controlled food challenge (DBPCFC) peanut sensitive individuals. None of these individuals were reported to have allergy to sesame seeds although one had sensitivity to mustard. Immunoblotting demonstrated some IgE binding in these sera, however this was concluded to be non-specific in nature. Furthermore

the applicant has suggested that Chia proteins may be highly glycosylated which could affect cross-reactivity.

26. Resistance to proteolytic digestion was investigated in Chia protein extracts using methodology based upon the recommendations of the 2001 Joint FAO/WHO expert consultation on foods derived from biotechnology. Immunoblot analysis demonstrated that all the Chia proteins were sensitive to peptic digestion with the exception of a 14kD band and protein bands below 6kD. The investigator suggests the 14kD band is non-specific cross-reactivity since this band was detected in the negative control serum.

27. Skin prick tests (SPT) were carried out on 12 individuals, selected because of sensitivity to peanut and tree nuts, to determine the clinical relevance of IgE binding activity observed in immunoblotting experiments. Two subjects gave positive SPT responses to Chia which were below the level of the histamine positive control challenge and therefore were considered of doubtful clinical significance. Both subjects were at the most broadly allergic end of the spectrum of sensitivities and both demonstrated sensitisation to sesame. Subsequent immunoblotting revealed a band that could represent an authentic IgE binding protein. This protein was shown to be susceptible to proteolytic digestion. The investigator speculates that this protein is related to sesame and its molecular weight could indicate it to be a profilin, a group of proteins associated with clinical food allergy.

Discussion *The Committee requested further information regarding the allergenic potential of the novel food. The applicant recognised the potential for such cross-reactivity but was unable to provide the requested data, citing logistic difficulties in assembling the necessary panel of individuals with such allergies. The applicant proposed instead to control this risk by including a precautionary statement on the label of chia-containing foods, informing consumers that the product was not suitable for people suffering from sesame and mustard seed allergies. The applicant also pointed out that chia will be used in softgrain bread products which often contain other ingredients which make them unsuitable for this group of allergic consumers.*

The Committee was disappointed that the applicant was unwilling to conduct additional allergy studies, but accepted that this approach would control the risk associated with cross-reactivity, although was concerned that the use of precautionary labelling might unnecessarily restrict the range of products available to allergic consumers.

Human clinical trials
pp 22-24 of the application dossier

28. The effects of dietary intervention with Chia on selected markers of coagulation and immune function were investigated in humans. The 4-week placebo-controlled dietary intervention study with Chia was carried out in 100 healthy male and female subjects (21-65yr) at the University of Ulster, Northern Ireland. The full study report can be found in the application dossier. Subjects were then randomly allocated to one of four intervention groups and Chia supplements were

included at breakfast. Chia intake was 2.5g (n=25), 5g (n=25) or 10g (n=20) per day for 4 weeks. The control group (n=25) received 4g of sunflower seeds per day. Fasting blood samples were taken before and after the intervention period and were assessed for haematological parameters, plasma lipid profiles and lymphocyte subset typing. Additionally, full anthropometric data, a lifestyle and food questionnaire and a questionnaire monitoring any possible adverse effects of the novel food were administered to each subject.

29. Dose response effects of Chia were statistically analysed. Differences between groups were compared using one-way ANOVA, and differences within groups were compared using the paired t-test. According to the investigator, no significant health-related effects associated with consumption of high levels (10g) of Chia seed were detected. However, analysis of the adverse effects questionnaire revealed a significant effect of consumption of 5g per day on tiredness and fatigue. The study investigators concluded this to be an anomalous result since it was a single effect that was not dose-related. Consequently, no significant adverse effects on human health or well-being were seen after consumption of Chia, even at levels exceeding the anticipated mean daily intake.

30. The applicant also describes a human feeding trial carried out at the University of Toronto, Canada, on subjects with type-2 diabetes, investigating the effects of Chia on measures of glycaemic control and traditional and non-traditional risk factors of cardiovascular disease. A randomised single blind crossover trial using 20 subjects with type-2 diabetes was carried out for 12 weeks with individuals consuming 25g Chia/1000kcals. Fasting blood samples and blood pressure measurements were taken at 0 and 12 weeks.

31. The results suggested that when used as a food supplement, the consumption of Chia significantly lowered systolic blood pressure compared to controls and favourably altered coagulation factors. No adverse effects were reported including no change in bleeding times, liver function or kidney parameters and no adverse effects on glycaemic control.

Laying hen and broiler chicken trials
pp 24 – 27 of the application dossier

32. The applicant presents three studies carried out at Queens University, Belfast, in laying hens and broilers, to assess the nutritional and compositional effects on foods produced from animals fed a diet enriched with Chia. These tests do not examine toxicological endpoints.

33. Two laying hen trials investigated the effects of Chia on hens' egg yolk composition by manipulating the feed. The main aim of the first study was to alter the fatty acid composition of the egg yolk by manipulating the hen's diet. The diets were carefully formulated to be isoenergetic and were supplemented with either 1.5% soya oil, 1.5% fish oil or 14% whole Chia seed. No adverse effects were observed, but again no specific toxicity tests were carried out.

Evaluation of n-3 enriched eggs in humans
p25 of the application dossier

34. This trial, carried out at the Northern Ireland Centre for Diet and Health at the University of Ulster, was intended to evaluate the bioavailability in humans of n-3 fatty acids in eggs produced by hens fed a modified diet supplemented with Chia. This study is not relevant to the assessment of Chia as an ingredient in food.

Additional information relevant to the application
p28 of the application dossier

35. The applicant has included information on the regulatory status of Chia seed as a food in the USA and Canada. Chia seed is considered to be exempt from pre-market regulatory evaluation in the USA and pre-market notification as a novel food in Canada. This regulatory information does not affect the evaluation of the current application since novel foods undergo a different regulatory process in the European Union.

Overall Discussion

36. The applicant has provided sufficient information of the proposed specification, intended use and microbiological safety measures, and indicated that on the basis of four samples analysed from four separate batches of seed, these criteria do not give rise to concern. The Committee noted that given the large transport distances involved and the nature of the product, a key element in preventing any undesirable substances from contaminating this product is adherence to the proposed HACCP procedure as described by the applicant.

37. With regard to the concerns about potential allergenicity, the applicant has indicated that they are unable to proceed with the additional studies that would offer further information regarding the allergenic potential of the seed. The Committee agreed with the applicant that mandatory product labelling, and the limited proposed use of the novel food would not present undue risk to the consumer. However, the Committee was in agreement that labelling on the basis that all individuals who have previously demonstrated symptoms of allergy when consuming other seed based products should not consume this product, restricted the choice of such individuals and could not be endorsed.

38. In addition, although the proposed labelling regime could be viewed as adequate to protect the consumer from potential harm when consuming this novel food, the Committee was cautious about agreeing to this approach particularly when the studies requested would better inform the public of the extent of the allergenic potential of the novel food.

Conclusion

The Committee is satisfied that in accordance with the criteria defined in Article 3(1) of Regulation (EC) 258/97, the evidence provided by the applicant demonstrates that the consumption of this product is not dangerous, misleading, or nutritionally disadvantageous to the consumer. With regard to the applicant's intention to use mandatory labelling to advise individuals of the potentially allergic nature of the novel

food, the Committee wish to note that that as the extent of allergenicity to this product remains unclear, this approach may be unduly restrictive of consumer choice. This issue is one of consumer choice and falls outside the scope of the safety criteria described in the regulation.

The Committee also advises that should this product be authorised then Member States should write and inform allergy clinics and allergy support groups of the introduction of this food these groups may then provide a useful source of on information on the prevalence of chia, and the potential cross-reactivity with existing food allergens.

April 2004

Appendix 14.a: Commission Decision of 13 October 2009

COMMISSION DECISION

of 13 October 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)

(Only the French text is authentic)

(2009/827/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ([1]), and in particular Article 7 thereof,

Whereas:

(1) On 30 June 2003 the company Robert Craig & Sons made a request to the competent authorities of the United Kingdom to place Chia seed (*Salvia hispanica*) and grounded seed on the market as a novel food ingredient; on 7 May 2004 the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that Chia (*Salvia hispanica*) is safe for the proposed uses in foodstuffs.

(2) The Commission forwarded the initial assessment report to all Member States on 14 June 2004.

(3) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections to the marketing of the product were raised in accordance with that provision; therefore the European Food Safety Authority (EFSA) was consulted on 4 April 2005 and issued its opinion on 5 October 2005. However, as the applicant could not provide sufficient data, EFSA in their opinion did not come to a conclusion on the safety, but was open to reconsider the application, if additional information would be provided by the applicant.

(4) On 30 September 2006, the responsibility for the application was transferred to the company Columbus Paradigm Institute S.A., who submitted additional data and information as requested by EFSA. Thus, EFSA was asked to finalise the assessment of Chia seed (*Salvia hispanica*) and grounded seed on 21 January 2008.

(5) EFSA delivered its second opinion on the safety of Chia seed (*Salvia hispanica*) and grounded seed as a food ingredient on 13 March 2009.

(6) In that opinion the EFSA acknowledged that the information provided was supportive evidence to allow for a positive conclusion on the safety of Chia seeds and ground whole Chia seeds. In particular EFSA came to the conclusion, it is unlikely that the use of Chia seed (*Salvia hispanica*) and ground seed in bread products under the specified conditions would have an adverse effect on public health.

(7) On the basis of the scientific assessment, it is established that the Chia seed (*Salvia hispanica*) and grounded Chia seed comply with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Chia seed (*Salvia hispanica*) and grounded Chia seed as specified in the Annex may be placed on the market in the Community as a novel food ingredient to be used in bread products with a maximum content of 5 % Chia (*Salvia hispanica*) seeds.

Article 2

The designation of the novel food ingredient authorised by this Decision on the labelling of the foodstuff containing it shall be 'Chia (*Salvia hispanica*) seeds'.

Article 3

This Decision is addressed to Columbus Paradigm Institute S.A., Chaussée de Tervuren 149, B-1410 Waterloo.

Done at Brussels, 13 October 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

([1]) OJ L 43, 14.2.1997, p. 1.

ANNEX

SPECIFICATIONS OF CHIA SEED (*SALVIA HISPANICA*)

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

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 fibre made mainly of indigestible cellulose, pentosans and lignin.

Appendix 14.b:

COMMISSION IMPLEMENTING DECISION

of 22 January 2013

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

(notified under document C(2013) 123)

(Only the English text is authentic)

(2013/50/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (1), and in particular Article 7 thereof,

Whereas:

(1) Commission Decision 2009/827/EC (2) authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of Chia (*Salvia hispanica*) seed as a novel food ingredient to be used in bread products with a maximum content of 5 % Chia (*Salvia hispanica*) seeds.

(2) On 14 April 2011 The Chia Company made a request to the competent authorities of the United Kingdom for an extension of use of Chia seed on the market as a novel food ingredient. In particular, they asked to use up to 10 % Chia seed in certain food categories and to sell pre- packed Chia seed with a recommended daily intake of up to 15 g.

(3) On 16 March 2012, the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that extending the use of Chia seeds for the proposed food categories meets the criteria set out in Article 3(1) of Regulation (EC) No 258/97.

(4) On 26 March 2012, the Commission forwarded the initial assessment report to all Member States.

(5) Reasoned objections were raised within the 60-day period laid down in the second subparagraph of Article 6(4) of Regulation (EC) No 258/97, in particular concerning the possible lack of toxicological data. Additional explanations by the applicant alleviated these concerns to the satisfaction of the Member States and the Commission. Therefore it was confirmed that the criteria set out in Article 3(1) of Regulation (EC) No 258/97 are fulfilled.

(6) Pursuant to Article 7(1) of Regulation (EC) No 258/97 an Implementing Decision should be adopted to authorise an extension of use of Chia seed as a novel food ingredient.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the food chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Chia (*Salvia hispanica*) seed as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses listed in Annex II.

Chia (*Salvia hispanica)* seed as such may be sold to the final consumer in a pre-packaged form only.

Article 2

The designation of Chia (*Salvia hispanica*) seed authorised by this Decision on the labelling of the foodstuffs containing it shall be 'Chia (*Salvia hispanica*) seeds'.

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

Article 3

This Decision is addressed to The Chia Company, 262-276 Lorimer Street, Port Melbourne, VIC 3207 Australia.

Done at Brussels, 22 January 2013.

For the Commission

Tonio BORG

*Member of the Commission*EN L 21/34 Official Journal of the European Union 24.1.2013

(1) OJ L 43, 14.2.1997, p. 1.

(2) OJ L 294, 11.11.2009, p. 14.

ANNEX I

SPECIFICATIONS OF CHIA (*SALVIA HISPANICA*) SEED

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.

Typical Composition of Chia Seed Dry matter

91-96 %

Protein

20-22 %

Fat

30-35 %

Carbohydrate

25-41 %

Dietary fibre (Crude Fibre (*))

18-30 %

Ash

4-6 %

(*) Crude fibre is the part of fibre made mainly of indigestible cellulose, pentosans and lignin.

ANNEX II

USES OF CHIA (*SALVIA HISPANICA*) SEED 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