Substantial Equivalence Dossier

Submitted by:
Jerry Zeifman
President

A request for an opinion on equivalence for Chia Seeds in accordance with Article 3(4) of regulation (EC) no. 258/97.

Substantial equivalence is sought between Advantage Health Matters Inc. Chia Seeds and the Chia Seeds produced and imported into the E.U. by The Chia Company.

ADVANTAGE HEALTH MATTERS INC.

5787 Steeles Ave. West
Toronto M9L 2W3
Ontario, Canada

1(800)-304-1497

1(888)-304-4810

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Contents

1. Summary

This notification dossier is submitted by Advantage Health Matters Inc. 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.).

Advantage Health Matters was founded in 2001 in Toronto, Canada. A multi-faceted company, with a sister company founded in the USA in 2009, Advantage Health Matters and Health Matters America develop, manufacture and distribute natural health food products such as organic foods and whole food supplements to natural health food retailers, grocery stores and supermarkets. Warehouses are located in Toronto, Canada and Buffalo, New York. Advantage Health Matters Inc. Chia seed's level of undesirable substances is also similar, and considered safe for human consumption. It is intended to be consumed in a manner identical to The Chia Company Chia seed.

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

Substantial equivalence is sought between the Chia seeds of Advantage Health Matter Inc. (hereinafter, the "**AHM seeds**") and the Chia seed manufactured by The Chia Company (hereinafter the "**TCC seeds")**.

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

2. Administrative Information

Applicant:

Advantage Health Matters Inc.
5787 Steeles Avenue West
Toronto M9L 2W3
Ontario, Canada

Telephone: 1(800)-304-1497
Fax: 1(888)-304-4810
www.advantagehealthmatters.com

Contact:

Jerry Zeifman
President
Advantage Health Matters Inc.

jerry@advantagehealthmatters.com

Name of novel food ingredient:

CHIA SEED (SALVIA HISPANICA L.)

Date of application:

06/09/2015

3. Composition

a) Information on source of organism

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

The Chia seed is a naturally grown grain containing all components of the dicot; the seed coat, cotyledons and the embryo. Chia seed contains high percentages of fibre, protein, and Omega-3 and Omega-6 ALA essential fatty acids, providing a nutritious and healthy food and food ingredient.

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

The 16th century Codex Mendoza provides evidence that it was cultivated by the Aztec in pre-Columbian times; it has been said that it was an important crop.
It is still used in Mexico and Guatemala, with the seeds sometimes ground, while whole seeds are used for nutritious drinks and as a food source.

b) Final composition of product

The analysis has been carried out on the following lot numbers by an ISO 17025 accredited lab i.e. I7, R2 and R4. These are the three representative samples used from the bulk lots of the chia seeds. These lots are analyzed and tested for different parameters namely nutrient profile, levels of undesirable contaminants (microbiological contaminants, heavy metals, aflatoxin, ochratoxin, etc.), Fatty acid profile, Amino Acid profile and Vitamin profile. The relative ratios of micro

nutrients found in the AHM seeds and the TCC seeds are significantly equivalent and it is clearly evident from the following comparative tables.

Table 1 Comparative Nutrient Tables between AHM seeds and TCC seeds

The table below compares the nutrient content of the AHM seeds to that of the TCC seeds. It is clearly evident from the below given table that the % of each nutrient in the AHM seeds is within the range of the % of nutrient of the TCC seeds except Dry Matter and Dietary Fibre. However, there is not a huge variation between the composition of the above given parameters. There are lots of factors affecting the composition of the seeds such as growth and harvesting times and difference in the geographical region and other environmental factors can lead to these variations such as temperature, light, soil type, growing cycles, mode of cultivation etc.

NUTRIENT	AHM SEEDS (%)*	TCC SEEDS(%)
Dry Matter	**92.7-94.34**	**95-96.8**
Protein	**17.93-21.43**	**17.4-22.4**
Fat	**25.67-31.51**	**28.5-34.7**
Carbohydrate	**38.2-42.6**	**37.1-42.6**
Dietary Fibre	**27.7-33.7**	**36.2-40.1**
Ash	**4.66-5.01**	**4.5-5.6**

*Certificates of analysis are provided in appendix

Table 2 Fatty Acid Composition for AHM seeds and TCC Chia seeds

The table below compares the % of Fatty Acid composition between the AHM seeds and TCC seeds. The Fatty Acid content of the AHM seeds and TCC seeds is comparable except a few variations. These differences are presumably due to the effects of one or more environmental factors. The effects of temperature, light, soil type etc. can affect the seed oil quantity and quality.

Fatty Acid Content	AHM seeds*(%)	TCC seeds (%)
Total Fat	**25.67-31.51(g/100g)**	**28.5 - 34.7(g/100g)**
Saturated Fat	**2.53-3.13(g/100g)**	**2.8 - 4.1(g/100g)**
Mono-unsaturated fat	**1.63-1.91(g/100g)**	**2 – 3 (g/100g)**
Poly-unsaturated Fat	**20.2-24.86(g/100g)**	**17.8 – 27.8(g/100g)**
Trans Fat	**0.03-0.06 (g./100g)**	**<0.1 – 0.1(g/100g)**
C06:0 Caproic	**<0.01**	**< 0.1**
C08:0 Caprylic	**<0.01**	**< 0.1**

C12:0 Lauric	**<0.01**	**< 0.1**
C14:0 Myristic	**0.07-0.08**	**< 0.1**
C15:0 Pentadecanoic	**<0.01-0.03**	**< 0.1**
C16:0 Palmitic	**7.06-7.27**	**7.1**
C18:0 Stearic	**2.73-2.79**	**3.7**
C20:0 Arachidic	**0.26**	**0.3**
C14:1 Miristoleic	**<0.01**	**< 0.1**
C16:1 Palmitoleic	**0.07-0.24**	**0.3**
C17:1 Heptadecanoic	**<0.01**	**< 0.1**
C18:1w9 Oleic	**6.22-6.30**	**8.7**
C20:1 w9 Eicosaenoic	**0.11-0.14**	**< 0.1**
C18:2 w6 Linoleic	**18.14-19.16**	**22.0**
C18:3 w3 Linolenic	**63.95-64.64**	**57.4**
C18:3 w6 Linolenic	**<0.01**	**< 0.1**
C20:2 w6 Eicosadienoic	**<0.01**	**< 0.1**
C20:3 w3 Eicosatrienoic	**<0.01**	**< 0.1**
C20:5 w3 Eicosapentaenoic	**<0.01**	**< 0.1**
C22:4 w6 Docosatetraenoic	**<0.01**	**< 0.1**
C22:5 w3 Docosapentaenoic	**<0.01**	**< 0.1**
C22:6 w3 Docosahexaenoic	**<0.01**	**< 0.1**
C24:0 Lignoceric	**0.11-0.12**	**0.1**

*Certificate of Analysis is provided in appendix.

Table 3 Mineral Content

In this table, a comparison is made between the Mineral content (mg/100g) of the AHM seeds and TCC seeds. The levels of all the minerals are well within the limits as specified in the TCC seeds. The upper range of Calcium and Potassium is slightly higher than that of the TCC seeds, but it is not a huge deviation. This difference might be due to the type of the soil, type of the seed used, time and temperature of the harvest.

Mineral Content	AHM seeds* (mg/100g)	TCC seeds (mg/100g)
Calcium	**623-715**	**500-640**
Copper	**1.38-1.87**	**Unknown**
Iron	**5.81-7.6**	**5.7-15**
Magnesium	**324-346**	**310-430**
Manganese	**2.87-4.18**	**Unknown**
Phosphorus	**761-845**	**600-870**

Potassium	**660-812**	**510-710**
Selenium	**0.01-0.07**	**Unknown**
Sodium	**<0.1-1.09**	**<0.1-6**
Zinc	**5.33-6.34**	**Unknown**

* Certificates of analysis are provided in appendix

Table 4 Vitamins Content

The TCC seeds and AHM seeds are compared for the Vitamin Content. The unit taken for the comparison is mg of Vitamin Content per 100g of the sample. The amount of Vitamins for the AHM seeds is within the range to that of the TCC seeds. Concerning Vitamin A content, the AHM seeds Vitamin A content is <50IU/100g of the seeds which is higher than that of the TCC seeds, but it does not possess any risk that could affect the health of the consumer. Moreover, the Vitamin A content (<85 IU/100g) of "ANDEAN GRAIN PRODUCTS LTD" was accepted as opposed to the 16 IU TCC seeds' Vitamin A.

Vitamin Content	AHM seeds* (mg/100g)	TCC seeds (mg/100g)
Vitamin A (Retinol)	**<50 IU**	**16IU**
Vitamin B1 (Thiamine)	**0.37-0.56**	**0.79-0.81**
Vitamin B2 (Riboflavin)	**0.17-0.20**	**0.05**
Vitamin B6	**0.29-0.34**	**Unknown**
Vitamin C	**<1.0-3.5**	**<1-6**
Vitamin E	**0.14-0.33**	**<0.1-0.3**

* Certificates of analysis are provided in appendix

Table 5 Amino Acid Content

The Amino Acid content of the AHM seeds and TCC seeds is depicted as % of total protein. The slight variations are due to the difference in the type and the colour of the seeds used for cultivating AHM seeds and TCC seeds. Also, these variations might be the result of different growing conditions by geographical region, time and temperature of harvest and local climate. These variations do not possess any kind of risk to the safety and efficacy of the AHM seeds. Moreover, the total PROTEIN content in the AHM seeds is within the range of the TCC seeds, it can be seen in "**Table 1 Comparative Nutrient Tables between AHM seeds and TCC seeds".**

Amino Acids	AHM seeds*(of % protein)	TCC seeds (of % protein)
Alanine	**0.99-1.31**	**Unknown**
Arginine	**2.08-2.83**	**Unknown**
Aspartic Acid	**1.73-2.21**	**Unknown**
Glutamic Acid	**3.59-4.97**	**Unknown**
Glycine	**0.95-1.20**	**Unknown**
Histidine	**0.63-0.70**	**Unknown**
Isoleucine	**0.64-0.96**	**3.05-3.53**
Leucine	**1.31-1.77**	**5.47-6.34**
Lysine	**1.12-1.40**	**3.87-4.42**
Phenylalanine	**1.01-1.40**	**4.19-4.71**
Methionine	**0.54-0.60**	**1.00-1.14**
Serine	**<0.01-1.17**	**Unknown**
Threonine	**0.38-0.72**	**2.90-3.42**
Tyrosine	**0.74-0.89**	**Unknown**
Valine	**0.77-1.35**	**3.86-4.56**

* Certificates of analysis are provided in appendix

4. Nutritional Values

a) General Description

1.) AHM seeds explain in **Table 1** the overall nutrition where the values are similar to the TCC seeds. The amount of nutrients is represented as % of each nutrient.

2.) **Table 2** shows AHM seeds fatty acid profile values that are similar and in the range of the TCC seeds; the values are given as % of Fatty Acid of Total Fatty Acid.

3.) **Table 3** shows the amounts of minerals (mg of mineral per 100g of the Chia seeds sample) present in the AHM seeds and their comparison to that of the TCC seeds.

4.) In **Table 4**, shows the comparison of the Vitamin profile of the AHM seeds and the TCC seeds. The unit is mg of Vitamin Content per 100 g of Chia seeds sample.

5.) The Amino acid profile in **Table 5** clearly shows the values of some of the amino acids that are unknown in the TCC seeds evaluation.

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

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

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

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

b) History of use

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

Chia is an important resource that was often managed by native peoples. The Chumash and Cahuilla were among those groups who would increase the following year's harvest by periodically burning stands of Chia plants (Timbrook et al. 1982; Bean & Saubel 1972).

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. Intended Use

AHM seeds are intended to be used under the European Commission Implementing Decision 2013/50/EU authorizing a substantial equivalence of use of Chia (Salvia hispanica L.) seed as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

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

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

The intended uses of AHM Chia (Salvia hispanica) seeds will be:

Baked products	Not more than 10%
Breakfast Cereals	Not more than 10%
Fruit, nut and seed mixes	Not more than 10%
Pre-packaged Chia as such	Not more than 15g per day
Bread Products	Not more than 5%

6. Level of undesirable substances

Advantage Health Matters Inc production process ensures that the levels of undesirable substances are well below the specified limits and equivalent to the TCC Seeds. The AHM seeds are very clean which is evident from the below given tables; TABLE 6 CONTAMINANTS and TABLE 7 MICROBIOLOGICAL. All the contaminants are well below the accepted tolerance levels set by the TCC seeds. Moreover, the below given tables depict that the AHM seeds are almost free from any kind of environmental, chemical and microbiological contaminants.

a) Chemical contaminants & Heavy Metals

Table 6 Contaminants

Contaminants	AHM seeds*	TCC seeds
Heavy Metals	**Result (ppm)**	**Result(ppm)**
Arsenic	**0.04**	**<0.1**
Mercury	**<0.005-0.01**	**<0.1-<0.02**
Lead	**<0.01**	**<0.5-<1**
Cadmium	**0.002-0.016**	**<0.1**
Aflatoxin	**Result (ppb)**	**Result(ppb)**
Aflatoxin B1	**<0.1**	**<1**
Aflatoxin B2	**<0.1**	**<1**
Aflatoxin G1	**<0.1**	**<1**
Aflatoxin G2	**<0.1**	**<1**
Ochratoxin A	**<0.5**	**<1**

*Certificates of analysis are provided in appendix

b) Microbiological Content

Table 7 Microbiological

Microbial Content	AHM seeds*	TCC seeds
Bacillus cereus	**<10 CFU/g**	**<100CFU/g - 200 CFU/g**
Coliforms	**<3 MPN/g (<10 CFU/g)**	**Unknown**
E.coli	**<3 MPN/g (<10 CFU/g)**	**<10 CFU/g – 20 CFU/g**
Enterobacteriaceae	**<10 CFU/g**	**Unknown**
Listeria monocytogenes	**Not detected/25g**	**Not detected/25g**
Salmonella	**Not detected/25g**	**Not detected/25g**
Staphylococcus aureus-Coagulase Positive	**<10 CFU/g**	**<100 CFU/g – 200 CFU/g**
Yeast	**<10 CFU/g-35 CFU/g**	**<200 CFU/g**
Mold	**<10 CFU/g-140 CFU/g**	**<200 CFU/g**

*Certificates of analysis are provided in appendix

c) Toxicity and safety studies

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

In addition to this, the safety has been further confirmed with the approval of the extended use by the EC, in its authorization on the 22nd January 2013 under regulation (EC) No 258/97 when used in baked products not more than 10%, breakfast cereals not more than 10%, fruit, nut and seed mixes not more than 10%, pre-packaged Chia seed as such not more than 15g per day.

The safety of Chia seeds has been previously investigated by FERNANDEZ I, VIDUEIROS SM, AYERZA R, COATES W and PALLARO A (FERNANDEZ I and al., 2008). This study was performed to analyze 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 200 (g/kg) protein and 70 (g/kg) oil, and were prepared according to the American Institute of Nutrition guidelines. No significant differences were observed in food intake, body weight, thymus weight, total thymocyte number and IgE levels when Chia was added to experimental diets as seeds (T1) or as oil (T2) when compared with the control (T3). Moreover, no symptoms such as dermatitis, diarrhoea and abnormal animal growth and behaviour were observed. Adding Chia seeds or oil to experimental diets did not produce any of the problems associated with other n-3 fatty acid sources such as flaxseed or marine products, e.g. fishy flavour, weight loss, digestive problems, diarrhoea and allergies. No safety concerns were identified by the Novel Food Reference Group of the FSANZ.

The labeling on the foodstuffs containing Chia seeds will be ‘Chia (Salvia hispanica) seeds’. Clear labelling of “seed” will also allow consumers who are allergic to other seeds to avoid consumption, this is coherent with the strategy applied in other markets and intended for use within the EU.

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

7. Quality Certificates

HACCP Certified*

Hazard Analysis Critical Control Point is an approach to food safety that is systematic and preventive. Advantage Health Matters Inc has a certified HACCP- Based Food Safety System implemented in accordance with the criteria set forth by HACCP Canada.

*Certificate is attached in Appendix

Conclusion

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

References:

1. EFSA (2009). "Opinion on the safety of Chia seeds (Salvia Hispanica L.) and ground whole Chia seeds' as a food ingredient." The EFSA Journal 996: 1-26.

2. EFSA (2010). EFSA sets European dietary reference values for nutrient intakes, European Food Safety Authority.

3. Hoare, J., L. Henderson, et al. (2004). The National Diet & Nutrition Survey: adults aged 19 to 64 years. Summary Report. London, Office of National Statistics, Medical Research Council Human Nutrition Research, Food Standards Agency. 5.

4. R. Craig and Sons Ltd (2006). Application for Approval of Whole Chia (Salvia hispanica L) Seed and Ground Whole Chia as Novel Food Ingredients. Antrim, R. Craig and Sons Ltd.

5. Diana L. Immel Formerly USDA, NRCS, National Plant Data Center, c/o Environmental Horticulture Department, University of California, Davis, California

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

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

8. 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.

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

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

11. Australian Heart Foundation, "Q & A Omega 3 Professionals", Date Unknown

12. Woolworths Ltd. (2010). "Woolworth Online Shopping." Retrieved 10 December 2010

Appendix

A.)Certificate of analysis

B.)Quality Certificates:

HACCP