Request for Substantial Equivalence

Request for an opinion on the equivalence of chia seeds under article 3(4) of the Novel Foods Regulation, 258/97

Please consider the following as evidence of substantial equivalence between Better Body Foods Chia seeds and those of The Chia Company that have already obtained novel foods approval.

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Introduction

Please accept this document as a request, by Better Body Foods, Ltd. for a scientific opinion on the equivalence of their chia seeds (*Salvia hispanica L.*) with those of The Chia Company under article 3(4) of the Novel Foods Regulation, 258/97.

The Applicant

Better Body Foods, was founded in 2007 and is based in Lindon, Utah, USA. The company employs more than 80 people and operates a 100,000 square foot, USDA organic- and Level III SQF-certified facility. It serves the mass retail end of the organic market, with their products being sold at notable retailers such as Walmart, Sam's Club and Costco. Initially the business started importing unique bulk commodity products and packaging them. Not long afterwards, the company started formulating products in the organic space, including: coconut oils, plant proteins, quinoa, agave, peanut butter, chia and other high-quality, natural and organic products. They currently market and sell several UK/EU-compliant versions of their products in the United Kingdom.

Background

Chia (*Salvia hispanica L.*) is an annual subtropical plant of the family *Labiatae*, with seeds that are a highly-concentrated source of essential, omega-3 fatty acids, along with omega-6 fats, high levels of fibre and significant levels of protein and essential micronutrients. The consumption of chia seeds at the turn of the century was negligible in Western, English-speaking countries but there is a long history of their cultivation and consumption in Mexico and Central America. Currently the sales growth of chia outside of these Latin markets is exponential and sales are expected to hit $1 bn by the year 2020[1].

Composition

Better Body Food's chia seeds are harvested mechanically, using a machine that is used also to harvest quinoa. No soy or wheat are processed with these machines and they are regularly cleaned and maintained. Fields are visited weekly to evaluate the growth and health of the crop.

The seeds are first tested for pesticides before cleaning. If they are free from chemicals and pesticides then they are sifted to separate from stems, flowers and other plant matter, then de-stoned, cleaned and pass through a magnet and sorting machine to ensure purity before being bagged. Once they are cleaned and classified, they are then packaged into new 25 kg polyurethane bags with BPA free liners or 1000kg super sacks, tagged with a lot number that identifies the field from which they came and also identified as organic and kosher.

The applicant wishes to use their chia seeds in the same manner as has been granted to The Chia Company as laid out in Commission Decision 2013/50/EU, by demonstrating substantial equivalence of the two sources of seeds. To this end, included in this submission are independent laboratory analysis of three separate samples/batches of seeds (See: Appendix 1) . Below, the results of these analyses are compared with the published composition of the approved chia seeds according to the five criteria set out in Article 3(4) of Regulation (EC)

258/97: composition, nutritional value, metabolism, intended use and the level of undesirable substances.

Macronutrient & Micronutrients

As demonstrated in Table 1 below, the macronutrient composition between the two sources of chia are very similar, with the range of macronutrient values crossing over, or even falling completely within, the ranges of that of The Chia Company.

Table 1 - Macronutrient Comparison

Nutrient (%)	Better Body Foods Chia	The Chia Company Chia
Dry Matter	93.61-94.25	95-96.8
Protein	16.71-20.83	17.4-22.4
Fat	26.18-29.09	28.5-34.7
Carbohydrate	40.27-46.60	37.1-42.6
Fibre*	35.82-44.00	32.8-40.2
Ash	3.45-4.77	4.5-5.6

*Sample Lot No. 017-221-002 was re-tested in triplicate by Eurofins Scientific, Inc. (C of A AR-16-QD-056629-02) due to a discordant result of the fibre content from Advanced Laboratory's result on that same sample (from, Lab No: 116352-01A).

Fatty Acids

As demonstrated in Table 2 below, the fatty acid composition between the two sources of chia are very similar. The Better Body Foods material falls perfectly within the ranges of The Chia Company for total fat, saturated fat, polyunsaturated fat and monounsaturated fat but having a higher omega-3 to omega-6 fatty acid ratio and slightly less stearic and oleic acid as compared to The Chia Company. Typical, contemporary Chia seeds often test above 60% for linolenic acid, according to our five independent laboratory results and those of others[2,3]. Moreover, fatty acid content of chia seeds can fluctuate as a result of a variety of environmental factors, such as: soil type, temperature, weather, etc. The table below contains the percent of total fat of all fatty acids which occur in significant amounts (greater than 1%) in either of the respective company's chia material.

Table 2 - Fatty Acid Comparison

Fatty Acid (%)	Better Body Foods Chia	The Chia Company Chia
Total Fat	29.96 - 31.80	28.5 - 34.7
Saturated Fat	3.51 - 3.65	2.8 - 4.1
Monounsaturated Fat	2.62 - 2.75	2.0 - 3.0
Polyunsaturated Fat	23.77 - 25.68	17.8 - 27.8
% Linolenic Acid (omega-3)	62.78 - 64.21	57.4
Palmitic Acid	6.80 - 7.10	7.1
Stearic Acid	3.06 - 3.18	3.7
Oleic Acid	6.44 - 6.74	8.7
Linoleic Acid (omega-6)	14.71 - 15.55	22

Minerals

As demonstrated in Table 3 below, the mineral composition between the two sources of chia are very similar, with magnesium, iron and phosphorus ranges crossing over but with Better Body Foods' chia having slightly higher concentrations of calcium, potassium and sodium. The content of minerals in chia and other crops is known to vary depending upon crop rotation practices, soil mineral content and other environmental influences, so this moderate difference between the two chia sources is not unusual. Indeed, sodium levels in chia can vary quite substantially. Some chia has been tested as being below 0.1mg (as with the Chia Company's material). However, the seeds of The Chia Company seem to constitute an outlying result, as the USDA's average measure of sodium in chia is 19mg/100g[4].

It should be noted that Better Body Foods Chia is grown using traditional methods. No system of exogenous irrigation is required (or desired) and no exogenous sources of minerals are introduced or required because the crops are usually in mountainous areas, which provides an environment conducive to a thriving chia crop. These traditional practices ensure that any increased levels of minerals will have been obtained naturally from the soil or rainfall.

The chia seeds are grown at higher altitude (1,000 to 6,000 ft), much of the soil in this area has high mineral content and when the area receives heavy rain, sodium can leach into the upper layers of the soil creating higher than normal sodium concentration. In several areas, the solonetz soil is well known to naturally contain higher concentrations of sodium.

Table 3 - Mineral Comparison

Minerals (mg/100g)	Better Body Foods Chia	The Chia Company Chia
Magnesium	345.1 - 535	310 - 430
Sodium	19.24 - 78.48	< 0.1 - 6
Calcium	677.5 - 716.4	500 - 640
Iron	6.71 - 7.23	5.7 - 15
Phosphorus	681.8 - 982	600 - 870
Potassium	735.4 - 1,046	510 - 710

Vitamins

As demonstrated in Table 4 below, the vitamin composition between the two sources of chia are broadly similar, with the vitamin C and E ranges crossing over and with vitamin B1 being very similar. The Better Body Foods' Chia material has higher levels of vitamin B2 and vitamin A (more on the vitamin A values below). So regarding vitamin content, the two forms of chia are mostly similar and all levels are well within Recommended Intakes, even on a 'per 100 gram' basis (note that daily intake will be several times lower than 100g), so this would not be expected to pose any kind of health risk to the consumer. Also, as with minerals and as the Advisory Committee on Novel Foods and Processes has stated in most other applications, the vitamin content in chia and other crops is known to vary depending upon growing conditions and other environmental influences, so in the applicant's view, these differences between the two chia sources should not be considered significant.

Vitamin A

In the below laboratory analysis, vitamin A has been measured not as "retinol" (as with The Chia Company and other Substantial Equivalence applications) but as both retinol ***and*** beta carotene. It is important to note that retinol is the "non-plant form" (animal "preformed" version) of vitamin A, whilst beta carotene is the predominant plant-based form of vitamin A[5,6]. So this represents a difference in "detection", rather than necessarily a difference in actual content of vitamin A. Also, unlike the preformed, "retinol" form of vitamin A, the various carotenoids have not been determined to be potentially toxic at high intakes and anywhere from two to 12 times as much of these carotenoid precursors are required to provide the same vitamin A nutritive value as compared to retinol[6]. Indeed, according to the Office of Dietary Supplements of the National Institutes of Health, "large amounts of beta-carotene and other provitamin A carotenoids are not associated with major adverse effects"[5]. So again, the vitamin A content does not exceed daily recommended intakes and there is no evidence-based reason to believe that the vitamin A content could be harmful to the consumer.

Table 4 - Vitamin Comparison

Vitamins (mg/100g)	Better Body Foods Chia	The Chia Company Chia
Vitamin A (Retinol + Beta Carotene)	467-2033IU*	16IU
Vitamin B1	0.92-1.19	0.79-0.81
Vitamin B2	0.17-11.29	0.05
Vitamin C	4.3-45.5	<1-6
Vitamin E (alpha tocopherol)	0.24	<0.1-0.3

*The value for Vitamin A is for retinol and beta carotene (The Chia Company value is for retinol only).

Nutritional Value & Metabolism

The nutritional profile of Better Body Foods' chia seeds (based upon the range of outcomes from three separate batches) is substantially similar to those of the Chia Company. Protein, carbohydrate, fat, fibre and fatty acid profile all fall within very similar values. In fact, in all macronutrient categories, the range of values crossed over between the two sources of chia. Even the values for linonenic acid were within approximately five percent.

A similar picture emerged when comparing micronutrients, with some cross over and most ranges of values within 10 percentage points of each other. Only vitamin B2 (riboflavin) and vitamin A showed deviation between the two materials but given that both values fall well within EU Recommended Intakes (particularly when considering the intended serving size), the applicant believes that this difference is not significant. Importantly, the higher riboflavin and vitamin A levels would not be expected to pose any kind of health risk to the consumer and the difference in vitamin A values is likely due to more specific (and appropriate) testing for the plant-based form of vitamin A in addition to retinol.

Based upon the very similar nutrient content of these two sources of chia, there is no reason to believe that they would be metabolised differently.

Intended Use

The intended use of Better Body Foods' chia seeds is as described by the Commission Implementing Decision 2013/50/EU, subject to a finding of substantial equivalence of use of chia (*Salvia hispanica L.*) as a novel food ingredient pursuant to Regulation (EC) No 258/97 of the European Parliament and of the Council.

Specifically, all directions, usage instructions and labelling on Better Body Foods' chia products will advise consumers to ingest no more than a 15 gram daily dosage. The intended composition of chia in 'mixed' products will be restricted to not more than 10% of 'baked

products', ‘breakfast products’ or ‘fruit / nut / seed mixes’. Furthermore, Better Bodies chia will not be sold as a bread product at a concentration over 5%.

Levels of undesirable Substances

Better Body Foods and their partners take great care in ensuring that their chia seeds are pure, natural and unadulterated. Equipment and facilities do not come in contact with the potential allergens wheat or soy and all batches are tested prior to cleaning for pesticide residues. During sorting, they are mechanically separated and tested for metals and other foreign material to ensure purity and are shipped in BPA-free packaging.

Chemical, Heavy Metal & Microbial Content

i) Chemical Contamination

As given below, all levels of chemical contamination are well below specified limits and all are at equivalent or lower levels than those of The Chia Company.

Table 5 - Chemicals & Heavy Metals

Heavy Metals:	Better Body Foods	The Chia Company
Mercury (ppm)	<0.01 - 0.012	<0.1 - <0.02
Lead (ppm)	0.012 - 0.11	<0.5-<1
Arsenic (ppm)	<0.001 - 0.05	<0.1
Cadmium (ppm)	0.015 - 0.1	<0.1
Mycotoxins:		
Aflatoxin B1 (ppb)	<0.4	<1
Aflatoxin B2 (ppb)	<0.4	<1
Aflatoxin G1 (ppb)	<0.4	<1
Aflatoxin G2 (ppb)	<0.4	<1
Aflatoxin (Total) (ppb)	<0.4	<5
Ochratoxin A (ppb)	<0.4	<1

Table 6 - Microbiological

Micro:	Better Body Foods	The Chia Company
Bacillus cereus	<10 CFU/g	<100-200CFU/g
Total Coliforms	<10 CFU/g	Unknown
E. coli	<10 CFU/g	<10-20 CFU/g
Enterobacteriaceae	<10 CFU/g	Unknown
Salmonella	Negative/25g	Negative/25g
Staphlococcus aureus	<10 CFU/g	<100-200CFU/g

Conclusion

Given the very similar macro- and micronutrient contents of Better Body Foods' Chia to that of The Chia Company, along with its low levels of toxicants and contaminants, it can be concluded that Better Body Foods' chia is substantially equivalent to that of The Chia Company in accordance with Article 5 of Regulation 258/97. Better Body Foods respectfully anticipates your considered draft opinion on this matter.

References:

1. Chia Boom: with 239% Growth, Chia Category Set to hit $1 bn by 2020, Stephen Daniells, Food Navigator USA, 22, Nov. 2013 [http://www.foodnavigator-usa.com/Markets/Chia-boom-With-239-growth-chia-category-set-to-hit-1-bn-by-2020]
2. Substantial Equivalence Dossier, Advantage Health Matters, Inc. Toronto, Canada. Jerry Zeifman, 2015
3. Application form Crescendo Organics and Natural Products, for an opinion on the substantial equivalence of their chia seeds grown in Argentina compared with The Chia Company's seeds. Crescendo Organics and Natural Products, The Netherlands. Maria Luisa Solari, 2015.
4. National Nutrient Database for Standard Reference Release 28, United States Department of Agriculture, Agricultural Research Service Basic Report: 12006, Seeds, chia seeds, dried.
5. The Office of Dietary Supplements (ODS) of the National Institutes of Health (NIH). Vitamin A Fact Sheet for Health Professionals. Updated: February 11, 2016
6. Otten JJ, Hellwig JP, Meyers LD, eds. Dietary Reference Intakes: The Essential Guide to Nutrient Requirements external link disclaimer. Washington, DC: The National Academies Press; 2006.