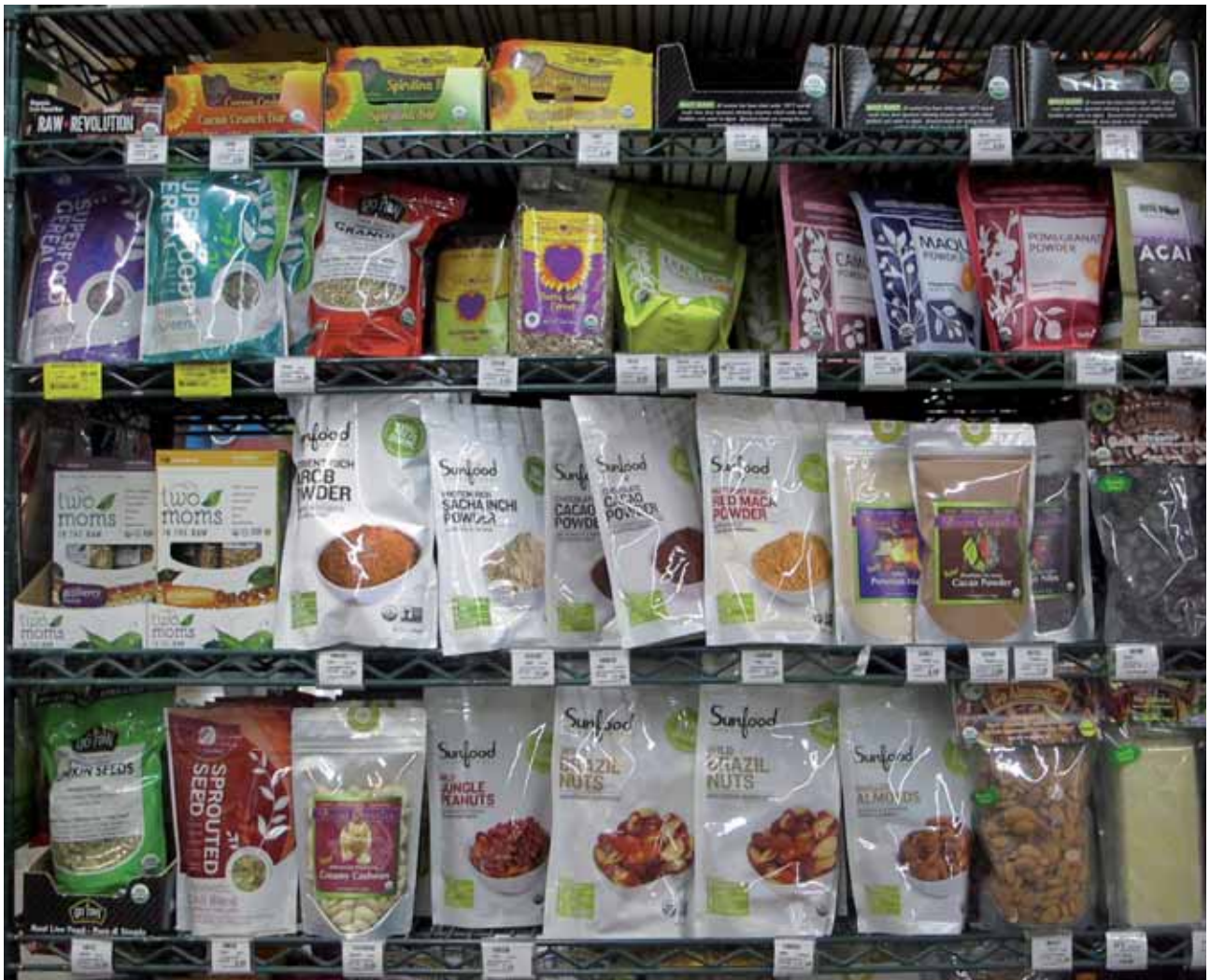


MARKET ANALYSIS FOR THREE PERUVIAN NATURAL INGREDIENTS



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MARKET ANALYSIS FOR THREE PERUVIAN NATURAL INGREDIENTS

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Comparative and competitive market analysis on market potentials in the United States and Canada of three selected Peruvian natural ingredients derived from biodiversity in the commercial forms of dried golden berry, Peruvian mesquite powder, sacha inchi seed and sacha inchi seed fatty oil.

Descriptors: Fruit, Dried Fruit, Berries, Oilseeds, Vegetable Oils, Peru, Biodiversity, Export Potential, Sustainable Development, Market Survey.

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English

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Sustainability Market Guides

This is part of a series of Sustainability Market Guides produced in ITC's Trade and Environment Unit and financed by the Government of Denmark.

The series aims to guide exporters, civil society and policymakers on trends and practical guidance about the growing market for sustainably produced goods and services.

For further information about this series and the Unit, please contact Alexander Kasterine at kasterine@intracen.org.

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Acronyms

All references to tons are to metric tons.

The following abbreviations are used:

AAIC	Agriculture and Agri-Food Canada (Canada)
AHP	American Herbal Pharmacopoeia
AHPA	American Herbal Products Association
AI	Adequate Intake
ALA	Alpha-Linolenic Acid
ATPA	Andean Trade Preference Act
BGH	Bovine Growth Hormone
BP	British Pharmacopoeia
CAGR	Compound Annual Growth Rate
CFIA	Canadian Food Inspection Agency (Canada)
CFR	Code of Federal Regulations (United States)
COTA	Canada Organic Trade Association (Canada)
cfu	Colony Forming Unit
COR	Canadian Organic Regime
DHA	Docosahexaenoic Acid (an omega-3 fatty acid)
DPA	Docosapentaenoic Acid
DSHEA	Dietary Supplement Health and Education Act of 1994 (United States)
DSP	Dietary Supplement Product (United States)
DV	Daily Value
EDQM	European Directorate for the Quality of Medicines (EU)
EFA	Essential Fatty Acid
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EPA	Eicosapentaenoic Acid (an omega-3 fatty acid)
FALCPA	Food Allergen Labelling and Consumer Protection Act of 2004 (United States)
FCC	Food Chemicals Codex
FDA	Food and Drug Administration (United States)
GACP	Good Agriculture and Collection Practice
GLA	Gamma-Linolenic Acid
GMO	Genetically Modified nm
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe (food)
GRASE	Generally Recognized as Safe and Effective (medicine)
GSP	Generalized System of Preferences
HDL	High Density Lipoprotein
HPLC	High Performance Liquid Chromatography
HTSUS	Harmonized Tariff Schedule of the United States
IQF	Instant Quick Frozen
IDF	Insoluble Dietary Fibre
IFOAM	International Federation of Organic Agriculture Movements
ITC	International Trade Centre

LA	Linoleic Acid
LCPUFAs	Long-chain Polyunsaturated Fatty Acids
LDL	Low Density Lipoprotein
max	Maximum
mg	Milligram
min	Minimum
MFN	Most Favoured Nation
NCC	Nutrient Content Claim
NDI	New Dietary Ingredient (for dietary supplement products in the United States)
NF	National Formulary
NHP	Natural Health Product (Canada)
NHPD	Natural Health Products Directorate (Canada)
NLT	Not-less-than
NMT	Not-more-than
NOP	National Organic Programme (regulated by USDA)
NPN	Natural Product Number (Canada)
ODI	Old Dietary Ingredient (for dietary supplement products in the United States)
OTA	Organic Trade Association (United States)
OTC	Over-the-counter (drug product)
PBD	Project Perubiodiverso
PhEur	European Pharmacopoeia (EU)
PROMPERU	Commission for the Promotion of Peru Export and Tourism
PTPA	United States-Peru Trade Promotion Agreement Implementation Act
PUFAs	Polyunsaturated Fatty Acids
QHC	Qualified Health Claim
RACC	Reference Amount Customarily Consumed
RAE	Retinal Activity Equivalents
RDA	Recommended Dietary Allowance
RDI	Reference Daily Value
SCN	Standardized Common Name
SDF	Soluble Dietary Fibre
SIICEX	Sistema Integrado de Información de Comercio Exterior
TAA	Total Amino Acids
TDF	Total Dietary Fibre
TE	Trolox Equivalents
TEAA	Total Essential Amino Acids
TEP	Trade and Environment Programme (of ITC)
THC	delta-9-tetrahydro-cannabinol
THMP	Traditional Herbal Medicinal Products (EU)
TOTOX	Total Oxidation Value
Tr	Trace
UNCTAD	United Nations Conference on Trade and Development
USDA	United States Department of Agriculture
USP	United States Pharmacopeia
WHO	World Health Organization

Executive summary

This comparative and competitive analysis study examines the market potentials in the United States of America and Canada for three prioritized Peruvian natural ingredients of biodiversity: golden berry, Peruvian mesquite and sacha inchi.

Chapter 1 provides detailed descriptions and crop profile summaries for each ingredient in the commercial forms of dried golden berry, Peruvian mesquite powder, sacha inchi seed and sacha inchi seed fatty oil.

Chapter 2 provides information about post-harvest processing and technology and a listing of the various processed forms that are commercialized for the export market.

Chapter 3 provides information on composition (macro- and micro-nutrient content, phytochemical content), documented pharmacological actions, recommended uses for each ingredient that are supported by clinical or scientific data or by traditional use evidence, as well as new uses described in patents.

Chapter 4 provides an analysis of the market environment by describing finished products in the Canadian and United States markets through narrative and photographic images for each of the prioritized Peruvian ingredients in four different market segments, namely non-drug cosmetic products, food products, food supplement products, and medicinal products. Each product description includes a corresponding website link which enables the users of this study to learn more about the specific companies who are taking a position on the marketing of new products that contain these Peruvian ingredients. Additionally chapter 4 offers possibly the most important summary in this study which is an overview of the most relevant trends affecting the sectors and market segments based on interviews with American companies and analysis of the most recent trend reports.

Chapter 5 provides the specific requirements for exporters of bulk ingredients with an emphasis on certified organic bulk ingredients for Canada and the United States. Additionally chapter 6 provides details on all of the relevant standards and certifications that have been identified as drivers of growth in the natural and organic sector. Information is provided not only about the standard and the certification organization but also examples of specific companies who are marketing products with the listed certifications, designations or verifications, for example, certified organic, certified gluten-free, fair trade certified, non-GMO project verified, vegan verified, raw food, etc.

Chapter 6 provides tariff classification and duty rates including up-to-date rulings information obtained from the U.S. Customs and Border Protection 'Customs Rulings Online Search System' (CROSS) for items that are not specifically listed in the Harmonized Tariff Schedule of the United States (HTSUS).

Chapter 7 provides an analysis of the comparable natural ingredients that the prioritized Peruvian ingredients may compete with, be combined with or be substituted for in same types of finished products, for example, golden berries are compared against cranberries, goji berries and raisins using a number of criteria including availability, composition, ease of application in production, pricing, recommended uses and regulatory status.

Chapter 8 describes the typical trade channels for these ingredients based on interviews with Peruvian exporters and United States importers.

Chapter 9 summarizes factors influencing price and provides concrete examples of how some United States distribution companies' structure prices, margins, mark-ups and discounts for these Peruvian ingredients.

Chapter 10 provides details on the most relevant trade promotion events in Canada and the United States as well as an extensive list of North American companies that are presently working with the Peruvian ingredients. The company listings are sorted into five separate sections, natural ingredient distribution companies, natural ingredient extraction and processing companies, contract manufacturer and private label companies, finished product manufacturing and marketing company, and finished product distribution companies.

This report is intended to provide actionable intelligence to Peruvian small- to medium- sized producer organizations as well as processing companies and exporters of Peruvian biodiversity ingredients and products. The information provided in this study should enable Peruvian companies to better understand the competitive landscape of natural ingredients available in the North American market and in particular the scale of production and availability of the selected comparable ingredients. Quantitative data is provided on the production acreage and annual yields of selected major North American competitive crops like cranberries, flax seed, hemp seed, raisins, walnuts, among others. The report will also provide Peruvian entrepreneurs with useful insights on the key drivers of natural and organic sector growth.

Site visits were made to harvesting areas and post-harvest processing and production facilities in Peru. Selected Peruvian companies were interviewed in Peru and some also at trade shows, for example at BioFach 2013 in Nuremberg, Bavaria and Natural Products Expo West 2013 in Anaheim, California. North American importing, processing and distributing companies were interviewed by telephone or Skype during March and April of 2013. Significant desk research was also necessary involving retrieval and analysis of published articles, scientific papers and reports as well as use of databases of governmental agencies, import- export trade databases and certification organization databases or lists of certified producers and certified traders. Current market trends reports based on scan data were also obtained.

Formerly separate niches have converged and are the new drivers of growth in the natural and organic products sector. New products that appeal to more than one specialty diet and whose labels carry the certifications and verifications that informed consumers are looking for are experiencing significant growth. Certification organizations are also beginning to offer joint certifications of two formerly disparate attributes, for example 'Earth Kosher Vegan Verified' or 'PETA Cruelty Free and Vegan'. Some of the attributes associated with the highest growth rates over the past 52 week period are products with allergen-free labelling, in particular 'Certified Gluten-Free' which is predicted to be among the top trends for new product launches and restaurant menus in 2013. Other drivers are products labelled with 'Non-GMO Project Verified' ingredients, 'Raw Food', and companies that are 'Certified B Corporations'.

The Peruvian biodiversity ingredients that are the subject of this study do not have application, availability or price advantages over the selected competitive ingredients analysed in this study. A different argument needs to be developed to justify their position with premium prices. They may, however, have advantages over the competing ingredients because they can satisfy almost all of the identified attributes that are driving growth. For example, while sachu inchi oil might presently compete with krill oil, krill oil will never be organic certifiable (it's a seafood), it cannot be kosher certified (it's a crustacean), it is a major food allergen (crustacean), and vegans, vegetarians and raw food consumers will of course never buy it.

Products with multiple certifications are the current drivers according to scan data. New products, based on these Peruvian ingredients could potentially be labelled and marketed with many or most of the identified attributes, namely organic, non-GMO, major allergen-free (dairy free, gluten free, lactose free, soy free, tree nut free), ethical (fair trade, fair choice, fair for life), suitable for vegetarians and vegans, kosher and halal, good sources of plant-based essential fatty acids, fibre, protein, etc., and raw.

The fasted growing protein ingredients are plant-based and positioned as raw. Not waiting for legislators, retail stores are beginning to implement timelines for mandatory GMO-labelling. The fact that Peru has passed a regulation for a 10-year ban on genetically engineered crops should be emphasized in marketing of Peruvian biodiversity products. That will be a big plus. Natural and organic shoppers are looking for authenticity, transparency, traceability, food safety, purity, simpler products with fewer ingredients, no GMOs, no artificial aromas, colours or flavours, more natural and wholesome ingredients and unprocessed as possible, originating from countries that have a clean image. Products originating from the Peruvian Amazon and the Peruvian Andes that carry these attributes can have a chance.

Peruvian producers however must obtain the capacity and technology required to produce consistent defined qualities of these ingredients, batch after batch, so that a Peruvian quality brand can be marketed effectively and the differences between Peruvian ecotypes or varieties compared against those of other origins can be clearly shown qualitatively and quantitatively.

Introduction

The International Trade Centre (ITC) with headquarters at Geneva, Switzerland, the development partner for export success, is the joint technical cooperation agency of the World Trade Organization and the United Nations. ITC aims to contribute to the achievement of the Millennium Development Goals, generates sustainable incomes and livelihoods especially for poor households, by connecting enterprises to global markets and enables small business export success in developing and transition countries by providing, with partners, inclusive and sustainable trade development solutions to the private sector, trade support institutions and policymakers.

ITC is implementing the Trade and Environment Programme (TEP), with the aim of strengthening the competitiveness of developing countries in environmental markets, to overcome obstacles and / or barriers that arise to access them. In this way it hopes to build capacity in small and medium-sized enterprises and the institutions that support access to these niche markets, such as organic products, products of biodiversity and carbon standards for agricultural products.

To this end, the TEP is implementing a project linked to biodiversity-based products from Peru (2010 – 2013), which aims to increase the competitiveness of small and medium-sized exporters in this sector. Its implementation will be through a strategic alliance with two organizations operating in Peru and have experience of intervention in this sector: Commission for the Promotion of Peru Export and Tourism (PROMPERU) and Project Perubiodiverso (PBD).

The PBD project aims to improve quality of life in rural communities through sustainable biodiversity use. The PBD Project is funded by the Swiss State Secretariat for Economic Affairs (SECO) and the German Cooperation Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) as well as by national counterparts (MINCETUR, PROMPERU and MINAM). Within the scope of the National Biotrade Promotion Programme (PNBP, in Spanish) PBD aims at promoting and supporting the creation and consolidation of Peruvian biotrade businesses based on native biodiversity as an incentive for conservation, applying environmental, social and economic sustainability issues. Promperú is the Peruvian Agency Organization that promotes exports, tourism and country image to international markets.

ITC is providing useful market competition data available to all Peruvian producers and exporters of the prioritized biodiversity ingredients that are the subject of the study. This study responds to the requests of Peruvian companies to better understand the market, regulatory and technical requirements for new ingredients that may compete against well-established ingredients in new product formulations. Successful marketing of these relatively new ingredients to product development and innovation decision-makers requires much more than competitive price data. Technical sales managers need to clearly understand the types of products that these ingredients might be used in, the comparative composition and physical characteristics of competing ingredients or of ingredients that will be combined or processed together, and the types of testing data and technical support that the prospective buyer will expect or require of the seller during phases of product development, scale-up and launch. Understanding the permitted claim statements for use of these ingredients, compared to the claim statements permitted for selected competitive well-established ingredients, will help the Peruvian producers and sellers to focus their sales and marketing plans towards suitable trade partners. This study also provides extensive links and contact details for finished-product companies that already use some Peruvian natural ingredients. These companies are the most likely partners to take a position on launching more new products containing the Peruvian ingredients that are the subject of this study.

The objective of the market study is to provide the United States and Canadian market profiles with emphasis on the following Peruvian biodiversity products:

- Dried golden berry;
- Peruvian mesquite flour;
- Sacha inchi seed;
- Sacha inchi seed oil.

Chapter 1 Product description

1. Golden berry – dried

1.1. Definitions

Plant source: *Physalis peruviana* L.

Synonyms: *Physalis edulis* Sims.

Family: Nightshade family (Solanaceae).

Taxonomic classification: *Physalis peruviana* has been classified into ecotypes that can be differentiated by size, colour and taste, shape of the flower head and the height and size of the plant, e.g. ecotypes 'Colombia', 'Ecuador', 'Kenya' and 'South Africa'. There are also several named cultivars including 'Garrison's pineapple flavour', 'Giant', 'Giant groundcherry', 'Golden berry', 'Inka', 'Obrazetc', 'Peace' and 'Plovdiv', among others.

Description: Whole dried fruit or cut pieces.

Common names: Engl: cape gooseberry (South Africa); golden berry or golden berry, Incan berry, Peruvian cherry or Peruvian groundcherry (United States); Fr.: coqueret du Pérou, groseillier du Cap (Canada); Ger: Andenbeere, Andenkirsche, Kapstachelbeere; Hawaiian: poha; Port: camapú, camapum, fisalis, joá-de-capote (Brazil); Span: aguaymanto (Peru), alquequenje (Spain), capulí (Peru), cereza del Peru (Mexico), physalis (Chile), totopoto (Venezuela, (Bolivarian Republic of)), uchuva (Colombia, Costa Rica), uvilla (Ecuador).

Native origin: Originally from the Northern Andes of South America (mainly Peru); occurs wild or adapted in the Andes between 1500 and 3000 m in altitude.

Producing countries: Cultivated in the South American Andes (Chile, Colombia, Ecuador and Peru) as well as in Africa (Kenya, South Africa and Zimbabwe), North America (Costa Rica, Hawaii and Mexico), Oceania (Australia and New Zealand), and parts of Asia (India, Chinese Taipei and Turkey).

Main exporting countries: Colombia (estimated 90% of world total), South Africa, Ecuador, Peru, Zimbabwe, Chile and Mexico.

1.2. Crop profile (cultivation and/or wild harvest practices)

Cultivation: There is extensive downloadable literature available for the cultivation practices of golden berries including publications by Álvarez et al. (2012),¹ Dostert et al. (2011),² PDRS/GIZ Cajamarca (2011),³ Villegas (2009)⁴ and Villena M. (2010).⁵

Wild harvesting: Some of the supply is wild collected in the Peruvian Andes.

1 Álvarez, G., G. Campoverde Vivanco and E. Espinosa Mejía (2012). Manual Técnico para el cultivo de uvilla (*Physalis peruviana* L) en Loja. Loja, Ecuador: Universidad Nacional de Loja. 2012. Available from: <http://www.unl.edu.ec/agropecuaria/wp-content/uploads/2012/03/Manual-T%C3%A9cnico-del-cultivo-de-Uvilla8.pdf>

2 Dostert, N., J. Roque and others (2011). Hoja botánica: Aguaymanto. Berlin, Germany: botconsult GmbH. Available from: http://www.botconsult.com/downloads/Hoja_Botanica_Aguaymanto_2012.pdf

3 PDRS/GIZ. El aguaymanto cultivo promisorio de la region Cajamarca. Proyecto de Desarrollo Rural Sostenible PDRS/GIZ Cajamarca. Available at: <http://perubiodiverso.pe/assets/Cadena-del-Aguaymanto-Documento.pdf>

4 Villegas, I.C. (2009) El cultivo de la uchuva (*Physalis peruviana*). Proyecto Microcuenca Plantón – Pacayas Boletín técnico No. 10. Available from: <http://www.mag.go.cr/bibliotecavirtual/a00170.pdf>

5 Villena, M. (2010) Resultados y Lecciones en Cultivo de Goldenberry (*Physalis peruviana* L.) en la zona central de Chile. Santiago, Chile: Fundación para la Innovación Agraria (FIA) Ministerio de Agricultura. Available from: http://bibliotecadigital.innovacionagraria.cl/qsdl/collect/publicac/index/assoc/HASHf6a1.dir/90_Libro_Physalis.pdf

2. Peruvian mesquite – flour

2.1. Definitions

Plant source: *Prosopis pallida* (Humboldt & Bonpland ex Willdenow) Kunth.

Synonyms: *Prosopis limensis* Benth.

Family: Pea family (Fabaceae).

Description: Dried, powdered fruit pods.

Common names: Engl: Peruvian mesquite, Peruvian carob; Ger: peruanischer Carob, weißer Carob; Hawaiian: kiawe; Port: algarobeira (Brazil); Quechua: huarango, guarango, thacco, taco (Peru); Span: algarrobo (costa norte y central del Perú).

Native origin: Native to north-western South America, i.e. the drier northern parts of Peru (e.g. desert area of Piura), southern Colombia and Ecuador, especially near the coast; introduced and naturalized in Australia, Bolivia (Plurinational State of), northeast Brazil, Hawaii, Puerto Rico and South Africa.

Main producing and exporting countries: Peru.

2.2. Crop profile (cultivation and/or wild harvest practices)

Cultivation: Although there is some cultivation as an orchard crop, the material of commerce is primarily obtained from wild populations. For information on cultivation, see Dostert et al. (2012).⁶

Wild harvesting: Wild collected in the arid and semiarid zones of Peru, mainly in the northern coastal regions from sea level up to 1500 m in altitude. See Alemán Peralta et al. (2009).⁷

3. Sacha inchi – seed and oil

3.1. Definitions

Plant sources: *Plukenetia volubilis* L. and *Plukenetia huayllabambana* sp. nov.

Synonyms (of *P. volubilis* L.): *Plukenetia peruviana* Muell. Arg.

Family: Spurge family (Euphorbiaceae).

Description:

- **Sacha inchi seed:** The oleaginous seed obtained from the star-shaped fruit of *Plukenetia volubilis* L. or *Plukenetia huayllabambana* sp. nov., characterized by its content of omega fatty acids.
- **Oil of sachá inchi:** Fatty oil sachá inchi seeds of the genus *Plukenetia*, characterized by its high content of unsaturated fatty acids (omega 3, 6 and 9).
- **Virgin oil of sachá inchi:** Fatty oil of sachá inchi seeds obtained by mechanical means, for example, extrusion, pressing and other methods, whose % of free acidity (expressed as oleic acid) is a maximum of 2 g per 100 g (< 2.0 mg KOH/g). The oil may be purified by sedimentation, filtration

⁶ Dostert, N., J. Roque and others (2012). Hoja botánica: Algarrobo. Berlin, Germany: botconsult GmbH. Available from: http://www.botconsult.com/downloads/Hoja_Botanica_Algarrobo_2012.pdf

⁷ Alemán Peralta, ML., EA. Espinoza Flores, and AP. Navarro Carrillo (2009). Plan de manejo forestal – recurso forestal *Prosopis pallida* 'algarrobo'. Asociación Comunal para el Manejo del Bosque Seco de la Cuenca de Bocapán. Available from: http://redpeia.minam.gob.pe/admin/files/item/4d8a4fa7462bc_Plan_de_Manejo_Forestal._Recurso_Forestal_Prosopis_pallida.pdf

and centrifugation. Excludes oils obtained by solvent extraction, chemical or biochemical action or by re-esterification processes and excludes mixture with other oils.

- **Extra virgin oil of sacha inchi:** Fatty oil of sacha inchi seeds whose % of free acidity (expressed as oleic acid) is a maximum of 1 g per 100 g (< 1.0 mg KOH/g), extracted without the application of heat (cold pressed).

Common names: Engl: Incan peanut, sacha inchi; Span: sacha inchi. According to Norma Técnica Peruana NTP 151.400:2009, other common names used in Peru include: Sacha Inchik, Inchic, Sacha maní; Maní del monte; Maní del inca; Inca Inchic.

Native origin: *P. huayllabambana* occurs in the Peruvian Región Amazonas, provinces of Rodríguez de Mendoza, Bongará and Chachapoyas, on the eastern slopes of the northern Peruvian Andes in dense cloud forest at altitudes between 1300 to 2200 m above sea level.⁸ *P. volubilis* occurs naturally in high altitude rainforests of the Andean region. Its area of distribution extends from the Caribbean Islands, Surinam, north-western sector of the Venezuela (Bolivarian Republic of) and Colombian Amazon basin to Ecuador, Peru, Bolivia (Plurinational State of), and Brazil.⁹

Main producing countries: Peru (mainly the provinces of San Martín (Tarapoto), Ucayali, Loreto and Junín, but also Cusco, Huánuco, Madre de Dios and Pasco) and southern Colombia. Sacha inchi has also been introduced in southwest Yunnan, China where some production is occurring.

Main exporting countries: Peru.

3.2. Crop profile (cultivation and/or wild harvest practices)

Cultivation: There is extensive literature available on cultivation practices of sacha inchi including a Peruvian standard for good agricultural practices (GAP) for cultivation of sacha inchi published by INDECOPI (Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual).¹⁰ See also downloadable publications by Dostert et al. (2009),¹¹ Manco (2006),¹² and Ventura (2009).¹³

Wild harvesting: Although it occurs in the wild, the material of commerce is mainly cultivated.

8 Bussmann, RW., C. Téllez and A. Glenn (2009). Plukenetia huayllabambana sp. (Euphorbiaceae) from the upper Amazon of Peru. Nordic Journal of Botany.;27:313-315.

9 Dostert, H., J. Roque, and others (2009). Hojas Botánicas: Sacha inchi - Plukenetia volubilis L. Berlin, Germany: botconsult GmbH. Available from: http://www.botconsult.com/downloads/Sacha_Inchi_Factsheet_final.pdf

10 INDECOPI (Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual) (2012). Norma Técnica Peruana NTP 151.402:2012 SACHA INCHI. Buenas prácticas agrícolas para el cultivo de Sacha Inchi (Plukenetia volubilis Linneo), 1ª Edición. Lima, Perú: INDECOPI.

11 Dostert, H., Roque, J. and others. (2009). Hojas Botánicas: Sacha inchi - Plukenetia volubilis L. Berlin, Germany: botconsult GmbH. Available from: http://www.botconsult.com/downloads/Sacha_Inchi_Factsheet_final.pdf

12 Instituto Nacional de Investigación y Extensión Agraria (INIA). (2006). El Cultivo de sacha inchi. Tarapoto, Peru.: Available from: <http://www.inia.gob.pe/SIT/consPR/adjuntos/1418.pdf>

13 Ventura, JA. (2009). Monografía del cultivo de sacha inchi. Lima, Perú: Perúbiodiverso. Available from: <http://perubiodiverso.pe/assets/Monograf%C3%ADa-del-cultivo-de-sacha-inchi.pdf>

Chapter 2 Post-harvest situation

1. Golden berry – dried

1.1. Processing and technology

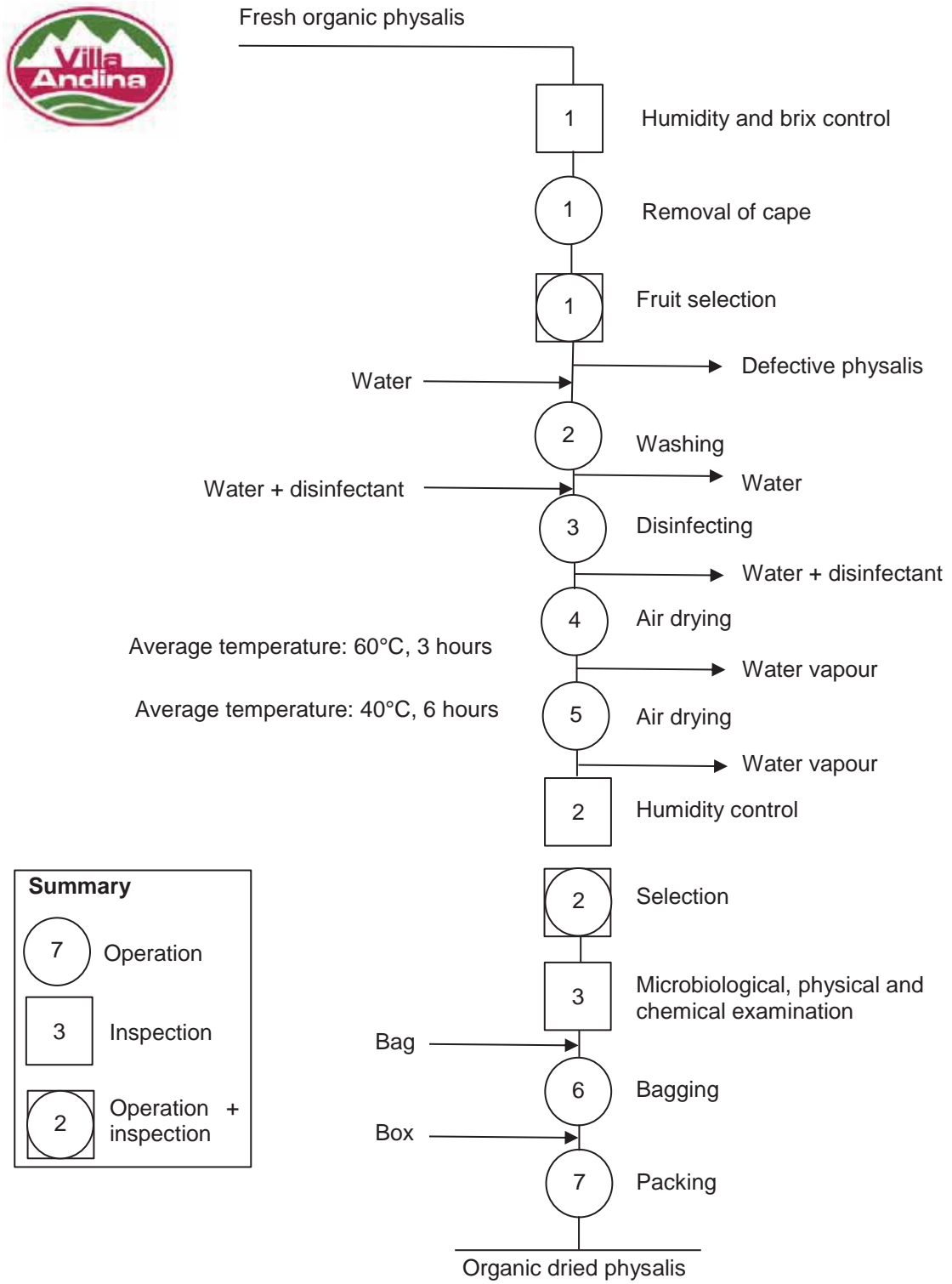
Before the whole fruits are dried down to a soft, wrinkled raisin-like appearance, the fresh fruits are dehusked either by hand or by mechanical means. After dehusking the fruits are washed, sorted and dried with low heat until reaching a moisture level of between 8% and 14% depending on the customer's specification requirement.

1.2. Various processed forms for export market

Commercial forms: dried whole or cut golden berries packed in vacuum sealed NY-LDPE bags; fresh whole golden berries with husks; fresh golden berries without husks packed in clamshell containers; fresh whole golden berries instant quick frozen (IQF) (Brix at 20°C: 12-15); fresh golden berry juice packed in tetra pack containers; fresh golden berry juice concentrate; fresh golden berry jam; various extracts for use in cosmetic and food products.

As an example, one Peruvian processor and exporter of golden berries provides a flow chart downloadable from their website. Figure 1 shows the flowchart of the company Villa Andina for their dried certified organic golden berries.

Figure 1. Villa Andina dried organic physalis flowchart



2. Peruvian mesquite – flour

2.1. Processing and technology

For certified organic production, the whole fruit pods are washed with a natural ascorbic acid containing disinfectant solution and selected and sorted by manual means (visual inspection) and mechanical means in order to remove defects. Before grinding, the selected pods are dried for 4 to 6 hours at 60°C spread out in thin layers on oven trays in forced-air tunnel dryer. The dried pods are milled and different fractions are separated using sieving and gravity separation, for example the exocarp and mesocarp (pulp) making up about 56% of the weight, the endocarp (pit) about 35% and the seeds about 9% of the weight. The pulp fraction is subjected to further particle size reduction for the production of bread flours, soluble instant powders, coffee substitutes, dietary fibre powders, etc., for example to 40 mesh, 60 mesh, 80 mesh or 100 mesh particle size, depending on the customer's physical characteristic specification requirement.

One of Peru's main processors and exporters of Peruvian mesquite flour, Algarrobos Orgánicos del Perú, provides an informative video in their website showing the various processing steps from whole pod to fine powder: <http://www.algarrobosorganicos.pe/videos.html>.

A very useful downloadable presentation by Gastón Cruz, Universidad de Piura, entitled 'La Algarrobina en el Perú – Experiencias de Comercialización, Innovación y Biocomercio' is available online.¹⁴

2.2. Various processed forms for export market

Commercial forms: Flour for use as a bakery ingredient; Toasted powder for use as a coffee substitute; Instant soluble powder for mixing in smoothies or other drinks or as topping in yoghurts or dips.

3. Sacha inchi – seed and oil

3.1. Processing and technology

Different methods and technologies for obtaining the fatty oil of sacha inchi seeds are used by different companies for different reasons, for example hydraulic expeller pressing and cold pressing. Oil is also expeller pressed from the seedcake that is produced from the first pressing. There are measurable differences in the yields, qualities and grades between the oils processed by the different technologies. There are markets for the different grades and there is a Peruvian standard that defines the grades and qualities with the required test methods for verifying compliance with the standard.

3.2. Various processed forms for export market

3.2.1. Sacha inchi seed

The whole raw, roasted or toasted oleaginous seed obtained from the star-shaped fruit of *Plukenetia volubilis* L. or *Plukenetia huayllabambana* sp. nov., characterized by its content of omega fatty acids.

3.2.2. Sacha inchi seedcake

'Plukenetia Volubilis Seedcake' is the residue obtained from the expression of oil from the seeds of *Plukenetia volubilis*, which is used in cosmetic products for skin conditioning (maintains the skin in good condition) function.

14 Cruz, G. (2011) La Algarrobina en el Perú – Experiencias de Comercialización, Innovación y Biocomercio. 1er Congreso de la Algarroba de Ibiza. Junio 2011. Available from: http://www.ceav.eu/garrova/images/Con_garrova/Docs/Ponencias/GASTON%20CRUZ-%20La%20algarrobina%20en%20el%20peru.%20experiencia%20y%20comercializacion.pdf

3.2.3. Sacha inchi seedcake extract

'Plukenetia Volubilis Seedcake Extract' is the extract of the seedcake of *Plukenetia volubilis*, which is used in cosmetic products for skin conditioning (maintains the skin in good condition) function.

3.2.4. Sacha inchi seed extract

'Plukenetia Volubilis Seed Extract' is the extract of the seeds of *Plukenetia volubilis*, which is used in cosmetic products for skin conditioning (maintains the skin in good condition) function.

3.2.5. Sacha inchi seed oil for cosmetic products

'Plukenetia Volubilis Seed Oil' is the oil expressed from the seeds of *Plukenetia volubilis*, which is used in cosmetic products for emollient, humectant and/or skin protectant functions:

- **Emollient:** Ingredients which help to maintain the soft, smooth, and pliable appearance of skin. Emollients function by their ability to remain on the skin surface or in the stratum corneum to act as lubricants, to reduce flaking, and to improve the skin's appearance.
- **Humectant:** Ingredients intended to increase the water content of the top layers of skin. This group of ingredients includes primarily hygroscopic agents employed for this specific purpose.
- **Skin protectant:** Substance that temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help to provide relief to such surfaces.

3.2.6. Sacha inchi seed oil, virgin and extra virgin

- **Oil of sachá inchi:** Fatty oil sachá inchi seeds of the genus *Plukenetia*, characterized by its high content of unsaturated fatty acids (omega 3, 6 and 9).
- **Virgin oil of sachá inchi:** Fatty oil of sachá inchi seeds obtained by mechanical means, for example, extrusion, pressing and other methods, whose % of free acidity (expressed as oleic acid) is a maximum of 2 g per 100 g (< 2.0 mg KOH/g). The oil may be purified by sedimentation, filtration and centrifugation. Excludes oils obtained by solvent extraction, chemical or biochemical action, or by re-esterification processes and excludes mixture with other oils.
- **Extra virgin oil of sachá inchi:** Fatty oil of sachá inchi seeds whose % of free acidity (expressed as oleic acid) is a maximum of 1 g per 100 g (< 1.0 mg KOH/g), extracted without the application of heat (cold pressed).

Chapter 3 Usage of ingredients

1. Golden berry – dried

1.1. Macro- and micronutrient content

Dried fruit: The following values are excerpted from the Nutrition Fact labels of selected packaged dried golden berry products of different origins that are available in the United States market. These nutrient content claims are presumed accurate but have not been verified by this author:

- **Colombia origin (NATIVAS NATURALS Brand):** per 28 g dried berries: calories 80, calories from fat 0, total fat 0 g (0% DV), saturated fat 0 g (0% DV), trans fat 0 g, cholesterol 0 mg (0% DV), sodium 25 mg (1% DV), total carbohydrates 17 g (6% DV), dietary fibre 3 g (12%), sugars 9 g, protein 2 g, vitamin A (45% DV), vitamin C (4% DV), calcium (0% DV), iron (6% DV).
- **Ecuador origin (OJIO Brand):** per 28 g dried berries: calories 100, calories from fat 5, total fat 0.5 g (1% DV), saturated fat 0 (0% DV), cholesterol 0 g (0% DV), sodium 10 mg (0% DV), total carbohydrates 22 g (7% DV), dietary fibre 7 g (28% DV), sugars 8 g, protein 2 g, lycopene 6.1 µg, vitamin A (10% DV), vitamin C (10% DV), calcium (2% DV), iron (4% DV).
- **Peru origin (PRANA Brand):** per 28 g dried berries: calories 82, fat 1 g (2% DV), saturated fat 0 g (0% DV), trans fat 0 g (0% DV), cholesterol 0 mg (0% DV), sodium 10 mg (0% DV), total carbohydrates 17 g (7% DV), dietary fibre 5.5 g (25% DV), sugars 8 g, protein 2 g, vitamin A (40% DV), vitamin C (4% DV), calcium (1% DV), iron (6% DV).
- **Undeclared origin (NOW FOODS Brand):** per 28 g (about 22 berries): calories 80, calories from fat 20, total fat 2 g (3% DV), saturated fat 0 g (0% DV), trans fat 0 g, cholesterol 0 mg (0% DV), sodium 0 mg (0% DV), potassium 510 mg (15% DV), total carbohydrates 17 g (6% DV), dietary fibre 5 g (20% DV), sugars 11 g, protein 2 g, vitamin A (45% DV), vitamin C (8% DV), calcium (0% DV), iron (4% DV).

Fresh fruit: Moisture 78.9-80.97%, ash 0.80-1.0 g/ 100 g, calories 76.8-88.72 kcal/100 g, carbohydrates 13.22-19.6 g/ 100 g, crude fibre 3.6-4.9 g/ 100 g, fat 0.0-0.2 g/ 100 g, total lipids 3.16 g/ 100 g, protein 0.3-1.9 g/ 100 g, aluminium 0.33 mg/ 100 g, barium 0.06 mg/ 100g, calcium 8.0-10.55 mg/100 g, carotene 1.6-2.64 mg/100 g, chromium 0.01 mg/ 100 g, cobalt 0.01 mg/ 100 g, copper 0.28 mg/ 100 g, iron 1.2-1.47 mg/100 g, magnesium 34.70 mg/ 100 g, manganese 0.26 mg/ 100 g, niacin 1.70 mg/ 100 g, phosphorus 37.9-55.3 mg/100 g, potassium 292.65-347.00 mg/100 g, riboflavin 0.03 mg/ 100 g, rubidium 0.42 mg/ 100 g, sodium 1.10 mg/ 100 g, strontium 0.04 mg/ 100 g, thiamine 0.1 mg/ 100 g, vitamin C 43.0-43.3 mg/100 g, zinc 0.4-0.49 mg/100 g (de Carrasco and Encina-Zelada 2008; Ramadan 2011; Rodrigues et al. 2009).^{15,16,17} Gutiérrez et al. (2007) reported ascorbic acid at 0.332 (±0.0262) mg per gram of sample as per HPLC method.¹⁸

1.2. Phytochemical content

Dried fruit: No quantitative data provided.

Fresh fruit: Ascorbic acid 43.3 ± 0.5 mg/100 g, carotenoids (*all-trans-β*-carotene comprises about 76.8% of total carotenoids, *9-cis-β*-carotene and *all-trans-α*-cryptoxanthin make up 3.6 and 3.4% respectively), fatty acids (mainly composed of linoleic 72.42%, oleic 10.03%, palmitic 9.38% and stearic 2.67%), hydroxyester disaccharides, steroidal lactones (withanolides), sterols (mainly campesterol and β-sitosterol

15 De Carrasco, RP and CR. Encina Zelada (2008). Determinación de la capacidad antioxidante y compuestos bioactivos de frutas nativas peruanas. Rev Soc Quím Perú. 74, N° 2 (108-124).

16 Ramadan, MF. (2011). Bioactive phytochemicals, nutritional value, and functional properties of cape gooseberry (*Physalis peruviana*): an overview. Food Research International; 44:1830-1836.

17 Rodrigues, E and others (2009). Minerals and essential fatty acids of the exotic fruit *Physalis peruviana* L. Ciência e Tecnologia de Alimentos. 29(3):642-645.

18 Gutiérrez, TM. and others. (2007). Determinación del contenido de ácido ascórbico en uchuva (*Physalis peruviana* L.) por cromatografía líquida de alta resolución (CLAR). Biotecnología en el Sector Agropecuario y Agroindustrial; 5(1):70-79.

in whole berry oil and seed oil and mainly Δ^5 -avenasterol and campesterol in pulp oil), phenolic compounds 154 ± 3 mg/ 100 g (gallic acid equivalent) (de Carrasco and Encina-Zelada 2008; Mayorga et al. 2002; Ramadan 2011; Rodrigues et al. 2009).¹⁹

1.3. Pharmacological actions

The scope of this section is limited to research carried out on the fruit or fruit preparations (e.g. juice). There are other studies, particularly from Asian researchers in China, India and Chinese Taipei involving the pharmacological actions of extracts of other plant parts, namely the calyces, leaves, leaves and stems, whole aerial parts and whole plant. That data cannot be generalized to the actions of the fruit.

In vitro experiments: Antioxidant capacity 729 ± 98 μ g equivalents of Trolox (TE) per gram of sample as determined by the DPPH [(1,1-diphenyl-2-picrylhydrazyl)] radical scavenging activity method but 1066 ± 28 μ g equivalents of TE per gram of sample using the ABTS [2, 20-azinobis (3-ethylbenzothiazoline-6-sulfonic acid)] radical scavenging assay (de Carrasco and Encina-Zelada 2008).

In vivo experiments: Experimental animals (*Mus musculus* var. *swis* males) that ingested orally administered golden berry dry extract experienced significant reductions ($p < 0.000$) in concentrations of both cholesterol and triglycerides (Campos et al. 2011).²⁰ Application of golden berry juice in eyes of rabbits suffering from pterygium (elevated, superficial, external ocular mass that forms over the perilimbal conjunctiva and extends onto the corneal surface) demonstrated anti-inflammatory and cytostatic effects using a novel rabbit eye inflammation model (Pardo et al. 2008).²¹

Human clinical trials: In a controlled comparative cross-over clinical trial involving 26 young adult volunteers (average age 25.03 ± 2.74 years, BMI 22.76 ± 1.48 kg/m²), oral ingestion of 25 g of fresh golden berries followed by a glucose challenge (40 minutes later) demonstrated that intake of golden berries significantly reduced postprandial glycaemia in young adults (Rodríguez and Rodríguez 2007).²²

1.4. Recommended uses supported by clinical or scientific data

Possible nutritional (food) uses:

- As a natural food source of vitamin C;
- As a natural food source of antioxidant vitamin C;
- A good source of dietary fibre;
- A good source of potassium;
- A good source of vitamin A.

Possible cosmetic (non-drug) uses:

- Extract of golden berry is used as a skin conditioning component of non-drug cosmetic products.

Possible medical (drug) uses:

- Orally ingested fruits for management or treatment of hyperglycaemia;
- Topical ophthalmic application of fruit juice preparations for adjunctive therapy in the treatment of pterygium and other eye diseases.

¹⁹ Mayorga, H and others (2002). Hydroxyester disaccharides from fruits of cape gooseberry (*Physalis peruviana*). *Phytochemistry*;59:439–445.

²⁰ Campos, J. and others (2011). Efecto del extracto del fruto de *Physalis peruviana* 'tomatillo' en *Mus musculus* var. *swis* con hiperlipidemia inducida. *Scientia Agropecuaria*; 2:83-89.

²¹ Pardo, JM. and others. (2008). Determining the pharmacological activity of *Physalis peruviana* fruit juice on rabbit eyes and fibroblast primary cultures. *Investigative Ophthalmology & Visual Science*; 29(7):3074-3079.

²² Rodríguez, S. and E. Rodríguez (2007). Efecto de la ingesta de *Physalis peruviana* (aguaymanto) sobre la glicemia postprandial en adultos jóvenes. *Rev. Med. Vallejiana*;4(1):44-53.

Notes on possible medical uses for golden berry preparations: For the marketing of drug products in the United States with the above listed medical uses the product would need to go through the Botanical Drug Review process in order to obtain marketing authorization from the U.S. Food and Drug Administration (FDA).²³ This was the pathway, for example, that was followed by an applicant that resulted in the FDA's 2012 approval of a *sangre de drago* drug product for treatment of diarrhoea.²⁴ Similarly for Canada, in order to market a product with these disease treatment claims statements, a product license application would need to be submitted to the Health Canada Natural Health Products Directorate (NHPD) in order to obtain marketing authorization and issuance of a Natural Product Number (NPN).²⁵

1.5. Recommended uses supported by traditional use evidence

According to Peru Biodiverso information, golden berry preparations are traditionally used in Peru for the relief of throat problems and as an antitussive (cough suppressant), as well as for treating asthmatic conditions, intestinal parasites, jaundice, dermatitis, menopausal conditions and rheumatism.

1.6. New uses described in patents

Treatment of gastric ulcers: There is a Chinese patent for an orally administered medicament for the treatment of gastric ulcers. The medication contains extract of *Physalis peruviana* in combination with extracts of various traditional Chinese medicinal plants such as Chinese skullcap root (*Scutellaria baicalensis*), lycium (goji) berries (*Lycium barbarum*) and long pepper fruit (*Piper longum*) among others (Zhang et al. 2011).²⁶

Treatment of pterygium: There is a Chinese patent for a topical ophthalmic medicament for the treatment of various eye diseases, suitable for use in patients with pterygium, cataracts, floaters and glaucoma. The medication contains extract of *Physalis peruviana* in combination with extracts of various traditional Chinese medicinal plants such as cao xue jie rhizome (*Polygonum paleaceum*), Chinese skullcap root (*Scutellaria baicalensis*) and coptis rhizome (*Coptis* spp.) among others, combined with non-botanical ingredients such as amber, dried alum, borax, sal ammoniac and calamine (Wang 2011).²⁷

Bleaching agent: There is a Japanese patent for a bleaching agent which claims to have a melanine production-inhibiting effect and a tyrosinase activity-inhibiting effect. The bleaching agent is characterized by containing an extract of one or more of the following plants: *Physalis peruviana*, *Physalis pruinosa* and *Physalis philadelphica* (Asami and Kazuhisa).²⁸

Cleansing and moisturizing cosmetic formula: There is a Japanese patent for a cosmetic composition, bath preparation or cleansing composition containing moisturizing plant ingredients claiming to exert a sustainable moisturizing effect and demonstrate efficacy on the skin in terms of the prophylaxis, mitigation or amelioration of dryness, rough skin, chap, dandruff, itch and inflammatory diseases, and on the hair, in terms of dryness, split hair, cut hair, glossing, etc. The cosmetic composition, contains extracts from at least one of the following botanicals: *Physalis peruviana*, *Physalis ixocarpa*, *Physalis minima*, *Genipa americana*, *Polakowskia tacaco*, *Sicana odorifera*, *Spondias purpurea*, *Garcinia atroviridis*, *Mammea americana*, *Diospyros ebenaster*, *Averrhoa bilimbi*, *Lansium domesticum*, *Lansium domesticum var. duku*, *Passiflora antioquiensis*, *Passiflora mollissima*, *Cyphomandra betacea*, *Solanum quitoense*, *Carica*

23 U.S. Food and Drug Administration (FDA). Botanical Drug Review. Available from: <http://www.fda.gov/Drugs/Development/ApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/BotanicalDrugReview/default.htm>

24 U.S. Food and Drug Administration (FDA). (2012) FDA approves first anti-diarrheal drug for HIV/AIDS patients. Silver Spring, MD: FDA. Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333701.htm>

25 Health Canada Natural Health Products Directorate (NHPD). Guidance Documents. Available at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/index-eng.php>

26 Zhang, B. (2011). Chinese medicinal composition for treating gastric ulcer and preparation method thereof. Chinese Patent: CN101810730 (A).

27 Wang, X. (2011). Toxicant elimination medicament for eyes. Chinese Patent: CN101869631(A).

28 Asami, Y. and M. Kazuhisa (2011). Bleaching agent. Japanese Patent: JP2011051920 (A).

pentagona, *Crataegus mexicana*, *Crataegus pubescens*, *Prunus capuli*, *Pachira aquatica*, *Myrciaria cauliflora*, *Casimiroa edulis*, *Periandra mediterranea*, and kiwano (Mitsuharo et al. 2001).²⁹

2. Peruvian mesquite – flour

2.1. Macro- and micronutrient content

Pulp (obtained from exocarp and mesocarp): Ash (36.0-36.7 g/kg dry matter), calories (3622.9 kcal/kg), dietary fibre [(insoluble dietary fibre (IDF) 231.4-306.0 g/kg, soluble dietary fibre (SDF) 16.2-25.7 g/kg, total dietary fibre (TDF) 257.1-322.2 g/kg)], total carbohydrates (826.0 g/kg), soluble sugars (539.5 ± 0.43 g/kg), total starch (8.4 ± 0.19 g/kg), protein (40.1-81.1 g/kg), fat (7.1-7.7 g/kg). reducing sugars (glucose, fructose, xylose, arabinose, galactose) (21.4 g/kg), sucrose (46.35 g/kg), total sugars (484.9 ± 25.6 g/kg), pectin (8.0 g/kg) (Bravo et al. 1998),³⁰ calcium (0.759-0.8 g/kg), copper (trace), iron (0.33 g/kg), magnesium (0.904 g/kg), manganese (trace), potassium (26.5 g/kg), sodium (1.13 g/kg), zinc (trace), vitamin A (not detected), vitamin E (5 mg/kg), vitamin B1 (1.9 mg/kg), vitamin B2 (0.6 mg/kg), vitamin B6 (2.35 mg/kg), nicotinic acid (31 mg/kg), vitamin C (60 mg/kg), folic acid (0.18 mg/kg), calcium pantothenate (10.5 mg/kg) (Choge et al. 2007; Grados and Cruz 1996; Grados et al. 1994; Prokopiuk et al. 2000).^{31,32,33,34}

2.2. Phytochemical content

Pulp (obtained from exocarp and mesocarp): Polyphenols [catechins (1.2-1.8 g/kg), condensed tannins (2.6-4.1 g/kg), total soluble polyphenols (8.2-12.4 g/kg)] (Bravo et al. 1998; Grados and Cruz 1996; Grados et al. 1994); volatile constituents in the flour [(5,6-dihydro-6-propyl-2H-pyran-2-one: 59.75 ± 7.07 mg/kg)] (Takeoka et al. 2009).³⁵

2.3. Pharmacological actions

In vitro experiments: An ethanolic extract of *Prosopis pallida* demonstrated antibacterial activity against *Staphylococcus aureus* (Bussmann et al. 2010).³⁶ Algarrobo has shown significant ACE (angiotensin-converting-enzyme) inhibitory activities reflecting antihypertensive potential. These in vitro results point to a potential use of Peruvian mesquite fruit preparations as a food-based strategy for complementing effective antidiabetes and antihypertension solutions based on further animal and clinical studies (Pinto Mda et al. 2009).³⁷

In vivo experiments: No information available.

Human clinical trials: No information available.

29 Mitsuharo and others (2001). Cosmetic composition containing moisturizing plant extract. Japanese Patent: JP2001122731 (A).

30 Bravo, L. and others (1998). Characterization of syrups and dietary fiber obtained from mesquite pods (*Prosopis pallida* L.). J. Agric. Food Chem.;46:1727-1733.

31 Choge, SK. and others. (2007). *Prosopis* pods as human food, with special reference to Kenya. Water SA.;33(3):419-424.

32 Grados, N. and G. Cruz (1996). New approaches to industrialization of algarrobo (*Prosopis pallida*) pods in Peru. In: Felker P, Moss J (eds). Proceedings: 'Prosopis: semiarid fuel Wood and forage tree, building consensus for the disenfranchised'. Washington, D.C.: Texas A&M University, Kingsville.

33 Grados, N., L. Bravo and F. Saura-Calixto (1994). Estudio comparativo entre algarroba peruana (*Prosopis pallida*) y Mediterránea (*Ceratonia siliqua*). Boletín de la Sociedad Química del Perú;60:103-117.

34 Prokopiuk, D., G. Cruz and others. (2000). Estudio comparativo entre frutos de *Prosopis alba* y *Prosopis pallida*. Multequina;9:35-45.

35 Takeoka, GR. and others (2009). Identification of 5,6-dihydro-6-propyl-2H-pyran-2-one as the major volatile constituent in mesquite (*Prosopis*) flour. Food Chemistry;115:1025-1027.

36 Bussmann, RW., A. Glenn and D. Sharon (2010). Antibacterial activity of medicinal plants of Northern Peru – can traditional applications provide leads for modern science? Indian Journal of Traditional Knowledge;9(4):742-753.

37 Pinto, Mda S and others (2009). Evaluation of antihyperglycemia and antihypertension potential of native Peruvian fruits using in vitro models. J Med Food;12(2):278-291.

2.4. Recommended uses supported by clinical and scientific data

Possible nutritional (food or dietary supplement) or 'medical food' uses:

- As a nutritive tonic;
- As a functional gluten-free flour or powder ingredient suitable for use in raw foods, vegan foods and gluten-free foods;
- As a medical food ingredient suitable for patients with diabetes and hypertension.

2.5. Recommended uses supported by traditional use evidence

Syrup made from aqueous decoction of Peruvian mesquite fruit and seeds traditionally used in Peru for respiratory disorders (bronchitis and cough) (Bussmann and Glenn 2010).³⁸

2.6. New uses described in patents

Cosmetic composition for moisture retention: There is a Japanese patent for a cosmetic, bath and detergent composition including a vegetable constituent having lasting moisture-retaining property which effectively prevents, decreases or improves conditions of drying, skin roughening, cracks on a skin, capped skin, scurf, pruritus or inflammatory disease to skin and hair such as drying, crumbling, split hair, broken hair, gloss imparting, etc. The composition contains one or more extracts of the following botanicals: Algarrobo (*Prosopis pallida*), Cupuazu (*Theobroma grandiflorum*), Maca (*Lepidium meyenii*), Molle (*Schinus molle*), Yacon (*Polymnia sonchifolia*), Aguaje (*Mauritia flexuosa*), Achira (*Canna edulis*), Huito (*Genipa americana*), Oca (*Oxalis tuberosa*), Olluco (*Ullucus tuberosus*), Kanihua (*Chenopodium pallidicaule*), Tarwi (*Lupinus mutabilis*) and Mashua (*Tropaeolum tuberosum*) (Masako et al. 2000).³⁹

3. Sacha inchi – seed and oil

3.1. Macro- and micronutrient content

Seed: Moisture (%) 3.3 ± 0.3 , fat (%) 42.0 ± 1.1 , protein (%) 24.7 ± 0.5 , ash (%) 4.0 ± 0.7 , total carbohydrate (%) 30.9 ± 0.6 , potassium (mg/kg) 5563.5 ± 6.4 , magnesium (mg/kg) 3210.0 ± 21.2 , calcium (mg/kg) 2406.0 ± 7.1 , iron (mg/kg) 103.5 ± 8.9 , zinc (mg/kg) 49.0 ± 1.1 , sodium (mg/kg) 15.4 ± 0.5 , copper (mg/kg) 12.9 ± 0.3 (Gutiérrez et al. 2011).⁴⁰

According to Hamaker et al. (1992), total protein 27% of which total amino acids (TAA) (976 mg / g of protein), total essential amino acids (TEAA) (411 mg /g of protein); histidine 26 mg /g protein, isoleucine 50 mg /g protein, leucine 64 mg / g protein, lysine 43 mg /g protein, methionine 12 mg /g protein, cysteine 25 mg /g protein, phenylalanine 24 mg /g protein, tyrosine 55 mg /g protein, threonine 43 mg /g protein, tryptophan 29 mg / g protein, valine 40 mg /g protein; nonessential amino acids: alanine 36 mg / g protein, arginine 55 mg / g protein, aspartic acid 111 mg /g protein, glutamic acid 133 mg /g protein, glycine 118 mg / g protein, proline 48 mg /g protein, serine 64 mg /g protein (Hamaker et al. 1992).⁴¹

38 Bussmann, RW. and A. Glenn (2010). Medicinal plants used in Peru for the treatment of respiratory disorders. Rev. peru. Boil.;17(2):331-346.

39 Masako and others (2000). Cosmetic composition including vegetable extract having moisture retaining property. Japanese Patent: JP2000319120 (A).

40 Gutiérrez, LF, LM. Rosada and A. Jiménez (2011). Chemical composition of Sacha Inchi (*Plukenetia volubilis* L.) seeds and characteristics of their lipid fraction. Grasas y Aceites. 62(1):76-83.

41 Hamaker, BR. and others (1992). Amino acid and fatty acid profiles of the Inca Peanut (*Plukenetia volubilis*). Cereal Chemistry. 1992;69(4):461-463.

3.2. Phytochemical content

Seed: The presence of secondary metabolites occurring in sacha inchi seed has been determined qualitatively indicating presence of saponins (abundant) and coumarins (moderate) in the seed and alkaloids (abundant) in both the aqueous and ethanolic extracts of the seed (Pariona-Mendoza 2008).⁴²

Seedcake: Phenolic compounds determined by HPLC method (caffeic acid 3.51 mg/kg, ferulic acid 1.68 mg/kg, rutin 42.93 mg/kg, hesperidin 28.46 mg/kg, morin 53.24 mg/kg) (Muñoz Jáuregui et al. 2010).⁴³

Fatty oil: Unsaturated fatty acids: oil of *Plukenetia volubilis* (oleic min. 8.9%, linoleic min. 32.1% and linolenic min. 44.7%); oil of *Plukenetia huayllabambana* (oleic min. 7.9%, linoleic min. 24.0% and linolenic min. 55.0%) (INDECOPI 2009).⁴⁴ Saturated fatty acids: oil of *Plukenetia volubilis* (myristic 0.0%, palmitic 4.4-4.5%, stearic 2.4-3.2%) (Gutiérrez et al. 2011; Hamaker et al. 1992). Triacylglycerol's (TAG); the predominant TAG components (>50%) have been identified as dilinolenoyl-linoleoylglycerol (LnLLn), dilinoleoyl-linolenoylglycerol (LLnL), and trilinolenin (LnLnLn) (Fanali et al. 2011).⁴⁵

Tocopherols (both *Plukenetia* species) min. 1900 mg/kg (gamma and delta tocopherols) (INDECOPI 2009); according to Fanali et al. (2011) α -tocopherol 0.004 g/kg, γ -tocopherol 1.257 g/kg and δ -tocopherol 0.869 g/kg Sterols (stigmasterol 75.49 mg/100g, beta-sitosterol 74.62 mg/100g) (Muñoz Jáuregui et al. 2010).

Total phenolic compounds: 6.20 mg/100 g of oil expressed as gallic acid equivalents (GAEs) as determined by Folin Ciocalteu method. Twenty-one phenolic compounds were detected; among them, 15 belonging to phenyl alcohol, flavonoid, seicoridoid, and lignan classes, were positively identified; Phenyl alcohols: hydroxytyrosol, tyrosol; Isocoumarins: bergenin; Flavonoids: alpinumisoflavone, phloretin-glucoside, isorhamnetin-glucoside, luteolin, apigenin; Secoiridoids: methyl decarboxymethyl oleuropein aglycon, oleuropeic acid, oleuropein aglycon; Lignans: pinoresinol, syringaresinol, hydroxy-pinoresinol; Organic acids: azaleic acid (Fanali et al. 2011).

3.3. Pharmacological actions

In vitro experiments: Antioxidant activity of sacha inchi oil was determined by ABTS method and DPPH method. The results showed that the lipophilic extract oil had higher antioxidant activity and showed a greater inhibitory capacity with DPPH method, however, the hydrophilic extract of the oil showed greater activity with the ABTS method (Muñoz Jáuregui et al. 2010).

In vivo experiments: A study was carried out to evaluate the oral toxicity at 60 days and to determine the lethal dose 50 (LD50) of raw sacha inchi (*Plukenetia volubilis*) and linseed (*Linum usitatissimum*) oils in rats and mice. The serum parameters in the rats indicated there is no toxicity at 60 days and that the administration of the oils lowered the levels of cholesterol, triglycerides and increased the HDL in comparison with the control group. The LD50 shows that the raw sacha inchi and linseed oils have doses above 37 g/kg of body weight. The researchers concluded that sacha inchi and linseed oils are harmless at 60 days and present a LD50 above the 37 g/kg of animal (Gorriti et al. 2010).⁴⁶

Human clinical trials: In a randomized controlled clinical trial involving 28 healthy young adult volunteers (medical students between 18 and 25 years old), the experimental group ingested 30 g per day of sacha inchi seeds (*Plukenetia volubilis*) for 6 weeks. The results of this study showed that daily ingestion of sacha inchi seeds may reduce triglyceride, total cholesterol, and LDL cholesterol, and increase HDL cholesterol

42 Pariona-Mendoza, N. (2008). Tesis: Obtención de los ácidos grasos del aceite de la *Plukenetia volubilis* L. 'Sacha Inchi' para la utilización en la industria y estudio fitoquímico cualitativo de la almendra. Universidad Nacional Mayor de San Marcos.

43 Muñoz Jáuregui, A. and others (2010). Evaluación del contenido de fitoesteroles, compuestos fenólicos y métodos químicos para determinar la actividad antioxidante en semilla de sacha inchi (*Plukenetia volubilis* L.). *Rev Soc Quím Perú*;76(3):234-241.

44 INDECOPI (Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual). (2009). Norma Técnica Peruana NTP 151.400 2009. Aceite de Sacha Inchi. Requisitos, 1ª Edición. Lima, Perú: INDECOPI.

45 Fanali, C. and others (2011). Chemical characterization of Sacha Inchi (*Plukenetia volubilis* L.) oil. *Journal of Agricultural and Food Chemistry*;59:13043-13049.

46 Gorriti, A. and others (2010). Toxicidad oral a 60 días del aceite de sacha inchi (*Plukenetia volubilis* L.) y linaza (*Linum usitatissimum* L.) y determinación de la dosis letal 50 en roedores. *Rev. peru. med. exp. salud pública*;27(3):352-360.

levels in young adults. The researchers suggest that further studies in populations of patients with dyslipidaemia should be carried out (Huamán et al. 2012).⁴⁷

In a pilot, experimental, open label study the effect, effective dosage and secondary effects of sacha inchi (*Plukenetia volúbilis* L) oil on the lipid profiles of patients with hypercholesterolemia (type IIa and type IIb) was investigated. The study included 24 patients (ages 35 to 75) whose total cholesterol (TC), HDL, triglycerides (Tg), glucose (G), nonesterified fatty acids (NEFA) and insulin (I) levels in blood were measured at baseline. The volunteers were then randomized to receive 5 ml or 10 ml of a suspension of sacha inchi oil (2gr/5ml) orally for four months. After four months, the oil intake produced a decrease in the mean values of TC, and NEFA, and a rise in HDL in both subgroups. The subgroup receiving 10 ml was associated with an increase in insulin levels. In this small study, daily use of sacha inchi oil appeared to have beneficial effects on the lipid profile of patients with dyslipidaemia, but their efficacy and security should be evaluated in randomized clinical trials (Garmendia et al. 2011).⁴⁸

To investigate plasma lipids reduction, in a randomized controlled clinical trial involving 12 healthy young adult volunteers (medical students between 18 and 25 years old), the experimental group ingested 50 g of sacha inchi seeds. This study found that consumption of sacha inchi seeds resulted in a statistically significant decrease in postprandial triglyceride levels in young adults (Huamán et al. 2008).⁴⁹

Patent claims: Topical application of fatty oil preparations: antipruritic, anti-inflammatory, dermatological, antiallergic and anti-seborrheic (Berthon 2006).⁵⁰

3.4. Recommended uses supported by clinical and scientific data

Possible cosmetic uses (oil):

- Emollient: Helps to maintain the soft, smooth, and pliable appearance of skin. Emollients function by their ability to remain on the skin surface or in the *stratum corneum* to act as lubricants, to reduce flaking, and to improve the skin's appearance;
- Humectant: Increases the water content of the top layers of skin. This group of ingredients includes primarily hygroscopic agents employed for this specific purpose;
- Skin protectant: Temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help to provide relief to such surfaces.

Possible nutritive (food or dietary supplement) uses:

- Helps maintain cholesterol levels that are already within normal range;
- Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease.

Possible medical (drug) uses:

- For management or treatment of dyslipidaemia or hyperlipidaemia.

47 Huamán Saavedra, J.J. and others.(2012). Efectos de la ingesta de *Plukenetia volubilis* Linneo o 'Sacha inchi' en el perfil lipídico de adultos jóvenes. *Acta Med Per*; 29(3):155-160.

48 Garmendia, F., R. Pando and G. Ronceros (2011). Efecto del aceite de sacha inchi (*Plukenetia volúbilis* L) sobre el perfil lipídico en pacientes con hiperlipoproteinemia. *Rev Peru Med Exp Salud Publica*; 28(4):628-32.

49 Huamán, J.J. and others (2008). Efecto de la *Plukenetia volubilis* Linneo (sacha inchi) en la trigliceridemia posprandial. *Anales de la Facultad de Medicina*; 69(4):263-236.

50 Berthon, J.Y. (2006). Use of oil or proteins extracted from *Plukenetia volubilis* seed as an active ingredient in the preparation of cosmetic composition or dermatological product e.g. as skin and hair care product. Patent FR2880278 (A1).

Notes on possible medical uses for sacha inchi preparations: For the marketing of drug products in the United States with the above listed medical uses the product would need to go through the Botanical Drug Review process in order to obtain marketing authorization from the FDA.⁵¹ This was the pathway, for example, that was followed by an applicant that resulted in the FDA's 2012 approval of a *sangre de drago* drug product for treatment of diarrhoea.⁵² Similarly for Canada, in order to market a product with these disease treatment claims statements, a product license application would need to be submitted to the Health Canada Natural Health Products Directorate (NHPD) in order to obtain marketing authorization and issuance of a Natural Product Number (NPN).⁵³

3.5. Recommended uses supported by traditional use evidence

The primary traditional use of sacha inchi is as food. The seeds are consumed toasted, as a component of typical foods of Peruvian region where the plant grows such as Ichi cucho (ají de maní), inchicapi (chicken soup), tamales, cheese, snacks or salads, etc. Consumption of the raw seed as a purgative (laxative) in traditional medicine has also been recorded, but it is recommended to take no more than two raw seeds for this use (Flores 2010).⁵⁴

3.6. New uses described in patents

Topical permeation enhancer: There is an application for a United States Patent and international patent for a composition to be used as a permeation enhancer. The composition may be added to topical cosmetics or pharmaceutical formulations that are topically applied. The composition comprises pracaxi oil (*Pentaclethra macroloba*), sacha inchi seed oil (*Plukenetia volubilis*), pataua palm oil (*Oenocarpus bataua*), inaja palm oil (*Maximiliana maripa*), and one of more emollients (Banov and Bassani 2012).⁵⁵

Active ingredient of cosmetic or dermatological preparation: There is a French Patent for the use of oil or proteins extracted from sacha inchi seed (*Plukenetia volubilis*) as an active ingredient in the preparation of cosmetic composition or dermatological product. An independent claim is also included for extracts of *Plukenetia volubilis* seed comprising an extraction solvent (water, alcohols, ketones, esters, glycerol, non-polar solvents (preferably hexane or isopropyl myristate), vegetable oils, synthetic oily solvents, chlorinated ethers and/or polyols solvents) where at least two of the solvents are miscible. The claimed pharmacological activities are antipruritic, anti-inflammatory, dermatological, antiallergic and anti-seborrheic. The claimed mechanism of action is 'adipocyte differentiation inhibitor' (Berthon 2006).⁵⁶

Anti-aging cosmetic: There is a United States Patent for a cosmetic preparation which includes a skin care complex claimed to have an anti-ageing effect. The complex consists of liposomes comprising a mixture of cosmetic oil, extract of *Plukenetia volubilis* seeds, extract of *Cynara scolymus* leaves and hydrogenated retinol. The liposomes are homogeneously dispersed in a gel network consisting of water and a gel-forming agent (Golz-Berner and Zastrow 2011).⁵⁷

51 U.S. Food and Drug Administration (FDA). Botanical Drug Review. Available from: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/BotanicalDrugReview/default.htm>

52 U.S. Food and Drug Administration (FDA). (2012). FDA approves first anti-diarrheal drug for HIV/AIDS patients. Silver Spring, MD: FDA. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333701.htm>

53 Health Canada Natural Health Products Directorate (NHPD). Guidance Documents. Available from: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/index-eng.php>

54 Flores, D. (2010). Uso Histórico: Sacha Inchi - *Plukenetia volubilis* L. In: Base de Datos Proyecto Perubiodiverso. Información bibliográfica sobre Historia y Usos tradicionales de 3 Plantas seleccionadas. Lima, Peru: Proyecto Biocomercio Peru.

55 Banov, D. and A.S. Bassani (2012). Permeation enhancers for topical formulations. WIPO Patent Application WO2012109151 (A1).

56 Berthon, J.Y. (2006). Use of oil or proteins extracted from *Plukenetia volubilis* seed as an active ingredient in the preparation of cosmetic composition or dermatological product e.g. as skin and hair care product. Patent FR2880278 (A1).

57 Golz-Berner, K and L. Zastrow (2011). Cosmetic skin care complex with anti-aging effect. U.S. Patent 7,968,129. 2011.

Extract for cosmetic use: There is a European patent application for the cosmetic use of an extract of a plant preferably belonging to the genus *Plukenetia*. Furthermore it relates to the cosmetic use of a protein or a mixture of proteins, whereby said protein or said mixture of proteins is extractable from a plant belonging to the genus *Plukenetia*. Furthermore the invention relates to the extract, protein or mixture of proteins for use as a medicament (Moser et al. 2007).⁵⁸

Skin care lotion: There is a Chinese Patent for an omega-3 fatty acid oil skin care lotion and a preparation method thereof. The omega-3 fatty acid oil skin care lotion glycerine, deionized water, *Plukenetia volubilis* linneo omega-3 fatty acid oil, octyl and decyl glycerate, methyl glucoside sesquistearate, methyl glucoside PEG-20 sesquistearate and isopropyl myristate, and other ingredients. The patent claims that this omega-3 fatty acid oil skin care lotion can keep skin elasticity and moisture, promote skin to sufficiently absorb omega-3 fatty acid, keep sufficient moisture and nutrient of the skin, effectively protect the skin from being damaged by ultraviolet radiation, strengthen skin elasticity, improve the coarse, dark and lacklustre skin and make the skin youthful (Cai and Yang 2011).⁵⁹

New conjugated linoleic acids: There is a United States Patent for a new conjugated linoleic acids, a process for preparation thereof and method of use. The invention concerns the preparation and purification of conjugated linoleic acids from materials rich in alpha or gamma linoleic acids, namely a vegetable oil comprising linseed oil, *Plukenetia volubilis* oil, borage oil or a mixture thereof. The reaction produces a mixture containing a 1:1 ratio of 9Z, 11E, 15Z-octadecatrienoic acid and 9Z, 13E, 15Z-octadecatrienoic acid. The mixture can be purified up to 90% by liquid chromatography, crystallization or urea crystallization. The mixture of 1:1 9Z, 11E, 15Z-octadecatrienoic acid and 9Z, 13E, 15E, 15Z-octadecatrienoic acid have anticancerous activities (Galvez et al. 2008).⁶⁰

Blood-fat reducing dietary supplement: There is a Chinese Patent for a blood fat-reducing dietary supplement product and a preparation method thereof. The preparation contains red yeast rice extract, Pu-Er ripe tea extract (*Camellia sinensis*), *Plukenetia volubilis* linneo oil and beeswax, filled into soft capsules. The *Plukenetia volubilis* linneo oil is the main ingredient. The patent claims that by combining sacha inchi oil with red yeast rice extract, Pu-Er ripe tea extract and beeswax, the mixture demonstrates safe and effective blood fat reducing and antithrombotic effects (Cai et al. 2011a).⁶¹

Polypeptide oral liquid: There is a Chinese Patent for a *Plukenetia volubilis* polypeptide oral liquid. *Plukenetia volubilis* kernels are soaked with water and then ground into thick liquid to obtain *Plukenetia volubilis* protein emulsion; the hydrolysates of the protein emulsion which is subject to twice enzyme destructions is filtered by a filter cloth of 500 meshes to obtain the *Plukenetia volubilis* polypeptide liquid; the *Plukenetia volubilis* polypeptide liquid is cooled to room temperature, etc. The patent application claims that *Plukenetia volubilis* polypeptide oral liquid provides a new valuable way for development and utilization of the *Plukenetia volubilis*. Enzyme engineering technology is used to extract oligopeptide, polypeptide and other compounds in the *Plukenetia volubilis* kernels, and various nutrition constituents, such as dextrose, fructooligosaccharide, vitamin C and the like are added, thus enabling the oral liquid to be absorbed by human bodies and improving delivery value and digestibility and absorption of the protein (Cai et al. 2011b).⁶²

58 Moser, F. and others (2007). An extract of a plant belonging to the genus *Plukenetia volubilis* and its cosmetic use. WIPO Patent Application KR20070073873 (A).

59 Cai, Z.Q. and Q. Yang (2011). Omega-3 fatty acid oil skin care lotion and preparation method thereof. Chinese Patent CN101978942 (A).

60 Galvez, J.M. and others (2008). Conjugated linolenic acids and methods of preparation and purification and uses thereof. United States Patent 7,417,159.

61 Cai, Z.Q. and others (2011a). Blood fat-reducing health-care food and preparation method thereof. Chinese Patent CN101999652 (A). 2011a.

62 Cai, Z.Q. and others (2011b). *Plukenetia volubilis* polypeptide oral liquid. Chinese Patent CN101982197 (A).

Chapter 4 Analysis of the market environment

1. Main market segments (cosmetic, food, food supplement, medicinal)

1.1. Golden berry – dried

1.1.1. As cosmetic product ingredient

1.1.1.1. Canada

Extracts of golden berry are starting to be used as skin conditioning ingredients of some newly developed non-drug cosmetic products. The main labelling and marketing attributes of some Canadian cosmetic products containing extract of golden berry include:

- 100% natural with certified organic ingredients
- Cruelty free
- Gluten free
- Suitable for vegans
- Made in Canada.

Selected examples of non-drug cosmetic products in the Canadian market that contain golden berry extract as an ingredient include the following:

- **Dr. M. Emerald Professional Formulations:**
 - **Golden berries Natural Organic, Extra Moisturizing, BIO-active Antiaging Cream for Women:** contains *Butyrospermum parkii* (shea) butter, *Argania spinosa* (argan) oil, *Oenothera biennis* (black currant) seed oil, *Borago officinalis* (borage) seed oil, *Persea americana* (avocado) oil, triglycerides, alpha lipoic acid, hyaluronic acid, micromolecular silk amino acids, L-arginine, *Cucurbita pepo* (pumpkin) peptides, *Avena sativa* (oat) beta glucans, *Physalis peruviana* (golden berries) extract, *Cucumis sativus* (cucumber) extract, *Carica papaya* (papaya) extract, chrysanthemum extract, caprylic acid / potassium sorbate, glycerine, full spectrum tocopherol (natural vitamin E): <http://www.thenaturalbeautystore.com/Goldenberries-Organic-Extra-Moisturizing-BIO-active-Anti-aging-cream-for-women.html>
 - **Golden berries Super Anti-Aging Stick:** contains *Butyrospermum parkii* (shea) butter, *Argania spinosa* (argan) oil, *Oenothera biennis* (black currant) seed oil, *Borago officinalis* (borage) seed oil, *Persea americana* (avocado) oil, triglycerides, alpha lipoic acid, hyaluronic acid, micromolecular silk amino acids, L-arginine, *Cucurbita pepo* (pumpkin) peptides, bayberry wax, *Avena sativa* (oat) beta glucans, *Physalis peruviana* (golden berries) extract, *Cucumis sativus* (cucumber) extract, *Carica papaya* (papaya) extract, chrysanthemum extract, caprylic acid / potassium sorbate, glycerine and natural vitamin E: <http://www.thenaturalbeautystore.com/Goldenberries-Super-Anti-Aging-Stick.html>

1.1.1.2. United States

It is possible that extracts of golden berry are being used as skin conditioning ingredients of some natural cosmetic products in the United States. No products were identified however during this research.

1.1.2. As food product ingredient

1.1.2.1. Canada

It is mainly packaged dried golden berries or chocolate covered dried golden berries labelled and marketed as healthy snack foods that are beginning to appear in the Canadian market. The main attributes for labelling and marketing include:

- Nutrient content claims;
- Certified organic;
- Non-GMO;
- Gluten free (wheat free);
- Raw food;
- Suitable for vegans and vegetarians.

Examples of conventional food products in the Canadian market that contain dried golden berry as an ingredient include the following:

- **Level Ground Trading Direct Fair Trade Golden Berry:** contains organic dried golden berries obtained from Fruandes, a Fair Trade organization operating out of Bogotá, Colombia: <http://www.levelground.com/origins/fruit/>
- **Health Matters Organic Chocolate Covered Golden Berries:** contain organic dried golden berries, dark chocolate and yacon syrup: <http://advantagehealthmatters.com/en/P-AHM266/Org-Chocolate-Covered-Golden-Berries-150g-%c2%b0.aspx>
- **Organic Traditions Organic Chocolate Covered Golden Berries:** contain organic dried golden berries, dark chocolate and yacon syrup: <http://www.advantagehealthmatters.com/en/P-AHM263/Org-Chocolate-Covered-Golden-Berries-100g-%c2%b0.aspx>
- **Organic Traditions Organic Golden Berries:** contains organic dried golden berries: <http://healthmattersamerica.com/Products/260-golden-inca-berries.aspx>
- **Prana Organic Golden berries:** contains organic dried golden berries from Peru: <http://prana.com/en/products/organic-goldenberries-physalis/>
- **Rainforest Herbal Products Golden Berries:** contain dried golden berries from Peru: <http://www.rainforestproduct.com/goldeninfo.html>

1.1.2.2. United States

Golden berries are beginning to show up in a range of natural products in the United States market including packaged dried golden berries and chocolate covered dried golden berries as well as products containing golden berries as a main ingredient, for example breakfast cereals and granolas, chocolate bars, biscotti breads, cookies and trail mixes. These healthy food products are, for the most part, labelled and marketed with main attributes including:

- Nutrient content claims (good source of vitamin A, vitamin C and dietary fibre);
- Certified organic;
- Non-GMO Project Verified;
- Gluten free (wheat free);
- Raw food;
- Suitable for vegans and vegetarians.

Front of pack pictures of selected golden berry food products marketed in the United States are shown in figure 2. Examples of conventional food products in the United States market that contain golden berry as an ingredient include the following:

- **Agi's Raw Foods Wake Up Time Cereal:** contains organic barley, organic sunflower seed, sliced almond, currant, organic raisin, organic goji berry, organic golden berry and cardamom seed: <http://www.agisrawfoods.com/products.php?category=4>
- **Coco Keeno Coco Goldrush:** contains organic dried golden berry, fairtrade and organic cocoa mass, fairtrade and organic sugar, fairtrade and organic cocoa butter, fairtrade and organic cocoa powder and organic tapioca maltodextrin: <http://wonderfoodco.com/index.php/2011-08-04-23-47-02/coco-keeno/item/113-coco-goldrush>
- **Coco Keeno Rainforest Delight:** contains fairtrade and organic sugar, fairtrade and organic cocoa mass, fairtrade and organic cocoa butter, organic dried pineapple, organic dried golden berry, organic dried mango, fairtrade and organic cocoa powder, organic tapioca maltodextrin and organic flavour powder mango: <http://wonderfoodco.com/index.php/2011-08-04-23-47-02/coco-keeno/item/122-rainforest-delight>
- **Endangered Species® Organic Dark Chocolate with Golden Berry and Lucuma:** contains 'non-GMO project verified' and certified organic dark chocolate (chocolate liquor, dried cane syrup, cocoa butter, soy lecithin, vanilla bean), golden berry and lucuma fruit powder: <http://chocolatebar.com/products.php?product=3oz.-Organic-Dark-Chocolate-with-Golden-Berry-and-Lucuma>
- **Extreme Health USA® Dark Chocolate Covered Golden Berries:** contain organic dried golden berries covered in organic dark chocolate: <http://www.extremehealthusa.com/products/48-dark-chocolate-covered-golden-berries.aspx>
- **Extreme Health USA® Raw Golden Berries:** contain organic dried golden berries: <http://www.extremehealthusa.com/products/47-raw-golden-berries.aspx>
- **Gnosis Chocolate Golden berry Jam:** contains 'Non-GMO Project Verified' and certified organic dried mulberries, dried golden berries, agave nectar, dried goji berries, pink Himalayan salt: <http://www.gnosischocolate.com/goldenberry-jam/>
- **Gopal's® Nature's Gift Raw Golden Berry Brazil Cookies:** contain organic brazil nuts, organic dates and organic dried golden berries: <http://gopalshealthfoods.com/goldenberry-brazil-cookies>
- **Kopali™ Organics Organic Golden berry:** contains organic dried golden berries: <http://kopali.net/products/fruits/goldenberry/>
- **Navitas Naturals Golden Berries:** contains dried organic dried golden berries from Colombia: <http://navitasnaturals.com/product/451/Goldenberries.html>
- **Navitas Naturals Golden Berry Powder:** contains freeze-dried powdered organic golden berries from Colombia: <http://navitasnaturals.com/product/526/Goldenberry-Powder.html>
- **Navitas Naturals Trail-3 Berry Cacao CashewTrail Mix:** contains cacao nibs, cashews, goji berries, golden berries and mulberries: <http://navitasnaturals.com/product/465/Trail-Mix-%283-Berry-Cacao-Nib-Cashew%29.html>
- **Now Foods® Organic Golden Berries:** contains organic dried golden berries: <http://www.nowfoods.com/Foods/Real-Food/Products/090391.htm>
- **Oh So Pure! Organic Chia Chips – IncaBerry:** contains certified organic chia seeds and hemp seeds, enzyme activated sprouted organic buckwheat and golden berries (Incaberry): <http://organicvegansuperfoods.com/products/oh-so-pure-organic-chia-chips-incaberry/>

- **Ojio™ Raw Wildcrafted Golden Berries:** contains organic dried golden berries from Ecuador: <http://ultimatesuperfoods.com/store/Products/Food/golden-berries/GOLBER?t=True>
- **RawONE Food Cacao Incan Berry Hazelnut Biscotti:** contains organic raw almonds, raw organic cacao, organic hazelnuts, organic dried golden berries, organic raw honey, organic citrus juice, organic bamboo and organic spices: <http://www.rawonefood.com/biscotti-cacao-incan-berry-hazelnut>
- **Sacha Vida Organic Chocolate Covered Golden berries:** contains organic dried golden berries and organic chocolate: http://89.44.200.101/alex/sacha_vida/wordpress/products/chocolate-covered-goldenberries/
- **Sacha Vida Organic Golden berries:** contains organic dried golden berries: http://89.44.200.101/alex/sacha_vida/wordpress/products/organic-goldenberries/
- **Sunburst Superfoods Organic Dried Golden berries:** contains non-GMO and organic dried golden berries from Peru: <http://www.sunburstsuperfoods.com/organic-dried-goldenberries/>
- **Sunfood® Superfoods Incan Golden Berries:** contains 'non-GMO project verified' and organic dried golden berries from Peru: <http://www.sunfood.com/food/incan-golden-berries/incan-berries-16oz-organic-raw.html>
- **Two Moms in the Raw – Golden berry Granola:** contains 'non-GMO project verified' and certified organic oats, millet, buckwheat, coconut, flaxseed, sunflower seeds, sesame seeds, pecans, almonds, petitas, apples, golden berries, agave, cinnamon bark and sea salt: <http://www.twomomsintheraw.com/products/goldenberry-granola-gluten-free>
- **Two Moms in the Raw – Golden berry Nut Bar:** contains 'non-GMO project verified' and certified organic almonds, pecans, walnuts, golden berries, agave, spices and sea salt: <http://www.twomomsintheraw.com/products/goldenberry-nut-bar-gluten-free>
- **YogaEarth™ Organic Golden berries:** contains organic dried golden berries: <http://www.yogaearth.com/shop/all-products/100-organic-goldenberries-eco-pack/>

Figure 2. Examples of golden berry food products in the United States



1.1.3. As food supplement ingredient

1.1.3.1. Canada

See section 1.1.4 (As medicinal product ingredient). Under Canadian Natural Health Product (NHP) regulations, dietary supplement or food supplement products are regulated as licensed NHPs as a subset of drug regulations.

1.1.3.2. United States

There are no known golden berry dietary supplement products (DSPs) in the United States market. Additionally a search for DSP notification letters, containing the key words 'golden' and 'berry' and/or 'Physalis' and 'peruviana', in the FDA website showed no results. It appears that most golden berry based products presently marketed in the United States are labelled as conventional food products. Some conventional food products may however make acceptable nutrient content claim statements if the golden berry serving size provides a sufficient percentage of the daily value (DV) of the claimed nutrient.

1.1.4. As medicinal product ingredient

1.1.4.1. Canada

As of the time of this report, there are no medicinal products containing golden berry as an ingredient listed in the Health Canada Licensed Natural Health Products Database (LNHPD). Furthermore, *Physalis peruviana* is not listed in the Health Canada Natural Health Products Ingredients Database (NHPID). Thus all golden berry containing products in the Canadian market at the time of this report would be either conventional food products (oral) or non-drug cosmetic products (topical).

1.1.4.2. United States

At the time of this of report, there are no over-the-counter (OTC) or prescription (Rx) drug products that contain any form of golden berry in the United States market.

Although none are known, it is conceivable that a homoeopathic preparation of golden berry could be used as an active ingredient of a homoeopathic drug product. Although there are homoeopathic dilutions of *Physalis peruviana* plant parts in the European market, none were identified in the United States market during this research.

1.2. Peruvian mesquite – powder

1.2.1. As cosmetic product ingredient

1.2.1.1. Canada

Peruvian mesquite powder is not known to occur as an ingredient of cosmetic products in Canada.

1.2.1.1. United States

Peruvian mesquite powder is not known to occur as an ingredient of cosmetic products in the United States.

1.2.2. As food product ingredient

1.2.2.1. Canada

Peruvian mesquite is beginning to show up in a range of natural products in the Canadian market including packaged dried powder and as a component of powder mixes such as smoothie mixes. These healthy food products are, for the most part, labelled and marketed with main attributes including:

- Nutrient content claims (excellent source of fibre, low glycaemic, low fat, good source of calcium, phosphorus, potassium and iron)
- Certified organic;
- Dairy free;
- Gluten free (wheat free);
- Non-GMO;

- Raw food;
- Suitable for vegans and vegetarians.

Examples of conventional food products in the Canadian market that contain dried Peruvian mesquite as an ingredient include the following listed products. Note that many United States products are also distributed and available in Canada. See the United States section for that list of products.

- **ECOFIELDS Mesquite Powder:** contains organic Peruvian mesquite powder: <http://www.ecofields.pe/en/products-mesquite.php>
- **Organic Lives Superfood Smoothie Mix:** contains heirloom Balinese cacao, Peruvian maca, tocotrienols, Peruvian lucuma and Peruvian mesquite: <http://organiclives.org/organic-food/superfoods/superfood-mixes>
- **Quinoa Peru Foods Mesquite Powder:** contains Peruvian mesquite powder: http://www.quinoaperufoods.com/Main/Product_Line.html
- **Rawganique Wild Raw Mesquite Powder:** contains raw mesquite pod meal: <http://www.rawganique.com/Food/wild-raw-mesquite-powder.htm>

1.2.2.2. United States

Peruvian mesquite is beginning to show up in a range of natural products in the United States market including packaged dried powder and as a component of cake and cookie mixes, flour mixes, smoothie mixes, breakfast cereals, chocolate bars, coated nut mixes, etc. These healthy food products are, for the most part, labelled and marketed with main attributes including:

- Certified gluten free (wheat free);
- Certified organic;
- Certified vegan or vegan verified;
- Dairy free;
- Earth Kosher;
- Non-GMO Project Verified;
- Nutrient content claims;
- Raw food.

For example, figure 3 shows the marketing of certifications for chocolate products containing Peruvian mesquite by Earth Source Organics, marketers of Righteously® Raw Cacao Bars, some containing Peruvian mesquite, with certifications including Certified Gluten Free, Certified Organic, Certified Vegan, Earth Kosher, Green America Approved Business, Non-GMO Project Verified and Vegan Verified.

Figure 3. Certifications used for marketing of Righteously® Raw Cacao Bars containing Peruvian mesquite



Front of pack pictures of selected Peruvian mesquite food products marketed in the United States are shown in figure 4. Examples of conventional food products in the United States market that contain Peruvian mesquite as an ingredient include the following:

- **Casa de Fruta® Mesquite Flour:** contains certified organic, gluten free and kosher mesquite flour made from the beans of trees from Argentina and Peru: <http://store.casadefruta.com/mesquite-flour-44-oz-p158.aspx>

- **Elite Green Protein™ Elite Mesquite:** contains spirulina, chlorella, mesquite pod, ginger rhizome, Nopal cactus, alfalfa grass juice, dandelion leaf juice, barley grass juice, oat grass juice, protease, amylase, lipase, cellulase, bromelain, papain and alpha-galactosidase: <http://healthforce.com/warrior-force/elite-green-protein-elite-mesquite>
- **Gnosis Chocolate Coco Almond Bar:** contains certified organic cacao beans, almonds, coconut, coconut palm sugar, Peruvian mesquite, maca root, stevia: <http://www.gnosischocolate.com/coconut-almond-raw-chocolate/>
- **Living Intentions Cacao Brownie Cake Mix:** contains sprouted flour (organic sprouted buckwheat, sprouted almonds, organic (Peruvian) mesquite pod powder, micro-fine white chia powder and agave inulin), organic cacao, organic coconut palm sugar, organic raw sun-dried cane juice crystals, organic coconut flour, organic coconut, raw brown rice bran and germ, organic maca powder, Himalayan crystal salt: <http://www.shop.livingintentions.com/product.sc?productId=104&categoryId=46>
- **Living Intentions Cacao Crunch Superfood Cereal:** contains organic buckwheat sprouts, organic coconut, organic coconut palm sugar, organic sunflower sprouts, cacao superfood blend (organic cacao powder, organic maca root, organic (Peruvian) mesquite pod powder, organic astragalus extract, and freeze-dried reishi mycelium), organic dates, organic raisins, raw brown rice bran and germ (grain free), cold milled organic golden flax meal, organic cacao butter, organic vanilla extract, and Himalayan crystal salt: <http://www.shop.livingintentions.com/product.sc?productId=53&categoryId=22>
- **Living Intentions Maple Mesquite Walnut:** contains sprouted organic walnuts, organic maple, organic (Peruvian) mesquite pod powder, organic cinnamon bark, Himalayan crystal salt and organic spices: <http://www.shop.livingintentions.com/product.sc?productId=25&categoryId=2>
- **Living Intentions Sprouted Super Flour:** contains sprouted organic buckwheat flour, sprouted almond meal, organic (Peruvian) mesquite pod powder, micro-fine white chia seed powder, and organic agave inulin: <http://www.shop.livingintentions.com/product.sc?productId=92&categoryId=46>
- **Love Raw Foods™ Mesquite Powder:** contains certified organic raw mesquite powder: <http://www.bluemountainorganics.com/by-type/superfoods/mesquite/mesquite-powder-6-oz>
- **Maca Picchu Smoothie Mix:** contains: Peruvian white carob, Kiwicha, Maca Magic™, quinoa, lucuma fruit, solcana, algarrobo, ground vanilla beans and vanilla powder: <http://www.herbdealer.com/macamart/proddetail.php?prod=FG00896>
- **Navitas Naturals Mesquite Powder:** contains certified organic raw Peruvian mesquite powder: <http://navitasnaturals.com/product/469/Mesquite-Powder.html>
- **Ojio™ Mesquite Powder:** contains certified organic raw mesquite powder: <http://ultimatesuperfoods.com/Store/Products/Food/mesquite/MESPOD/MSQO2O>
- **Righteously® Raw Goji Cacao Bar:** contains certified organic, 'Non-GMO Project Verified', raw cacao, goji berries, Himalayan pink salt, golden raisins, agave nectar, mesquite pod and vanilla beans: http://www.righteouslyrawchocolate.com/righteously-raw_goji_cacao-bar.php
- **Righteously® Raw Maca Bar:** contains certified organic, 'Non-GMO Project Verified', raw cacao, maca root, Himalayan pink salt, golden raisins, agave nectar, Bahri dates, coconut oil, mesquite pod and vanilla beans: http://www.righteouslyrawchocolate.com/righteously-raw_maca-bar_chocolate.php
- **Righteously® Raw Rawcholatl Cacao Spice Drink:** contains powders of cacao, mesquite pod meal, Aji Amarillo, Aji Panca, vanilla bean, cinnamon and allspice with coconut palm sugar and black sesame seeds: http://www.righteouslyrawchocolate.com/rawcholatl_cacao_spice_drink.php
- **Sunfood™ Organic Mesquite Powder:** contains certified organic, 'Non-GMO Project Verified', raw Peruvian mesquite powder: <http://www.sunfood.com/mesquite-meal-8oz-peru-organic-raw.html>

- **Wildbar® Mayan Spice:** contains organic cacao (cacao paste, cacao butter, whole cacao powder), organic dark blue agave nectar, organic macadamia nuts, organic (Peruvian) mesquite, organic hemp seed, Crystal Manna™ (organic wild blue-green algae), organic maca, organic poppy seed, organic cinnamon, organic vanilla bean powder, organic orange rind powder, pink Himalayan salt crystals, organic cayenne pepper: <http://www.wildbar.info/>
- **Wildbar® Mountain Mint:** contains organic cacao (cacao paste, cacao butter, whole cacao powder), organic clear blue agave nectar, organic macadamia nuts, organic (Peruvian) mesquite, organic hemp seed, Crystal Manna™ (organic wild blue-green algae), organic maca, organic poppy seed, organic vanilla bean powder, pink Himalayan salt crystals, organic essential oil of peppermint: <http://www.wildbar.info/>
- **Zócalo Gourmet Mesquite – Algarrobo Organic Flour:** contains certified organic raw Peruvian mesquite flour: <http://zocalogourmet.com/products/mesquite.html>

Figure 4. Examples of Peruvian mesquite food products in the United States market



1.2.3. As food supplement ingredient

1.2.3.1. Canada

See section 1.2.4 (As medicinal product ingredient). Under Canadian Natural Health Product (NHP) regulations, dietary supplement or food supplement products are regulated as licensed NHPs as a subset of drug regulations.

1.2.3.1. United States

While most Peruvian mesquite products in the United States market are labelled as conventional food products, for example with nutrient content claim statements, there are some mesquite-containing products that are labelled and marketed as dietary supplement products (DSPs), which may carry structure and function claim statements as well as nutrient content claim statements. For example:

- **Thor's Raw Power! Protein Superfood Blend (Original):** contains certified organic and raw brazil nut protein powder, hemp protein powder, maca root, goji berry powder, mesquite powder and 'Maca Extreme' (dried powdered juice of fresh maca root): <http://www.rawpower.com/Supplements/Protein-Products/Raw-Power-Protein-Superfood-Original-16-oz-raw-certified-organic-0002.html>

1.2.4. As medicinal product ingredient

1.2.4.1. Canada

As of the time of this report, there are no medicinal products containing Peruvian mesquite (*Prosopis pallida*) as an ingredient listed in the Health Canada Licensed Natural Health Products Database (LNHPD). Furthermore, *Prosopis pallida* is not listed in the Health Canada Natural Health Products Ingredients Database (NHPID). Thus all products containing Peruvian mesquite powder in the Canadian market at the time of this report are conventional food products.

1.2.4.1. United States

At the time of this of report, there are no over-the-counter (OTC) drug products or prescription (Rx) drug products that contain any form of mesquite pod in the United States market.

1.3. Sacha inchi – seed and oil

1.3.1. As cosmetic product ingredient

1.3.1.1. Canada

'Plukenetia Volubilis Seed Oil' is classified as a non-medicinal ingredient approved for use as a component of licensed natural health products (NHPs) for topical route of administration and for the following non-medicinal purposes:⁶³

- Emollient: Helps to maintain the soft, smooth, and pliable appearance of skin. Emollients function by their ability to remain on the skin surface or in the *stratum corneum* to act as lubricants, to reduce flaking, and to improve the skin's appearance;
- Humectant: Increases the water content of the top layers of skin. This group of ingredients includes primarily hygroscopic agents employed for this specific purpose;
- Skin protectant: Temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help to provide relief to such surfaces; if the ingredient is not associated with a claim and/or pharmaceutical use.

Examples of cosmetic products in the Canadian market that contain sachu inchi oil include:

- **Néolia® HYDRA-PLUS Body Lotion:** contains sachu inchi oil, cranberry and calendula flower: <http://www.neolia.com/node/65>

1.3.1.2. United States

There are some non-drug cosmetic products marketed in the United States containing sachu inchi oil as a component, for example:

- **A'wée Baby Lotion:** contains rainwater, emulsifying wax, flaxseed oil, *Triticum vulgare* (Wheat) gluten extract (Lipowheat), steric acid, cetearyl glucoside, Lactis proteinum extract, sachu inchi oil, pumpkin seed oil, vitamin C, xanthan gum, silver citrate and citric acid, potassium sorbate, vitamins (E, A), ferulic acid, vitamin K2, vanilla extract, geranium rose and lavender: <http://www.navajoskincare.com/products/Baby-Lotion-and-Diaper-Cream.html>

63 Health Canada Natural Health Products Directorate (NHPD). Plukenetia Volubilis Seed Oil. In: Natural Health Products Ingredients Database (NHPID). Available from: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/online-enligne/nhpid-bipsn-eng.php>

- **Dr. Bo's® Body Lotion Moisturizer infused with Sacha Inchi:** contains aloe vera gel, organic sachu inchi oil, avocado oil, vitamin E, jojoba oil, green clover, Sicilian bergamot, bamboo, rosemary, lily, lavender and sheer musk: <http://www.drbo.com/body-lotion-moisturizer>
- **Dr. Bo's® Moisturizing Body Wash infused with Sacha Inchi:** contains sachu inchi oil infused in extracts of aloe, chamomile, cucumber, seaweed, elderberry, orange peel and rose: <http://www.drbo.com/moisturizing-body-wash>
- **John Frieda® Full Repair® Full Body Conditioner:** contains water, glycerine, cetearyl alcohol, dimethicone behenamidopropyl dimethylamine, trisiloxane, cetyl esters, stearyl alcohol, lactic acid, fragrance, propylene glycol, quaternium-91, diazolidinyl urea, cetrimonium methosulfate, glycine, *Plukenetia volubilis* seed oil, malic acid, stearoxypropyl dimethylamine, c14-28 isoalkyl acid, iodopropynyl butylcarbamate, c14-28 alkyl acid, tocopherols: <http://www.johnfrieda.com/en-US/ProductDetail/Hair-Care/Full-Repair/Full-Body-Conditioner#/ingredients/>
- **New Spirit Naturals Revitalizing Conditioner:** contains aloe, sachu inchi, StimuCap™, amino acids and colour lock agent: <https://www.newspirit.com/products/revitalizing-conditioner>

1.3.2. As food product ingredient

1.3.2.1. Canada

It is mainly packaged roasted sachu inchi seeds and chocolate covered sachu inchi seed products labelled and marketed as healthy snack foods that are beginning to appear in the Canadian market as well as vegetable oil or salad dressing products. The main attributes for labelling and marketing include:

- Nutrient content claims (source of fibre and omega 3 fatty acids);
- Certified organic;
- Gluten free (wheat free);
- Non-GMO;
- Raw food;
- Suitable for vegans and vegetarians.

Examples of conventional food products in the Canadian market that contain sachu inchi as an ingredient include the following:

- **Health Matters Organic Dark Chocolate Sachu Inchi Seeds:** contain organic dark chocolate, sachu inchi seeds, yacon syrup: <http://advantagehealthmatters.com/en/P-AHM709/Org-Sachu-Inchi-Seeds%2c-Dark-Chocolate-100g--%c2%b0.aspx>
- **Health Matters Organic Sachu Inchi Seeds:** contain organic dried sachu inchi seeds: <http://advantagehealthmatters.com/en/P-AHM810/Org-Sachu-Inchi-Dried-Seeds-100g--%c2%b0.aspx>
- **Organic Traditions Organic Dark Chocolate Sachu Inchi Seeds:** contain organic dark chocolate, sachu inchi seeds, yacon syrup: <http://advantagehealthmatters.com/en/P-AHM718/Org-Chocolate-Covered-Sachu-Inchi-Seeds-150g--%c2%b0.aspx>
- **Organic Traditions Organic Sachu Inchi Seeds:** contain organic dried sachu inchi seeds: <http://advantagehealthmatters.com/en/P-AHM812/Org-Sachu-Inchi-Seeds-150g--%c2%b0.aspx>
- **Rainforest Wild Caramel Covered Sachu Inchi; Rainforest Wild Chocolate Covered Sachu Inchi; Rainforest Wild Pink Salt Sachu Inchi:** <http://www.rainforestproduct.com/organic-products-sachu-inchi.html>
- **Total Image Fitness™ Sachu Inchi Oil:** contains cold pressed extra virgin sachu inchi oil filled into a glass bottle: <http://www.totalimagefitness.ca/sachu-inchi-oil>
- **Vega™ Savi Seed™:** contains roasted sachu inchi seeds: <http://myvega.com/products/vega-saviseed/features-benefits>

1.3.2.2. United States

It is mainly packaged roasted sacha inchi seeds and chocolate covered sacha inchi seed products labelled and marketed as healthy snack foods that are beginning to appear in the United States market as well as vegetable oil or salad dressing products. The main attributes for labelling and marketing include:

- Nutrient content claims (source of omega 3 fatty acids);
- Certified organic;
- Non-GMO;
- Gluten free (wheat free);
- Dairy free;
- Raw food;
- Suitable for vegans and vegetarians.

Examples of conventional food products in the United States market that contain sacha inchi as an ingredient include the following:

- **Blamac Natural Products Sacha Inchi Extra Virgin Oil:** contains 100% vegetable, cold pressed extra virgin oil from Peruvian Sacha Inchi, antioxidants Vitamin E and Vitamin A: <http://www.blamacnaturalproducts.com/sacha-inchi-extra-virgin-oil>
- **Eco Ola Crunchy Sacha Inchi Seeds:** contain toasted sacha inchi seeds with toasted ground sesame seeds: <http://www.eco-ola.com/products/toasted-sacha-inchi-crunchy-2/>
- **Eco Ola Extra Virgin Sacha Inchi Oil:** contains cold pressed extra virgin sacha inchi oil filled into glass bottles: <http://www.eco-ola.com/products/extra-virgin-sacha-inchi-oil/>
- **Eco Ola Sacha Inchi Protein Powder:** contains powdered sacha inchi seeds: <http://www.eco-ola.com/products/sacha-inchi-protein-powder/>
- **Eco Ola Spicy Charapita Pepper Sacha Inchi Seeds:** contain toasted sacha inchi seeds with charapita pepper (*Capsicum* spp.): <http://www.eco-ola.com/products/toasted-sacha-inchi-charapita/>
- **Eco Ola Toasted Sacha Inchi Seeds:** contain toasted sacha inchi seeds: <http://www.eco-ola.com/products/toasted-sacha-inchi/>
- **Essential Living Foods (ELF) Sacha Inchi Oil 250 ml:** contains sacha inchi oil filled into 250 ml glass bottles: <http://essentiallivingfoods.com/products/sacha-inchi-oil-organic-250ml>
- **New World Naturals ChocOmega:** contains chocolate liquor, soy lecithin, cocoa butter, vanilla, sacha inchi nuts and golden berries: <http://www.newworldnaturals.org/ChocOmega.php>
- **Sacha Vida Naturally Roasted Sacha Inchi Seeds:** contain organic sacha inchi seeds: <http://sachavida.com/sacha-vida-products/sacha-vida-snacks/naturally-roasted/>
- **Sacha Vida Organic Chocolate Covered Sacha Inchi Seeds:** contain organic sacha inchi seeds, organic 55% cacao (cocoa powder, cocoa butter, cocoa liquor) and organic sugar: <http://sachavida.com/sacha-vida-products/sacha-vida-snacks/chocolate/#>
- **Sacha Vida Organic Roasted and Salted Sacha Inchi Seeds:** contain organic sacha inchi seeds, organic salt: <http://sachavida.com/sacha-vida-products/sacha-vida-snacks/roasted-salted/>
- **Sacha Vida Oil:** contains cold pressed extra virgin sacha inchi oil filled into glass bottle: <http://sachavida.com/sacha-vida-oil/product-highlights/>
- **TerrAmazon Sacha Inchi Roasted Seeds:** contain roasted sacha inchi seeds: <http://www.terramazon.com/eng/index.html>

Figure 5. Examples sacha inchi food products in the United States market



1.3.3. As food supplement ingredient

1.3.3.1. Canada

See Section 5.1.3.4 (As Medicinal Product Ingredient). Under Canadian Natural Health Product (NHP) regulations, dietary supplement or food supplement products are regulated as licensed NHPs as a subset of drug regulations.

1.3.3.2. United States

There are some sacha inchi products labelled and marketed as dietary supplement products (DSPs) in the United States market, which may carry structure and function claim statements as well as nutrient content claim statements (so long as the company has notified the FDA within 30 days of marketing the product and comply with DSP Good Manufacturing Practices (GMPs). Mainly these products are marketed with nutrient content claim statements such as 'source of EPA and DHA Omega 3 Fatty acids as well as Omega 6' but some are also marketed with structure and function claim statements, for example 'helps supply the body with essential fatty acids needed for a healthy lifestyle, heart and circulatory health and general well-being'.

- **Blacmac OMEGA 3 Sacha Inchi Oil Gelcaps:** contains sacha inchi oil filled into gel caps: <http://sachamax.com/>
- **New Pharma Inc. EPAMAX Dietary Supplement:** contains fatty oil of sacha inchi filled into softgel caps: <http://www.newpharmainc.com/medicines/epamax.html>
- **North American Herb & Spice PureOmega™:** contains sacha inchi oil filled into a glass bottle for taking as a supplement by the teaspoonful: <http://www.p-73.com/proddetail.asp?prod=9094>
- **Shakeology® Greenberry:** contains 1000 mg sacha inchi meal per serving along with many other ingredients. See: http://www.shakeology.com/c/document_library/get_file?uuid=ec8c9e06-5208-4177-8ed3-c43696462193&groupId=59860
- **Vitamins Because® You're Worth It Sacha Inchi 600mg 100 Capsules:** contains sacha inchi seed, gelatine and rice powder: http://www.doctorvitaminstore.com/11251_SachaInchi_Pg2.html

Figure 6. Examples of sachachi dietary supplement products in the United States market



1.3.4. As medicinal product ingredient

1.3.4.1. Canada

Canada

Sacha inchi seed is classified as a Natural Health Product (NHP) under Schedule 1 of the Canadian NHP Regulations. There are a few licensed natural health products (NHPs) that contain sachachi seed powder with marketing authorizations granted by the Health Canada Natural Health Products Directorate (NHPD), for example ‘Shakeology Greenberry/Chocolate’.⁶⁴

License Holder:	Beachbody, LLC
Brand Name:	Shakeology Greenberry/Chocolate
Natural Product Number (NPN):	80038209
Current Status:	Active
Dosage Form:	Powder
Recommended Route of Administration:	Oral
Recommendation Dose (Adults):	1 scoop of powder daily

Recommended Use or Purpose: A factor in the maintenance of good health. Source of antioxidants for the maintenance of good health. Provides live microorganisms that temporarily modify gut flora. Provides support for healthy glucose metabolism. Helps the body to metabolize carbohydrates, fats and proteins. Helps to maintain immune function. Digestive enzymes.

Medicinal Ingredients: *Plukenetia volubilis* 1000.0 mg, *Amaranthus cruentus* 50.0 mg, *Chenopodium quinoa* 150.0 mg, *Euterpe oleracea* 150 mg, *Lepidium meyenii* 1000.0 mg, *Malpighia glabra* 300.0 mg, *Salvia hispanica* 500.0 mg, *Smallanthus sonchifolius* 1000.0 mg, 4-(1,3;1,4)-beta-D-glucan 4-glucanohydrolase 20.0 mg (20.0 FCC CU), 4-alpha-D-glucan glucanohydrolase 25.0 mg (125.0 FCC DU), *Astragalus membranaceus* 200.0 mg, beta-carotene 3000.0 mcg (5000.0 IU), beta-D-galactoside galactohydrolase 20.0 mg (20.0 FCC ALU), *Bifidobacterium longum* subsp. *longum* 0.5 billion cfu, biotin 90.0 mcg, calcium 500.0 mg, *Camellia sinensis* extract (2:1) 50.0 mg, *Chlorella vulgaris* 350.0 mg, chromium 60.0 mcg, *Cinnamomum aromaticum* 150.0 mg, citrus bioflavonoids 50.0 mg, copper 800.0 mcg, D-pantothenic acid 5 mg, folate 200.0 mcg, fruit bromelain 100.0 mcg (900.0 FCC PU) fungal protease 20.0 mg (100.0 FCC HUT), *Ganoderma lucidum* 100.0 mg, *Ginkgo biloba* 25.0 mg, *Grifola frondosa* 100 mg, *Hebanthe eriantha* 50.0 mg, iodine 52.5 mcg, iron 4.5 mg, *Lactobacillus acidophilus* 1.25 billion cfu,

⁶⁴ Health Canada Natural Health Products Directorate (NHPD). (2012). Shakeology Greenberry / Chocolate. In: Licensed Natural Health Products Database. Available from: <http://webprod3.hc-sc.gc.ca/lnhpd-bdpsnh/index-eng.jsp>

Lactobacillus casei 0.5 billion cfu, *Lactobacillus delbrueckii* subsp. *bulgaricus* 0.5 billion cfu, *Linum usitatissimum* 700 mg, magnesium 70.0 mg, manganese 2.0 mg, methylsulfonylmethane 150 mg, molybdenum 30 mcg, niacin 5.0 mg, *Ocimum tenuiflorum* 50 mg, *Ophiocordyceps sinensis* 100 mg, papain 25.0 mg (50.0 FCC PU), phosphorus 250.0 mg, *Pisum sativum* 150 mg, *Punica granatum* 250 mg, riboflavin 1.3 mg, *Rosa canina* 50.0 mg, *Schisandra chinensis* 50.0 mg, *Spirulina platensis* 350.0 mg, *Streptococcus salivarius* subsp. *thermophiles* 0.5 billion cfu, thiamine 1.5 mg, triacylglycerol lipase 20.0 mg (20.0 FCC LU), *Vaccinium myrtillus* 200.0 mg, vitamin B12 6.0 mcg, vitamin B6 2 mg, vitamin C 180.0 mg, vitamin D 5.0 mcg (200.0 IU), vitamin E 10.05 mg AT (15.0 IU), vitamin K1 40.0 mcg, *Vitis vinifera* extract (2:1) 50.0 mg, whey protein isolate 15000.0 mg, *Withania somnifera* 100.0 mg, zinc 6.0 mg.

Non-medicinal ingredients: Banana flavour, barley grass, blueberry flavour, carrot root powder, chocolate flavour, cocoa powder, D-fructose, guar gum, lycium fruit, orange flavour, pectin, pineapple fruit juice, raspberry flavour, spinach, *Stevia rebaudiana* leaf, strawberry flavour, vanilla flavour, wheatgrass, xanthan gum.

At the time of this report the only licensed NHPs in Canada that contain sacha inchi as an active ingredient were those of the Shakeology brand as outlined above. Other NHP-type products were identified in the Canadian market, but were not found to be listed in the Health Canada Licensed Natural Health Product Database (LNHPD), such as:

- **Sacha Inchi Corporation Sacha Oil:** contain 500 mg sacha inchi oil per gelcap: <http://www.totalimagefitness.ca/sacha-inchi-oil>

1.3.4.2. United States

At the time of this report, there are no over-the-counter (OTC) or prescription (Rx) drug products that contain any form of sacha inchi in the United States market.

1.4. Overview of most relevant trends affecting the sectors and market segments



According to a March 2013 trends in natural and organics report (based on SPINS scan data) by United Natural Foods Inc. (UNFI), the leading independent national distributor of natural, organic and specialty foods and related products including nutritional supplements, personal care items and organic produce, in the United States, products labelled with 'Raw', 'Gluten-Free' and 'Non-GMO Project Verified' designations posted double digit growth during January-March 2013 compared to same period 2012. The report also states that growth across all channels is being driven by certain popular product attributes, in particular products that are labelled with multiple designations namely 'Raw', 'Non-GMO Project Verified', 'Certified Gluten-Free', 'Certified Organic', 'Certified B Corporation', and 'Certified Fair Trade'. The reason for this trend is explained as consumers demanding transparency and authenticity which these independent standards and certifications satisfy. The top emerging protein attribute are those positioned as 'Raw'.

In recent years there has been a notable convergence of several formerly niche market attributes evidenced by the fact that many new market entries are no longer labelled as only 'natural' and/or 'organic' but have several seals and/or claim statements displayed prominently on the front of package and in website. Many of the product examples summarized in this report are labelled and marketed with multiple certifications and/or claims in order to address a range of concerns that informed shoppers are in fact seeking out in measurably growing numbers.



This product comes from farmers and processors who share our contempt for processed foods and have made the investment in, and commitment to, low temperature drying processes. The result is nutrient-dense foods with their enzymatic life force intact. Our company owns and operates a USDA-certified organic packaging facility in Bend Oregon. Our organic products are



certified by Oregon Tilth and are guaranteed to be free of pesticides and herbicides. This product is kosher certified by Earth Kosher. Even if your diet isn't kosher, you may still appreciate that our foods, facility and processes have undergone the scrutiny of kosher inspectors. Adding on to organic certification in many cases are certifications or verifications of non-GMO, caffeine free, dairy free, gluten free, vegan and vegetarian, fair trade, halal and kosher (especially Earth Kosher and Green-K-Kosher) and 'Raw'. New products carrying many or most of these assurances are reaching a broader mainstream audience and no longer only the natural food store shopper. It is not uncommon for conventional grocery stores to now group products with many or most of these attributes into a single category with dedicated aisle sections or end-aisles. Added to this is the notion that many food products with these attributes are considered to be so-called super foods. Thus, a cacao bar with goji berries and golden berries that is labelled as organic, non-GMO, fair trade, gluten free, raw and vegan becomes a functional food, health food and/or super food.

It is possible that this trend is being driven in part by young parents who are actively looking for simpler products for their children in a context of increasing concerns over food safety and traceability and scepticism about certain widely used 'approved' food ingredients and/or food technologies (for modifying ingredients) that may actually be linked to a range of paediatric diseases or disorders and to the childhood obesity epidemic in the United States. Parents are looking for natural products with a smaller number of ingredients listed, without chemical isolate or synthetic ingredients, without artificial aromas, colours and flavours, and more importantly with assurances that the products are allergen free. People are worried about adulteration, undeclared ingredients and country of origin (e.g. general lack of trust for products made in China). There is a growing mistrust of products manufactured in certain countries where food safety regulations may be lax or enforcement of good manufacturing practices (GMPs) may be non-existent.

Emerging niche markets are catering to the growing number of shoppers who have developed a healthy mistrust for governmental assurances, for example that milk from cows given bovine growth hormone (BGH) is just as safe as organic milk or raw milk; assertions that high fructose corn syrup is a generally safe sweetener and that genetically engineered crops pose no risks, among many other examples. The increasing demand for certified organic milk can be linked to the awareness that non-organic milk will likely contain BGH. The increasing demand for products sweetened with organic agave nectar, organic stevia extract or organic sugar cane juice, among others, can be viewed in the context of a growing awareness of the processes used to manufacture high fructose corn syrup and how pervasive its use has become in conventional food products (and a possible relationship to the obesity epidemic). The growing concern and mistrust of assurances that food ingredients containing genetically modified organisms (GMOs) are safe is evidenced by the fact that there are 'right to know' labelling initiatives being fought at the State and Federal levels. Many brands and retailers are not waiting for the regulators. More and more brands are going for non-GMO product labelling and some large retailers plan to require GMO labelling of products sold in their stores within the next few years.

Simpler products – the fewer ingredients the better

According to a report in *Food Business News*®, David Turner, global food and drink analyst at Mintel International, stated that consumers are looking for products with fewer ingredients. 'Naturalness is a real opportunity because the barrier is people who are concerned about the number of ingredients,' Mr. Turner said. 'Products with fewer ingredients and certainly ones that are additive- or preservative-free and MSG-free are real drivers.' Low-sodium, low-sugar, and low- or non-fat products also may entice consumers, he added.⁶⁵

Dairy alternative seed milks – increasing demand for allergen free milk alternatives

In the 1980's the non-dairy milk-alternative market was dominated by soy milk. In the 1990's rice milk was a new entry that became main competition for the soy milk space (rice milk is still #2). In the 2000's a wide range of new entries of dairy-free milk alternatives began to fill the retail store shelves and refrigerated cases including beverages made from oilseeds (e.g. flax milk, hemp milk, soy milk, sunflower milk), grains (e.g. oat milk, quinoa milk, rice milk) and nuts (e.g. almond milk).

⁶⁵ Watrous, M. (2013). Ethnic flavors gain favor in cooking sauces. *Food Business News*®.

Sales of dairy alternative beverages in the United States hit US\$ 1.3 billion in 2011 and are projected to exceed US\$ 1.7 billion by 2016, according to a report by Packaged Facts. Although soy milk sales declined by 10% in 2011, it is still the #1 milk alternative accounting for two-thirds of the market share.⁶⁶ According to *Innova Market Insights*, alternative dairy beverages represented 5% of total dairy new product launches in the last year. This category is now moving out of the specialty health food segment and into the mainstream aisle. Although soy milk still has the largest market share, it is declining and facing challenges due to health scares. People are looking for non-soy and non-dairy alternatives. Rice drinks remain number two in the category but there are many new entrants including combinations with milks of other grains, nuts or seeds.⁶⁷

The non-dairy seed milk beverages are labelled and marketed with main attributes of major allergen free (e.g. dairy free, lactose free, gluten free, soy free, tree nut free) with nutrient content claims (e.g. good source of plant-based protein and omega 3s, cholesterol free, low sodium), organic and non-GMO, kosher, vegetarian and vegan friendly.

This is an area where sacha inchi seed milk could possibly compete depending on availability for national distribution, competitive pricing, taste acceptance and nutritional profile. Figure 7 shows examples of competitive non-dairy seed milk beverages in the United States market.

Figure 7. Examples of oilseed non dairy drinks in the United States market: chia, flax, hemp, sunflower



Ancient grains – moving into the mainstream

According to *Functional Foods*, one of the top-five food trends for 2013 is ancient grains and seeds (e.g. quinoa, flax, chia and others) beginning to appear in mainstream products, including granolas, cereals, crackers and breads. These ingredients are being used in new product developments as good sources of plant-based protein, fibre and omega-3 fatty acids.⁶⁸

Peruvian cuisine – traditional Peruvian recipes and flavours are becoming popular

The National Restaurant Association's 'What's Hot 2013 Chef Survey' of more than 1,800 members of the American Culinary Federation forecast Peruvian cuisine as having the most impact on menus across the

66 Hu, J. (2013). Nut milk alternatives pour it on. From almond to pecan, dairy-free options on the rise. San Francisco Chronicle. Available from: <http://www.sfchronicle.com/recipes/article/Nut-milk-alternatives-pour-it-on-4395795.php>

67 Anon. (2013). Emerging trends: More ingredients are being used for dairy alternatives. Culinology.

68 Blackwell, K. (2013). 5 food trends for the year ahead. Functional Ingredients. Available from: <http://newhope360.com/ingredients-trends/5-food-trends-year-ahead>

United States in 2013. It is possible that the growing interest in Peruvian food is related to the growing Hispanic population in the United States.⁶⁹

Gluten Free – catalyst for growth in the natural channel

According to a 2013 report by the natural products market analyst organization SPINS, 'gluten-free' has been the catalyst for growth in the natural channel for years. The growth of the items labelled and/or 'certified gluten free' outpaced the channel by over six full percentage points for the 52 weeks ending 16 February 2013, vs. year ago (YA) and represents a dollar growth rate of 21.9% compared to the channel growth rate of 15.4%.⁷⁰

Of the top 20 trends for United States restaurant menus in 2013, 'gluten-free' cuisine ranked at #8 in a survey of 1,800 members of the American Culinary Federation.⁷¹ And according to a report by *Functional Ingredients*, one of the top-five trends for 2013 will be the introduction of more gluten-free convenience foods like nutrition bars. Another of the top-five trends is 'specialty diet snacking.' The evidence of this trend is that 7 out of 10 new snack foods launched this year make a health claim, such as 'all natural,' 'gluten free,' or 'whole grain.' Gluten-free, vegan and raw snacks will continue their upward trajectory in 2013. Additionally, this trend includes the tailoring of new snack food products to appeal to more than one specialty diet, for example 'gluten and dairy free' or 'vegan and gluten free.'⁷²

Although there are no regulations for labelling of gluten-free products in the United States, the increasing consumer demand for such products is evidenced by the fact that several independent organizations have developed standards for gluten-free product certification and labelling, for example:

- **Celiac Sprue Association® (CSA)**, the largest non-profit celiac support group in America, with chapters and resource units across the country, and members worldwide, offers a CSA Recognition Seal and Certification Programme.⁷³



- **Gluten Free Certification Organization (GFCO)** is a certification programme of the Gluten Intolerance Group (GIG).⁷⁴



69 Weisberg, K. (2013). A growing passion for Peruvian cuisine. *Culinology*.

70 SPINSscan Natural.(2013). Gluten Free – The Trend Continues. *Presence News*. Available from: <http://www.pmidpi.com/files/Download/Newsletter.pdf>

71 Natural Restaurant Association. What's Hot 2013 Chef Survey. Available from: <http://www.restaurant.org/Downloads/PDFs/News-Research/WhatsHotFood2013.pdf>

72 Blackwell, K. (2013). 5 food trends for the year ahead. *Functional Ingredients*. Available from: <http://newhope360.com/ingredients-trends/5-food-trends-year-ahead>

73 Celiac Sprue Association® (CSA). CSA Recognition and Seal Programme. Available from: http://www.csaceliacs.info/csa_recognition_seal.jsp

74 Gluten-Free Certification Organization (GFCO). Gluten-Free certification. Available from: <http://www.gluten.net/Programs/industry-programs/gluten-free-certification-organization>

- **Natural Food Certifiers (NFC)** offers a 'Gluten Guard' certification programme for natural and organic products labelling.⁷⁵



- **Quality Assurance International (QAI)** offers a QAI/NSF Gluten-Free certification programme.⁷⁶



- **Non-GMO – retailers beginning to require GMO labelling**



Following the Peruvian regulations that prohibit the importation, production and use of GMO foods in the country that came into effect in 2012, the growing trend for non-GMO products in the United States and Canada is an area for Peruvian products to emphasize. Associating Peru's GMO ban with Peruvian natural and organic product exports would be a positive link to make in brand building and marketing.

The trend towards preference of non-GMO products and labelling of products that contain GMO components continues and is not likely to let up. Major brands and retailers are demanding truth in labelling and activists are pushing for mandatory labelling regulations as well as bans on new approvals of genetically engineered crops.

According to *Functional Foods*, one of the top-five trends in 2013 is 'true transparency', i.e. clean food labels are becoming increasingly important; consumers are demanding more transparency for what is in their food and how it is made. In this context it is predicted that the non-GMO discussion will gain widespread momentum.⁷⁷

In March 2013, at the 30th annual Natural Products Expo West in Anaheim California, Whole Foods Market announced that all products sold in its United States and Canadian stores containing genetically modified ingredients must be labelled by 2018. 'We are committed to full GMO transparency within 5 years,' Walter Robb, co-CEO of Whole Foods told *newhope360.com*. 'Working together with our suppliers, which we are going to need to do, every product that does contain GMOs or may contain GMOs will be labelled as such. It's a big step up for the customer's right to know.'⁷⁸

75 Natural Food Certifiers (NFC). Information about Gluten Guard. Available from: <http://nfccertification.info/extra-view/gluten-guard/>

76 Quality Assurance International. QAI Gluten-Free Certification Programme. Available from: http://www.qai-inc.com/services/gluten_free_program.asp

77 Blackwell, K. (2013). 5 food trends for the year ahead. *Functional Ingredients*. 09 April 2013. Available at: <http://newhope360.com/ingredients-trends/5-food-trends-year-ahead>

78 Mast, C. (2013). Whole Foods commits to 100 percent GMO transparency by 2018. *Newhope360.com*. Available from: <http://newhope360.com/non-gmo/whole-foods-commits-100-percent-gmo-transparency-2018>

According to co-CEO A.C. Gallo, Whole Foods is seeing sales increases of 15% to 30% for non-GMO verified products. Whole Foods Market told USA Today that it currently sells more than 3,000 products that have gone through the non-GMO verification process, more than any other retailer in North America. Additionally, Whole Foods Market, Aldi's and Trader Joe's announced that they would not sell genetically engineered salmon, if the FDA approves it (which is under review at the time of this report).⁷⁹

According to an October 2012 SPINS report, sales of Non-GMO Project verified foods grew by 66% year-over-year for the past 52-week period. Recent-year sales totalled US\$ 2.4 billion, with more than US\$ 1 billion of that sold in three categories: chips, pretzels and snacks; non-dairy beverages; and cold cereal.⁸⁰

Superfruits – the rise and fall of ORAC marketing

Over the past decade companies have marketed 'superfruit' products on the basis of oxygen radical absorbance capacity (ORAC) levels. Now even the original proponents of associating ORAC values with health benefit are backing off as the science behind this has changed. The United States Department of Agriculture (USDA) has withdrawn its list of ORAC values for fruits and other food ingredients due to 'mounting evidence that the values indicating antioxidant capacity have no relevance to the effects of specific bioactive compounds, including polyphenols, on human health'. So a new marketing approach to communicate the health benefits of superfruits must emerge.⁸¹

Organic – The United States is the largest single market for organic products globally



Demand for products with organic certification has been growing for decades and continues to grow in the United States and Canada with no end in sight. The Organic Trade Association's (OTA) '2011 Organic Industry Survey' reported 'the United States organic industry grew at a rate of nearly 8% in 2010, bucking the current trend whereby 'flat is the new growth' for many other segments of the economy. In 2010, the organic industry grew to over US\$ 28.6 billion'.⁸²

According to a report by the International Federation of Organic Agriculture Movements (IFOAM), 'The countries with the largest organic markets in 2011 were the United States, Germany and France, with the United States the largest single market. Switzerland, Denmark and Luxemburg reported the highest per capita consumption'.⁸³

According to a 2013 news release from the Canada Organic Trade Association (COTA), Canada's organic market grew to US\$ 3.7 billion in 2012, with national sales of certified organic food and non-alcoholic beverages reaching US\$ 3 billion. The value of the Canadian organic food market has tripled since 2006, far outpacing the growth rate of other agri-food sectors. A diverse consumer base is driving the sector, with 58% of all Canadians buying organic products every week.⁸⁴

79 Hoffman, S. (2013). GMO Labeling Update: Whole Foods Market to require GMO transparency; Washington State's I-522 best bet for GMO labelling in 2013. Presence News; 10(3):16-17. Available from: <http://www.pmidpi.com/files/Download/Newsletter.pdf>

80 Kapperman, C. (2012). Non-GMO verified product sales increase 66% over last year. Newhope360.com. Available from: <http://newhope360.com/managing-your-business/non-gmo-verified-product-sales-increase-66-over-last-year>

81 Phillips, D. (2012). Interest in superfruits into new phase. Food Business News.

82 Organic Trade Association (OTA). Market Trends. Available at: <http://www.ota.com/organic/mt.html>

83 Organic Trade Association (OTA). (2013). Global sales of organic food nears US\$ 63 billion. The Organic Report.

84 Mackinnon, S. (2013). Canada's Organic Market - National Highlights, 2013. Canada Organic Trade Association (COTA). Available from: http://www.ota.com/pics/media_photos.171.img_filename.pdf

Plant- or Algal- based Essential Fatty Acids (EFAs)

The market for certified organic plant-based and/or algal-based sources of essential fatty acids (EFAs) is growing for a variety of reasons including:

- Concerns about the purity and safety of fatty oils obtained from fish, i.e. environmental contaminants detected in fish oil may include heavy metals (cadmium, lead, mercury, arsenic), polychlorinated biphenyls (PCBs), dioxins and furans and radiation contamination;
- Questions of the long-term sustainability for supply of marine-based oils (over-fishing – endangered or threatened species) whether obtained from wild harvested fish (e.g. salmon), crustaceans (e.g. krill) or mammals (e.g. seal blubber);
- Concerns about the environmental impact and safety of farmed fish including genetically engineered farmed fish (especially if they should escape into the wild and compete with wild fish);
- Non-vegetarians may even prefer plant-based EFA products either for sensory reasons (odour and taste preference), for price reasons or for product traceability and certification reasons, i.e. organic plant-based EFAs may be more attractive than non-certifiable marine sources.

Sustainable natural resource management, traceability and food safety with independent verification or certification for the supply of EFA ingredients is far more practical with plant-based and/or algal-based starting materials as opposed to marine oils.

Vegetarian and Vegan Verified

According to a 2012 poll, commissioned by the Vegetarian Resource Network (VRN) ‘Four per cent of United States adults were found to be vegetarian. With United States adults 18 and over numbering about 230 million, we can estimate the number of vegetarians in the United States adult population, based on this poll, to be approximately nine million adults. Vegans included in the vegetarian figures would be around 2 million people. If you take into account the margin of sampling error of the poll, we can estimate the number of vegetarians in the United States population to range from approximately 5 million to about 14 million adults. With margin of sampling error, vegans could range as high as 6.9 million’.⁸⁵

Due to increased demand for vegetarian and vegan products, more and more labels are making vegetarian or vegan friendly claim statements and in recent years independent inspection and certification organizations have begun to offer certified vegan or vegan verified designations for product labels. For example:

- **Earth Kosher**, Kosher Certification Agency, offers joint vegan (‘Vegan Verified’) and kosher (‘Earth Kosher’) certification.⁸⁶



⁸⁵ Stahler, C. (2012). How often do Americans eat vegetarian meals? And how many adults in the U.S. are vegetarian? Available from: <http://www.vrg.org/blog/2012/05/18/how-often-do-americans-eat-vegetarian-meals-and-how-many-adults-in-the-u-s-are-vegetarian/>

⁸⁶ Earth Kosher. Joint vegan and kosher certification: <http://earthkosher.com/joint-vegan-and-kosher-certification/>

- The non-profit organization **Vegan Action** offers a 'Certified Vegan' designation for product labels.⁸⁷



- The **American Vegetarian Association (AVA)** offers 'AVA Certified Vegetarian' and 'AVA Certified Vegan' designations for product labels.⁸⁸



- The natural and organic products certification organization, **Natural Food Certifiers (NFC)**, offers a 'Vegan Certified' programme.⁸⁹



- **People for the Ethical Treatment of Animals (PETA)**, the largest animal rights organization, with more than 3 million members and supporters, offers a joint 'Cruelty-Free and Vegan' certification.⁹⁰



87 Vegan Action. Vegan certification and the 'Certified Vegan' logo. Available from: <http://vegan.org/certify/>

88 American Vegetarian Association (AVA). Certification. Available from: <http://www.amerveg.org/certification.html>

89 Natural Food Certifiers (NFC). Vegan certification. Available from: <http://nfccertification.info/>

90 People for the Ethical Treatment of Animals (PETA). How does a company license PETA's cruelty-free bunny logo? Available from: <http://www.peta.org/living/beauty-and-personal-care/companies/default.aspx>

Chapter 5 Market and buyer requirements

1. Specific requirements for ingredient (packaging, labelling, documents)

1.1. Canada

The basic packaging and labelling requirements necessary for foreign agricultural exports to Canada are:⁹¹

- Labels in English and French;
- Net quantities expressed in metric units;
- List of ingredients, (including food allergens);
- Durable life date (if shelf life 90 days or less);
- Common name of product;
- Name and address of Manufacturer /Canadian Dealer, noted 'imported for/importé pour';
- Nutrition Facts Table in accordance with the Canadian format;
- Starting August 2012, declaration of food allergens on pre-packaged foods;
- Follow minimum type size specifications;
- Conformity to standardized package sizes stipulated in the regulations;
- Country of origin labelling on shipping container.

There are specific labelling requirements for certified organic materials. If the imported natural ingredient is certified organic, the following Canadian Organic Regime (COR) regulations apply. Labelling of bulk packaging, i.e. wholesale containers, boxes, non-retail containers, etc. of ingredients or products labelled as organic should bear at least the following information:

- The name and address of the person or organization responsible for the production, preparation or distribution of the organic product;
- The name of the product;
- The organic status of the product;
- Information that ensures traceability (e.g. lot number);
- The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the product;
- The COR seal.

If the imported botanical ingredient is classified as 'Bulk Natural Health Product' (unpackaged dosage form, usually in quantities larger than the largest commercially available package size), the Natural Health Products (NHP) labelling regulations may apply. However if the NHP is shipped to a Canadian product manufacturer or distribution company (and not to retailer or consumer), it does not require labelling and packaging in accordance with the NHP regulations.

1.2. United States

Depending on the specific natural ingredient(s) being imported into the United States, one or more governmental agencies may become involved in the inspection of the imported goods, their packaging, labelling and related documentation, including the Animal and Plant Health Inspection Service (APHIS), Drug Enforcement Agency (DEA), FDA, Food Safety Inspection Service (FSIS), USDA, and the U.S. Customs Service.

In addition to regulatory requirements for the packaging and labelling of imported ingredients, the buyers or importers are likely to have their own specific, additional packaging and labelling requirements, for example requirements that the seller's lot number is stencilled on each sack or drum as well as the buyer's

⁹¹ Evans, B. (2012). GAIN Report Number: CA12030. Canada Food and Agricultural Import Regulations and Standards – Narrative. USDA Foreign Agricultural Service (FAS). Available from: <https://s3.amazonaws.com/ProductionContentBucket/pdf/20120930191548407.pdf>

item code number and the purchase order number. The buyer may also specify the packaging type (e.g. poly-lined 55 gallon fibre drum) and the pallet type and configuration. In general, natural ingredients should be packed in tightly sealed, lined containers that will protect against cross-contamination, spillage, moisture damage, and insect infestation. Basic labelling requirements include:

- English standard common name of the ingredient;
- English name of country of origin;
- Name and address of the producer or exporting company;
- Gross weight expressed in both metric (kilograms or litres) and United States Customary System (pounds or fluid ounces) ;
- Net and tare weights;
- Vendor's lot number (must match lot number on packing list) ;
- Any other information requested by the buyer (e.g. buyer's item code).

There are specific ingredient labelling requirements for certified organic materials. If the imported natural ingredient is certified organic, the following USDA National Organic Programme (NOP) regulations apply.⁹²

Labelling of nonretail containers used for only shipping or storage of raw or processed agricultural products labelled as '100% organic,' 'organic,' or 'made with organic (specified ingredients or food group(s)).'

- Nonretail containers used only to ship or store raw or processed agricultural product labelled as containing organic ingredients may display the following terms or marks;
- The name and contact information of the certifying agent which certified the handler which assembled the final product;
- Identification of the product as organic;
- Special handling instructions needed to maintain the organic integrity of the product;
- The USDA seal;
- The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product;
- Nonretail containers used to ship or store raw or processed agricultural product labelled as containing organic ingredients must display the production lot number of the product if applicable.

For examples of labels and labelling of non-retail and retail organic containers, visit the USDA NOP Online Training at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5098489>

The following guidance concerning useful information to consider for the packaging, labelling and storage of botanical raw materials is excerpted from Chapter 3.8 of the 'American Herbal Products Association (AHPA) and American Herbal Pharmacopoeia (AHP) Good Agricultural and Collection Practice (GACP) for Herbal Raw Materials'.⁹³

The use of adequate packaging equipment and materials will affect the quality of packaged herbal crops, as will storage conditions. The following practices are relevant to packaging (including drums, boxes, bags and all other packaging) and storage operations for bulk herbs.

- **Packaging materials.** Use only food- or pharmaceutical-grade packaging materials. Do not reuse any packaging material, except that packaging material that includes recycled material is acceptable so long as the recycling process results in packaging material that maintains food-grade or pharmaceutical-grade status.

92 United States Department of Agriculture (USDA). (2013). Title 7 § 205.307 - Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as '100 percent organic,' 'organic,' or 'made with organic (specified ingredients or food group(s)).' In: Code of Federal Regulations. Washington, D.C.: U.S. Government Printing Office (GPO). Available at: <http://www.gpo.gov/fdsys/pkg/CFR-2013-title7-vol3/pdf/CFR-2013-title7-vol3-sec205-307.pdf>

93 American Herbal Products Association (AHPA) and American Herbal Pharmacopoeia. (2006). AHPA-AHP Good Agricultural and Collection Practice (GACP) for Herbal Raw Materials. Silver Spring, MD: American Herbal Products Association. Available from: http://www.ahpa.org/portals/0/pdfs/06_1208_AHPA-AHP_GACP.pdf

- **Conformity to specifications.** Use only packaging material that conforms to the product's packaging specifications, if any. For example, high volatile-oil-containing herbs should be stored in non-plastic containers.
- **Package labelling.** Label all packages to identify the contents by the plant name (both by its standard common English name and by its scientific binomial name); the part of the plant; the form of the material (e.g., whole, tea bag cut, powder, etc.); the name and contact information of the grower and/or the distributor; the country of harvest or collection; a date of production; the quantity by weight in the package; the item number (if any); the identity and quantity or proportion of any substances added to the material, if any (e.g., anticaking or flow agents used in a milling operation); and a lot number. Labels must be clearly printed, permanently affixed, and conform to any labelling regulations in the country in which the material was produced and in any countries to which it is intended to be shipped.
- **Storage.** Store packaged herbal crops in cool, dry areas away from direct sunlight and exterior walls and off the ground in containers that protect against excessive exposure to air, light, and moisture. Storage facilities should be dry, well ventilated, and have sufficient insulation or other temperature-control features to avoid extreme temperature fluctuations.
- **Separation from non-food storage.** Segregate packaged herbal materials in different areas from non-food items.
- **Control of odour absorption.** Segregate herbal materials that are high in essential oils so that other herbs do not inadvertently absorb their odours. For example, peppermint leaf should not be stored in close confinement with black tea leaf.

2. Relevant standards, certifications and memberships

The following are standards, certifications and memberships that are of relevance to North American companies that import, process, manufacture, label and market finished products that contain Peruvian natural ingredients of biodiversity.

2.1. B Corporation (B-Corps)



B Corporation: <http://www.bcorporation.net/> – Sistema B: <http://www.sistemab.org/>

B Corp certification is to sustainable business what Fair Trade certification is to coffee or USDA Organic certification is to milk. B Corps are certified by the non-profit organization 'B Lab' to meet rigorous standards of social and environmental performance, accountability, and transparency. Today, there is a growing community of more than 715 Certified B Corps from 24 countries and 60 industries working together toward 1 unifying goal: to redefine success in business.

Examples of Certified B Corporations that market natural ingredients or products containing some ingredients from Peru include:

- **Alter Eco Foods:** <http://www.bcorporation.net/community/alter-eco-fair-trade>
- **Andean Natural Inc.:** <http://www.bcorporation.net/community/andean-naturals-inc>
- **Grounds for Change:** <http://www.bcorporation.net/community/grounds-change>
- **Pachamama Coffee Co-op:** <http://www.bcorporation.net/community/pachamama-coffee-co-op>
- **Salt Spring Coffee:** <http://www.bcorporation.net/community/salt-spring-coffee>
- **Sambazon®:** <http://sambazon.com/>

2.2. Certified gluten-free (celiac sprue association)



Celiac Sprue Association: http://www.csaceliacs.info/csa_recognition_seal_program_requirements.jsp

The Celiac Sprue Association (CSA) Recognition Seal displayed on product packaging consists of the CSA registered trademark five crossed grain symbol. The CSA Recognition Seal denotes products that are completely free of wheat, barley, rye, oats, their crosses and derivatives in product, processing and packaging (WBRO-free).

Examples of North American companies marketing products containing Peruvian ingredients that are CSA certified gluten free include:

- **Essential Living Foods:** <http://essentiallivingfoods.com/>
- **Kiwa®:** <http://www.kiwalife.com/home/quality-certifications/>
- **Righteously® Raw Chocolates:** <http://www.righteouslyrawchocolate.com/>

2.3. Certified Gluten-Free (gluten intolerance group)



Gluten-Free Certification Organization: <http://www.gluten.net/Programs/industry-programs/gluten-free-certification-organization>

The Gluten-Free Certification Organization (GFCO) is a programme of The Gluten Intolerance Group. GFCO's Scientific and Professional Board review the practices of GFCO. GFCO inspects products and manufacturing facilities for gluten. GFCO does not certify products for other potential allergens. The contents of this site are not intended as medical advice.

Examples of North American companies marketing products containing Peruvian ingredients that are GFCO certified gluten free include:

- **Endangered Species® Chocolate:** <http://chocolatebar.com/pages.php?pageid=56>
- **Essential Living Foods:** <http://essentiallivingfoods.com/>
- **Two Moms in the Raw:** <http://www.twomomsintheraw.com/>
- **Vigilant Eats:** <http://www.vigilant-eats.com/>

2.4. Certified vegan (vegan action)



Vegan Action: <http://vegan.org/certify/>

Vegan is defined as: no animal or animal by-products to include flesh, bones, dairy, eggs, honey, fur, leather, wool, down feathers, and cosmetics or chemical products tested on animals. The 'Certified Vegan' Logo is a registered trademark, similar in nature to the 'kosher' mark, for products that do not contain animal products or by-products and that have not been tested on animals. The Logo is administered by The Vegan Awareness Foundation (official name of Vegan Action), a 501(c)3 non-profit organization dedicated to educating the public about veganism and to assist vegan-friendly businesses.

Examples of North American companies marketing products containing Peruvian ingredients that are Certified Vegan include:

- **Endangered Species® Chocolate Company:** <http://chocolatebar.com/pages.php?pageid=56>
- **Essential Living Foods:** <http://essentiallivingfoods.com/>
- **Gnosis Chocolate:** <http://www.gnosischocolate.com/>
- **Living Intentions:** <http://www.livingintentions.com/>
- **Organic Vegan Superfoods LLC:** <http://organicvegansuperfoods.com/>
- **Righteously® Raw Chocolates (Earth Source Organics):**
<http://www.righteouslyrawchocolate.com/>

2.5. Cruelty free certified (leaping bunny programme)



The Coalition for Consumer Information on Cosmetics (CCIC): <http://www.leapingbunny.org/>

The Coalition for Consumer Information on Cosmetics' (CCIC) Leaping Bunny Programme administers a cruelty-free standard and the internationally recognized Leaping Bunny Logo for companies producing cosmetic, personal care, and household products. The Leaping Bunny Programme provides the best assurance that no new animal testing is used in any phase of product development by the company, its laboratories, or suppliers.

Examples of companies marketing products in North America containing Peruvian ingredients that are Cruelty Free Certified include:

- **Queen Helene®** (products with Peruvian cocoa butter):
http://www.queenhelene.com/we_care.php
- **The Body Shop®** (products with Peruvian maca): <http://www.thebodyshop-usa.com/values/AgainstAnimalTesting.aspx>
- **W.S. Badger Company** (products with Peruvian cocoa butter): <http://www.badgerbalm.com/>

2.6. Demeter biodynamic® (Demeter U.S.A.)



Demeter Association Inc.: <http://demeter-usa.org/>

In order for a farm to refer to itself as Biodynamic, it must have achieved certification through Demeter by adhering to the Demeter Farm Standard for a minimum of three years if conventionally farmed, or a

minimum of one year if organically farmed. The entire farm must be certified, not just a portion of land within the farm. Farms are inspected annually to ensure that the Standard is being met. The Demeter Biodynamic® Farm Standard is a comprehensive organic farming method that requires the creation and management of a closed system minimally dependent on imported materials, and instead meets its needs from the living dynamics of the farm itself.

There are no certified Biodynamic® operators in Perú yet. There are, however, an increasing number of certified biodynamic products coming from other South American countries, namely Argentina (yerba maté), Brazil (honey and various medicinal plants), Chile (grapes and olives) and Ecuador (cacao, cocoa and chocolates).

2.7. Earth Kosher



Earth Kosher: <http://earthkosher.com/>

Examples of North American companies with EarthKosher certified products that contain Peruvian ingredients include:

- **Blue Mountain Organics:** <http://www.bluemountainorganics.com/>
- **Gnosis Chocolate:** <http://www.gnosischocolate.com/>
- **Navitas Naturals:** <http://navitasnaturals.com/>
- **Righteously® Raw Chocolates (Earth Source Organics):** <http://www.righteouslyrawchocolate.com/>
- **Ultimate Superfoods:** <http://www.ultimatesuperfoods.com/>

2.8. Ecocert Fair Trade (EFT)



EcoCert Fair Trade (EFT): <http://www.ecocert.com/en/fair-trade>

The EFT standard (Ecocert Fair Trade) applies to food, cosmetics and textiles meeting both organic farming and fair trade criteria. Social, economic and environmental criteria are checked all along the value chain. The 'Ecocert Fair Trade' label guarantees the transparency over products that are both organic and fair trade. Consistent with Ecocert's commitment, the EFT standard meets the expectations of consumers with a globally public-spirited philosophy who want to buy environmentally friendly, socially-responsible products.

Examples of North American companies that market EFT certified ingredients or finished products that contain some natural ingredients from Peru include:

- **Ciranda Organic Ingredients:** <http://www.ciranda.com/>
- **Sambazon®:** <http://sambazon.com/>

2.9. Fair choice (control union)



Control Union (CU) Fair Choice: <http://www.fairchoicecertification.com/>

CU Fair Choice is an inspection and certification system based in the International Human Rights Declarations and Labour Conventions that protect and assure the fair treatment to all those involved within the control and influence of the company that implement the system. It also includes requirements on health, safety and environmental protection.

Examples of some Peruvian companies offering natural ingredients or products with CU Fair Choice certification include:

- **Algarrobos Orgánicos del Perú (EcoFields):** <http://www.algarrobosorganicos.pe/>
- **Ecoandino Agroindustria Orgánica:** <http://ecoandino.com/>
- **Macchu Picchu Trading S.A.C.:** <http://www.mpf.com.pe/mpf/>
- **Shanantina S.A.C.:** <http://www.shanantina.com/en/about-us/our-commitment.html>

2.10. Fair for life (institute for market ecology)



Institute for Market Ecology (IMO) Fair For Life: <http://www.fairforlife.net/>

The aim of the Fair for Life Social & FairTrade Programme is to ensure fair and positive relations between producers and their cooperatives or contracting companies, between workers and their employer, between seller and buyers on the world market while at the same time ensuring performance of standards. Social Responsibility Certification confirms that workers enjoy good working conditions and that producer groups have well working, accountable internal structures. The Fair for Life programme builds on widely acknowledged baseline standards such as the conventions of ILO, SA 8000 and the social criteria of the International Federation of Organic Agriculture Movements (IFOAM).

Examples of some Peruvian companies offering natural ingredients or products with IMO Fair For Life certification include:

- **Erboristi Lendi Asociación de Productores de Puquina, Chiguata, Tuctumpaya y Ubi (Arequipa):** Peruvian pepper fruit (*Schinus molle*), Oregano herb (*Origanum* spp.), Thyme herb (*Thymus* spp.), Rosemary leaf (*Rosmarinus officinalis*), Marjoram (*Origanum majorana*), Lemongrass leaf (*Cymbopogon* spp.).
- **Promotora Agroindustrial de Cultivos Andinos Promaca EIRL:** Maca products (*Lepidium meyenii*).

Examples of North American companies marketing products with Fair For Life certification that contain some Peruvian ingredients include:

- **Equal Exchange:** <http://equalexchange.coop/faq/fair-trade>
- **Good Superfood LLC (Good Cacao):** <http://www.goodcacao.com/>
- **Salve Sister LLC:** <http://www.salvesister.com/our-ingredients/>
- **Theo Chocolate:** <https://www.theochocolate.com/>

2.11. Fairtrade Canada



Fairtrade Canada: <http://fairtrade.ca/en>

Fairtrade Canada is a national, non-profit Fair Trade certification organization, and the only Canadian member of the Fairtrade International (FLO). Fairtrade Canada is responsible for certifying that Canadian products bearing the Fairtrade certification marks meet international Fairtrade standards. While the entire certification system monitors supply chains from the producers until the final point of packaging, we are responsible for monitoring and auditing products once they enter Canada, to ensure what is sold as Fairtrade certified actually is. Fairtrade Canada licenses Canadian companies to use the Fairtrade certification marks on their products, and as part of that licenced companies must abide by strict mark-use standards. It is of paramount importance that these marks not be used in a way that is misleading to the public, and we work with companies to ensure their use does not undermine the integrity of the marks.

Examples of companies registered with Fairtrade Canada that market products containing some ingredients from Peru include:

- **Alter Eco Foods:** <http://www.alterecofoods.com/>
- **Andean Naturals Inc.:** <http://www.andeannaturals.com/>
- **Equal Exchange:** <http://equalexchange.coop/faq/fair-trade>
- **La Siembra Co-operative, Inc.:** <http://www.lasiembra.com/camino/>
- **Level Ground Trading:** <http://www.levelground.com/>

2.12. Fairtrade International USA (FIU)



Fairtrade International USA (FIU): <http://fairtradeinternational.us/>

Fairtrade International (FLO) is the organization that coordinates Fairtrade labelling at an international level. FLO sets international Fairtrade standards, organizes support for producers around the world, develops global Fairtrade strategies, and promotes trade justice internationally. Fairtrade International USA (FIU) is a national, Fair Trade certification organization, and the only United States member of FLO.

Examples of companies registered with Fairtrade International USA that market products containing some ingredients from Peru include:

- **La Siembra Co-operative, Inc.:** <http://www.lasiembra.com/camino/>
- **Wonder Food Company, Inc.:** <http://wonderfoodco.com/>

2.13. Fair Trade Federation (FTF)



Fair Trade Federation (FTF): <http://www.fairtradefederation.org/>

The Fair Trade Federation (FTF) is the trade association that strengthens and promotes North American organizations fully committed to fair trade. FTF is part of the global fair trade movement, building equitable and sustainable trading partnerships and creating opportunities to alleviate poverty. The Federation's values guide our work to create a just and sustainable economic system.

Examples of FTF member companies that market products with some Peruvian ingredients include:

- **Alter Eco Foods:** <http://www.alterecofoods.com/>
- **Andean Dream™ LLC:** <http://www.andeandream.com/>
- **Andean Naturals Inc.:** <http://www.andeannaturals.com/>
- **Equal Exchange:** <http://equalexchange.coop/faq/fair-trade>
- **Global Exchange:** <http://www.globalexchange.org/>

2.14. Fair Trade USA (FTUSA)



Fair Trade USA (FTUSA): <http://www.fairtradeusa.org/>

Fair Trade USA (FTUSA), a 501 (c) (3) non-profit organization, is the leading third-party certifier of Fair Trade products in the United States. FTUSA enables sustainable development and community empowerment by cultivating a more equitable global trade model that benefits farmers, workers, consumers, industry and the earth. We achieve our mission by certifying and promoting Fair Trade products.

Examples of companies registered with Fair Trade USA that market products containing some ingredients from Peru include:

- **Alter Eco Foods:** <http://www.alterecofoods.com/>
- **Andean Naturals Inc.:** <http://www.andeannaturals.com/>
- **Equal Exchange:** <http://equalexchange.coop/faq/fair-trade>
- **W.S. Badger Company:** <http://www.badgerbalm.com/>

2.15. FairWild (Fair Wild Foundation)

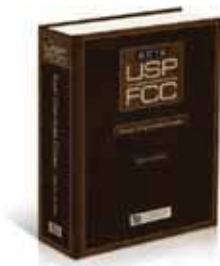


Fair Wild Foundation (FWF): <http://www.fairwild.org/>

The FairWild Foundation (FWF), a non-profit foundation based in Switzerland, promotes the sustainable use of wild-collected ingredients, with a fair deal for all those involved throughout the supply chain. The FairWild Foundation promotes the FairWild Standard and certification system for the sustainable management and collection of wild plants.

There are no FairWild® Certified operators in Perú yet. The Fair Wild Standard has been implemented, however, in Bolivia (Plurinational State of) for sustainably wild harvested cocoa beans and there are implementation projects for various plant species with companies in Brazil.

2.16. Food Chemicals Codex (FCC)



Food Chemicals Codex (FCC): <http://www.usp.org/food-ingredients/food-chemicals-codex>

The Food Chemicals Codex (FCC) is a compendium of internationally recognized standards for the purity and identity of food ingredients. Various FCC specifications are incorporated in the US Code of Federal Regulations (CFR) to define specific ingredients. The FCC monographs include food-grade coatings, colouring agents, emulsifiers, flavouring agents, masticatory substances (e.g. Chicle FCC), nutrients (e.g., Kelp FCC as a source of iodine), thickeners and stabilizers, vitamins, and functional food ingredients.

Examples of FCC monographs for botanical ingredients that may originate from Peru include Annatto Extract (*Bixa orellana*), Balsam Peru Oil (*Myroxylon pereirae*), Copaiba Oil (*Copaifera* spp..) and Tara Gum (*Caesalpinia spinosa*), among others.

Ingredients that test in compliance with the FCC monograph may be labelled with the FCC quality designation.

2.17. GMO Guard Verified (Natural Food Certifiers)



Natural Food Certifiers (NFC) GMO Guard: <http://nfccertification.info/extra-view/gmo-guard/>

The NFC GMO Guard Verification Programme meets the 'no-GMO' claim for the entire process from farm to table. The programme is designed to be clear and easy to navigate and is also affordable.

This is a newly announced standard (in 2013). At the time of this report there are no known certified companies with products containing ingredients from Peru.

2.18. Green America



Green America: <http://www.greenamerica.org/>

Green America® is a not-for-profit membership organization founded in 1982. Green America certifies businesses that are committed to using business as a platform for social change.

Examples of Green America certified North American companies that market products containing some Peruvian ingredients include:

- **Endangered Species® Chocolate:** <http://chocolatebar.com/pages.php?pageid=56>
- **Equal Exchange:** <http://equalexchange.coop/faq/fair-trade>
- **Gnosis Chocolate:** <http://www.gnosischocolate.com/>
- **Righteously® Raw Chocolates (Earth Source Organics):** <http://www.righteouslyrawchocolate.com/>
- **Salve Sister LLC:** <http://www.salvesister.com/our-ingredients/>
- **Theo Chocolate:** <https://www.theochocolate.com/>

2.19. Green-K-Kosher-Organic (Kosher Organics Council)



Kosher Organics Council (KOC) Green-K-Kosher: <http://green-k.org/>

The Kosher Organics Council offers Green-K kosher certification for products that maintain the strictest orthodox kosher supervision and certification criteria, and the highest organic and natural standards. The Kosher Organics Council is a worldwide organization founded in 2008 by a cross section of Rabbi's and observant lay leaders who saw the need for educating and building business and Jewish community support around the central theme of healthy and sustainable lifestyles.

Examples of North American companies with Green-K-Kosher certified products that contain Peruvian ingredients include:

- **Akea LLC:** <http://goodlifewith.akealife.com/>
- **Raw One (Cacao Incan Berry Biscotti):** <http://www.rawonefood.com/>

2.20. Non-GMO Project Verified



Non-GMO Project: <http://www.nongmoproject.org/>

The Non-GMO Project, a non-profit 501(c)3 organization, offers North America's only third party verification and labelling for non-GMO (genetically modified organism) food and products. The Non-GMO Project is committed to preserving and building sources of non-GMO products, educating consumers, and providing verified non-GMO choices.

Examples of companies marketing Non-GMO Project Verified products that contain some Peruvian ingredients include:

- **Alter Eco Foods:** <http://www.alterecofoods.com/>
- **Endangered Species® Chocolate:** <http://chocolatebar.com/pages.php?pageid=56>
- **Essential Living Foods:** <http://essentiallivingfoods.com/>
- **Gnosis Chocolate:** <http://www.gnosischocolate.com/>
- **Kiwa®:** <http://www.kiwalife.com/home/quality-certifications/>
- **Navitas Naturals:** <http://navitasnaturals.com/>
- **Righteously® Raw Chocolates (Earth Source Organics):** <http://www.righteouslyrawchocolate.com/>
- **Salba Smart®:** <http://www.salbasmart.com/>

- **Sunfood™ Super Foods:** <http://www.sunfood.com/>
- **Theo Chocolate:** <https://www.theochocolate.com/>
- **Two Moms in the Raw:** <http://www.twomomsintheraw.com/>
- **Vega™ Savi Seed™:** contains roasted sacha inchi seeds: <http://myvega.com/>
- **Vigilant Eats:** <http://www.vigilant-eats.com/>

2.21. Raw Food

There are no raw food standards available yet for independent third party inspection and certification or verification. Many finished product companies however label and market their products with raw food claim statements and/or their own raw food logo or designations.

Examples of North American companies marketing raw food products that contain some Peruvian ingredients include:

- **Agj's Raw Foods:** <http://www.agisrawfoods.com/>
- **Gnosis Chocolate:** <http://www.gnosischocolate.com/>
- **Gopal's® Nature's Gift:** <http://gopalshealthfoods.com/>
- **Love Raw Foods™ (Blue Mountain Organics):** <http://www.bluemountainorganics.com/>
- **Navitas Naturals:** <http://navitasnaturals.com/>
- **Ojio™ (Ultimate Superfoods):** <http://ultimatesuperfoods.com/>
- **Raw One:** <http://www.rawonefood.com/>
- **Righteously® Raw Chocolates (Earth Source Organics):** <http://www.righteouslyrawchocolate.com/>
- **Sunfood™ Super Foods:** <http://www.sunfood.com/>
- **Two Moms in the Raw:** <http://www.twomomsintheraw.com/>

2.22. Sustainable Food Trade Association (SFTA)



Sustainable Food Trade Association (SFTA): <http://www.sustainablefoodtrade.org/>

The Sustainable Food Trade Association is a non-profit trade association that represents North American, mission-aligned organic food companies. SFTA's membership is comprised of a diverse mix of organic producers, processors, manufacturers, distributors and retailers. SFTA supports its members in implementing innovative sustainable business practices across the supply chain, from farm to retail. The SFTA mission is to build the capacity of the organic food trade to transition to sustainable business models.

Examples of SFTA members who market some Peruvian ingredients include:

- **Ciranda Organic Ingredients:** <http://www.ciranda.com/>

2.23. USDA National Organic Programme (NOP)



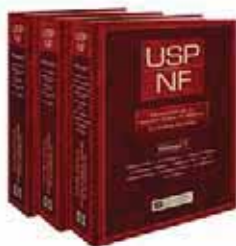
United States Department of Agriculture (USDA) National Organic Programme (NOP): <http://www.ams.usda.gov/AMSV1.0/nop>

The NOP regulates all organic crops, livestock, and agricultural products certified to the USDA organic standards. Organic certification agencies inspect and verify that organic farmers, ranchers, distributors, processors, and traders are complying with the USDA organic regulations. USDA conducts audits and ensures that the more than 90 organic certification agencies operating around the world are properly certifying organic products. In addition, USDA conducts investigations and conducts enforcement activities to ensure all products labelled as organic meet the USDA organic regulations. In order to sell, label, or represent their products as organic, operations must follow all of the specifications set out by the USDA organic regulations.

Examples of North American companies with NOP certified products that contain some Peruvian ingredients include, among many others:

- **Alter Eco Foods:** <http://www.alterecofoods.com/>
- **Endangered Species® Chocolate:** <http://chocolatebar.com/pages.php?pageid=56>
- **Gnosis Chocolate:** <http://www.gnosischocolate.com/>
- **Love Raw Foods™ (Blue Mountain Organics):** <http://www.bluemountainorganics.com/>
- **Navitas Naturals:** <http://navitasnaturals.com/>
- **Organic Vegan Superfoods LLC:** <http://organicvegansuperfoods.com/>
- **Righteously® Raw Chocolates (Earth Source Organics):** <http://www.righteouslyrawchocolate.com/>
- **Sunfood™ Super Foods:** <http://www.sunfood.com/>
- **Vigilant Eats:** <http://www.vigilant-eats.com/>
- **Wonder Food Company, Inc.:** <http://wonderfoodco.com/>

2.24. United States Pharmacopeia – National Formulary (USP-NF)



United States Pharmacopeia (USP) – National Formulary (NF): <http://www.usp.org/>

The United States Pharmacopeia (USP) is a non-governmental, official public standards-setting authority for prescription (Rx) and over-the-counter (OTC) medicines and other healthcare products manufactured or sold in the United States, including excipients, food ingredients, and dietary supplement components. The USP's standards are recognized and used in more than 130 countries around the globe. The USP produces 4 types of monographs that cover a large range of botanical ingredients: (1) dietary supplement component; (2) excipient; (3) food ingredient; and (4) pharmaceutical active ingredient (OTC and Rx). Examples of USP monographs for botanical ingredients that could originate from Peru include Capsicum Oleoresin USP (*Capsicum annuum* var. *minimum* and *C. frutescens*), Cat's Claw USP (*Uncaria tomentosa*) and Ipecac USP (*Cephaelis acuminata* or *C. ipecacuanha*), among others.⁹⁴

The National Formulary (NF) is also an official compendium. The NF provides specifications for excipients (e.g., antioxidants, binders, bulking agents, colouring agents, flavouring agents, perfumes, pharmaceutical bases, sweetening agents). Examples of NF monographs for botanical ingredients that could originate from Peru include Chocolate powder NF (*Theobroma cacao*), Cocoa butter NF (*Theobroma cacao*) and Potato starch NF (*Solanum tuberosum*), among others. Ingredients that test in compliance with a USP or NF monograph may be labelled with the USP or NF quality designation.

⁹⁴ Brinckmann, J.A. (2011). Reproducible efficacy and safety depend on reproducible quality: Matching the various quality standards that have been established for botanical ingredients with their intended uses in cosmetics, dietary supplements, foods, and medicines. *HerbalGram: The Journal of the American Botanical Council*; 91:40-55.

2.25. USP Verified Dietary Ingredients



USP Verified Ingredients: <http://www.usp.org/usp-verification-services/usp-verified-dietary-ingredients>

Manufacturers of dietary ingredients that pass USP Verification can display the USP Verified Ingredient Mark on containers of verified products, as well as on an accompanying Certificate of Analysis. When the manufacturers of dietary supplement finished products see this distinctive mark on the containers of ingredients they buy, they can feel confident that

- The ingredients are consistent in quality from batch to batch.
- The ingredients meet label or certificate of analysis claims for identity, strength, purity, and quality.
- The ingredients are prepared in accordance with accepted manufacturing practices.
- The ingredients meet requirements for acceptable limits of contamination

2.26. USP Verified Dietary Supplements



USP Verified Dietary Supplements: <http://www.usp.org/usp-verification-services/usp-verified-dietary-supplements>

Products that meet the programme's stringent criteria are awarded the distinctive USP Verified Mark for use on labels, packaging, and promotional materials. The Mark makes it easy for customers, healthcare practitioners, and retailers to identify USP Verified products. Seeing the USP Verified Mark on a label indicates that the dietary supplement product inside:

- Contains the ingredients listed on the label, in the declared potency and amounts.
- Does not contain harmful levels of specified contaminants.
- Will break down and release into the body within a specified amount of time.
- Has been made according to FDA current Good Manufacturing Practices using sanitary and well-controlled procedures.

2.27. Vegan Certified (Natural Food Certifiers)



Natural Food Certifiers (NFC) Vegan Certified: <http://nfccertification.com/companies/>

Examples of North American companies marketing products containing Peruvian ingredients that are NFC Vegan Certified include:

- **Two Moms in the Raw:** <http://www.twomomsintheraw.com/>
- **Vigilant Eats:** <http://www.vigilant-eats.com/>

2.28. Vegan Verified (Earth Kosher)



EarthKosher® Vegan Verified: <http://earthkosher.com/joint-vegan-and-kosher-certification/>

In response to the call for a more reliable and responsive mechanism for verifying the authenticity of Vegan products EarthKosher now offers a Vegan Verification programme. The standards for the Vegan Verification programme are that a product contains no animal products or animal product derivatives whatsoever, i.e. 'Zero Tolerance'.

Examples of North American companies with EarthKosher® Vegan Verified products that contain Peruvian ingredients include:

- **Righteously® Raw Chocolates (Earth Source Organics):** <http://www.righteouslyrawchocolate.com/>

Chapter 6 Tariff classification and duty rates

1. Golden Berry – Dried

According to the tariff schedules of Colombia and Peru, respectively, 'fresh' Cape gooseberry (*Physalis peruviana*) also known as Uchuvas ('uvillas') has the Harmonized System (HS) code of 0810.90.5000. 'Dried' golden berry would be classified under HS 0813.40 lumped with other dried fruits and nuts (*Las demás frutas u otros frutos*).

1.1. Canada

The Canada Customs Tariff code for 'fresh' gooseberry is HS 0810.30.000 (lumped together with black, red or white currants) with a most favoured nation (MFN) tariff of 'free' and a preferential tariff applicable to Peru of 'free'.

'Other' fresh berries have the code HS 0810.90.0020 and may also enter Canada duty free.

Frozen gooseberries (uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter) has the code HS 0811.20.0090 with a preferential tariff applicable to Peru of 'free'.

'Other' dried fruits have the code HS 0813.40.0090 with a preferential tariff applicable to Peru of 'free'.

1.2. United States

In January 2012, there was a U.S. Customs and Border Protection ruling for a 'Dragon Fruit & Cape Gooseberry' snack mix product being imported into the United States from Colombia.⁹⁵ While U.S. Customs ruled that the Harmonized Tariff Schedule of the United States (HTSUS) code for this dried fruit mix would be 0813.50.0020 at a rate of duty of 14% ad valorem, it was also stated that 'Articles classifiable under subheading 0813.50.0020, HTSUS, which are products of Colombia may be entitled to duty free treatment under the Andean Trade Preference Act (ATPA) upon compliance with all applicable regulations'.

Indeed, the HTSUS 2013 edition⁹⁶ states that 'other' dried berries (HS 0813.40.2060) have a 'general' rate of duty of 1.4 cents per kg and dried fruit mixtures (HS 0813.50.0020) have a general rate of duty of 14%, both if exported by a Peruvian company should qualify for a special rate of duty as per the provisions of the United States-Peru Trade Promotion Agreement Implementation Act (PTPA).

The 'General' or normal trade relations (NTR) rates are applicable to products of those countries which are not entitled to special tariff treatment. The 'Special' rates of duty under one or more special tariff treatment programmes apply to those products which are properly classified under a provision for which a special rate is indicated and for which all of the legal requirements for eligibility for such programme or programmes have been met.

Because dried golden berries from Peru are plants and plant products harvested or gathered in the territory of Peru, they should qualify as duty free as per PTPA.

95 United States Customs and Border Protection. (2012). The tariff classification of snack mixes from Colombia. In: Customs Rulings Online Search System (CROSS). Available from: <http://rulings.cbp.gov/index.asp?ru=n199680&qu=gooseberry&vw=detail>

96 United States International Trade Commission (USITC) (2013). Harmonized Tariff Schedule of the United States. Washington, D.C.: USITC. Available from: <http://www.usitc.gov/publications/docs/tata/hts/bychapter/1300htsa.pdf>

2. Peruvian mesquite – flour

2.1. Canada

In the Canada Customs Tariff, Peruvian mesquite flour should be grouped within HS 1901.90.20 (Food preparations of flour, meal, starch or malt extract) with a preferential tariff applicable to Peru of 'free'.

2.2. United States

In July 1996, there was a U.S. Customs and Border Protection ruling for mesquite powder (*Prosopis pallida*, known as algarrobo) being imported into the United States from Peru.⁹⁷ U.S. Customs ruled that the applicable subheading for the mesquite powder will be 1901.90.9095, Harmonized Tariff Schedule of the United States (HTSUS), which provides for food preparations of flour, meal, starch or malt extract...not elsewhere specified or included... other...other...other, and that the rate of duty would be 8.8% ad valorem.

At that time, U.S. Customs also stated that:

'Articles classifiable under subheading 1901.90.9095, HTS, which are products of Peru, are entitled to duty free treatment under the Andean Trade Preference Act (ATPA), upon compliance with all applicable regulations. The importation of this merchandise may be subject to restrictions imposed by the United States Department of Agriculture (USDA) and/or Food and Drug Administration (FDA). It is suggested you contact these agencies directly for further information. This ruling is being issued under the provisions of Part 177 of the Customs Regulations (19 CFR 177).'

However, the current HTSUS 2013 edition states that HS 1901.90.9095 has a 'general' rate of duty of 6.4%, but if exported by a Peruvian company it should qualify for a 'special' rate of duty as per the provisions of the United States-Peru Trade Promotion Agreement Implementation Act (PTPA).

Because mesquite flour from Peru is a plant or plant product harvested or gathered in the territory of Peru, it should qualify as duty free as per PTPA.

3. Sacha inchi – seed and oil

According to SIICEX (Sistema Integrado de Información de Comercio Exterior), the tariff code for sachá inchi seed could be HS 1207.99.9000 (other oil seeds and oleaginous fruits) or HS 2008.19.9000 (other nuts).

The tariff code for sachá inchi oil could be HS 1515.90.0000 (other fixed vegetable fats and oils and their fractions, whether or not refined, but not chemically modified) or HS 1518.00.9000 (other vegetable fats and oils and their fractions, boiled, oxidized, dehydrated, sulfurized, blown, polymerized by heat in vacuum or in inert gas or otherwise chemically modified).

3.1. Canada

In the Canada Customs Tariff, roasted sachá inchi seeds should be grouped within HS 2008.19.9090 (other nuts) with a preferential tariff applicable to Peru of 'free'.

Sachá inchi oil, whether grouped within HS 1515.90 (other...other fixed vegetable fats and oils fractions, whether or not refined, but not chemically modified) or within HS 1518.00.90 (other vegetable fats and oils and their fractions; chemically modified) would qualify for a preferential tariff applicable to Peru of 'free'.

⁹⁷ United States Customer and Border Protection (1996). The tariff classification of mesquite powder from Peru. In: Customs Rulings Online Search System (CROSS). Available from: <http://rulings.cbp.gov/index.asp?ru=a82977&qu=Prosopis&vw=detail>

3.2. United States

In June 2007, there was a U.S. Customs and Border Protection ruling for roasted sachu inchi nuts (also known as 'Inca peanut' or 'Inca nut,' the seed from the plant *Plukenetia volubilis* L.) being imported into the United States from Peru.⁹⁸ U.S. Customs ruled that the applicable subheading for the roasted sachu inchi nuts will be 2008.19.9090, HTSUS, which provides for fruit, nuts and other edible parts of plants, otherwise prepared or preserved...nuts, peanuts (ground nuts) and other seeds...other...other...other; with a rate of duty of 17.9% ad valorem.

However, at that time, U.S. Customs additionally stated the following:

'Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided on World Wide Web at <http://www.usitc.gov/tata/hts/>.

Articles classifiable under subheading 2008.19.9090, HTS, which are products of Peru may be entitled to duty free treatment under the Generalized System of Preferences (GSP) upon compliance with all applicable regulations. The GSP is subject to modification and periodic suspension, which may affect the status of your transaction at the time of entry for consumption or withdrawal from warehouse. To obtain current information on GSP, check our website at www.cbp.gov and search for the term 'GSP'.

These goods may be subject to regulations or restrictions administered by the United States Department of Agriculture (USDA), Animal and Plant Health Division (APHIS). You may contact this agency regarding possible applicable regulations at the following location: United States Department of Agriculture APHIS Plant Protection and Quarantine Permit Unit 4700 River Road, Unit 136 Riverdale, MD 20737-1236 Telephone number: 877-770-5990.

This merchandise is also subject to The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The Bioterrorism Act), which is regulated by the Food and Drug Administration (FDA). Information on the Bioterrorism Act can be obtained by calling FDA at 301-575-0156, or at the website www.fda.gov/oc/bioterrorism/bioact.html.

However, the current HTSUS 2013 edition states that HS 2008.19.9090 has a 'general' rate of duty of 17.9%, but if exported by a Peruvian company it should qualify for a 'special' rate of duty of 'free' as per the provisions of the United States-Peru Trade Promotion Agreement Implementation Act (PTPA).

Because sachu inchi seed from Peru is a plant or plant product harvested or gathered in the territory of Peru, it should qualify as duty free as per PTPA.

Regarding sachu inchi oil, there have been no rulings. However, if classified within HS 1515.90 (other fixed fats and oils from nuts or seeds; not chemically modified) or within HS 1518.00 (other vegetable fats and oils and their fractions; chemically modified), in either case the oil should qualify for a 'special' rate of duty of 'free' as per the PTPA.

98 United States Customs and Border Protection. (2007). The tariff classification of roasted sachu inchi nuts from Peru. In: Customs Rulings Online Search System (CROSS). Available from: <http://rulings.cbp.gov/index.asp?ru=n011450&qu=Plukenetia&vw=detail>

Chapter 7 Competitor analysis

1. Golden berry – existing competitors

Companies interviewed for this study, both Peruvian and North American, suggested that the main existing competitors for golden berry would be small dried berries or other small dried fruits that could be used as components of breakfast cereals such as granola or muesli, nutrition bars, carob- or chocolate- coated bars or fruits, healthy snacks or trail mixes (combinations of dried fruits, nuts and seeds). In this regard, most often mentioned were cranberry, goji berry and raisin.

1.1. Cranberry

Harmonized Tariff Schedule of the United States (HTSUS):

HS 0810.40.0030	Cranberries, fresh
HS 0811.90.3500	Cranberries, frozen
HS 2008.90.0000	Cranberries, prepared or preserved
HS 2008.99.2000	Cranberry, sauce (packed for retail)
HS 2008.99.2100	Cranberries, prepared or preserved, other
HS 2008.99.2140	Cranberries, dried
HS 2009.81.0000	Cranberry, juice

Defined in the monograph of the 'American Herbal Pharmacopoeia (AHP) and Therapeutic Compendium', 'Cranberry fruit consists of the fresh or dried whole, crushed, or powdered mature fruits of *Vaccinium macrocarpon* Aiton (Fam. Ericaceae) conforming to the methods of identification and standards provided'.⁹⁹

For preparations to be used as components of Dietary Supplement Products (DSPs), the 'Cranberry Liquid Preparation' monograph of the USP is available: 'Cranberry Liquid Preparation is a bright red juice derived from the fruits of *Vaccinium macrocarpon* Aiton or *Vaccinium oxycoccos* L. (Fam. Ericaceae). It contains no added substances'.¹⁰⁰

For use as a conventional food ingredient, the USDA enforces the 'United States Standards for Grades of Fresh Cranberries',¹⁰¹ the 'United States Standards for Grades of Fresh Cranberries for Processing',¹⁰² and the 'United States Standards for Grades of Frozen Cranberries'.¹⁰³

In Canada, Cranberry fruit is used as a medicinal ingredient of licensed Natural Health Products (NHPs)¹⁰⁴ usually in the form of dried extract or dried juice concentrate (powder or granules) in capsule or tablet form but also in liquid dosage forms or oral administration. At this time there are nearly 400 licensed NHPs that contain Cranberry fruit (extract or juice) as an active ingredient. Some of these carry antioxidant claim statements but most are indicated for the prevention of recurrent urinary tract infections or are components

99 Upton, R. (ed.) et al. (2002). Cranberry Fruit *Vaccinium macrocarpon* Aiton. In: American Herbal Pharmacopoeia™ and Therapeutic Compendium. Scotts Valley, CA: American Herbal Pharmacopoeia.

100 United States Pharmacopeial Convention. (2012) United States Pharmacopeia, 35th Revision (USP 35). Rockville, MD: United States Pharmacopeia Convention.

101 United States Department of Agriculture (USDA). (1971). United States Standards for Grades of Fresh Cranberries. Washington, D.C.: USDA. Available from: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5050346>

102 United States Department of Agriculture (USDA). (1957). United States Standards for Grades of Fresh Cranberries for Processing. Washington, D.C.: USDA. Available from: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5050411>

103 United States Department of Agriculture (USDA) (1971). United States Standards for Grades of Frozen Cranberries. Washington, D.C.: USDA. Available at: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3019659>

104 Health Canada Natural Health Products Directorate (NHPD). (2011). Monograph: Cranberry. Available at: <http://webprod.hc-sc.gc.ca/nhp/nd-bdpsn/monoReq.do?id=71&lang=eng>

of diuretic formulations. As a non-medicinal ingredient of licensed NHPs, Cranberry fruit (in extract or juice forms, dry or liquid) is also permitted for use as a flavour enhancer component (albeit at non-therapeutic dosage levels). For the use of Cranberry fruit as an ingredient of conventional food products, Canada's 'Grades and Standards for Cranberries' are found in the 'Fresh Fruit and Vegetable Regulations' published by the Minister of Justice.

In addition to the use of Cranberry fruit ingredients as components of DSPs in the United States and NHPs in Canada, the dried berries are used in both countries as components of natural breakfast cereals, fruit bars, trail mixes (with nuts and seeds) and other health food products.

Figure 8. Examples of cranberry licensed natural health products in the Canadian market



Figure 9. Examples of cranberry food products in the United States market



1.2. Goji berry

Harmonized Tariff Schedule of the United States (HTSUS):

- HS 1211.90.8090 Goji Berry (*Lycii fructus*), dried
- HS 1302.19.9140 Goji Berry, liquid extract
- HS 2009.80.6029 Goji Berry, fruit juice

Goji berry is an Americanized name based on its Chinese name '*gou qi zi*'. Its Standardized Common Name (SCN) in the United States is 'Lycium fruit'. Use of the name 'goji fruit' is, however, an accepted common name in Canada (along with *Lycii Fructus*) and it is also widely used in the United States.

Because the practice of Traditional Chinese Medicine (TCM) is legal in Canada as well as in many States of the United States – and because the Canadian Natural Health Product (NHP) regulations expressly permit the marketing authorization of traditional medicine products of the Oriental systems of medicine, the standards for goji berry from the pharmacopoeias of China (PPRC), Japan (JP), and Korea (KP), respectively, can be relevant:

- Lycii Fructus JP – is the fruit of *Lycium chinense* Miller or *Lycium barbarum* Linné (Solanaceae).¹⁰⁵
- Lycii Fructus KP – is the dried fruit of *Lycium chinense* Miller or *Lycium barbarum* Linné (Solanaceae). Lycium fruit, when dried, contains not-less-than (NLT) 0.5% of betaine.¹⁰⁶
- Lycii Fructus PPRC – is the dried ripe fruit of *Lycium barbarum* L. (Fam. Solanaceae). The drug is collected in summer and autumn when the fruit turns red, hot-air dried and removed from the fruit stalk; or dried in the shade until the exocarp is shrunk, and dried in the sun to dryness, removed from the fruit stalk. Contains NLT 0.30% of betaine.¹⁰⁷

In the United States and Canada, Goji berries are dispensed to patients as active ingredients of TCM formulations that are prescribed by Licensed Acupuncturists (L.Ac.) and/or Naturopathic Doctors (N.D.). In the United States they are also a popular component of Dietary Supplement Products (DSPs) as well as of healthy food products, particularly those marketed in the emerging niche categories of certified organic, non-GMO verified, certified gluten-free, certified vegan, and certified raw foods.

In Canada, presently there are over 200 licensed NHPs that contain Lycium fruit as a medicinal ingredient, most that are authorized with recommended uses according to Asian systems of traditional medicine (see table 1). There are also certain forms of Lycium fruit that are permitted for specific uses as non-medicinal ingredients of NHPs. For example,

- ‘Lycium Chinense Fruit Extract’ is permitted for use as a ‘Preservative Antioxidant’ ingredient of topical application NHPs;
- ‘Lycium Barbarum Fruit Flavour’ is permitted for use as a ‘Flavour Enhancer’ component of oral ingestion NHPs;
- ‘Lycium Barbarum Fruit Extract’ (dry or liquid) is permitted for use as a ‘Hair-conditioning Agent’, ‘Nail-conditioning Agent’ and/or ‘Skin-conditioning Agent’ of topical application NHPs; and
- ‘Lycium Barbarum Fruit’ (dried) is permitted for use as a ‘Flavour Enhancer’ component of oral ingestion NHPs (except it would be a medicinal ingredient when used as a component of Traditional Chinese Medicine (TCM) products).

105 Japanese Pharmacopoeia, (2011). Sixteenth Edition. Tokyo, Japan: Ministry of Health, Labour and Welfare.

106 Korean Pharmacopoeia, Ninth Edition (KP IX). (2007) Seoul, Republic of Korea: Korea Food and Drug Administration. 2007.

107 Pharmacopoeia of the People’s Republic of China. (2010). Beijing, China: China Medical Science Press. 2010.

Figure 10. Examples of goji berry licensed natural health products in the Canadian market



Figure 11. Examples of goji berry food products in the United States market



1.3. Raisin

Harmonized Tariff Schedule of the United States (HTSUS):

HS 0806.20.10	Raisins made from seedless grapes
HS 0806.20.1010	Currants
HS 0860.20.1012	Sultanas
HS 0806.20.1090	Other
HS 0806.20.2000	Other raisins

Verification of compliance with the ‘United States Standards for Grades of Processed Raisins’ falls under the authority of the USDA Agricultural Marketing Service (AMS). The standards serve as a basis for inspection and grading and upon request a company can have the grade of their raisins verified by USDA.

‘Processed Raisins are dried grapes of the Vinifera varieties, such as Thompson Seedless (Sultanina), Muscat of Alexandria, Muscatel Gordo Blanco, Sultana, Black Corinth or White Corinth. The processed raisins are prepared from clean, sound, dried grapes; are properly stemmed and capstemmed except for

cluster or uncapstemmed raisins; are properly seeded in seeded styles; are sorted or cleaned, or both; and except for cluster or uncapstemmed raisins, are washed in water to assure a wholesome product'.¹⁰⁸

Additionally, there are specific regulations in place for raisins that are produced from grapes grown in the State of California.¹⁰⁹

For the most part, in both Canada and the United States, raisins are used as components of conventional food products such as breakfast cereals including granola and muesli, fruit bars, breads like cinnamon-raisin bread, carob covered or chocolate covered raisins, oatmeal-raisin cookies and pastries, trail mixes (combined with nuts and seeds), and raisins eaten directly as a healthy food product.

Figure 12. Examples of raisin food products in the United States market



2. Golden berry – potential for new producers to enter market

Interview respondents for this study remarked there is a potential for a distinct Peruvian variety or ecotype of golden berry to enter the North American market but this would require effective marketing strategies involving consumer education necessary to differentiate Peruvian qualities (by appearance, colour and taste) from the Colombian and Ecuadorian varieties that presently dominate the market. At the same time, it would require the development of a Peruvian standard (in contrast to the already established Colombian standard) with corresponding implementation of Good Agricultural Practices (GAPs) specific to golden berry in order to offer a consistent grade and quality that can be recognized, labelled and marketed as distinctly Peruvian.

One respondent stated that the market potential for the whole dried berries (for use as components of bars, breakfast cereals and cookies) is greater than for other processed forms like jams, preserves, juices and instant quick frozen (IQF). Another respondent stated that Peruvian golden berry could become as big in the North American market as the Brazilian acai berry (*Euterpe oleracea*). However, for the market to grow to that size, several respondents emphasized the need to clearly differentiate Peruvian golden berry from Colombian golden berry. One respondent was even concerned that if the United States consumer's first experience of golden berry is the Colombian variety, this could be detrimental to the market for Peruvian golden berries. The reason for this concern is that people do not yet realize that other ecotypes or varieties may have significantly different organoleptic characteristics (appearance, colour, odour and taste). Peruvian golden berry needs a clearly defined Peruvian brand identity that can be positioned as a unique grade that is distinct from Colombian, in particular, and could possibly justify a price premium associated with a specified grade designation.

108 United States Department of Agriculture (USDA) (1978). United States Standards for Grades of Processed Raisins. Washington, D.C.: USDA. Available from: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5068897>

109 United States Department of Agriculture (USDA) (2012). Raisins produced from grapes grown in California. In: Code of Federal Regulations, Title 7, Part 989 (7CFR §989). Washington, D.C.: United States Government Printing Office. Available at: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title7-vol8/pdf/CFR-2012-title7-vol8-part989.pdf>

Many respondents stated that interest in the application of golden berry in new product development projects is high. There are more requests than presently can be fulfilled in consideration of currently available quantities for export. Cultivation and production capacity in Peru is still a challenge and limited (by comparison to the scale of production in Colombia). Scaling up cultivation however is possible and capacity could increase rapidly with investment, prioritization, and GAP training for golden berry growers.

New producers of Peruvian golden berries should have a good chance to enter the United States and Canadian markets if:

- Unique Peruvian standards for grades of golden berries can be defined and implemented for labelling and export marketing;
- GAPs specific to Peruvian golden berry can be implemented along with other relevant quality assurance management systems for food safety, hygiene, quality control and traceability;
- Investment in more efficient harvesting and post-harvest technologies can occur coupled with reduced costs from new economies of scale;
- An effective marketing campaign articulates the distinguishing characteristics that differentiate Peruvian golden berry from all other competing origins.

3. Golden berry – substitution and comparison of features

3.1. Availability comparison

Comparing the relative market availability of similar dried fruit ingredients that golden berry would compete against (or be substituted with) both cranberries and raisins are major crops in the United States for domestic consumption and for export. Cranberries are also produced on a large scale in Canada. The supply of goji berry is imported entirely from its country of origin China and has become a very popular component of food products and dietary supplement products over the past decade. The ready availability of these competing dried fruits in the United States and Canada is strong and they are generally in stock year round at warehouses of most wholesale distribution companies that supply bulk dried fruit ingredients to product manufacturers.

The following is a summary of the commercial availability of cranberries, goji berries and raisins in the United States.

Cranberries

In August of 2012 United States cranberry production for the season was forecast at 7,684,500 barrels, which at 45.3597 kg per barrel would equal 348,566,610 kg of fresh cranberries, down less than 1% from the 2011 harvested total of 7,711,700 barrels (= 349,800,390 kg).¹¹⁰

The United States is the world's leading producer, consumer and exporter of cranberry fruit ingredients. Canada is the second largest producer and exporter. Cranberry is a Native American species for which the global supply is cultivated almost entirely in northern North America. In the United States, most of the supply is cultivated in the States of Wisconsin (about 57%) and Massachusetts (about 28%) with smaller amounts grown in New Jersey, Oregon, Washington, and Maine. In Canada, over half of the production occurs in the Province of British Columbia, followed by Quebec, New Brunswick, Nova Scotia, and Prince Edward Island.¹¹¹

In the United States the production and handling of cranberries is regulated under the Federal Cranberry Marketing Order, which is part of the Agricultural Marketing Agreement Act of 1937. This Act specifies

¹¹⁰ United States Department of Agriculture (USDA) (2012). National Agricultural Statistics Service (NASS). Cranberries: 2012 cranberry production down slightly. Available at: <http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1044>

¹¹¹ Brinckmann, J.A. (2010). Taking a closer look at the cranberry fruit trade from the United States. Market News Service for Medicinal Plants and Extracts; No. 37:45-51

cranberries as a commodity that may be covered, regulations that may be issued, guidelines for administering the programmes, and privileges and limitations granted by United States Congress. The Cranberry Marketing Committee was established as a Federal Marketing Order in 1962 to maintain favourable supply and demand equilibrium for the United States cranberry industry.

The regulation defines the cranberry production area as limited to the States of Massachusetts, Rhode Island, Connecticut, New Jersey, Wisconsin, Michigan, Minnesota, Oregon, Washington, and Long Island in the State of New York. Each season prior to making any recommendation the Cranberry Marketing Committee must submit to the Secretary of the United States Department of Agriculture a report setting forth its marketing policy for the crop year. The marketing policy must contain the following information for the current crop year:

- The estimated total production of cranberries;
- The expected general quality of such cranberry production;
- The estimated carryover, as of September 1, of frozen cranberries and other cranberry products;
- The expected demand conditions for cranberries in different market outlets;
- The recommended desirable total marketable quantity of cranberries including a recommended adequate carryover into the following crop year of frozen cranberries and other cranberry products;
- Other factors having a bearing on the marketing of cranberries.

Similarly in Canada, provincial commodity marketing boards are established, such as The British Columbia Cranberry Marketing Commission, with the authority to promote, regulate and control in any and all respects, the transportation, processing, packing, storing and marketing of cranberries. The British Columbia Cranberry Marketing Scheme was enacted by the Province of British Columbia in 1968 by British Columbia Regulation 259/68.

Goji Berries

China is the world's leading consumer, producer and exporter of goji berries (*Fructus Lycii*), with a 2009 export trade volume of 5,825,141 kg dry weight (= customs value of US\$ 29,168,519) which was about 61.5% greater than previous year. Although China is the only producer for the global market, China imports a very small amount from the Democratic People's Republic of Korea; e.g. only 22,736 kg in 2009.

In terms of volume (kg), the top-five importers of goji berries in 2009 accounted for over 68% of total Chinese exports; (1) Hong Kong SAR (19.64%), (2) Chinese Taipei (15.78%), (3) Spain (15.23%), (4) Republic of Korea (11.29%), and (5) the Netherlands (6.85%).¹¹²

It is important to consider however that much or most of the goji that is imported by Hong Kong SAR is re-exported, for example to western countries like Canada, Commonwealth of Australia, the United Kingdom and the United States, among others. It is difficult to determine the precise quantities imported by the United States or Canada without access to Hong Kong SAR re-export data for this item.

The main production areas for goji berries in China are the Tianjin area of Hebei Province, the Zhongning County and Zhongwei City areas of Ningxia Hui Autonomous Region, as well as in the Xinjiang Uyghur Autonomous Region, and areas in the Provinces of Gansu, Qinghai, Henan, Shaanxi, Sichuan, and Jiangsu, among others. Three different regional products can be distinguished: (1) western goji (*xi gou qi zi*) from Ningxia, Gansu, and Qinghai; (2) Tianjin goji (*jin gou qi zi*) from the Tianjin area of Hebei Province; and (3) local goji (*tu gou qi zi*), also called mountain goji (*shan gou qi zi*), which is the wild-crafted product from Henan Province.

Raisins

According to a report by Huntrods et al. (2013), raisins are the most popular dried fruit in the United States, accounting for about two-thirds of total dried fruit consumption. Raisins are primarily produced in the State of

112 Brinckmann, J.A. (2010). Taking a closer look at the lycium fruit (goji) trade from China. Market News Service for Medicinal Plants and Extracts. No. 37:15-22.

California's San Joaquin Valley and are sun dried. California raisin acreage (essentially accounting for all United States raisin acreage) has remained at 205,000 acres for the last two years.¹¹³

Global raisin production for the 2012/13 season is forecast at 1,153,000 tons with the United States as the leading producer at 300,000 tons (down from 335,200 tons in previous 2011/12 season). Following the United States are Turkey (270,000 tons), China (175,000 tons), Islamic Republic of Iran (155,000 tons), Chile (80,000 tons), South Africa (40,000 tons), Argentina (35,000 tons), Uzbekistan (35,000 tons), Afghanistan (34,000 tons), Commonwealth of Australia (10,000 tons) and other countries (19,000 tons).

In terms of domestic consumption the United States ranks at #2 whilst the EU-27 ranks at #1 and China at #3. In terms of exports, the United States also ranks at #2 whilst Turkey ranks at #1 and Iran ranks at #3. Consumption is forecast to keep pace with output on strong demand in a majority of markets.¹¹⁴

Sun-dried seedless raisins constitute 93% of the total raisin crop. These raisins are the most popular raisin for cooking, baking, salads, desserts and eating out of hand. Golden seedless raisins account for 5% of the total raisin crop. Golden raisins are mechanically dehydrated and specially treated with sulphur dioxide to preserve the golden colour. They are popular in fruitcakes. Currants are seedless mini-raisins made from a specific variety of grape, they are sun dried for use in baking.¹¹⁵

The California raisin marketing season lasts from the beginning of September to the end of May. The Raisin Administrative Committee (RAC), established through the federal Raisin Marketing Order regulating raisins produced from California grapes, has authority to determine the quality, volume and price of raisins that may be shipped by handlers in any marketing channel or that must be placed in a reserve pool to be disposed of by RAC.

The 56 page 'Marketing Policy and Industry Statistics 2012-2013 Marketing Season'¹¹⁶ by the RAC is downloadable at: http://www.raisins.org/images/marketing_policy_2012.pdf

3.2. Composition (nutrient, phytochemical) and quality characteristics comparison

Table 1 compares typical quality specifications of selected dried fruit ingredients that would compete with Golden Berry.

Table 1. Quality specifications comparison of fruits that compete with golden berry

	Cranberry (company specifications)	Goji Berry (KP-Grade or PPRC-Grade)	Golden Berry (company specifications)	Raisin (United States Grade A Seedless)
Appearance	Whole, sound, mature berries, individual and intact	Whole dried ripe berries; pericarp is soft, tough and crumpled; sarcocarp is pulpy, soft and tender	Whole dried berries, wrinkled surface, similar to a raisin	Whole dried berries; NLT 80% are well-matured or reasonably well-matured
Size	NMT 1% pass through US #4 screen	6-20 mm long, 3-10 mm diameter	5-20 mm long	NMT 60% pass through holes 22/64' diameter; NMT 10% pass through holes 20/64' diameter

113 Boriss, H., H. Brunke and M. Kreith (2006). Raisin profile. Agricultural Issues Center, University of California. Updated February 2013 by Diane Huntrods, AgMRC, Iowa State University. Available from: http://www.agmrc.org/commodities_products/fruits/raisin-profile/

114 United States Department of Agriculture (USDA) Foreign Agricultural Service (FAS). (2012). Raisins: World Markets and Trade. Washington, D.C.: USDA. Available from: <http://usda01.library.cornell.edu/usda/current/raiswm/raiswm-09-14-2012.pdf>

115 Boriss, H., H. Brunke and M. Kreith (2013). Raisin profile. Agricultural Issues Center, University of California. Updated February 2013 by Diane Huntrods, AgMRC, Iowa State University. Available at: http://www.agmrc.org/commodities_products/fruits/raisin-profile/

116 Raisin Administrative Committee (RAC). (2012). Marketing Policy & Industry Statistics 2012-2013 Marketing Season. Fresno, California RAC. Available from: http://www.raisins.org/images/marketing_policy_2012.pdf

	Cranberry (company specifications)	Goji Berry (KP-Grade or PPRC- Grade)	Golden Berry (company specifications)	Raisin (United States Grade A Seedless)
Colour	Typical uniform cranberry red	Red or dark red	Different tones of orange to brown	Typical dark reddish brown
Flavour	Typical – no off flavours	Sweet	Characteristic; sweet and slightly sour	Characteristic
Odour	Typical – no off odours	Slight	Characteristic	Not specified
Texture	Soft, chewy	Soft, chewy	Soft, chewy	Soft, chewy
Water (moisture)	13-18%	NMT 13.0%	8-14%	NMT 18%
Water activity	0.48-0.67	No standard	Aw < 0.7	Not specified
pH	2.0 to 3.0	No standard	Not specified	Not specified
Total ash	0.20 g / 100 g	NMT 5.0%	< 6.5%	Not specified
Foreign matter	None	NMT 3.0% of branch, fruit stalk and other foreign matter	Absent	Pieces of stem:NMT 1/6 per lb Capstems: NMT 15 per lb
Extraneous plant material (stalks, stems, leaves)	2 max /11.34 kg			
Defects	Not specified	Not specified	Not specified	NMT 4% discoloured, damaged, or mouldy raisins
Water soluble-extractives	Not specified	NLT 55.0%	Not specified	Not specified
Content	Not specified	NLT 0.30%betaine NLT 1.8% Polysaccharides	0.02% Vitamin C	Not specified
Lead	Not specified	NMT 5 ppm	Not specified	Not specified
Cadmium	Not specified	NMT 0.3 ppm	Not specified	Not specified
Arsenic	Not specified	NMT 2 ppm	Not specified	Not specified
Mercury	Not specified	NMT 0.2 ppm	Not specified	Not specified
Copper	0.055 mg /100g	NMT 20 ppm	Not specified	Not specified

Sources: Cranberry: Fruit d'Or Specification Sheet: Organic Whole Dried Cranberries¹¹⁷ and OceanSpray® Specification: Classic Whole Sweetened Dried Cranberries.¹¹⁸

Goji Berry: Pharmacopoeia of the People's Republic of China (PPRC 2010)¹¹⁹ and Korean Pharmacopoeia, Ninth Edition (KP IX).¹²⁰
Golden Berry: Inversiones 2A S.R.L. Ficha Técnica: Aguaymanto Deshidratado / Pasas; Isabelle Fruits Specification: Dried Golden berry; Peruvian Nature S&S SAC Ficha Técnica: Aguaymanto Fruta Deshidratada and Villa Andina Technical Data Sheet: Dehydrated Aguaymanto.

Raisin: United States Standards for Grades of Processed Raisins (USDA).

117 Fruit d'Or Inc. (2011). Specifications Sheet: Organic Whole Dried Cranberries. Available from: <http://www.fruit-dor.ca/en/bulk/organic/organic-cranberries/organic-dried-cranberries/11A01000-organic-whole-dried-cranberries.html>

118 Ocean Spray Cranberries Ingredient Technology Group. (2010). Customer Ingredient Specification: Classic Whole Sweetened Dried Cranberries. Available from: http://www.oceansprayitg.com/downloads/sdc/specs/UPC_98008_Classic_Whole_SDC_090309.pdf

119 Chinese Pharmacopoeia Commission. (2010). Lycii Fructus. In: Pharmacopoeia of the People's Republic of China, Volume I. Beijing, China: China Medical Science Press; 262-263.

120 Korean Pharmacopoeia, Ninth Edition (KP IX). (2007). Seoul, Republic of Korea: Korea Food and Drug Administration;1058.

3.3. Ease of application comparison

Dried golden berry and the other similar dried berries discussed in this chapter (cranberries, goji berries and raisins) have comparable physical characteristics (similar size, moisture content, soft and chewy texture). These dried berries are already being used as components of the same types of finished product formulations namely baked goods (breads, cakes, cookies, pastries), bars, breakfast cereals including granolas and mueslis, confectionaries and chocolates, frozen desserts (gelato, ice cream, sorbet), fruit and nut snack mixes, etc.

It appears that product formulators / innovators may substitute one small berry for the other or even combine them for flavour differentiation or uniqueness without requiring different processes or technologies for manufacturing the finished product. The ease of application for product developers to substitute or add golden berries to products formerly or presently containing cranberries or raisins appears to be possible without presenting new significant production challenges.

It would be helpful for the Peruvian golden berry industry to organize useful information through a website platform that is specifically geared towards professionals (e.g. new product innovators, chefs, dieticians and nutritionists, product manufacturers) similar to that of the California Raisin Marketing Board, available at: <http://www.calraisins.org/>, and/or the Cranberry Marketing Committee, available at: <http://www.uscranberries.com/>. Such a website would encourage new use of golden berries by providing concrete examples of ease of application along with the nutritional and technical information that is needed by professionals who are considering the use of golden berries in new product concepts or recipes.

3.4. Price comparison

Table 2 provides a typical average bulk ingredient pricing structure comparison at three tiers (distributor price, wholesale price and retail price) for dried cranberries, goji berries, golden berries and raisins in the United States natural foods channel. The prices shown are generic or typical catalogue prices for certified organic bulk ingredients which were current as the time of this study (April 2013). They do not take into account any special pricing for high volume or large customer contract pricing whereby the seller may take a lower margin in consideration of overall business.

Table 2. Price comparisons (US\$/lb): organic cranberry, goji berry, golden berry and raisin

Description	Pack size (lb)	Distributor price (US\$/lb)	Wholesale price (US\$/lb)	Retail price (US\$/lb)
Cranberries (apple juice sweetened) – origin: the United States	25	3.49	4.64	6.95
Cranberries (sweetened) – origin: the United States	25	2.10	2.79	4.19
Goji berries origin: China	10	12.61	16.77	25.15
Golden berries – origin: Not known	11	7.03	9.35	14.05
Golden raisins (sulphured) – origin: California	30	1.79	2.38	3.55
Jumbo flame raisins – origin: California	30	1.74	2.31	3.45
Thompson raisins – origin: California	30	1.35	1.79	2.69

Source: Price information in table 2 was provided confidentially by an information provider at a major independent national distributor of natural, organic and specialty foods and related products.

Note: 1.0 lb = 0.453597 kg.

3.5. Recommended uses comparison

Table 3. Recommended uses comparison for golden berry competitive products

Substance	Canada	United States
Cranberry	<p>Conventional food ingredient (labelled without health claims)</p> <hr/> <p>NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Traditionally used in Herbal Medicine to help prevent (recurrent) urinary tract infections (UTIs) • Used in Herbal Medicine to help prevent recurrent urinary tract infections (UTIs) in women • Provides antioxidants for the maintenance of good health <hr/> <p>Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> • Flavour enhancer 	<p>Conventional food ingredient (labelled without health claims)</p> <hr/> <p>DSP component (with structure / function claim statements):</p> <ul style="list-style-type: none"> • Supports a healthy urinary tract • For urinary tract health
Goji Berry	<p>Conventional food ingredient (labelled without health claims)</p> <hr/> <p>NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Traditional Chinese Medicine used as a liver and kidney tonic to replenish <i>Qi</i> (vital energy), <i>Xue</i> (blood) and improve eyesight • Traditional Chinese Medicine to reinforce the liver and the kidney, replenish vital essence and improve eyesight • Source of antioxidants for the maintenance of good health <hr/> <p>Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> • Flavour enhancer 	<p>Conventional food ingredient (labelled without health claims)</p> <hr/> <p>DSP component (with structure / function claim statements):</p> <ul style="list-style-type: none"> • Supports eye health • Supports healthy immune function <hr/> <p>TCM formulation component (dispensed by licensed clinicians):</p> <ul style="list-style-type: none"> • To nourish the liver and kidney, replenish essence to improve vision
Golden berry	Conventional food ingredient (labelled without health claims)	Conventional food ingredient (labelled without health claims)
Raisin	Conventional food ingredient (labelled without health claims)	Conventional food ingredient (labelling without health claims)

Sources: Health Canada Natural Health Products Directorate (NHPD) Natural Health Products Ingredients Database (NHPID), Health Canada Food and Drug Regulations, U.S. Food and Drug Administration (FDA) Dietary Supplement notification letters, and various FDA and USDA regulations

3.6. Regulatory status comparison

Table 4. Regulatory status comparison for golden berry competitive products

Substance	Canada	United States
Cranberry	<ul style="list-style-type: none"> Conventional food ingredient NHP medicinal ingredient Non-medicinal NHP ingredient (as flavour enhancer) 	<ul style="list-style-type: none"> Conventional food ingredient DSP component
Goji berry	<ul style="list-style-type: none"> Conventional food ingredient NHP medicinal ingredient Non-medicinal NHP ingredient (as flavour enhancer) TCM component (prescribed by clinicians) 	<ul style="list-style-type: none"> Conventional food ingredient. DSP component TCM component (prescribed by clinicians)
Golden berry	Conventional food ingredient	Conventional food ingredient
Raisin	Conventional food ingredient	Conventional food ingredient

Sources: Health Canada Natural Health Products Directorate (NHPD) Natural Health Products Ingredients Database (NHPID), Health Canada Food and Drug Regulations, U.S. Food and Drug Administration (FDA) Dietary Supplement notification letters, and various FDA and USDA regulations.

4. Peruvian mesquite powder – existing competitors

Companies interviewed for this study, both Peruvian and North American, suggested that the main existing competitors for Peruvian mesquite powder would be comparable tasting gluten-free flours or powders that could be used as components of baked goods (cookies, cakes, sweet breads), baking mixes (brownie mixes, cake mixes, pancake mixes), breakfast cereals, coated nuts, nutrition bars and drink mixes (cocoa type and smoothie type). In this regard, most often mentioned were cacao powder and carob powder.

In fact, many of the products in the North American market that contain Peruvian mesquite powder as a component also contain cacao based ingredients and have a chocolate type taste profile.

4.1. Cacao powder (chocolate powder or cocoa powder)

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1801.00.0000	Cocoa beans, whole or broken, raw or roasted
HS 1805.00.0000	Cocoa powder, not containing added sugar or other sweetening matter
HS 1806.10.0500	Cocoa powder, containing added sugar or other sweetening matter; containing less than 65% by weight of sugar

Cacao powder, also known as ‘cocoa powder’ or ‘chocolate powder’, is a ‘cocoa product’ derived from cocoa beans, i.e. the seeds of *Theobroma cacao* L. or a closely related species.

The National Formulary (NF) defines ‘chocolate’ as ‘a powder prepared from the roasted, cured kernels of the ripe seed of *Theobroma cacao* L. (Fam. Sterculiaceae). Chocolate yields NLT 10.0% and NMT 22.0% of non-volatile ether-soluble extractive.’¹²¹

‘Cocoa’ is defined by the U.S. Food and Drug Administration (FDA) in the Code of Federal Regulations (CFR) as follows:¹²²

121 United States Pharmacopeial Convention (2012). United States Pharmacopeia, 35th Revision (USP 35). Rockville, MD: United States Pharmacopeia Convention.

122 U.S. Food and Drug Administration (FDA) (2012). Part 163 – Cacao Products. In: Code of Federal Regulations, Title 21 (21CFR). Washington, D.C.: U.S. Government Printing Office. Available at: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol2/pdf/CFR-2012-title21-vol2-part163.pdf>

- Description:
 - Cocoa is the food prepared by pulverizing the material remaining after part of the cacao fat has been removed from ground cacao nibs. Cocoa contains less than 22% by weight of cacao fat, but not less than 10% cacao fat content.
 - Optional alkali ingredients may be used as such in the preparation of cocoa under certain conditions and limitations.
 - Optional neutralizing agents may be used as such in the preparation of the cocoa under certain conditions and limitations.
 - Cocoa may be spiced, flavoured, or seasoned with one or more of the ingredients listed.
- Optional ingredients. The following safe and suitable ingredients may be used:
 - Alkali ingredients. Ammonium, potassium, or sodium bicarbonate, carbonate, or hydroxide, or magnesium carbonate or oxide, used as such, or in aqueous solution;
 - Neutralizing agents. Phosphoric acid, citric acid and L-tartaric acid, used as such, or in aqueous solution;
 - Spices, natural and artificial flavourings, and other seasonings that do not either singly or in combination impart a flavour that imitates the flavour of chocolate, milk, or butter; or
 - Salt.

The Canadian Food and Drug Regulations define cocoa powder as follows:¹²³

Cocoa or cocoa powder

- Shall be the product that
 - Is obtained by pulverising the remaining material from partially defatted cocoa liquor (the product obtained from the mechanical disintegration of the cocoa nib (the product prepared by removing the shell from cleaned cocoa beans) with or without removal or addition of any of its constituents) by mechanical means.
 - Contains not less than 10% cocoa butter.
- May contain
 - Spices, flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,
 - Salt, and
 - Any of the following emulsifying agents, which singly shall not exceed the maximum level of use, and in combination shall not exceed 1.5% by mass of cocoa product, namely,
 - Mono-glycerides and mono- and diglycerides;
 - Lecithin and hydroxylated lecithin;
 - Ammonium salts of phosphorylated glycerides.

In Canada, although cocoa powder can be approved as a medicinal ingredient of licensed natural health products (NHPs), it is mainly permitted for use as a non-medicinal component of licensed NHPs for the following functions:

123 Government of Canada (2013). Cocoa powder. In: Consolidation Food and Drug Regulations, C.R.C., c. 870. Ottawa, Ontario: Minister of Justice. 2013. Available at: http://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._870.pdf

- **Abrasive (in dental and topical NHPs):** Used to remove unwanted tissue or foreign materials from various body surfaces. The removed materials may include dead skin surface cells, callus, or dental plaque. As a rule, abrasives are irregularly shaped fine or coarse solids. Harder abrasives include special forms of hydrated silica used for tooth cleansing, while softer abrasives such as oatmeal are employed to remove dead skin surface cells.
- **Colour additive (in oral and topical NHPs):** Used to impart colour to liquid, solid, or semisolid (e.g. tablets, capsules, gels) formulations.
- **Flavour enhancer (in oral and topical NHPs):** Substances used to impart a pleasant flavour to a health product that is put in or on the mouth, such as those with oral, buccal or dental routes of administration, or topical in such products as lipsticks and lip balm. Includes substances used to modify the original flavour of a preparation e.g. by masking the flavour of the medicinal ingredient. Among the substances with flavour enhancer purpose are spices, seasonings, essential oils, oleoresins, extracts, fruit and vegetable purees and juices, and artificial flavour chemicals.

Figure 13 shows examples of Canadian licensed NHPs that contain cacao powder as either a medicinal ingredient (e.g. SuperFoods Daily Power Shake) or as a non-medicinal ingredient (e.g. Herbal Vigor® Femme).

Figure 13. Examples of cacao-containing licensed natural health products in the Canadian market



Figure 14 shows examples of U.S. DSPs that contain cacao as a component that is the subject of the dietary supplement structure / function claim statement.

Figure 14. Examples of cacao containing dietary supplement products in the United States market



4.2. Carob powder

Harmonized Tariff Schedule of the United States (HTSUS): HS 1212.10.0000 Carob powder

Carob powder is obtained from the ripe, dry pods of *Ceratonia siliqua* L. The pods are used after crushing to separate seed and pulp. The pulp can be ground into a fine powder for use in human nutrition. Carob powder consists of 46% sugar, 7% protein and small amounts of numerous minerals and vitamins. The dry powder is used as a component of cakes, breads, sweets, ice creams or drinks and as a flavouring.

For quality control there is an International Standard available from the International Organization for Standardization (ISO 7907:1987(E) – Carob – Specification).¹²⁴ There is also an African Standard for carob available from the African Organization for Standardization (ARS 877:2012(E) – Carob – Specification).¹²⁵

In Canada, although carob powder can be accepted as a medicinal ingredient of licensed natural health products (NHPs), it is mainly used as a non-medicinal component of licensed NHPs for the following functions:

- **Colour additive (in oral and topical NHPs):** Used to impart colour to liquid, solid, or semisolid (e.g. tablets, capsules, gels) formulations.
- **Flavour enhancer (in oral and topical NHPs):** Substances used to impart a pleasant flavour to a health product that is put in or on the mouth, such as those with oral, buccal or dental routes of administration, or topical in such products as lipsticks and lip balm. Includes substances used to modify the original flavour of a preparation e.g. by masking the flavour of the medicinal ingredient. Among the substances with flavour enhancer purpose are spices, seasonings, essential oils, oleoresins, extracts, fruit and vegetable purees and juices, and artificial flavour chemicals.

Figure 15 shows examples of Canadian licensed NHPs that contain carob powder as either a medicinal ingredient (e.g. Clarify NatruLAX and fem MED®) or as a non-medicinal ingredient (e.g. PMS Tea® and ProstCare®). Figure 16 shows examples of U.S. DSPs that contain carob as a component.

Figure 15. Examples of carob-containing licensed natural health products in the Canadian market



124 International Organization for Standardization (ISO)(1987). Carob – Specification. ISO 7907, First Edition. Geneva, Switzerland: ISO.

125 African Organization for Standardization (ARS) (2012). Carob – Specification. ARS 877:2012(E). Nairobi, Kenya: ARS.

Figure 16. Examples of carob containing food products in the United States market

5. Peruvian mesquite – potential for new producers to enter market

At the moment, most finished products in the North American market that contain Peruvian mesquite powder are using it as either a substitute for European carob powder (raw or roasted), as a caffeine-free alternative to cacao or cocoa powder, or are admixing it with cacao or cocoa powder in order to augment or enhance the chocolate taste profile of the product. For example, one company markets their Peruvian mesquite powder by recommending 'Same uses as carob powder but much more aromatic and flavourful. Tastes and used like malted chocolate without the caffeine'. In many cases it serves as an additional flavour component of cacao-based products, such as chocolate bars, chocolate brownie or cake mixes and chocolate drink mixes. The name of the product generally emphasises cacao, chocolate or cocoa whilst Peruvian mesquite powder is only found as one of the other ingredients listed on the side of label.

To increase demand and use and display Peruvian mesquite prominently on the front of product labels it will need something special that causes it to compete with a broader range of ingredients and not only cacao and/or carob, as is mainly the case as present.

The potential for new producers of Peruvian mesquite powder to enter (and remain) in the United States and Canadian food product markets may depend on the ability to effectively articulate its main 'reason for being' and differentiate it from other similar and seemingly interchangeable flours and powders. To some extent, Peruvian mesquite may be experiencing an identity crisis because it appears to be viewed as an 'alternative' or 'secondary' ingredient rather than as a 'primary' ingredient that can really stand on its own.

At the same time, ingredient marketers and product developers presently appear to view Peruvian mesquite flour as no different and/or interchangeable with Argentine mesquite flour (*Prosopis alba*) from Argentina, Velvet mesquite flour (*Prosopis velutina*) from Arizona, Western honey mesquite flour (*Prosopis glandulosa* var. *torreyana*) also from Arizona as well as the Peruvian species of mesquite (*Prosopis pallida*) grown in Hawaii and marketed under the name 'Hawaiian Kiawe Mesquite Flour'. Proponents of the 'local' food movement may prefer to buy the mesquite flours native to Arizona and consumers who look to 'buy American' products (as opposed to imported imports) may prefer either the Arizona and/or Hawaiian harvested mesquites.

While there is already a Peruvian national standard for Peruvian mesquite flour (Harina de algarroba – NTP 209.602: 2007) which provides quality specifications and definitions, this important fact needs to be emphasized in documentation, labelling and marketing in order to stand out, at least from the other mesquite flours already competing with Peruvian mesquite in the United States and Canadian markets. But at the same time, one interview respondent remarked that consistent quality has been a problem, even when importing from the same producer organization. It was stated that it is still difficult to count on batch-to-batch uniformity. Quality differences between shipments can be measurable which implies a lack of process control.

Another interview respondent suggested however that the future potential for new entries of Peruvian mesquite powder products and producers is not only in the carob or cocoa space but rather as a great vegetarian source of protein. Repositioned as a plant-based source of protein, as 'Peruvian Mesquite

Protein Powder' would allow it to compete with the whole range of emerging vegetarian sources of protein including chia protein powder, hemp protein powder, pea protein powder, rice protein powder, sacha inchi protein powder and soy protein powder, among others.

In this context Peruvian Mesquite Protein Powder could be marketed effectively by new producers and suppliers as a great baking ingredient or raw food ingredient that is a good non-animal source of protein, has a uniquely sweet and nutty molasses-like taste, is free of major allergens (e.g. dairy free, gluten free, soy free, tree nut free), is caffeine free, GMO-free and organic, and suitable for kosher and halal consumers as well as vegetarians and vegans.

6. Peruvian mesquite – substitution and comparison of features

6.1. Availability comparison

Comparing the relative market availability of similar powdered ingredients that Peruvian mesquite would compete against (or be substituted with) neither cocoa nor carob are products of the United States or Canada and are imported mainly from European countries.

In 2011, the United States imported 103,053,940 kg of cocoa powder (HS 1805.00.0000), mainly from European re-exporters (e.g. the Netherlands, Spain and France) but also directly from some producer countries including Ghana, Brazil, Malaysia, Côte d'Ivoire and Dominican Republic.

The United States and Canada import carob pods and powder from the countries of its native habitat in Southern Europe, Mediterranean Region and North Africa. World carob production has been estimated at about 315,000 tons per year with the main producers being Spain (42%), Italy (16%), Portugal (10%), Morocco (8%), Hellenic Republic (6.5%), Cyprus (5.5%) and Turkey (4.8%).¹²⁶ Some of the certified organic supply of wild harvested carob however is originating from Croatia.

According to SIICEX, 76.11% of Peru's exports of Peruvian mesquite are processed into powdered form. The United States accounted for about 23.89% of all Peruvian mesquite exports in 2012 but almost 60% of Peruvian exports in the previous year of 2011. Even so, by comparison to United States imports of comparable cacao and carob powders, the imported quantity of Peruvian mesquite powder is still relatively low. SIICEX reports that United States imports of Peruvian mesquite (all forms) was 3.597,87 kg in 2012, 19.701,26 kg in 2011 and 14.844,46 in 2010.¹²⁷

The ready availability of the competing powders (cacao and carob) in the United States and Canada is steady and they are generally in stock year round at warehouses of most wholesale distribution companies that supply bulk powdered natural food ingredients to product manufacturers.

6.2. Composition (nutrient, phytochemical) and quality characteristics comparison

Table 5 compares typical quality specifications of selected powders that would compete with Peruvian mesquite, namely cacao (cocoa or chocolate) powder and carob powder.

126 Ciesla WM. Chapter 7 Fruits. In: Non-Wood Forest Products 15: Non-Wood Forest Products from Temperate Broad-Leaved Trees. Rome, Italy: Food and Agriculture Organization of the United Nations (FAO). 2002. Available at: <ftp://ftp.fao.org/docrep/fao/005/y4351E/y4351e07.pdf>

127 SIICEX. EXPORTACIÓN DEL PRODUCTO ALGARROBO SEGÚN SUS PRINCIPALES MERCADOS EN KG 2008 – 2013. Available at: <http://www.siicex.gob.pe/siicex/apb/ReporteProducto.aspx?psector=1025&preporte=prodmercvolu&pvalor=1917>

Table 5. Quality specifications comparison of powders that compete with Peruvian mesquite

	Cacao Chocolate NF	Carob African Standard	Peruvian mesquite Norma Técnica Peruana
Description	Powder prepared from the roasted, cured kernels of the ripe seed of <i>Theobroma cacao</i> L.	Prepared from the ripe, dry pods of <i>Ceratonia siliqua</i> L.	Prepared from ripe, dry pods of <i>Prosopis pallida</i> ; after removal of endocarp and seeds
Identity	Microscopic test as per NF monograph description	Macroscopic examination of whole fruits before powdering	Macroscopic examination of whole fruits before powdering
Organoleptic characteristics	Not specified	Characteristic of carob fruit, free from foreign odour and taste, particularly rancidity	Appearance: homogenous powder, free of lumps; Odour: intense, characteristic of Peruvian mesquite; Taste: characteristic; sweet, slightly bitter and astringent; Colour: beige to dark beige depending on degree of drying
Content	10.0% to 22.0% of non-volatile ether-soluble extractive	Not specified	Not specified
Total ash	NMT 8.0%	Not specified	NMT 5%
Acid-insoluble ash	NMT 0.4%	Not specified	Not specified
Crude fibre	NMT 7.0%	Not specified	Not specified
Crude protein	Not specified	Not specified	7% to 15 %
Extraneous matter	Not specified	NMT 1.0%	Not specified
Defects	Not specified	NMT 9.5% spoiled carobs other than mouldy and rotten carobs, but including pest-infected and rodent-damaged fruits. NMT 0.5% mouldy and rotten carobs.	Not specified
Moisture	Not specified	NMT 12 % (m/m)	NMT 5%
Particle size	Not specified	Not specified	NMT 0.5% remain on 180 micron mesh and NMT 50% remain on 150 micron mesh
Total bacterial count	NMT 5×10^3 cfu/g	Not specified	NMT 10^2 cfu/g
Yeasts and moulds	Not specified	NMT 10^5 cfu/g	NMT 10^2 cfu/g
<i>Escherichia coli</i>	Absent in 10 g	Not detectable in 1 g	NMT 10^2 cfu/g
<i>Salmonella spp.</i>	Not specified	Not detectable in 25 g	Not detectable in 25 g
<i>Staphylococcus aureus</i>	Not specified	Not detectable in 25 g	NMT 10^2 cfu/g
Total aflatoxins	Not specified	NMT 10 ppb with B1; NMT 5 ppb as per ISO 16050 method	NMT 10 ppb (B1, B2, G1, G2) as per AOAC 968.22 method
Arsenic	Not specified	NMT 0.10 ppm	Should not contain heavy metals at levels harmful to human health
Copper	Not specified	NMT 5.0 ppm	
Lead	Not specified	NMT 0.20 ppm	
Cadmium	Not specified	NMT 0.02 ppm	
Mercury	Not specified	NMT 0.01 ppm	

Sources: Cacao: Chocolate – Natural Formulary – NF 30 – 2012; Carob: Carob – African Organization for Standardization – ARS 877:2012; Peruvian mesquite: Harina de Algarroba – Norma Técnica Peruana – NTP 209.602 2007.

6.3. Ease of application comparison

Peruvian mesquite powder and the other similar powders discussed in this chapter (cacao / cocoa powder and carob powder) have comparable organoleptic (appearance, colour, odour and taste) and physical characteristics (hygroscopic, soluble, gluten-free powder). These powders are already being used as components of the same types of finished product formulations namely baked goods (cookies, cakes, sweet breads), baking mixes (brownie mixes, cake mixes, pancake mixes), breakfast cereals, coated nuts, nutrition bars and drink mixes (cocoa type and smoothie type). Peruvian mesquite powder is often used in combination with cacao powder. The mixing and powder filling equipment is likely the same for both powders in finished product manufacturing.

It appears that product formulators / innovators could substitute one powder for the other or even combine them for flavour differentiation or uniqueness without requiring different processes or technologies for manufacturing the finished product. The ease of application for product developers to substitute or add Peruvian mesquite powder to products formerly or presently containing cacao powder and/or carob powder appears to be possible without presenting new significant production challenges.

It is worth noting however that some American distributors of mesquite flours or powders offer a range of mesquite powders of different species, varieties and/or origins, all being marketed as comparable and interchangeable in application. For example, Peruvian Mesquite Flour is marketed alongside, and at comparable or same prices as, Argentine mesquite flour (*Prosopis alba*) from Argentina, Velvet Mesquite Flour (*Prosopis velutina*) and Western Honey Mesquite Flour (*Prosopis glandulosa* var. *torreyana*) both from Arizona (the United States) as well as Hawai'ian Kiawe Mesquite Flour (*Prosopis pallida*) from Hawaii (the United States).

6.4. Price comparison

Table 6 provides a typical average bulk ingredient pricing structure comparison at three tiers (distributor price, wholesale price and retail price) for carob powder, cocoa powder and Peruvian mesquite powder in the United States natural foods channel. The prices shown are generic or typical catalogue prices for certified organic bulk ingredients which were current as the time of this study (April 2013). They do not take into account any special pricing for high volume or large customer contract pricing whereby the seller may take a lower margin in consideration of overall business.

Table 6. Price comparisons (US\$/lb): organic carob, cocoa and Peruvian mesquite powder

Description	Pack sizes (lb)	Distributor price (US\$/lb)	Wholesale price (US\$/lb)	Retail price (US\$/lb)
Carob powder – raw	5	1.64	2.18	3.25
Carob powder – toasted	5	1.70	2.26	3.39
Cocoa powder	25	4.18	5.56	8.29
Peruvian mesquite powder*	5-25		8.25-9.90 ¹²⁸ 11.46 ¹²⁹ 10.97-11.97 ¹³⁰	11.00 12.60 6.91-11.18 ¹³¹ 12.97

Sources: Price information in table 6 for carob and cocoa was provided confidentially by an information provider at a major independent national distributor of natural, organic and specialty foods and related products. Pricing for Peruvian mesquite powder was not available from the same source as the other items in the table. Thus they are not calculated on the same basis or margins. Bulk prices for Mesquite powder (Peruvian and/or Argentinian) ranged significantly from one wholesaler to the next. The various bulk prices offered in different catalogues are shown in the wholesale price column whilst 1 lb prices are shown in the retail price column with footnotes to the source of the price.

Note: 1.0 lb = 0.453597 kg.

128 Mountain Rose Herbs: <http://www.mountainroseherbs.com/bulkherb/m.php>

129 Azure Standard: <http://www.azurestandard.com/shop/product/6581/>

130 Sunburst Superfoods: <http://www.sunburstsuperfoods.com/organic-mesquite-powder/>

131 Casa de Fruta®: <http://store.casadefruta.com/mesquite-sale-c74.aspx>

6.5. Recommended uses comparison

Table 7. Recommended uses comparison for Peruvian mesquite powder competitive products

Substance	Canada	United States
Cacao powder, also known as cocoa powder and/or chocolate powder	<p>Conventional food ingredient (labelled without health claims)</p> <hr/> <p>NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Source of antioxidants for the maintenance of good health • Helps to maintain and/or support cardiovascular health <hr/> <p>Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> • Abrasive (in dental and topical NHPs) • Colour additive • Flavour enhancer 	<p>Conventional food ingredient (labelled without health claims); 'Flavouring agent'</p> <hr/> <p>DSP component (with nutrient content and/or structure / function claim statements):</p> <ul style="list-style-type: none"> • Cocoa and naturally sourced plant flavanols may help support healthy endothelial, circulatory and overall cardiovascular function • Contains alkaloids theobromine and caffeine – responsible for a stimulant effect • Contains catechins • Contains plant flavanols • Healthy heart support • Low glycaemic
Carob powder, also known as St. John's bread powder	<p>Conventional food ingredient (labelled without health claims)</p> <hr/> <p>NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • An antioxidant for the maintenance of good health <hr/> <p>Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> • Colour additive • Flavour enhancer 	<p>Conventional food ingredient (labelled without health claims)</p> <hr/> <p>Food or DSP with allergen free and/or nutrient content claim statements:</p> <ul style="list-style-type: none"> • Caffeine free • Dairy free • Gluten free • No caffeine or theobromine found in cacao (can be enjoyed by those with chocolate allergies) • Substitute for cocoa powder
Peruvian mesquite powder	<p>Conventional food ingredient (labelled without health claims)</p> <hr/> <p>NHP ingredient: Not yet classified as an acceptable NHP ingredient whether medicinal or non-medicinal</p>	<p>Conventional food ingredient (labelled without health claims)</p> <hr/> <p>Food or DSP with nutrient content claim statements:</p> <ul style="list-style-type: none"> • Gluten free • Good source of dietary fibre • Good source of digestible proteins (including lysine) • Low glycaemic

Sources: Health Canada Natural Health Products Directorate (NHPD) Natural Health Products Ingredients Database (NHPID), Health Canada Food and Drug Regulations, U.S. Food and Drug Administration (FDA) Dietary Supplement notification letters, and various FDA and USDA regulations.

6.6. Regulatory status comparison

Table 8. Regulatory status comparison for Peruvian mesquite competitive products

Substance	Canada	United States
Cacao powder	<ul style="list-style-type: none"> Conventional food ingredient NHP medicinal ingredient Non-medicinal NHP ingredient (as an abrasive, colour additive and/or flavour enhancer) 	<ul style="list-style-type: none"> Conventional food ingredient DSP component
Carob powder	<ul style="list-style-type: none"> Conventional food ingredient NHP medicinal ingredient Non-medicinal NHP ingredient (as colour additive and/or flavour enhancer) 	<ul style="list-style-type: none"> Conventional food ingredient DSP component
Peruvian mesquite powder	<ul style="list-style-type: none"> Conventional food ingredient Has potential to become an approved NHP component (not yet classified by the NHPD) 	<ul style="list-style-type: none"> Conventional food ingredient Has potential for use as a DSP component (no known DSP notifications yet with FDA)

Sources: Health Canada Natural Health Products Directorate (NHPD) Natural Health Products Ingredients Database (NHPID), Health Canada Food and Drug Regulations, U.S. Food and Drug Administration (FDA) Dietary Supplement notification letters, and various FDA and USDA regulations.

7. Sacha inchi oil – existing competitors

The North American market for healthy products that contain essential fatty acids (EFAs) continues to grow and there appears to be an ever-expanding list of new entries into this already crowded category. Source materials for EFA ingredients and products include:

- **Algal sources**, e.g. oil obtained from fermentation and extraction of certain species of algae;
- **Animal sources**, e.g. fatty oil obtained from crustaceans such as krill, or fish such as salmon, or even marine mammals such as seals; and
- **Plant sources**, e.g. fatty oil from seeds of borage, evening primrose or flax.

The FDA permits use of the following ‘Qualified Health Claim’ (QHC) statement for the labelling and marketing of certain conventional food products as well as certain dietary supplement products (DSPs) that contain EPA and DHA omega-3 fatty acids:

‘Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the product] provides [x] gram of EPA and DHA omega-3 fatty acids.’¹³²

In the EFA category, the USP has already published official quality standards monographs for Cod Liver Oil, *Cryptocodinium cohnii* Oil, Fish Oil, and *Schizochytrium* Oil. New USP monographs are in development for publication in 2013 for Borage Oil, Evening Primrose Oil, Flax Oil and Krill Oil for use as components of DSPs.

Health Canada’s Natural Health Products Directorate (NHPD) authorizes the licensing of EFA-containing natural health products (NHPs) and has published labelling standards monographs for Borage Oil, Cod Liver Oil, Evening Primrose Oil, Fish Oil, Flaxseed Oil, Krill Oil, Multiple Ingredient Oil Products, and Seal Oil. The NHPD monographs specify that the medicinal ingredient may comply with the quality specifications outlined in monographs of the British Pharmacopoeia (BP), European Pharmacopoeia

132 U.S. Food and Drug Administration (FDA) (2009). 12. Appendix D: Qualified Health Claims. In: Guidance for Industry: A Food Labeling Guide. Available from: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064923.htm>

(PhEur), or USP. Typical claim statements permitted by the NHPD for labelling and marketing of EPA-containing NHPs include:

- Source of essential fatty acids for the maintenance of good health;
- Source of omega-3 fatty acids for the maintenance of good health;
- Source of omega-6 fatty acids for the maintenance of good health; or
- Source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) for the maintenance of good health.

In some cases, other stronger or more specific claim statements are permitted by NHPD depending on the composition of the oil and the recommended daily dosage. For example, fish oil products providing 100-3,000 mg EPA + DHA including at least 100 mg DHA, per day, may be labelling and marketed with the claim statement: 'Helps support cognitive health and/or brain function.'¹³³

The following sections provide compendial definitions and comparative data for the various EFA ingredients that would compete with sachachi oil in the Canadian and United States markets.

7.1. Borage oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1515.90 Borage Oil

HS 2106.90.9998 Borage Oil Dietary Supplement Products in Capsules

The European Pharmacopoeia (PhEur) defines 'Refined Borage (Starflower) Oil' (Pharmacopoeial name: *Boraginis officinalis oleum raffinatum*) as the fatty oil obtained from seeds of *Borago officinalis* L. (Fam. Boraginaceae) by extraction and/or expression. It is then refined. A suitable antioxidant may be added.¹³⁴

In Canada, it is used as a medicinal ingredient of licensed Natural Health Products (NHPs) usually in soft-gel capsule dosage form but also in liquid forms.¹³⁵ At this time there are over 260 licensed NHPs that contain borage as an ingredient, mostly in the fatty oil form as a source of essential fatty acids. In some products, Borage Oil is used in combination with other essential fatty acid active ingredients usually with Fish Oil and/or Flaxseed Oil. For example, there is a Health Canada Natural Health Products Directorate (NHPD) labelling standards monograph for 'Multiple Ingredient Oil Products' which permits the combining of Borage Oil with Fish Oil, Evening Primrose Oil, Flaxseed Oil and/or Seal Oil as combined active ingredients of licensed NHPs.¹³⁶ For topical application, Borage Oil is also permitted for use as a non-medicinal component of licensed NHPs to function as a skin conditioning agent – emollient.

In the United States Borage Oil is used mainly as a Dietary Supplement Product (DSP) component with the similar uses as in Canada. A USP quality standard for Borage Oil is expected to be published in 2013. In the meantime, the aforementioned PhEur monograph may be used for the quality control testing and release of Borage Oil when used as either a component of a DSP in the United States or as a medicinal ingredient of an NHP in Canada.

7.2. Chia oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1515.90.90 Chia seed oil

133 Health Canada Natural Health Products Directorate (NHPD) (2012). Monograph: Fish Oil. Available from: <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/monoReq.do?id=88&lang=eng>

134 European Pharmacopoeia Commission. (2012). European Pharmacopoeia, 7th edition. Strasbourg, France: European Directorate for the Quality of Medicines (EDQM).

135 Health Canada Natural Health Products Directorate (NHPD) (2009). Monograph: Borage Oil. Available from: <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/monoReq.do?id=49&lang=eng>

136 Health Canada Natural Health Products Directorate (NHPD) (2012). Monograph: Multiple Ingredient Oil Products. Available from: <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq.do?atid=multiple.oil&lang=eng>

Chia Oil is the fatty oil obtained from ripe seeds of *Salvia hispanica* L. (Fam. Lamiaceae) by extraction and/or expression. There are no known quality standards monographs available for companies to base their Chia Oil specifications. Companies marketing Chia Oil containing DSPs in the United States or NHPs in Canada must therefore establish appropriate specifications for quality control testing and release of the ingredient prior to use in a batch.

In the United States, Chia Oil is used mainly as a DSP component that is labelled and marketed with quantified Nutrient Content Claim statements as a source of essential fatty acids.

In Canada, Chia Oil is used as a medicinal ingredient of licensed NHPs usually in soft-gel capsule form but also in gummies or liquid forms (taken by teaspoonful) and usually in combination with other essential fatty acid active ingredients, for example along with Cranberry Seed Oil, or Fish Oil, or Olive Oil or Safflower Oil.

7.3. Cod liver oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1504.10.2000 Cod Liver Oil

The USP defines 'Cod Liver Oil' as the partially destearinated fixed oil obtained from fresh livers of *Gadus morrhua* L. and other species of Fam. Gadidae. 'Cod Liver Oil USP' contains, in each g, NLT 180 µg (600 USP Units) and NMT 750 µg (2500 USP Units) of vitamin A and NLT 1.5 µg (60 USP Units) and NMT 6.25 µg (250 USP Units) of vitamin D. Cod Liver Oil may be flavoured by the addition of NMT 1% of a suitable flavour or a mixture of flavours. A suitable antioxidant may be added.¹³⁷

Health Canada's NHPD labelling standards monograph provides greater detail on acceptable source materials.¹³⁸ 'Cod Liver Oil NHPD' is defined as 'oil from one or more of the following sources in its natural triglyceride/triacylglycerol form and/or its concentrated esterified form:

- Liver of Atlantic cod, *Gadus morhua* L. (Gadidae) (PhEur 2012; USP 35; ITIS 2004);
- Liver of Greenland cod, *Gadus ogac* Richardson (Gadidae) (PhEur 2012; USP 35; ITIS 2004);
- Liver of Pacific cod, *Gadus macrocephalus* Tilesius (Gadidae) (PhEur 2012; USP 35; ITIS 2004);
- Liver from Arctic cod, *Arctogadus glacialis* Peters (1872) (Gadidae) (PhEur 2012; USP 35; ITIS 2004);
- Liver from all species of Gadidae (Cod family) (BP 2012; PhEur 2012; USP 35)'.

In Canada, Cod Liver Oil is permitted as a medicinal ingredient of both oral and topical application NHPs. Cod Liver Oil NHPs for oral use are a source of vitamin A and vitamin D as well as omega-3 fatty acids. Cod Liver Oil NHPs for topical application are medicated skin care products.¹³⁹ The NHPD labelling standards monograph states that the medicinal ingredient may comply with the specifications of Cod Liver Oil monographs published in the American (USP), British (BP) and European (PhEur) pharmacopoeias.

In the United States, Cod Liver Oil is taken orally as a DSP component and is also applied topically as an active ingredient of skin protectant drug products¹⁴⁰ as well as of anorectal drug products for over-the-counter (OTC) human use.¹⁴¹

137 United States Pharmacopoeial Convention (2012). United States Pharmacopoeia, 35th Revision (USP 35). Rockville, MD: United States Pharmacopoeial Convention.

138 Health Canada Natural Health Products Directorate (NHPD) (2012). Cod Liver Oil. Available from: <http://webprod.hc-sc.gc.ca/nhp/d-bdipsn/atReq.do?atid=cod.liver.oil&lang=eng>

139 Health Canada Natural Health Products Directorate (NHPD).(2007). Medicated Skin Care Products. Available from: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/mono_skin-peau-eng.php

140 U.S. Food and Drug Administration (FDA) (2012). Skin Protectant Drug Products for Over-the-Counter Human Use. In: Code of Federal Regulations, Title 21, Part 347. Washington, D.C.: United States Government Printing Office. Available from: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol5/pdf/CFR-2012-title21-vol5-part347.pdf>

141 U.S. Food and Drug Administration (FDA) (2012). Anorectal Drug Products for Over-the-Counter Human Use. In: Code of Federal Regulations, Title 21, Part 346. Washington, D.C.: United States Government Printing Office. Available from: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol5/pdf/CFR-2012-title21-vol5-part346.pdf>

7.4. *Cryptocodinium cohnii* oil

Harmonized Tariff Schedule of the United States (HTSUS):

None assigned – No rulings

The USP defines '*Cryptocodinium cohnii*' as a substance obtained from the fermentation and extraction of algae of the species *Cryptocodinium cohnii* and contains NLT 35.0% (w/w) of docosahexaenoic acid (DHA, C₂₂H₃₂O₂) (C22: 6 n-3), as the only significant polyunsaturated fatty acid present. Suitable antioxidants in appropriate concentration may be added.¹⁴²

In the United States, '*Cryptocodinium cohnii* Oil USP', also known as Algal Oil, is used as a DSP component that is labelled and marketed with quantified Nutrient Content Claims as a source of DHA. In Canada it is used as a medicinal ingredient of licensed NHPs, usually in soft-gel capsule form, also marketed as a source of DHA. The USP monograph may be used for quality control testing and release when used as either a component of a DSP in the United States or as a medicinal ingredient of an NHP in Canada.

7.5. DHA from algal (*Ulkenia*) oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 2106.90.9998 DHA Oil Dietary Supplement Products in Capsules

HS 9802.00.50 Microencapsulated DHA Oil from algal sources into DHA powder

The Food Chemicals Codex (FCC), which is published by the USP, defines '*DHA from Algal (Ulkenia) Oil*' as a slightly waxy to liquid, light yellow to orange coloured oil providing a source of docosahexaenoic acid (DHA, C₂₂H₃₂O₂) (C22:6 n-3), an omega-3 long-chain polyunsaturated fatty acid. It is obtained from fermentation of a thraustochytrid microalgae, *Ulkenia* sp., followed by extraction and refining. Extraction can be pure pressing or supported by solvents approved for food processing. Solvents, if used, are subsequently removed by vacuum distillation. The oil may be degummed, deacidified, winterized, bleached, and deodorized to substantially remove free fatty acids, phospholipids, odour and flavour components, and other material. Docosahexaenoic acid is the main polyunsaturated fatty acid present; DHA content may be standardized with other oils. Suitable antioxidants may be added.¹⁴³

In the United States, '*Algal (Ulkenia) Oil*' is used as a DSP that is labelled and marketed with quantified Nutrient Content Claim statements a source of DHA. It can also be used as a source of DHA in fortified conventional food products. For example, in 2010 the Swiss company Lonza Ltd submitted a GRAS Notice application to FDA for their ingredient '*Micro-algal oil Ulkenia* sp. SAM2179' which has since been affirmed by FDA for use as an ingredient in the same food categories that are permitted for Menhaden Oil,¹⁴⁴ albeit at levels up to 40% of the levels that are specified for Menhaden Oil in the Code of Federal Regulations (21CFR §184.1472(a)(3)) – and not to be combined with any other added oil that is a significant source of eicosapentaenoic acid or docosahexaenoic acid.¹⁴⁵

In Canada, this oil is used as a medicinal ingredient of licensed NHPs usually in soft-gel capsule dosage form and in combination with other essential fatty acid active ingredients such as Flaxseed Oil. For example there is a licensed NHP marketed by Bioforce Canada Inc. that contains, per capsule, 198.95 mg

142 United States Pharmacopoeial Convention (2012). *United States Pharmacopoeia*, 35th Revision (USP 35). Rockville, MD: United States Pharmacopoeial Convention.

143 United States Pharmacopoeial Convention (2012). *Food Chemicals Codex*, 8th edition (FCC 8). Rockville, MD: United States Pharmacopoeial Convention.

144 U.S. Food and Drug Administration. Menhaden oil (2012). In: Code of Federal Regulations, Title 21, Part 184 (21CFR §184.1472). Washington, D.C.: United States Government Printing Office. Available from: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol3/pdf/CFR-2012-title21-vol3-sec184-1472.pdf>

145 U.S. Food and Drug Administration (FDA) (2010). GRAS Notice Inventory: Micro-algal oil *Ulkenia* sp. SAM2179. Available from: <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=319>

Algal Oil (*Ulkenia amoeboides*) of which 75.0 mg is DHA and 400.0 mg of Flaxseed Oil (*Linum usitatissimum*) of which 200.0 mg is ALA.¹⁴⁶

Concerning its use in food products, one company, Martek Biosciences Corporation (now part of Royal DSM), achieved Novel Food approval from Health Canada for their branded DHA Algal Oil ingredients for use in a range of conventional food products and infant formulas.¹⁴⁷

The FCC monograph 'DHA from Algal (*Ulkenia*) Oil' may be used for quality control testing and release when this oil is used as either a component of a DSP in the United States or as a medicinal ingredient of an NHP in Canada.

7.6. Evening primrose oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1515.90.4000	Evening Primrose Oil – bulk in steel drums
HS 1515.90.4090	Evening Primrose Oil – encapsulated
HS 1515.90.8090	Evening Primrose Oil in 500 mg Capsules
HS 2106.90.9998	Evening Primrose Oil Powdered as Dietary Supplement

The European Pharmacopoeia (PhEur) defines 'Refined Evening Primrose Oil' (Pharmacopoeial name: *Oenotherae oleum raffinatum*) as the fatty oil obtained from the seeds of *Oenothera biennis* L. or *Oenothera lamarckiana* L. (Fam. Onagraceae) by extraction and/or expression. It is then refined. A suitable antioxidant may be added.

In Canada, it is used as a medicinal ingredient of licensed NHPs usually in soft-gel capsule dosage form but also in liquid forms. At this time there are nearly 300 licensed NHPs that contain Evening Primrose Oil as an active ingredient. In many products it is used in combination with other essential fatty acid active ingredients. For example, there is a Health Canada NHPD labelling standards monograph for 'Multiple Ingredient Oil Products' which permits the combining of Evening Primrose Oil with Fish Oil, Borage Oil, Flaxseed Oil and/or Seal Oil as active ingredients of licensed NHPs.

As a non-medicinal ingredient of licensed NHPs, Evening Primrose Oil is permitted for specified uses including diluent, oleaginous vehicle, and/or skin-conditioning agent. For example it is used as a non-medicinal ingredient of various skin creams or ointments, diaper rash creams, sun screens, and skin cleanser products.

In the United States Evening Primrose Oil is used as a DSP component labelled and marketed with quantified Nutrient Content Claims as a source of essential fatty acids but in some products it is also marketed for relief of pre-menstrual syndrome (PMS) conditions.

A USP quality standard for Evening Primrose Oil is expected to be published in 2013. In the meantime, the aforementioned PhEur monograph may be used for the quality control testing and release of Evening Primrose Oil when used as either a component of a DSP in the United States or as a medicinal ingredient of an NHP in Canada.

7.7. Fish oil

Harmonized Tariff Schedule of the United States (HTSUS):

Fats and oils and their fractions, of fish, other than liver oils:

146 Health Canada. Bioforce Canada Inc. (2012). A. Vogel Omega-3 Vegi. Natural Product Number (NPN): 80033829. In: Licensed Natural Health Products Database. Available from: <http://webprod3.hc-sc.gc.ca/lnhpd-bdpsnh/>

147 Health Canada. Approved Products – Novel Food Decisions. Available from: <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php>

HS 1504.20.2000	Cod Oil
HS 1504.20.4000	Herring Oil
HS 1504.20.6020	Menhaden Oil
HS 1504.20.6040	Other: Salmon Oil, Tuna Oil

The USP defines 'Fish Oil Containing Omega-3 Acids' as the purified, winterized, and deodorized fatty oil obtained from fish of the families Engraulidae, Carangidae, Clupeidae, Osmeridae, Scombroidae, and Ammodytidae. The omega-3 acids are defined as the following: alpha-linolenic acid (C18:3 n3), moroctic acid (C18:4 n3), eicosatetraenoic acid (C20:4 n3), eicosapentaenoic acid (EPA) (C20:5 n3), heneicosapentaenoic acid (C21:5 n3), docosapentaenoic acid (C22:5 n3), and docosahexaenoic acid (DHA) (C22:6n3). It contains not-less-than (NLT) 28.0% (w/w) of total omega-3 acids, expressed as free acids, consisting of NLT 13.0% of EPA and NLT 9.0% of DHA. Suitable antioxidants in appropriate concentrations may be added.

- In the United States, Fish Oil is used as a DSP that is labelled and marketed with quantified Nutrient Content Claims as a source of omega-3 fatty acids but can also be labelled and marketed with a Qualified Health Claim for reducing the risk of coronary heart disease. Additionally, four different fish oil substances have been affirmed as Generally Recognized as Safe (GRAS) for use in certain food products albeit with certain limitations on levels of use:
- Fish Oil (Ocean Nutrition Canada Ltd.): for use as a direct food ingredient in the food categories listed for Menhaden Oil in the Code of Federal Regulations (21CFR §184.1472(a)(3)). Two formulations are provided: an oil (to be used at a level that are no more than 67% of the levels specified for Menhaden Oil and a microencapsulated oil (to be used at levels that are no more than 120% of the levels specified for Menhaden Oil.
- Fish oil (predominantly sardine and anchovy); tuna oil (Peluva Biotech, Spain): for use as direct food ingredient in the same food categories as permitted for Menhaden Oil at levels that are no more than 67% of the levels specified for Menhaden Oil.
- Fish Oil Concentrate (Unilever United States Inc.): for use as an ingredient in the same food categories as permitted for Menhaden Oil at a level that is approximately 57% of the levels specified for Menhaden Oil.
- Tailored triglycerides enriched in omega-3 fatty acids from fish oil (Twin Rivers Technologies): for use as a direct food ingredient in the same food categories as permitted for Menhaden Oil at levels that are no more than 36% of the levels specified for Menhaden Oil.

In Canada, Fish Oil is used as a medicinal ingredient of licensed NHPs usually in soft-gel capsule dosage form and sometimes in combination with other essential fatty acid active ingredients. For example, there is a Health Canada NHPD labelling standards monograph for 'Multiple Ingredient Oil Products' which permits the combining of Fish Oil with Borage Oil, Evening Primrose Oil, Flaxseed Oil and/or Seal Oil as active ingredients of licensed NHPs. Fish Oil is also included in NHPD's monograph for 'Multiple Ingredient Joint Health Products' which permits the combining of Fish Oil with Chondroitin sulphate, Devil's Claw secondary root tuber (*Harpagophytum procumbens* (Burch.) DC. ex Meisn.), Glucosamine hydrochloride, Glucosamine sulphate, and/or with Methylsulfonylmethane (MSM).

While Health Canada's Fish Oil monograph expressly accepts that the quality standard for this medicinal ingredient may be specified for compliance with the USP monograph, NHPD does provide greater detail on the acceptable source materials for Fish Oil NHPD, as follows:

- Engraulidae – Whole
- Carangidae – Whole
- Clupeidae – Whole
- Osmeridae – Whole
- Scombridae – Whole
- Ammodytidae – Whole
- Salmonidae – Whole

The above corresponds to oil from the body of one or more of the following species in its natural triglyceride/triacylglycerol form and/or its concentrated esterified form:

- Anchovy (any species of Engraulidae)
- Jack or pompano (any species of Carangidae)
- Herring, shad, sardine, or menhaden (any species of Clupeidae)
- Smelt (any species of Osmeridae)
- Mackerel, tuna, or bonito (any species of Scombridae)
- Sand lance (any species of Ammodytidae)
- Salmonids (any species of Salmonidae)

The USP monograph 'Fish Oil Containing Omega-3 Acids' may be used for quality control testing and release when the substance is used as either a component of a DSP in the United States or as a medicinal ingredient of an NHP in Canada.

7.8. Flaxseed oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1204.00.0020	Flaxseed for use as oil stock
HS 1515	Other fixed vegetable fats and oils and their fractions, whether or not refined, but not chemically modified:
HS 1515.11.0000	Linseed oil and its fractions: Crude oil
HS 1515.19.0000	Other: Encapsulated Flax Oil
HS 1518.00	Animal or vegetable fats and oils and their fractions, boiled, oxidized, dehydrated, sulfurized, blown, polymerized by heat in vacuum or in inert gas or otherwise chemically modified, excluding those of heading 1516; inedible mixtures or preparations:
HS 1518.00.2000	Of linseed or flaxseed oil
HS 2306	Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of vegetable fats or oils, other than those of heading 2304 or 2305:
HS 2306.20.0000	Of linseed

The terms Flax Oil, Flaxseed Oil and Linseed Oil are used interchangeably. The USP defines Flax Oil as 'derived from flaxseed or linseed (*Linum usitatissimum* L.) The oil is extracted from hard, tiny seeds by cold pressing. No solvents or external heat are employed in the extraction process. It contains no added substances'. The European Pharmacopoeia (PhEur) defines 'Virgin Linseed Oil' (Pharmacopoeial name: Lini oleum virginale) as 'the fatty oil obtained by cold expression from ripe seeds of *Linum usitatissimum* L. (Fam. Linaceae). A suitable antioxidant may be added'.

In the United States the oil is mainly used as a DSP component in liquid form (taken by the teaspoonful) and/or in soft-gel capsules labelled and marketed with quantified Nutrient Content Claim statements as a source of essential fatty acids. It has also been affirmed as Generally Recognized as Safe (GRAS) for use as a component in conventional food products.

In Canada, it is used as a medicinal ingredient of licensed NHPs usually in soft-gel capsule dosage form and sometimes in combination with other essential fatty acid active ingredients. For example, there is a Health Canada NHPD labelling standards monograph for 'Multiple Ingredient Oil Products' which permits the combining of Flaxseed Oil with Fish Oil, Borage Oil, Evening Primrose Oil and/or Seal Oil as active ingredients of licensed NHPs. At this time there are over 500 licensed NHPs that contain Flaxseed Oil as a medicinal ingredient.

As a non-medicinal ingredient of licensed NHPs, Flaxseed Oil is permitted for specified uses including diluent, fragrance ingredient, skin-conditioning agent, and/or skin-conditioning agent – occlusive.

A USP quality standard for Flaxseed Oil is expected to be published in 2013. In the meantime, the aforementioned PhEur monograph may be used for the quality control testing and release of Flaxseed Oil when used as either a component of a DSP in the United States or as a medicinal ingredient of an NHP in Canada.

7.9. Hemp seed oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1207.99.0320	Hemp seed (for oil)
HS 1515	Other fixed vegetable fats and oils and their fractions, whether or not refined, but not chemically modified:
HS 1515.90.8010	Hemp Oil
HS 2306	Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of vegetable fats or oils, other than those of heading 2304 or 2305:
HS 2306.90.0130	Of hemp seeds.

Hemp Seed Oil is the fatty oil obtained from ripe seeds of *Cannabis sativa* L. (Fam. Cannabaceae) by extraction and/or expression. There are no known quality standards monographs available to use as specifications for the testing of Hempseed Oil ingredients. Companies marketing Hempseed Oil DSPs in the United States or NHPs in Canada must therefore establish appropriate specifications for quality control testing and release of the ingredient prior to use in a batch.

In Canada, Hemp products including Hemp Seed Oil cannot contain more than 10 ppm of delta-9-tetrahydro-cannabinol (THC), and their production must be in compliance with the Industrial Hemp Regulations.¹⁴⁸ Hemp Seed Oil is used as a medicinal ingredient of licensed NHPs usually in soft-gel capsule or liquid forms (taken by teaspoonful) and often in combination with other essential fatty acid active ingredients. For example, the Canadian company Bioriginal Food and Science Corporation markets a licensed NHP in liquid dosage form called 'Omega 3-6-9'¹⁴⁹ composed of, per tablespoonful, 2340.0 mg Hemp Seed Oil [4.0% Gamma-Linolenic Acid, 18.5% Alpha Linolenic Acid], 1560.0 mg Flaxseed Oil [52.0% Alpha Linolenic Acid, 14.0% Oleic Acid, 14.0% Linoleic Acid], and 780.0 mg Borage Oil [20.0% Gamma-Linolenic Acid, 15.0% Oleic Acid, 31.0% Linoleic Acid] with the authorized claim statements: 'Source of essential fatty acids for the maintenance of good health. Source of alpha-linolenic acid for the maintenance of good health. Source of omega-3 acids for the maintenance of good health'.

Hemp Seed Oil is also permitted for use as a non-medicinal ingredient as a dispersing agent and/or as an oleaginous vehicle in oral ingestion NHPs and also as skin-conditioning agent of topical NHPs. For example it is found as a skin-conditioning component of topical transdermal skin cream products and sunscreen lip balm products and also as a dispersing agent or oleaginous vehicle in multi-vitamin and mineral capsules.

In 2000, the United States FDA rejected a GRAS Notice application for proposed uses of Hemp Seed Oil in conventional food products as a flavouring agent, adjuvant solvent, vehicle, stabilizer, thickener, emulsifier, or texturizer. There are, however, liquid Hemp Seed Oil food products for direct oral ingestion (labelled with Nutrition Facts) as well as Hemp Seed Oil DSPs (labelled with Supplement Facts and Nutrient Content Claim statements) in liquid and capsule forms.

148 Health Canada. Cannabis sativa Seed Oil. In: Natural Health Products Ingredients Database. Available from: <http://webprod.hc-sc.gc.ca/nhpid-bdpsn/ingredReq.do?id=4497&lang=eng>

149 Health Canada. (2012). Bioriginal Food and Science Corporation. Omega 3-6-9 (Flax/Borage Oil Emulsion). Natural Product Number (NPN): 80036307. In: Licensed Natural Health Products Database. Available from: <http://webprod3.hc-sc.gc.ca/nhpid-bdpsnh/>

Additionally, Hemp Seed Oil is used as a skin-conditioning agent in non-drug cosmetics in the United States. For example, the popular American soap company 'Dr. Bronner's Magic Soaps' features the use of organic Hemp Seed Oil as a component in a large range of organic and fair trade bar soap, body balm, lip balm, skin lotion, hair conditioner and style crème products.¹⁵⁰

7.10. Krill oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1306	Crustaceans, whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine; smoked crustaceans, whether in shell or not, whether or not cooked before or during the smoking process; crustaceans, in shell, cooked by steaming or by boiling:
HS 1306.19.00	Other, including flours, meals and pellets of crustaceans, fit for human consumption
HS 1306.19.0030	Antarctic krill (<i>Euphausia superba</i>)
HS 1511	Animal products not elsewhere specified or included; dead animals of chapter 1 or 3, unfit for human consumption:
HS 1511.99	Other
HS 1511.99.30	Products chiefly used as food for animals or as ingredients in such food:
HS 1511.99.3030	Antarctic krill (<i>Euphausia superba</i>)

The USP defines 'Krill Oil' as the fixed oil extracted from frozen and crushed Antarctic krill (*Euphausia superba* Dana) with acetone. Krill Oil contains NLT 12.0% (w/w) of eicosapentaenoic acid (EPA) and NLT 7.0% (w/w) of docosahexaenoic acid (DHA) in the form of phospholipids. It also contains NLT 0.1% and NMT 0.15% of astaxanthin.

In the United States, Krill Oil is used as a DSP component usually filled in soft-gel capsules that are labelled and marketed with quantified Nutrient Content Claims as a source of omega-3 fatty acids. Krill Oil might also be labelled and marketed with a Qualified Health Claim for reducing the risk of coronary heart disease.

Additionally, GRAS Notice applications submitted to FDA by three foreign companies (from Canada, Israel and Norway) resulted in four Krill Oil ingredients being affirmed as Generally Recognized as Safe (GRAS) for use in certain food products albeit with certain limitations on levels of use:¹⁵¹

- Krill Oil (Neptune Technologies and Bioresources, Quebec): for use as a direct food ingredient in breakfast cereals, cheese, beverages (non-alcoholic), fruit juices, frozen dairy desserts, milk products, and medical foods at levels up to 500 mg per serving.
- Krill Oil (EVP Documentation, Norway): for use as a direct food ingredient in breakfast cereals, cheese, beverages (non-alcoholic), fruit juices, frozen dairy desserts, milk products, and medical foods at levels up to 500 mg per serving.
- Krill-based phosphatidylserine (Enzymotec Ltd., Israel): for use as an ingredient in breakfast cereals, dairy product analogs, grain products and pastas, milk products, and processed fruits and fruit juices, at a use level intended to provide 30 mg of phosphatidylserine per serving; and, as an ingredient in medical foods at levels that would not exceed 300 mg of phosphatidylserine per day.

¹⁵⁰ Dr. Bronner's Magic Soaps: <http://www.drbronner.com/>

¹⁵¹ U.S. Food and Drug Administration (FDA) GRAS Notice Inventory: <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing>

- Lecithin derived from Krill (Enzymotec Ltd., Israel): for use as an ingredient in breakfast bars at a level of 3.8%, dairy product analogs (soy products) and milk-based beverages at a level of 0.6%, fat spreads at a level of 10%, yogurt at a level of 0.7%, and soft candy at a level of 3.3%.

In Canada, Krill Oil is used as a medicinal ingredient of licensed NHPs¹⁵² usually in soft-gel capsule dosage form and sometimes in combination with other essential fatty acid active ingredients, mainly with Fish Oil. At this time there are nearly 80 licensed NHPs containing Krill Oil as an active ingredient.

The USP monograph 'Krill Oil' may be used for quality control testing and release when the substance is used as either a component of a DSP in the United States or as a medicinal ingredient of an NHP in Canada.

7.11. Menhaden oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1504.20 Fats and oils and their fractions, of fish, other than liver oils:

HS 1504.20.6020 Menhaden Oil

The Food Chemicals Codex (FCC), which is published by the USP, defines 'Refined Menhaden Oil' as a substance prepared from fish of the genus, *Brevoortia*, commonly known as menhaden, by cooking, pressing, and refining. Winterization may separate the oil and produce a solid fraction. It functions as a source of long-chain (greater than C18) omega-3 polyunsaturated fatty acids and is used as a blend with other fats and oils.¹⁵³

In Canada, Menhaden Oil is included within the scope of the Health Canada NHPD Fish Oil monograph as a medicinal ingredient of licensed Natural Health Products (NHPs).¹⁵⁴

Menhaden Oil may also be included within the scope of the USP dietary supplement monograph 'Fish Oil Containing Omega-3 Acids' because the monograph includes fish of the Clupeidae family which Menhaden is a member of.¹⁵⁵

In the United States, FDA also permits the use of Menhaden Oil as a GRAS ingredient in certain conventional food products within specific limitations and maximum levels of use, for example, as a component of cereals, fats and oils products, frozen dairy desserts, gelatines and puddings, milk products, non-alcoholic beverages, processed fruit and/or vegetable juices, snack foods, and soup mixes, among other types of products.¹⁵⁶

Table 9, excerpted from the United States Code of Federal Regulations (CFR), lists the specific types of foods that Menhaden Oil may be a component of but only within the specific limitations (maximum level of use) in order to ensure that total intake of EPA or DHA does not exceed 3.0 g per person per day.

The case of Menhaden Oil as a GRAS food ingredient may be particularly useful to consider in terms of a strategy for eventual submission of a GRAS Notice application for Sacha Inchi oil. That is because a number of other successful GRAS submissions for EFA fatty oil substances have been based on the conditions set forth in the Menhaden Oil GRAS affirmation.

152 Health Canada Natural Health Products Directorate (NHPD) (2012). Monograph: Krill Oil. Available from: <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/monoReq.do?id=205&lang=eng>

153 United States Pharmacopeial Convention (2012). Food Chemicals Codex, 8th Edition. Rockville, MD: United States Pharmacopeial Convention.

154 Health Canada Natural Health Products Directorate (NHPD) (2012). Monograph: Fish Oil. Available from: <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/monoReq.do?id=88&lang=eng>

155 United States Pharmacopeial Convention (2012). United States Pharmacopoeia, 35th Revision (USP 35). Rockville, MD: United States Pharmacopoeial Convention.

156 U.S. Food and Drug Administration (2012). Menhaden oil. In: Code of Federal Regulations, Title 21, Part 184 (21CFR §184.1472). Washington, D.C.: United States Government Printing Office. Available from: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol3/pdf/CFR-2012-title21-vol3-sec184-1472.pdf>

Table 9. Conventional food products in which menhaden oil may be used with limits

Category of food	Maximum level of use in food (as served)
Baked goods, baking mixes, 21 CFR § 170.3(n)(1) of this chapter	5.0%
Cereals, 21 CFR § 170.3(n)(4) of this chapter	4.0%
Cheese products, 21 CFR § 170.3(n)(5) of this chapter	5.0%
Chewing gum, 21 CFR § 170.3(n)(6) of this chapter	3.0%
Condiments, 21 CFR § 170.3(n)(8) of this chapter	5.0%
Confections, frostings, 21 CFR § 170.3(n)(9) of this chapter	5.0%
Dairy product analogs, 21 CFR § 170.3(n)(10) of this chapter	5.0%
Egg products, 21 CFR § 170.3(n)(11) of this chapter	5.0%
Fats, oils, § 170.3(n)(12) of this chapter, but not in infant formula	12.0%
Fish products, § 170.3(n)(13) of this chapter	5.0%
Frozen dairy desserts, § 170.3(n)(20) of this chapter	5.0%
Gelatines, puddings, § 170.3(n)(22) of this chapter	1.0%
Gravies, sauces, § 170.3(n)(24) of this chapter	5.0%
Hard candy, § 170.3(n)(25) of this chapter	10.0%
Jams, jellies, § 170.3(n)(28) of this chapter	7.0%
Meat products, § 170.3(n)(29) of this chapter	5.0%
Milk products, § 170.3(n)(31) of this chapter	5.0%
Non-alcoholic beverages, § 170.3(n)(3) of this chapter	0.5%
Nut products, § 170.3(n)(32) of this chapter	5.0%
Pastas, § 170.3(n)(23) of this chapter	2.0%
Plant protein products, § 170.3(n)(33) of this chapter	5.0%
Poultry products, § 170.3(n)(34) of this chapter	3.0%
Processed fruit juices, § 170.3(n)(35) of this chapter	1.0%
Processed vegetable juices, § 170.3(n)(36) of this chapter	1.0%
Snack foods, § 170.3(n)(37) of this chapter	5.0%
Soft candy, § 170.3(n)(38) of this chapter	4.0%
Soup mixes, § 170.3(n)(40) of this chapter	3.0%
Sugar substitutes, § 170.3(n)(42) of this chapter	10.0%
Sweet sauces, toppings, syrups, § 170.3(n)(43) of this chapter	5.0%
White granulated sugar, § 170.3(n)(41) of this chapter	4.0%

Sources: U.S. Food and Drug Administration (2012). Menhaden oil. In: Code of Federal Regulations, Title 21, Part 184 (21CFR §184.1472). Washington, D.C.: United States Government Printing Office. Available from: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol3/pdf/CFR-2012-title21-vol3-sec184-1472.pdf>

7.12. Olive oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1509	Olive oil and its fractions, whether or not refined, but not chemically modified:
HS 1509.10	Virgin
HS 1509.10.2000	Weighing with the immediate container under 18 kg
HS 1509.10.4000	Virgin and extra virgin olive oils weighing with the immediate container 18 kg or over
HS 1509.90	Other
HS 1509.90.2000	Refined olive oils weighing with the immediate container under 18 kg
HS 1509.90.4000	Refined olive oils weighing with the immediate container 18 kg or over
HS 1510.00	Other oils and their fractions, obtained solely from olives, whether or not refined, but not chemically modified, including blends of these oils and fractions with oils or fractions of heading 1509:
HS 1510.00.2000	Rendered unfit for use as food
HS 1510.00.4000	Other: Olive pomace oil and the refined olive pomace oil weighing with the immediate container under 18 kg
HS 1510.00.6000	Other: Olive pomace oil and the refined olive pomace oil weighing with the immediate container 18 kg or over.

The USP National Formulary (NF) defines 'Olive Oil' as the refined fixed oil obtained from the ripe fruit of *Olea europaea* (Linné) (Fam. Oleaceae). It may contain suitable antioxidants.¹⁵⁷ Additionally, the USDA has published the 'United States Standards for Grades of Olive Oil and Olive-Pomace Oil'¹⁵⁸ with a corresponding 'USDA Grading Manual for Olive Oil and Olive-Pomace Oil'.¹⁵⁹ USDA defines Olive Oil, Virgin Olive Oils, and Olive-Pomace Oils as follows:

- **Olive oil** is the oil obtained solely from the fruit of the olive tree (*Olea europaea* L.), to the exclusion of oils obtained using solvents or re-esterification processes and of any mixture with oils of other kinds;
- **Virgin olive oils** are the oils obtained from the fruit of the olive tree solely by mechanical or other physical means under conditions, including thermal conditions, that do not lead to alterations in the oil, and which have not undergone any treatment other than washing, decantation, centrifugation, and filtration;
- **Olive-pomace oil** is the oil obtained by treating olive pomace (the product remaining after the mechanical extraction of olive oil) with solvents or other physical treatments, to the exclusion of oils obtained by synthetic processes and mixture with oils of other kinds

In the United States, Olive Oil is used first and foremost in food products like salad dressings but increasingly is being used as a component of DSPs as well as a component of non-drug cosmetic products like bar soaps and conditioning hair rinse products.

Similarly in Canada, while most Olive Oil is used in culinary food products and cosmetics, Olive Oil is also classified as a medicinal ingredient of licensed Natural Health Products (NHPs) including liquids for oral ingestion (for laxative and purgative action), for otic application (to loosen and help remove accumulated earwax) and for external application (to temporarily protect and help relieve minor skin irritation and

157 United States Pharmacopeial Convention (2012). United States Pharmacopeia, 35th Revision (USP 35). Rockville, MD: United States Pharmacopoeial Convention.

158 United States Department of Agriculture (USDA) (2010). United States Standards for Grades of Olive Oil and Olive-Pomace Oil. Washington, D.C.: USDA. Available from: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3011889>

159 United States Department of Agriculture (USDA) (2012). USDA Grading Manual for Olive Oil and Olive-Pomace Oil. Washington, D.C.: USDA. Available at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=stelprdc5098497>

itching). Olive Oil is used in several combination NHPs in gummy, soft-gel capsule and liquid forms, for example combined with Chia Seed Oil and Cranberry Seed Oil as a source of omega-3 fatty acids. In topical medicated skin care products, 'Olive Oil NF' is considered medicinal at any concentration, and, as such is listed as an active ingredient in NHPD's monograph 'Medicated Skin Care Products'.¹⁶⁰ For certain products, the NHPD also permits the use of Olive Oil as a non-medicinal ingredient to function as an oleaginous vehicle (in oral and topical administration products) and as a skin-conditioning agent – occlusive (in topical NHPs).

The NF monograph 'Olive Oil' may be used for quality control testing and release when the substance is used as either a component of a DSP in the United States or as a medicinal ingredient of an NHP in Canada. Products labelled and marketed with specified quality grades, for example 'U.S. Extra Virgin Olive Oil', 'U.S. Virgin Olive Oil', 'U.S. Olive Oil', or 'U.S. Refined Olive Oil' must test in compliance with their respective specification as defined in the 'United States Standards for Grades of Olive Oil and Olive-Pomace Oil'.

7.13. Schizoschytrium oil

Harmonized Tariff Schedule of the United States (HTSUS):

None assigned – No rulings

The USP defines 'Schizochytrium Oil' as a substance obtained by fermentation and extraction of algae of the genus *Schizochytrium* that contains NLT 30.0% (w/w) of docosahexaenoic acid (DHA, C₂₂H₃₂O₂) (C22:6 n-3), as the main polyunsaturated fatty acid. Suitable antioxidants in appropriate concentration may be added.¹⁶¹

In the United States, 'Schizochytrium Oil USP' is used as a DSP component that is labelled and marketed as a source of DHA. Concerning its use in conventional food products, one company, Martek Biosciences Corporation (now part of Royal DSM), submitted a GRAS Notice application to FDA for Algal oil (*Schizochytrium* sp.) which has since been affirmed as GRAS; as a direct food ingredient in the food categories listed in the Code of Federal Regulations for Menhaden Oil (21CFR §184.1472(a)(3)) at levels that are no more than 29% of the levels specified for Menhaden Oil as well as in some additional food categories that are listed their GRAS Notice submission.¹⁶²

In Canada this oil is used as a medicinal ingredient of licensed NHPs, usually in soft-gel capsule form and often as an active ingredient of combination products. For example, the company Amway Canada Corporation markets a licensed NHP called 'Nutrilite Veggie 150 Omega Complex' in soft-gel capsule form containing, per capsule, 309.0 mg Schizochytrium Oil with 414.0 mg Flaxseed Oil, with the authorized claim statement: 'Helps ensure you get good sources of Omega-3 fatty acids to help support mental and visual functions as well as overall general health'. Bayer Inc. markets a licensed NHP called 'Flintstones Gummies Plus Omega-3 DHA' in gummy dosage form containing Schizochytrium Oil in multi-vitamin combination with folate, with the authorized claim statements: 'An excellent source of omega-3 DHA. Helps to maintain eyesight, skin, membranes and immune function. Helps in the development and maintenance of night vision. Helps to prevent vitamin B6 deficiency. Helps to prevent vitamin B12 deficiency'.

Concerning use in food products, Martek Biosciences Corporation achieved Novel Food approval from Health Canada for their branded ingredient (Martek DHA-S) for use in a range of conventional food products and infant formulas.¹⁶³

160 Health Canada Natural Health Products Directorate (NHPD) (2007). Medicated Skin Care Products. Available from: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/mono_skin-peau-eng.php

161 United States Pharmacopoeial Convention (2012). United States Pharmacopeia, 35th Revision (USP 35). Rockville, MD: United States Pharmacopoeial Convention.

162 U.S. Food and Drug Administration (FDA) GRAS Notice Inventory: <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing>

163 Health Canada. Approved Products – Novel Food Decisions. Available from: <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php>

The USP monograph may be used for quality control testing and release when used as either a component of a DSP in the United States or as a medicinal ingredient of an NHP in Canada.

7.14. Seal blubber oil

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1504	Fats and oils and their fractions, of fish or marine mammals, whether or not refined, but not chemically modified:
HS 1504.30.0000	Fats and oils and their fractions, of marine mammals
HS 1516	Animal or vegetable fats and oils and their fractions, partly or wholly hydrogenated, inter-esterified, re-esterified or elaidinized, whether or not refined, but not further prepared:
HS 1516.10.0000	Animal fats and oils and their fractions
HS 1518.00	Animal or vegetable fats and oils and their fractions, boiled, oxidized, dehydrated, sulfurized, blown, polymerized by heat in vacuum or in inert gas or otherwise chemically modified, excluding those of heading 1516; inedible mixtures or preparations.

Health Canada Natural Health Products Directorate (NHPD) defines 'Seal Oil'¹⁶⁴ as the oil from the blubber of one or more of the following species in its natural triglyceride/triacylglycerol form and/or its concentrated esterified form:

- Bearded seal (*Erignathus barbatus*) (ITIS 2011)
- Gray seal (*Halichoerus grypus*) (ITIS 2011)
- Harbour seal (*Phoca vitulina*) (ITIS 2011) except the *Phoca vitulina mellonae* of the Lac des Loups Marins population (EC 2011, 2008)
- Harp seal (*Pagophilus groenlandicus*, synonym: *Phoca groenlandica*) (ITIS 2011)
- Hooded seal (*Cystophora cristata*) (ITIS 2011)
- Ringed seal (*Phoca hispida*) (ITIS 2011)

In Canada, it is used as a medicinal ingredient of licensed NHPs usually in soft-gel capsule dosage form but also chewables (e.g. gummies, tablets) or liquid and sometimes in combination with other essential fatty acid active ingredients. For example, there is a Health Canada NHPD labelling standards monograph for 'Multiple Ingredient Oil Products' which permits the combining of Seal Blubber Oil with Fish Oil, Borage Oil, Evening Primrose Oil and/or Flaxseed Oil as active ingredients of licensed NHPs.¹⁶⁵

The global production of seal oil however is very marginal compared to fish oil – less than 1-2% or about 2000-3000 tons annually. Seal blubber is only exported in limited scale and processed by a few companies in Canada and Norway. The refined seal blubber oil is sold to health product companies and pharmaceutical companies, and marketed as dietary supplement and/or functional food ingredients. The main markets are Norway, South Korea, and emerging markets include China and Japan. The most common products containing seal blubber oil are Omega3 capsules and animal food, and to a lesser extent in pharmaceutical products.¹⁶⁶

164 Health Canada Natural Health Products Directorate (NHPD) (2012). Monograph: Seal Oil. Available from: <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq.do?atid=seal.oil&lang=eng>

165 Health Canada Natural Health Products Directorate (NHPD) (2012). Monograph: Multiple Ingredient Oil Products. Available from: <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq.do?atid=multiple.oil&lang=eng>

166 European Commission Directorate General Environment (2010). Study on implementing measures for trade in seal products. Final Report. Available from: http://ec.europa.eu/environment/biodiversity/animal_welfare/seals/pdf/study_implementing_measures.pdf

8. Sacha inchi oil – potential for new producers to enter market

According to a 2012 report by *Packaged Facts*, the market value of EPA/DHA omega-3 packaged products is projected to reach US\$ 34.7 billion in 2016, representing a compound annual growth rate (CAGR) of 6.4% over 2011. The report summary states ‘Expanding public awareness of EPA/DHA omega-3 health benefit through positive media coverage of scientific research findings, as well as developments in regulatory markets, will contribute significantly to continued growth in the global market for EPA/DHA omega-3 products. Other factors that will continue to create a positive growth environment for EPA/DHA omega-3 products include:

- Consumer interest in functional food and fortified product line expansions;
- Increasing demand for fortified infant formula due to population growth and rising middle class in emerging economies;
- Continued popularity of EPA/DHA omega-3 nutritional supplement products, including krill oil and vegetarian algae-based supplements;
- Introduction of pharmaceutical-grade products into South America and approval of generic forms in existing markets;
- Expanding clinical nutrition market opportunities for disease- and disorder-specific formula applications, created through additional R&D and aggressive marketing by ingredient suppliers;
- Premiumization of pet foods due to humanization of companion animals¹⁶⁷.

The *Packaged Facts* study summary emphasizes krill oil as well as vegetarian algal-based sources. According to ‘SPINS’ scan data, krill oil sales increased by 43% in 2012, with growth particularly high in the food, drug and mass channel.¹⁶⁸

Other data sources, however, show that there is growing concern over the purity, safety and sustainability of marine sources of EFAs such as fatty oils obtained from crustaceans (e.g. krill) wild fish (e.g. wild salmon) as well as farmed fish (especially if FDA approves farming of genetically engineered salmon which is under consideration at the time of this study). Additionally there is growing demand for products that are free of major food allergens. Fatty oils from crustaceans and/or fish are classified as major food allergens. And there is continued growth in product categories with certifications that provide consumers some assurance of purity, quality, safety and traceability such as organically grown crops from the Americas.

In the context that the market for omega-3 products continues to grow, new entries of sachu inchi oil producers and products can have a chance especially when positioned as a safe plant-based source of omega-3s that is allergen free, non-GMO and organic, and suitable for vegans and vegetarians. Fish oil and krill oil will never be able to compete against sachu inchi oil in any of the aforementioned areas because:

- Crustaceans and fish are both major food allergens;
- Kosher certification for krill is not possible (crustaceans and other shellfish are not kosher);
- Organic certification for seafood is not possible (although there is a draft organic aquaculture standard in development for farmed fish);
- Vegan verification for seafood is not possible.

What new entries of sachu inchi oil to the North American market do have to contend with is the fact that other plant-based omega-3 oils are produced on a very large scale in Canada and in the United States, in particular, borage oil, flax oil and hemp oil. Sachu inchi oil will not be able to compete with these oils on a price or availability basis. Sachu inchi is not a commodity-oil but rather it is a specialty-oil and it needs to be marketed as such with a clear link to origin, i.e. produced only in the exotic biodiversity of the Peruvian Amazon.

167 Packaged Facts (2012). Abstract: The Global Market for EPA/DHA Omega-3 Products. Available from: <http://www.packagedfacts.com/Global-EPA-DHA-7145087/>

168 Anon (2012). Krill sales well. *Natural Products Insider*®;17(12):10.

In order to be positioned as a regional specialty associated with a Peruvian quality brand, consistent quality in line with the grades defined in the Peruvian sachu inchi oil standard needs to be assured. This would require investment and training programmes for implementation of the sachu inchi good agricultural practices (GAPs) for Peruvian sachu inchi farming communities as well as implementation of sachu inchi good manufacturing practices (GMPs) for Peruvian oil manufacturing companies. There needs to be commercial quantities of consistent quality oil in order to effectively market the Peruvian brand at a premium by comparison to less expensive flax and hemp oils.

9. Sachu inchi oil – substitution and comparison of features

9.1. Availability comparison

Comparing the relative market availability of similar fatty oil ingredients that sachu inchi seed oil would compete against (or be substituted with), borage seed oil, evening primrose oil, flax seed oil and hemp seed oil as well as fish oil and seal blubber oil are major products of Canada while both flax seed oil and fish oil are major products of the United States for domestic consumption and for export. China however has become the world's leading producer of evening primrose oil.

For borage oil, about half the world production occurs in Canada, New Zealand and the United Kingdom. A 2004 report estimated that borage seed world production exceeded 3,500 ha, of which about half was being grown in eastern England. The global production of borage oil was estimated at that time to be about 350 tons, or about one fifth or one quarter of evening primrose oil annual production volume.¹⁶⁹ According to Berti et al. (2010),¹⁷⁰ the main producers of borage seed are Canada, the United Kingdom, the United States and Chile. During the years 2004, 2005, and 2006, Chile had 2,000 ha of borage under contract and borage was starting to become an interesting alternative crop for Chile. The contracts came to an end in 2007 however due to decreasing international prices and lower cost GLA-containing oils available from other sources. Berti also reported that the market for borage oil, as well as for evening primrose oil, fluctuates dramatically with some years of over-supply and others of low production. One of the reasons for this is that the major borage producer is Canada, where growers can produce seed at the lowest cost, but where there is a high risk for crop failure due to early frosts. At the same time, lower-priced evening primrose oil available from China flooded the North American market in the early 2000's. The quantity of borage seed marketed each year is variable, fluctuating between 500 and 2,000 tons worldwide and borage seed and borage oil fluctuate accordingly.

For evening primrose oil, according to Deng et al. (2001),¹⁷¹ China is the major producer in the world, with an estimated 90% of total market share, which it has been able to achieve through the combination of low-cost hand labour, and growing conditions which are ideally suited to the crop. In the early 2000's export demand was usually estimated to be running at 1,000-1,200 tons of oil per year (8,000 – 9,500 tons seed-equivalent).

For flax, Canada is the world's leader in production and export presently representing about 40% of world flax seed production. Flax is one of Canada's top five crops alongside wheat, barley, oats and canola. Most Canadian flax is cultivated in Saskatchewan Province with smaller amounts produced in the Provinces of Manitoba and Alberta. Canada's 2012 crop was estimated at 489,000 tons. Following Canada, the combined production of China, India and United States accounts for about another 40% world flax production.¹⁷² In the United States, most of the flax is produced in the state of North Dakota with minor amounts grown in Montana, South Dakota and Minnesota. The 2012 United States flax crop was estimated

169 Laurence, R. (2004). Borage production for oil and gamma-linolenic acid. Barton ACT, Australia: Rural Industries Research and Development Corporation.

170 Berti, M. and others (2010). Borage (*Borago officinalis* L.) response to N, P, K, and S fertilization in South Central Chile. *Chilean J. Agric. Res*;70(2):228-236.

171 Deng, Y.C. and others (2001). Studies on the cultivation and uses of evening primrose (*Oenothera* spp.) in China. *Economic Botany*;55(1):83-92.

172 Flax Council of Canada: <http://www.flaxcouncil.ca/english/index.jsp?p=market>

at 146,360 tons.¹⁷³ The capacity for economical large scale flax oil production in both Canada and the United States is significant.

For hemp oil, most Canadian hemp seed is grown in the Provinces of Manitoba, Saskatchewan and Alberta. Minor amounts are grown in the Provinces of British Columbia, Ontario and Quebec. Most of Canada's hemp crop is certified organic. According to the Canadian Hemp Trade Alliance (CHTA), the production area for hemp in Canada grew from 2,700 ha in 2003 to an estimated 25,000 ha in 2010. Canada produces all of its hemp seed requirements (does not import) and in 2007, according to Statistics Canada exported 700 tons of hemp seeds in 2007 with a customs value of Can\$ 2,656,276. In the same year Canada exported 77 tons of hemp seed oil with a customs value of Can\$ 695,870.

Due to their relatively large scale production in North America, sachu inchi seed oil would not likely be able to compete with fatty oils of flax and/or hemp on the basis of price or availability. Therefore other differentiating characteristics need to be emphasized for substitution in new products. In the cases of borage oil and evening primrose oil there is wider price fluctuation from year to year.

While the market for EFA-based dietary supplement products, health food products and natural health products continues to grow, consumers are not yet well educated on the differences between the various sources of EFA. As a result, consumer purchase decisions may be largely price driven without a clear understanding of the main points of differentiation between the many omega-3 oil options.

To compete in this area, sachu inchi oil may need to be carefully positioned as a regional high-end specialty oil, i.e. only available from the Peruvian amazon, as non-GMO verified and certified organic, allergen-free (fish-free, gluten-free, lactose-free, nut-tree-free, soy-free) and suitable for vegetarians (unlike fish oil, krill oil and/or seal blubber oil). It is not clear whether consumers are interested to take the time necessary to understand the differences in fatty acid profiles between the wide range of products that essentially make the same or similar health claim statements on their labels, advertising and websites.

9.2. Composition (nutrient, phytochemical) and quality characteristics comparison

Table 10 compares the fatty acid profiles of animal-based fatty oil ingredients that would compete with Sachu Inchi Oil either as a food ingredient, dietary supplement ingredient or medicinal ingredient.

Table 11 compares the profiles of plant- or algal- based fatty oil ingredients that would complete Sachu Inchi Oil. The values are shown in % ranges of lower limit to upper limit.

173 United States Department of Agriculture (USDA) (2012). National Agricultural Statistics Service (NASS). Crop Production 2012 Summary. Available at: <http://usda01.library.cornell.edu/usda/current/CropProdSu/CropProdSu-01-11-2013.txt>

Table 10. Typical fatty acid profiles (% of total fatty acids) of animal-based oils that compete with sacha inchi oil

Fatty Acid / Shorthand	CLO	FO	KO	MO	SI-h	SI-v
Saturated						
Myristic (C14:0)	2-6			7.0-11.0		
Saturated fatty acids < C16:0						
Palmitic (C16:0)	7.0-14.0			12.0-31.0	3.8-4.1	3.8-4.1
Heptadecanoic (C17:0)					0.1	0.1
Stearic (C18:0)	1.0-4.0			2.0-5.0	2.7-3.3	2.7-3.3
Arachidic (C20:0)				Tr	0.1	0.1
Behenic (C22:0)				Tr		
Lignoceric (C24:0)						
Monounsaturated						
Palmitoleic (C16:1 <i>n</i> -7)	4.5-11.5		X		<0.1	<0.1
<i>cis</i> -10 Heptadecanoic (C17:1)					<0.1	<0.1
<i>cis</i> -Vaccenic (C18:1 <i>n</i> -7)	2.0-7.0		X			
Oleic (C18:1 <i>n</i> -9)	12.0-21.0		X	9.0-11.0	min 7.9	min 8.9
Gadoleic (Eicosenoic) (C20:1 <i>n</i> -11)	1.0-5.5			1.0-2.0	0.2-0.3	0.2-0.3
Gondoic (Eicosenic) (C20:1 <i>n</i> -9)	5.0-17.0		X			
Erucic (C22:1 <i>n</i> -9)	0.0-1.5		X	Tr		
Cetoleic (C22:1 <i>n</i> -11)	5-12					
Nervonic (C24:1)						
Polyunsaturated						
(C16:p2)				4-5		
(C18:p)				6-9		
Linoleic (LA) (C18:2 <i>n</i> -6)	0.5-3.0		X		min 24.0	min 32.1
Linolenic (C18:3)					min 55.0	min 44.7
α -Linolenic (ALA) (C18:3 <i>n</i> -3)	0.0-2.0		X			
γ -Linolenic (GLA) (C18:3 <i>n</i> -6)						
Stearidonic (SDA) (C18:4 <i>n</i> -3)	0.5-4.5		X			
Dihomo- γ -linolenic (C20:3 <i>n</i> -6)						
Arachidonic (C20:4 <i>n</i> -6)				1.5-2.5		
Eicosatetraenoic (C20:4 <i>n</i> -3)		X				
Eicosapentaenoic (EPA) (C20:5 <i>n</i> -3)	7.0-16.0	min 13.0	min 12.0	11.0-14.0		
Heneicosapentaenoic / 21:5 <i>n</i> -3		X				
Docosapentaenoic (DPA) (C22:5 <i>n</i> -6)				1.0-1.3		
Docosapentaenoic (Clupanodonic) (C22:5 <i>n</i> -3)			X			
Docosahexaenoic (DHA) (C22:6 <i>n</i> -3)	6.0-18.0	min 9.0	min 7.0	7.0-11.0		

Legend and sources of data shown in tables

AO	DHA from Algal (<i>Ulkenia</i>) Oil	Food Chemicals Codex, 8th Edition (FCC 8)
BO	Borage Oil	European Pharmacopoeia, 7th Edition (PhEur 7.0)
CCO	Cryptocodium <i>cohnii</i> Oil	United States Pharmacopeia, 36th Revision (USP 36)
CLO	Cod Liver Oil	United States Pharmacopeia, 36th Revision (USP 36)
CSO	Chia Seed Oil	Ricardo Ayerza (2011) ¹⁷⁴
EPO	Refined Evening Primrose Oil	European Pharmacopoeia, 7th Edition (PhEur 7.0)
FO	Fish Oil Containing Omega-3 Acids	United States Pharmacopeia, 36th Revision (USP 36)
FSO	Virgin Linseed (Flaxseed) Oil	European Pharmacopoeia, 7th Edition (PhEur 7.0)
HSO	Hemp Seed Oil	(1) Australia New Zealand Food Authority ¹⁷⁵ (2) J.C. Calloway (2010) ¹⁷⁶
KO	Krill Oil	(1) United States Pharmacopeia, 36th Rev. (USP 36) (2) Health Canada Krill Oil Monograph (4 July 2012)
MO	Menhaden Oil	Food Chemicals Codex, 8th Edition (FCC 8)
OO	Olive Oil	National Formulary, 31st Edition (NF 31)
SI-h	Sacha Inchi (<i>P. huayllabambana</i>)	Norma Técnica Peruana (NTP 151.400 2009)
SI-v	Sacha Inchi (<i>P. volubilis</i>)	Norma Técnica Peruana (NTP 151.400 2009)
SO	Schizochytrium Oil	United States Pharmacopeia, 36th Revision (USP 36)

Table 11. Typical fatty acid profiles (% of total fatty acids) of plant- or algal-based oils that compete with sacha inchi oil

Fatty Acid / Shorthand	AO	BO	CCO	CSO	EPO	FSO	HSO	OO	SI-h	SI-v	SO
Saturated											
Myristic (C14:0)	1.5-4.5										
Saturated fatty acids less than C16:0		max 0.3			max 0.3	max 1.0		<0.1			
Palmitic (C16:0)		9.0-12.0		6.9	4.0-10.0	3.0-8.0	6.0	7.5-20.0	3.8-4.1	3.8-4.1	
Heptadecanoic (C17:0)									0.1	0.1	
Stearic (C18:0)	0.5-2.0	2.0-6.0		3.6	1.0-4.0	2.0-8.0	2.0	0.5-5.0	2.7-3.3	2.7-3.3	
Arachidic (C20:0)		max 0.5				max 1.0		<0.7	0.1	0.1	
Behenic (C22:0)								<0.2			
Lignoceric (C24:0)								<0.2			
Monounsaturated											
Palmitoleic (C16:1 <i>n-7</i>)		max 0.6				max 1.0		<3.5	<0.1	<0.1	
<i>cis</i> -10 Heptadecanoic (C17:1)									<0.1	<0.1	
<i>cis</i> -Vaccenic (C18:1 <i>n-7</i>)											
Oleic (C18:1 <i>n-9</i>)		12.0-22.0		7.3	5.0-12.0	11.0-35.0	12.0	56.0-85.0	min 7.9	min 8.9	
Gadoleic (Eicosenoic) (C20:1 <i>n-11</i>)		2.8-4.4						<0.4	0.2-0.3	0.2-0.3	

174 Ayerza, R. (2011). The seed's oil content and fatty acid composition of chia (*Salvia hispanica* L.) var. Iztac 1, grown under six tropical ecosystems conditions. *Interciencia*; 36(8):620-624.

175 Australia New Zealand Food Authority (ANZFA). (2002). Final Assessment Report - Use of Industrial Hemp as a Novel Food.

176 Calloway, J.C. (2010). Hempseed oil in a nutshell. *AOCS Inform.*

Fatty Acid / Shorthand	AO	BO	CCO	CSO	EPO	FSO	HSO	OO	SI-h	SI-v	SO
Gondoic (Eicosenic) (C20:1 <i>n</i> -9)											
Erucic (C22:1 <i>n</i> -9)		max 3.0									
Cetoleic (C22:1 <i>n</i> -11)											
Nervonic (C24:1)		<4.5									
Polyunsaturated											
(C16:p2)											
(C18:p)											
Linoleic (LA) (C18:2 <i>n</i> -6)		30.0- 41.0	0.0-1.0	18.5	65.0- 85.0	11.0- 24.0	55.0	3.5- 20.0	min 24.0	min 32.1	
Linolenic (C18:3)						35.0- 65.0		<1.2	min 55.0	min 44.7	
α -Linolenic (ALA) (C18:3 <i>n</i> -3)		max 0.5		62.4	max 0.5		22.0				
γ -Linolenic (GLA) (C18:3 <i>n</i> -6)		17.0- 27.0			7.0- 14.0		4.0				
Stearidonic (SDA) (C18:4 <i>n</i> -3)							2.0				
Dihomo- γ -linolenic (C20:3 <i>n</i> -6)											1.7- 2.8
Arachidonic (C20:4 <i>n</i> -6)											0.6- 1.3
Eicosatetraenoic (C20:4 <i>n</i> -3)											
Eicosapentaenoic (EPA) (C20:5 <i>n</i> -3)	0.0-0.5		0.0-0.1								1.3- 3.9
Heneicosapentaenoic / 21:5 <i>n</i> -3											
Docosapentaenoic (DPA) (C22:5 <i>n</i> -6)	8.0- 14.0		0.0-0.1								10.5- 16.5
Docosapentaenoic (Clupanodonic) (C22:5 <i>n</i> -3)	0.2-1.5										
Docosahexaenoic (DHA) (C22:6 <i>n</i> -3)	40.0- 55.0		35.0- 47.0								30.0- 40.0

Table 12 compares the typical levels of other nutritional or phytochemical constituents of fatty oil ingredients that would compete with Sacha Inchi Oil.

Table 12. Composition and quality characteristics comparison of oils that compete with sachachi oil

	AO	BO	CCO	CLO	EPO	FO	FSO	HSO	KO	MO	OO	SI	SO
Relative density		0.921	0.91-0.93	0.918-0.927	0.923		0.931	0.923-0.925				0.926-0.931	
Unsaponifiable matter (%)	max 4.5	max 2.0	max 3.5	max 1.30	max 2.5	max 1.5	max 1.5	max 1.0	max 1.5	max 1.5	max 1.5	max 0.36	max 2.5
p-Anisidine value			max 20.0	max 30		max 20.0			max 20				max 20.0
Acid value	max 0.5	max 0.5	max 1.42	max 1.0	max 0.5	max 3	max 5.0				max 0.3		max 1.42
Free fatty acids (%)										max 0.1		max 1.0	
Peroxide value (mEq/kg)	max 5.0	max 10.0	max 5.0	max 5.0	max 10.0	max 5.0	max 15.0		max 5.0	max 5.0	max 10.0	max 10.0	max 5.0
Total oxidation value			max 26	max 26		max 26			max 26				max 26
Iodine value				145-180			160-200	140-175		min 120		183-199	
Saponification value				180-192			188-195	190-193		180-200		192-196	
Refractive index (20°C)		1.476			1.478		1.480	1.470-1.473				1.478-1.481	
Water (%)		max 0.1			max 0.1		max 0.1				max 0.1	max 0.14	
Tocopherols (mg/kg)												min 1900	
Vitamin A (µg/g)				180-750									
Vitamin D (µg/g)				1.5-6.25									
Brassicasterol (in sterol fraction)		max 0.3			max 0.3								
Campesterol (%)											□4.0		
Cholesterol (%)											□0.5		
□7-Stigmastenol (%)											□0.5		
Sum of the contents of □5,23-stigmastadienol, clerosterol, □-sitosterol, sitostanol, □5-avenas-terol, and □5,24-stigmastadienol											□93.0		

9.3. Ease of application comparison

Sacha inchi oil and the other similar fatty oils discussed in this chapter (e.g. borage oil, evening primrose oil, flax oil, hemp oil) have comparable physical characteristics (e.g. relative density, moisture content, refractive index, etc.). These oils are already being used as components of the same types of finished product formulations, for example as liquids filled into soft-gel capsules or into glass bottles for consumers to take by the spoonful.

For its use as a food ingredient such as in salad dressings or on its own for consumers or chefs to mix with other ingredients like vinegars and seasonings, the equipment necessary to bottle sachu inchi oil is no different from the bottling equipment used for olive oil or other vegetable oils.

It appears that product formulators / innovators could substitute one vegetable oil for the other or even combine them for EFA composition uniqueness (e.g. sachu inchi oil with chia oil) or taste uniqueness (e.g. sachu inchi oil with olive oil) without requiring different processes or technologies for manufacturing the finished product. The ease of application for product developers to substitute or add sachu inchi oil to products formerly or presently containing, for example flax oil or hemp oil, appears to be possible without presenting new significant production challenges.

9.4. Price comparison

Table 13 provides a typical average pricing structure comparison at four levels (25 gallon, 5 gallon, 1 gallon and 16 ounce) for selected bulk and/or bottled fatty oils in the United States natural foods channel. The prices shown are generic or typical catalogue prices for certified organic fatty oils which were current as the time of this study (April 2013). They do not take into account any special pricing for high volume or large customer contract pricing whereby the seller may take a lower margin in consideration of overall business.

Table 13. Price comparisons: organic oils of borage, evening primrose, flax, hemp, olive, pumpkin

Description	5 gallon price (US\$)	1 gallon price (US\$)	Retail price – 16 oz. (US\$)
Borage seed oil		346.00	51.00
Evening primrose oil	952.00	224.00	33.00
Flax seed oil		28.95-42.95	6.80-8.85
Hemp seed oil	416.00	8.00	14.50-16.08
Olive oil, extra virgin	229.00	38.50-\$54.00	8.00
Pumpkin seed oil		122.00	18.00

Price sources: Azure Standard: <http://www.azurestandard.com/shop/category/OL>
 Glory Bee Foods: <http://wholesale.glorybee.com/shop/Olive-Oil/>
 Mountain Rose Herbs: <http://www.mountainroseherbs.com/oils/herbal.html>

Note: 1.0 United States gallon = 3.78541 litres'

9.5. Recommended uses comparison

The following Table 14 provides a summary of the accepted or authorized recommended uses for a range of fatty oils that would compete with Sachu Inchi Oil.

For Canada, the table includes the main oral ingestion uses whether the oil is classified as a medicinal ingredient or as a non-medicinal ingredient of licensed Natural Health Products (NHPs). Topical application uses are also included, again whether classified as a non-medicinal ingredient or medicinal ingredient of licensed NHPs. In some cases there are authorized medicinal and non-medicinal uses depending on the dosage.

For the United States, the table includes the main oral ingestion uses whether the oil is classified as a conventional food ingredient or as a component of Dietary Supplement Products (DSPs). These uses fall into different types of allowable claim statements including 'Nutrient Content Claims', 'Qualified Health Claims', and 'Structure and Function Claims'. Topical application uses are also included, whether classified as non-drug cosmetic ingredients or as active ingredients of over-the-counter (OTC) drug products for human use.

Table 14. Recommended uses comparison for sachai inchi oil competitive products

Substance	Canada	United States
Borage Oil	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Source of essential fatty acids for the maintenance of good health • Source of omega-6 fatty acids for the maintenance of good health • Source of linoleic acid (LA) for the maintenance of good health 	<p>Oral: DSP component with Nutrient Content Claims:</p> <ul style="list-style-type: none"> • Provides [x] gram of essential fatty acids per serving for the maintenance of good health • Provides [x] gram of omega-6 fatty acids per serving for the maintenance of good health • Provides [x] gram of linoleic acid (LA) per serving for the maintenance of good health
	<p>Topical: Non-medicinal NHP ingredient to function as a:</p> <ul style="list-style-type: none"> • Skin-conditioning Agent – Emollient (Ingredients which help to maintain the soft, smooth, and pliable appearance of skin. Emollients function by their ability to remain on the skin surface or in the stratum corneum to act as lubricants, to reduce flaking, and to improve the skin's appearance) 	<p>Topical: Non-drug cosmetic ingredient for skin conditioning function.</p>
Chia Oil	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Source of alpha linolenic acid (ALA) for the maintenance of good health • Source of omega-3 fatty acids for the maintenance of good health • Source of linoleic acid (LA) for the maintenance of good health • Source of essential fatty acids for the maintenance of good health 	<p>Oral: DSP component with Nutrient Content Claims:</p> <ul style="list-style-type: none"> • Provides [x] gram of alpha linolenic acid (ALA) per serving for the maintenance of good health • Provides [x] gram of linoleic acid (LA) per serving for the maintenance of good health • Provides [x] gram of essential fatty acids for the maintenance of good health
Cod Liver Oil	<p>Oral: NHP medicinal ingredient. For products providing 100-1,360 mg EPA + DHA, per day:</p> <ul style="list-style-type: none"> • Source of omega-3 fatty acids for the maintenance of good health • Source of EPA and DHA for the maintenance of good health <p>For products providing 100-1,360 mg EPA + DHA including at least 100 mg DHA, per day:</p> <ul style="list-style-type: none"> • Helps support cognitive health and/or brain function <p>For products providing 150-1,360 mg EPA + DHA including at least 150 mg DHA, per day:</p> <ul style="list-style-type: none"> • Helps support the development of the brain, eyes and nerves in children up to 12 years of age 	<p>Oral: DSP component with Nutrient Content Claims:</p> <ul style="list-style-type: none"> • Provides [x] gram of omega-3 fatty acids per serving for the maintenance of good health • Provides [x] gram of EPA and DHA per serving for the maintenance of good health <p>and/or Qualified Health Claims:</p> <ul style="list-style-type: none"> • Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the product] provides [x] gram of EPA and DHA omega-3 fatty acids
	<p>Topical: Medicinal ingredient of medicated skin care NHPs:</p> <ul style="list-style-type: none"> • Temporarily protects and helps relieve minor skin irritation and itching of minor cuts, scrapes and burns 	<p>Topical: Active ingredient of skin protectant OTC drug products:</p> <ul style="list-style-type: none"> • Temporarily protects minor cuts, scrapes, burns' • Helps prevent and temporarily protects chapped or cracked skin and lips' • Helps prevent and protect from the drying effects of wind and cold weather
	<p>Topical: as a non-medicinal NHP ingredient to function as a:</p> <ul style="list-style-type: none"> • Fragrance ingredient: for its odorous, odour-enhancing or blending properties; or as a 	

Substance	Canada	United States
	<ul style="list-style-type: none"> • Skin-Conditioning Agent –Occlusive: ingredients which retard the evaporation of water from the skin surface. By blocking the evaporative loss of water, occlusive materials increase the water content of skin. Occlusive agents are generally lipids which tend to remain on the skin surface 	
Crypthecodinium cohnii Oil	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Source of DHA for the maintenance of good health 	<p>Oral: DSP component:</p> <ul style="list-style-type: none"> • Provides [x] gram of DHA per serving for the maintenance of good health
DHA from Algal (Ulkenia) Oil	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Source of DHA for the maintenance of good health 	<p>Oral: DSP component:</p> <ul style="list-style-type: none"> • Provides [x] gram of DHA per serving for the maintenance of good health
Evening Primrose Oil	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Source of essential fatty acids for the maintenance of good health • Source of omega-6 fatty acids for the maintenance of good health • Source of linoleic acid for the maintenance of good health <p>Oral and Topical: Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> • Oleaginous Vehicle: a carrying agent for a medicinal ingredient with oily properties <p>Topical: Non-medicinal ingredient:</p> <ul style="list-style-type: none"> • Skin-Conditioning Agent: an ingredient used to create special effects on skin to maintain the skin in good condition. This group includes substances believed to enhance the appearance of dry or damaged skin and substantive materials which adhere to the skin to reduce flaking and restore suppleness <p>Dental, Ophthalmic, Oral or Topical: Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> • Diluent: a substance used to dilute or reduce the concentration of the medicinal ingredient 	<p>Oral: DSP component with Nutrient Content Claims:</p> <ul style="list-style-type: none"> • Provides [x] gram of essential fatty acids for the maintenance of good health • Provides [x] gram of omega-6 fatty acids for the maintenance of good health • Provides [x] gram of linoleic acid for the maintenance of good health
Fish Oil	<p>Oral: NHP medicinal ingredient:</p> <p>For products providing 100-3000 mg EPA+DHA, per day:</p> <ul style="list-style-type: none"> • Source of omega-3 fatty acids for the maintenance of good health • Source of EPA and DHA for the maintenance of good health <p>For products providing 100-3000 mg EPA+DHA including at least 100 mg DHA, per day:</p> <ul style="list-style-type: none"> • Helps support cognitive health and/or brain function <p>For products providing 150-2000 mg EPA+DHA including at least 150 mg DHA, per day:</p> <ul style="list-style-type: none"> • Helps support the development of the brain, eyes and nerves in children up to 12 years of age <p>For products providing 500-3000 mg EPA+DHA, per day and containing a ratio of EPA:DHA between 0.5:1 and 2:1:</p>	<p>Oral: DSP component with Nutrient Content Claims:</p> <ul style="list-style-type: none"> • Provides [x] gram of omega-3 fatty acids per serving for the maintenance of good health • Provides [x] gram of EPA and DHA per serving for the maintenance of good health <p>and/or Qualified Health Claims:</p> <ul style="list-style-type: none"> • Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the product] provides [x] gram of EPA and DHA omega-3 fatty acids

Substance	Canada	United States
	<ul style="list-style-type: none"> Helps maintain / support cardiovascular health <p>For products providing 1000-3000 mg EPA+DHA and containing a ratio of EPA:DHA between 0.5:1 and 2:1, per day:</p> <ul style="list-style-type: none"> Helps to reduce serum triglycerides/triacylglycerols <p>For products providing 2800-3000 mg EPA+DHA and containing a ratio of EPA:DHA between 0.5:1 and 2:1, per day:</p> <ul style="list-style-type: none"> In conjunction with conventional therapy, helps to reduce the pain of rheumatoid arthritis in adults <p>For products providing 1500-3000 mg EPA+DHA and containing a ratio of EPA:DHA between 1.75:1 and 2:1, including at least 1000 mg EPA, per day:</p> <ul style="list-style-type: none"> Helps to promote healthy mood balance 	
Flaxseed Oil	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> Source of essential fatty acids for the maintenance of good health Source of omega-3 fatty acids for the maintenance of good health Source of alpha-linolenic acid (ALA) for the maintenance of good health Source of omega-6 fatty acids for the maintenance of good health Source of linoleic acid (LA) for the maintenance of good health <p>Dental, Ophthalmic, Oral or Topical: Non-medicinal ingredient:</p> <ul style="list-style-type: none"> Diluent: a substance used to dilute or reduce the concentration of the medicinal ingredient <p>Topical: Non-medicinal NHP ingredient to function as a:</p> <ul style="list-style-type: none"> Fragrance ingredient: for its odorous, odour-enhancing or blending properties Skin-Conditioning Agent: an ingredient used to create special effects on skin to maintain the skin in good condition. This group includes substances believed to enhance the appearance of dry or damaged skin and substantive materials which adhere to the skin to reduce flaking and restore suppleness Skin-Conditioning Agent –Occlusive: ingredients which retard the evaporation of water from the skin surface. By blocking the evaporative loss of water, occlusive materials increase the water content of skin. Occlusive agents are generally lipids which tend to remain on the skin surface 	<p>Oral: DSP component with Nutrient Content Claims:</p> <ul style="list-style-type: none"> Provides [x] gram of essential fatty acids per serving for the maintenance of good health Provides [x] gram of omega-3 fatty acids per serving for the maintenance of good health Provides [x] gram of alpha-linolenic acid (ALA) per serving for the maintenance of good health Provides [x] gram of omega-6 fatty acids for the maintenance of good health
Hemp Seed Oil	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> Source of Essential Fatty Acids for the maintenance of good health <p>Oral: Non-medicinal NHP ingredient to function as a:</p>	<p>Oral: DSP component with Nutrient Content Claims:</p> <ul style="list-style-type: none"> Provides [x] gram of essential fatty acids per serving for the maintenance of good health

Substance	Canada	United States
	<ul style="list-style-type: none"> Dispersing Agent: substances that help maintain the dispersion of small particles in a formulation Oleaginous Vehicle: a carrying agent for a medicinal ingredient with oily properties <p>Topical: Non-medicinal NHP ingredient to function as a:</p> <ul style="list-style-type: none"> Skin-Conditioning Agent: an ingredient used to create special effects on skin to maintain the skin in good condition. This group includes substances believed to enhance the appearance of dry or damaged skin and substantive materials which adhere to the skin to reduce flaking and restore suppleness 	<ul style="list-style-type: none"> Provides [x] gram of omega-3 fatty acids and [x] gram of omega-6 fatty acids per serving for the maintenance of good health <p>Topical: as a non-drug cosmetic ingredient for use as an emollient, oleaginous vehicle, and for skin-conditioning function.</p>
Krill Oil	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> Source of EPA and DHA for the maintenance of good health Source of omega-3 fatty acids for the maintenance of good health 	<p>Oral: DSP component with Nutrient Content Claims:</p> <ul style="list-style-type: none"> Provides [x] gram of omega-3 fatty acids per serving for the maintenance of good health Provides [x] gram of EPA and DHA per serving for the maintenance of good health <p>and/or Qualified Health Claims:</p> <ul style="list-style-type: none"> Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the product] provides [x] gram of EPA and DHA omega-3 fatty acids
Menhaden Oil	See Fish Oil	See Fish Oil
Olive Oil	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> Laxative and purgative <p>Otic: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> To loosen and help remove accumulated earwax <p>Topical: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> Dermatologic emollient Temporarily protects and helps relieve minor skin irritation and itching <p>Oral and Topical: Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> Oleaginous Vehicle: a carrying agent for a medicinal ingredient with oily properties <p>Topical: Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> Skin-Conditioning Agent –Occlusive: ingredients which retard the evaporation of water from the skin surface. By blocking the evaporative loss of water, occlusive materials increase the water content of skin. Occlusive agents are generally lipids which tend to remain on the skin surface 	<p>Oral: Conventional food and DSP component.</p> <p>Topical: Non-drug cosmetic ingredient (emollient, oleaginous vehicle, skin-conditioning agent – occlusive).</p>

Substance	Canada	United States
Sacha Inchi Oil	<p>Oral: Although 'Sacha Inchi Seed' is classified as a NHP medicinal ingredient, 'Sacha Inchi Oil' is not yet listed as a medicinal ingredient.</p>	<p>Oral: While food products and DSPs already exist in the United States market, their legal status is uncertain, whether affirmed as GRAS for use in food products or whether considered as an Old Dietary Ingredient (ODI) for use in DSPs.</p>
	<p>Topical: Non-medicinal NHP Ingredient:</p> <ul style="list-style-type: none"> • Skin-Conditioning Agent – Emollient: ingredients which help to maintain the soft, smooth, and pliable appearance of skin. Emollients function by their ability to remain on the skin surface or in the stratum corneum to act as lubricants, to reduce flaking, and to improve the skin's appearance • Skin-Conditioning Agent – Humectant: ingredients intended to increase the water content of the top layers of skin. This group of ingredients includes primarily hygroscopic agents employed for this specific purpose • Skin Protectant: substance that temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help to provide relief to such surfaces; if the ingredient is not associated with a claim and/or pharmaceutical use 	<p>Topical: Non-drug cosmetic ingredient (skin conditioning agent – emollient or humectant).</p>
Schizochytrium Oil	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Source of DHA for the maintenance of good health 	<p>Oral: DSP component:</p> <ul style="list-style-type: none"> • Provides [x] gram of DHA per serving for the maintenance of good health
Seal Oil	<p>Oral: NHP medicinal ingredient:</p> <p>For products providing 100-3,000 mg EPA + DHA, per day:</p> <ul style="list-style-type: none"> • Source of omega-3 fatty acids for the maintenance of good health • Source of EPA, DHA and DPA for the maintenance of good health <p>For products providing 140-2,000 mg EPA+DHA including at least 150 mg DHA, per day:</p> <ul style="list-style-type: none"> • Helps to support the development of the brain, eyes and nerves in children up to 12 years of age 	<p>Not legal to market seal oil products in the United States.</p>

Sources: Health Canada Natural Health Products Directorate (NHPD) Natural Health Products Ingredients Database (NHPID), Health Canada Food and Drug Regulations, U.S. Food and Drug Administration (FDA) Dietary Supplement notification letters, and various FDA and USDA regulations.

10. Sacha inchi seed – existing competitors

Companies interviewed for this study, both Peruvian and North American, suggested that the main existing competitors for sachu inchi seed would be other oilseeds or nuts that have an interesting EFA profile and that could be used as components of healthy breakfast cereals, nutrition bars, chocolates, healthy snacks or trail mixes (combinations of dried fruits, nuts and seeds) or eaten directly. In this regard, most often mentioned were chia seed, flax seed, hemp seed, pumpkin seed and walnut.

10.1. Chia seed

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1207	Other oil seeds and oleaginous fruits, whether or not broken:
HS 1207.99.0391	Other: Chia seed
HS 1209.98.4080	Chia seeds for sowing

Chia seed, a.k.a. White Chia, is the dried, ripe seed of *Salvia hispanica* L. (Fam. Labiatae or Lamiaceae). Post-harvest the seeds are cleaned mechanically and the flowers, leaves and other parts of the plant are removed.¹⁷⁷ Whole ground Chia is produced by passing the whole seeds through a variable speed hammer mill.

In Canada, Chia Seed is used as a medicinal ingredient of licensed NHPs usually in granule or powder form and/or as a component of nutritional shake mixes (e.g. Shakeology®). For example, in 2012, one Canadian company, Vita Health Products Inc., received NHP marketing authorization for their Chia Seed granule with the authorized recommended use statements: 'Natural source of fibre and Omega-3 fatty acids. Source of antioxidant. Source of Alpha-Linolenic acid (ALA) and Linoleic Acid (LA)'.¹⁷⁸ Also in 2012, a California company Beachbody LLC, received NHP marketing authorization for their powdered nutritional shake mix called 'Vegan Chocolate Shakeology', which contains powdered chia seed in combination with powders of flaxseed (*Linum usitatissimum*), maca root (*Lepidium meyenii*), quinoa seed (*Chenopodium quinoa*), and sacha inchi seed (*Plukenetia volubilis*), among other ingredients, with the authorized recommended use statements: 'Source of essential amino acids for the maintenance of good health. Digestive enzyme'.¹⁷⁹

In the United States, whole dried Chia Seed as well as Chia Sprouted Seed Powder are used as food ingredients (e.g. recommended for adding to baked goods, cereals, piecrusts, and salads, and/or as a thickener for soups, smoothies and shakes) and also as DSP components, labelled and marketed with quantified Nutrient Content Claim statements. For example, the company 'Health From The Sun®' markets a DSP called 'Raw Chia Seed' as a 100% vegetarian and gluten-free source of fibre, providing omega-3, plant lignans and a complete source of protein. A California Company 'Navitas Naturals' instead labels and markets their 'Raw Chia Seed' product as a conventional food product.

Figure 17 shows the Supplement Facts label of the Health From the Sun® brand of 'Raw Chia Seed' with quantified nutrients (including dietary fibre and omega-3, -6 and -9 fatty acids). Figure 18 shows the Nutrition Facts label of the Navitas Naturals brand of 'Raw Chia Seed'. Both seemingly comparable products are found in the same market channels, one labelled and marketed as a conventional food product and the other labelled and marketed as a dietary supplement product.

177 European Commission (EC) (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. Official Journal of the European Union.

178 Health Canada (2012). Vita Health Products Inc. Chia Seeds granules. Natural Product Number (NPN): 80036201. In: Licensed Natural Health Products Database. Available from: <http://webprod3.hc-sc.gc.ca/lnhpd-bdpsnh/>

179 Health Canada (2012). Beachbody LLC. Vegan Chocolate Shakeology. Natural Product Number (NPN): 80038206. In: Licensed Natural Health Products Database. Available from: <http://webprod3.hc-sc.gc.ca/lnhpd-bdpsnh/>

Figure 17. Health from The Sun®' Raw Chia Seed – dietary supplement product-supplement facts

SUPPLEMENT FACTS

Serving size 1 tbsp. (12 g)

	Amount per serving	% Daily value
Calories	40	
Calories from Fat	35	
Total Fat	4 g	6%†
Saturated Fat	0.5 g	3%†
Total Carbohydrate	4 g	1%†
Dietary Fibre	4 g	16%†
Protein	2 g	4%†
Whole Chia Seed (<i>Salvia hispanica</i> L.)	12 g	*
- Alpha Linolenic Acid (omega-3)	2,400 mg	*
- Linoleic Acid (Omega-6)	780 mg	*
Oleic Acid (Omega-9)	190 mg	*

† Per cent Daily Value based on a 2,000 calorie diet.
* Daily Value not established.

Figure 18. Navitas naturals raw chia seed – food product – nutrition facts

Nutrition Facts		Amount/Serving	% Daily Value*	Amount/Serving	% Daily Value*
Serving Size: 15g (2 Tbsp)		Total Fat 4.5g	7%	Total Carbohydrate 7g	2%
Servings Per Container:		Saturated Fat 0g	0%	Dietary Fiber 6g	24%
Calories 70		Trans Fat 0g		Sugars 0g	
Calories from Fat 40		Cholesterol 0mg	0%	Protein 3g	
		Sodium 0mg	0%		
		Vitamin A 0%	Vitamin C 4%	Calcium 10%	Iron 8%

INGREDIENTS: CERTIFIED ORGANIC CHIA SEEDS (SALVIA HISPANICA)
PRODUCT OF: MEXICO, PARAGUAY & ARGENTINA
ALLERGEN INFORMATION: PACKAGED IN A FACILITY THAT ALSO HANDLES TREE NUTS.
STORAGE INFORMATION: REFRIGERATION NOT REQUIRED. STORE IN A COOL, DARK, DRY PLACE.

Figure 19. Examples of chia seed food products in the United States market



Figure 20. Examples of chia seed dietary supplement products in the United States market



10.2. Flax seed

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1204.00.00	Flaxseed (linseed), whether or not broken
HS 1204.00.0010	Flaxseed for sowing
HS 1204.00.0020	Flaxseed for use as oil stock
HS 1204.00.0090	Other: Ground or milled flaxseed

The terms Flaxseed and Linseed are used interchangeably. The European Pharmacopoeia (PhEur) defines ‘Linseed’ (Pharmacopoeial name: *Lini semen*) as the dried, ripe seeds of *Linum usitatissimum* L. (Fam. Linaceae). There is not yet a USP monograph for Flaxseed as a DSP component. The USDA does have official United States Standards for Flaxseed, which defines the grade requirements for flaxseed grades U.S. No. 1, U.S. No. 2, and U.S. sample grade.¹⁸⁰

In the United States flaxseed is mainly used as a health food ingredient (in crackers, healthy breads and breakfast cereals) but also as a DSP component. In both cases certain authorized Health Claim statements and/or Nutrient Content Claims statements are permitted. For example, fibre-containing grain products, whether conventional food product or DSP, may be labelled and marketed with either of the following FDA-authorized Health Claim statements, as long as the product also meets the requirements of being low cholesterol and low fat, and is in fact a good source of dietary fibre (without fortification):¹⁸¹

‘Low fat diets rich in fibre-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors’

‘Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fibre, particularly soluble fibre, may reduce the risk of heart disease, a disease associated with many factors.’

A famous breakfast cereal ‘Uncle Sam® Original Cereal’ (Attune Foods™, San Francisco, California), marketed in the United States for over 100 years (since 1908), contains only whole wheat kernels, whole flaxseed, salt, and barley malt, and is now promoted as a low glycaemic, heart healthy cereal, kosher

180 United States Department of Agriculture (USDA) (2012). United States Standards for Flaxseed. In: Code of Federal Regulations, Title 7, Part 810 (7 CFR §810). Washington, D.C.: United States Government Printing Office. Available from: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title7-vol7/pdf/CFR-2012-title7-vol7-part810-subpartE.pdf>

181 U.S. Food and Drug Administration (FDA) (2012). Specific Requirements for Health Claims. In: Code of Federal Regulations, Title 21, Part 101 (21 CFR §101). Washington, D.C.: United States Government Printing Office. Available from: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol2/pdf/CFR-2012-title21-vol2-part101-subpartE.pdf>

certified and non-GMO project verified.¹⁸² Another example is the popular health food bread 'Essential Flax Seed Bread' (Alvarado Street Bakery Co-operative, Petaluma, California), non-GMO project verified and made with organic sprouted whole flaxseeds, available in supermarkets and natural food stores throughout the United States.¹⁸³ Powdered flaxseed is also a component of popular DSPs like 'Vegan Chocolate Shakeology' (Beachbody LLC, Santa Monica, California), which also contains powders of amaranth seed (*Amaranthus hypochondriacus*), chia seed (*Salvia hispanica*), maca root (*Lepidium meyenii*), quinoa seed (*Chenopodium quinoa*), and sacha inchi seed (*Plukenetia volubilis*), among other ingredients,

In Canada, Flaxseed is used as a medicinal ingredient of licensed NHPs specifically in whole, ground, and powdered dosage forms, as well as in 'dry damaged' form (A 'dry damaged' preparation means a preparation where the dried herbal material is bruised, milled, cracked, cut or crushed but remains identifiable under close visual inspection'. There is a Natural Health Products Directorate (NHPD) compendial monograph available for the labelling and marketing authorization of Flaxseed NHPs with authorized recommended uses including:¹⁸⁴

- Source of essential fatty acids for the maintenance of good health;
- Source of omega-3 fatty acids for the maintenance of good health;
- Source of alpha-linolenic acid (ALA) for the maintenance of good health;
- Source of omega-6 fatty acids for the maintenance of good health;
- Source of linoleic acid (LA) for the maintenance of good health;
- Used in Herbal Medicine as a bulk-forming laxative;
- Used in Herbal Medicine to promote bowel movement by increasing bulk volume and water content;
- Used in Herbal Medicine to provide gentle relief of constipation and/or irregularity;
- Used in Herbal Medicine to help reduce blood lipid levels in adults;
- Provides antioxidants for the maintenance of good health.

As a non-medicinal ingredient of licensed NHPs, it is also possible to use Flaxseed as a flavour enhancer ingredient, albeit at non-therapeutic dosage levels.

In the absence of a Flaxseed USP monograph, the aforementioned PhEur monograph may be used for the quality control testing and release of Flaxseed when used as either a component of a DSP in the United States or as a medicinal ingredient of an NHP in Canada.

Worth noting is a Canadian government-funded national initiative called 'Flax Canada 2015 Phase II' (FC2015)¹⁸⁵ which has been established to identify and utilize value-added opportunities for flax. The FC2015 initiative aims to enhance the value of flax by making it an important component in the preventative approach to human and animal health. FC2015 will support the value-added sector with a strategy for total utilization of flax for food, feed, fibre, health, and industrial uses. It is claimed that this national initiative is a strategy to improve Canadian health, wellness and environmental sustainability, positioning flax as one of the main drivers of the Canadian bio-economy. The potential social, economic, and ecological benefits of FC2015's strategic plan include:

- Strengthened vitality and quality of life in rural communities
- Increased economic options and profitability for producers
- More value-added, locally-based processing industries
- Increased availability of high-quality flax products in the marketplace
- Improved pest management
- Greater biological and crop diversity in agro-ecosystems

182 Attune Foods™ (2012). Uncle Sam® Original Cereal - 10 oz. – Description. Available from: <http://www.attunefoods.com/products/Uncle-Sam/uncle-sam-original-heart-healthy-cereal-10oz>

183 Alvarado (2012). Street Bakery Co-operative. Essential Flax Seed Bread. Available from: http://www.alvaradostreetbakery.com/product_detail.php?id=26

184 Health Canada Natural Health Products Directorate (NHPD). (2010). Monograph: Flaxseed. Available from: <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/monoReq.do?id=219&lang=eng>

185 Flax Council of Canada. FC2015. Available from: <http://www.flaxcouncil.ca/english/index.jsp?p=home&mp=fc2015>

- Enhanced environmental quality – improved air, water and soil quality
- Health benefits associated with improved nutrition and environment.

Figure 21. Examples of flaxseed-containing products in the United States



10.3. Hemp seed

Harmonized Tariff Schedule of the United States (HTSUS):

HS 1207.99.0320	Hemp seed (for oil)
HS 1207.99.0090	Hemp seed (sterilized – non viable)
HS 1901.90.9095	Hemp seed (defatted) protein flour or meal
HS 2008.19.9090	Roasted hemp seed snack
HS 2202.10.0040	Hemp Soda (containing extract of sterilized hemp seeds)
HS 2306	Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of vegetable fats or oils, other than those of heading 2304 or 2305:
HS 2306.90.0130	of hemp seeds
HS 2306.90.0140	Hemp seedcake protein powder

Hemp Seed is the dried ripe fruit of *Cannabis sativa* L. (Fam. Cannabaceae). Historically it has been used as a component of Traditional Oriental Medicine (TOM) formulations in the United States and Canada where TOM (e.g. Japanese Kampo Medicine, Traditional Chinese Medicine and Traditional Korean Medicine) has been practiced since the 19th century and has legal recognition today as a primary healthcare system. Therefore quality standards for hemp seed are available in the English editions of the Pharmacopoeia of the Japanese Pharmacopoeia (JP),¹⁸⁶ People’s Republic of China (PPRC)¹⁸⁷ and The Korean Herbal Pharmacopoeia (KHP).¹⁸⁸

Hemp Seed is also being used more and more as a food ingredient. According to the Hemp Industries Association (HIA), hemp seed food uses include in beer, breads, brownies, burgers, chips, chocolate bars, coffees, cookies, defatted hempseed meal, shelled hempseeds, dry mixes – cake, cookie, pancake and

186 Japanese Pharmacopoeia Committee. (2011). Cannabis Fructus. In: The Japanese Pharmacopoeia, Sixteenth Edition (JP XVI). Tokyo, Japan: Japanese Ministry of Health, Labour and Welfare; page 1661.

187 Chinese Pharmacopoeia Commission. Cannabis Fructus. In: Pharmacopoeia of the People’s Republic of China (2010) Volume I. Beijing, China: China Medical Science Press. 2010; page 87.

188 Korean Food and Drug Administration (KFDA).(2002). Cannabis Semen. In: The Korean Herbal Pharmacopoeia. Seoul, Republic of Korea: SFDA; page 42.

pizza dough, energy bars, flour, hummus, ice cream (non-dairy desserts), nut bars, nut-butter, oil, pasta, pretzels, protein powders, roasted seeds, salad dressings and spiced hemp seeds.¹⁸⁹

In Canada, non-viable hemp seeds are classified as medicinal Natural Health Products (NHPs) under Schedule 1, item 1 (plant or plant material) of the NHP Regulations. *Cannabis sativa*, in part, includes hemp: non-viable hemp seeds, mature stalks that do not include leaves, flowers, seeds or branches, and fibre derived from such stalks. Hemp seed derivatives such as hemp seed oil and protein fall under Item 2 of Schedule 1 to the NHP Regulations, as extracts or isolates of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation. Licensed NHPs containing hemp seed cannot contain more than 10 ppm of delta-9-tetrahydro-cannabinol (THC), and their production must be in compliance with the Industrial Hemp Regulations.

There are licensed NHPs, for example Vega One Nutritional Shake Powder (Sequel Naturals Ltd.; Natural Product Number (NPN): 80040400), which contains the medicinal ingredient hemp seed protein in combination with sacha inchi seed protein, chia seed, flax seed, flax seed protein and pea protein, among other active ingredients. The United States version of same product also contains sacha inchi protein.

Figure 22. Examples of hemp seed-containing products in the United States and/or Canada



10.4. Pumpkin seed

Harmonized Tariff Schedule of the United States (HTSUS):

- HS 1209.91.8055 Pumpkin seeds, unhulled, for sowing
- HS 1212.99.91 Other: Pumpkin seeds, hulled, used primarily for human consumption, not elsewhere specified or included
- HS 1901.90.9095 Pumpkin seed flour (bread pre-mixes or drink mixes)
- HS 2008.19.9090 Pumpkin seed spread

The World Health Organization (WHO) monograph defines ‘Pumpkin Seed’ (Pharmacopoeial names: Cucurbitae Semen or Cucurbitae Peponis Semen) as dried seeds of *Cucurbita pepo* L. (Fam. Cucurbitaceae) or its cultivars.¹⁹⁰ Although Pumpkin Seeds, whole or powdered, are commonly used as components of healthy snacks like trail mixes (combined with dried fruits, nuts and seeds), health bars (granola bars) and breakfast cereals (granolas and mueslis), they are also used therapeutically as described in the WHO monograph.

189 Hemp Industries Association (HIA). Products. Summerland, CA: HIA: <http://www.thehia.org/products.html>

190 World Health Organization (WHO) (2009). Cucurbitae Semen. In: WHO Monographs on Selected Medicinal Plants, Volume 4. Geneva, Switzerland: WHO; 83-91. Available from: <http://www.who.int/medicines/areas/traditional/SelectMonoVol4.pdf>

According to the European Medicines Agency (EMA) community herbal monograph on Pumpkin Seed, the whole, ripe and dried seeds, at a daily dosage of 10–20 g, may be registered and marketed as a ‘Traditional herbal medicinal product (THMP) for the relief of lower urinary tract symptoms related to benign prostatic hyperplasia or related to an overactive bladder, after serious conditions have been excluded by a medical doctor’.¹⁹¹ The EU status of Pumpkin Seed as a THMP is relevant for certain non-EU countries where the marketing authorization of herbal medicinal products based on EU monographs is accepted. For example, this is the case in certain Member States of the Commonwealth of Nations including North American members like Canada.

In Canada, Pumpkin Seed as well as extracts and/or fixed oils of Pumpkin Seed are classified as medicinal ingredients of licensed Natural Health Products (NHPs). Dried powdered Pumpkin Seed, however, is also permitted for use as a non-medicinal component of oral and/or topical licensed NHPs to function as a flavour enhancer; substances used to impart a pleasant flavour to a health product that is put in or on the mouth, such as those with oral, buccal or dental routes of administration, or topical in such products as lipsticks and lip balm.

In the United States, dried Pumpkin Seed, whether raw, roasted and salted or sprouted, is used mainly as a food ingredient (in bars, butters, chips, cereals, and trail mixes) but also as a Dietary Supplement Product (DSP) component (in protein bars and powders). In most cases, the processed forms used in DSPs are the dried extract, soft extract or the fatty oil in soft-gel capsules.

Figure 23. Examples of pumpkin seed products in the United States



10.5. Walnuts

Harmonized Tariff Schedule of the United States (HTSUS):

- HS 0802.31.0000 Walnuts, in shell
- HS 0802.32.0000 Walnuts, shelled

There are two United States Grades for walnuts, U.S. No. 1 and U.S. commercial grade. Walnuts that do not meet the quality requirements of these two grades are designated as ‘unclassified’. Verification of compliance with the ‘United States Standards for Grades of Shelled Walnuts (*Juglans regia*)’¹⁹² falls under the authority of the USDA Agricultural Marketing Service (AMS). The standards serve as a basis for inspection and grading and upon request a company can have the grade of their walnuts verified by USDA.

Under FDA regulations, walnuts are classified as a ‘major food allergen’. All packaged food products in the United States must comply with the food allergen labelling requirements of the ‘Food Allergen Labelling and Consumer Protection Act of 2004’ (FALCPA). Under FALCPA, major food allergens must be listed on the Information Panel of the label in a ‘Contains’ statement; for example if the food product contains any

191 European Medicines Agency (EMA) and Committee on Herbal Medicinal Products (HMPC). (2011). Draft Community Herbal Monograph on Cucurbita pepo L., semen. London, UK: EMA. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_Community_herbal_monograph/2011/10/WC500116580.pdf

192 United States Department of Agriculture (USDA) and Agricultural Marketing Service (AMS) (1968). United States Standards for Grades of Shelled Walnuts (*Juglans regia*). Washington, D.C.: USDA. Reprinted January 1997. Available from: <http://www.agfoodsafety.org/wp-content/uploads/2012/01/helledWalnuts.pdf>

ingredients derived from milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and/or soybeans. The specific type of Crustacean shellfish, fish, or tree nut (e.g. Walnut) must be declared in the statement. The 'Contains statement' must begin with the word 'Contains' with a capital 'C' followed by the names of the food sources for all major food allergens that either are in the food or are contained in ingredients of the food. For example: **Contains Walnuts**.

Figure 24. Examples of walnut products in the United States



11. Sacha inchi seed – potential for new producers to enter market

At the moment, the very few packaged products found in the Canadian or United States markets that contain sachu inchi seed are differentiated as:

- Slow dried (not roasted) whole seeds;
- Gently roasted (or toasted) whole seeds;
- Roasted and salted whole seeds;
- Toasted whole seeds mixed with other seeds such as toasted, ground sesame seeds (*Sesamum indicum*) and/or with pungent spices, e.g. charapita pepper (*Capsicum* spp.) or with pink salt;
- Caramel covered whole seeds (Note: Caramel is a complex mixture of compounds produced from food-grade nutritive sweeteners consisting of fructose, dextrose (glucose), invert sugar, sucrose, malt syrup, molasses, and starch hydrolysates and fractions thereof);
- Caramelized roasted whole seeds lightly glazed in cane sugar (*Saccharum* spp.); or
- Chocolate (*Theobroma cacao*; cocoa liquor, cocoa butter and cocoa powder) covered whole seeds – on their own or combined with golden berries (*Physalis peruviana*), or extract of vanilla fruit (*Vanilla planifolia*) or syrup of yacon root (*Smallanthus sonchifolius*) or sugar.

The first North American natural product marketers to invest in the promotion of these new sachu inchi healthy snack products have, thus far, positioned their products with the following types of claim statements:

- **Food allergen claims:**
 - Dairy free
 - Gluten free
 - Soy free
- **Nutrient content claims:**
 - Good source of plant-based omega 3 fatty acids
 - Fish alternative: more Omega-3 per ounce than wild Sockeye salmon
 - Good source of plant-based protein – complete protein
 - Good source of dietary fibre
 - Cholesterol free

- **Purity claims:**
 - Tastes better than fish oils with no polychlorinated biphenyls (PCBs) or mercury residue
- **Sustainability claims:**
 - Certified organic
 - Sustainably grown in partnership with Peruvian farmers
 - Harvested in eco-friendly farms in the Amazon rainforest
 - Natural rainforest product harvested organically
- **Vegetarian or vegan claims:**
 - 100% vegan
 - Completely acceptable for your vegetarian patients
 - Fish alternative
 - Vegetarian source of healthy omega-3 polyunsaturated fat, fibre and iron

One interview respondent stated that while the market demand for plant-based omega 3 products is certainly not slowing down, and while the potential for new sacha inchi product entries should be high due to its unique omega 3 composition, there remains some risk due to inconsistent or even poor agricultural practices (e.g. lack of specialized crop-specific training for farmers) and no implementation of standard post-harvest processing methods for drying, microbial reduction and roasting or toasting techniques. The current inconsistency means that products in the market may have considerable and discernible differences in composition (omega 3 profile) and sensory characteristics (appearance, colour, mouth feel, odour and taste) from different producer groups in the same region. There are many other healthy seeds and nuts for consumers to choose from so it is important to establish a taste profile for sacha inchi seeds that is consistent (can be replicated) from batch-to-batch through agricultural and processing controls.

The potential for new producers and marketers of sacha inchi seed products to enter (and remain) in the United States and Canadian natural product markets may depend on prioritized investment in training and capacity building, equipment and appropriate technologies at the farm village level.

While there is already a Peruvian national standard for good agricultural practices (GAPs) for cultivation of sacha inchi (Norma Técnica Peruana NTP 151.402: 2012),¹⁹³ which was developed through multi-stakeholder consultations involving most of the main companies in the Peruvian sacha inchi trade, assistance and technical support for the individual farmers to implement these GAPs is still much needed, especially in areas where additional expenditures might be required to attain best practices.

It was also stated that there is an increasing opportunity for plant-based omega 3 and protein food products that are produced hygienically from certified and traceable sources in the Americas, due to an increasing mistrust of food ingredients and food products being imported from distant Asian countries, in particular from China. This is also a point to consider because experimental farming of sacha inchi is already occurring in China.¹⁹⁴ It is conceivable that Chinese grown sacha inchi could eventually enter the global market and compete with authentic Peruvian grown material. If this should occur it will become exceedingly important to define and specify geo-authentic Peruvian grades and qualities of sacha inchi. Without a standard approach to cultivation techniques and post-harvest processing, there may be some risk that a special Peruvian quality grade would not be consistently available to the market.

Another respondent stated that there are some major companies looking at sacha inchi seed ingredients, including the seed and the seedcake powder. One reason for the interest is the growing demand for simpler, wholesome and natural foods, with as few ingredients as possible and as little processing as possible. In this area, sacha inchi seed products can be marketed by new producers and suppliers as a

193 INDECOPI (2012). Norma Técnica Peruana NTP 151.402:2012 - Buenas prácticas agrícolas para el cultivo de Sacha Inchi (*Plukenetia volubilis* Linneo), 1ª Edición. Lima, Perú: INDEPCOPI.

194 Cai, Z.Q. and others (2012). Leaf Photosynthesis, Growth, and Seed Chemicals of Sacha Inchi Plants Cultivated Along an Altitude Gradient. *Crop Science*; 52:1-9.

healthy natural food that is a good non-animal source of omega 3s and protein, is free of major allergens (e.g. dairy free, gluten free, soy free, tree nut free), GMO-free and organic, and suitable for kosher and halal consumers as well as vegetarians and vegans.

12. Sacha inchi seed – substitution and comparison of features

12.1. Availability comparison

Comparing the relative market availability of similar oilseed and nut ingredients that sachá inchi seed would compete against (or be substituted with) both flax seed and hemp seed are major crops in Canada while both flax seed and walnuts are major crops in the United States for domestic consumption and for export. Due to their relatively large scale cultivation in North America, sachá inchi seeds would not be able to compete with flax, hemp or walnut on the basis of price or availability. Therefore other differentiating characteristics need to be emphasized for substitution in new products. For example, tree nuts such as walnuts are classified as a major food allergen whilst sachá inchi seeds are not considered to be a major food allergen.

Pumpkin seeds are produced in many countries throughout the world including both China and the United States. Chia seeds are imported mainly from Latin American countries especially from neighbouring Mexico but also from Argentina and Peru, among others. The ready availability of these competing oilseeds or nuts, in particular flax, hemp and walnut, in the United States and Canada is strong and they are generally in stock year round at warehouses of most wholesale distribution companies that supply bulk dried seed and nut ingredients to product manufacturers.

The following is a summary of the commercial availability of flax seed, hemp seed and walnut in the United States and/or Canada.

Flax seed

Flax is one of the world's oldest cultivated crops dating back over 5,000 years. Canada, where flax cultivation was introduced about 400 years ago, has been the world's leader in production and export of flax since 1994, presently representing about 40% of world production. Flax is one of Canada's top five crops alongside wheat, barley, oats and canola. Most Canadian flax is cultivated in Saskatchewan Province with smaller amounts produced in the Provinces of Manitoba and Alberta. Canada's 2012 crop was estimated at 489,000 tons.

Following Canada, the combined production of China, India and United States accounts for about another 40% world flax production. In the past two years, however, Kazakhstan, the Russian Federation and Ukraine have become major producers and exporters of flax. The European Union (EU) was once Canada's largest export market but in the past two years exports to the EU have dropped off considerably due to the new competition from Kazakh, Russian and Ukrainian exporters. Canada's main customers are now the United States and China followed by the EU and Japan.¹⁹⁵

In the United States, most of the flax is produced in the States of North Dakota with minor amounts grown in Montana, South Dakota and Minnesota. The 2012 United States flax crop was estimated at 146,360 tons.¹⁹⁶

Hemp seed

Most Canadian hemp is grown in the Provinces of Manitoba, Saskatchewan and Alberta. Minor amounts are grown in the Provinces of British Columbia, Ontario and Quebec. Most of Canada's hemp crop is certified organic. According to the Canadian Hemp Trade Alliance (CHTA), the production area for hemp in Canada grew from 2,700 hectares in 2003 to an estimated 25,000 hectares in 2010. Canada produces all of its hemp seed requirements (does not import) and in 2007, according to Statistics Canada export 700

¹⁹⁵ Flax Council of Canada: <http://www.flaxcouncil.ca/english/index.jsp?p=market>

¹⁹⁶ United States Department of Agriculture (USDA) and National Agricultural Statistics Service (NASS) (2013). Crop Production 2012 Summary. Available from: <http://usda01.library.cornell.edu/usda/current/CropProdSu/CropProdSu-01-11-2013.txt>

tons of hemp seeds in 2007 with a customs value of Can\$ 2,656,276. In the same year Canada exported 77 tons of hemp seed oil with a customs value of Can\$ 695,870.

Walnut

The world's top walnut producers are China, the United States, the Islamic Republic of Iran, Turkey, Ukraine and Romania. China and the United States combined make up over 75% of world production. The majority of China's production, however, is consumed domestically and not exported. Nearly 100% of the United States production occurs in the State of California, where there are over 4,600 walnut growers, a large majority being family farms. In fact, California is the largest producer of all tree nuts in the United States, being the predominant supplier of almonds, walnuts and pistachios. In 2011, the United States produced 461,000 tons of walnuts, down from 2010. The United States value of walnut production that year totalled US\$ 1.3 billion. 2012 walnut production was forecast at 470,000 tons, up 2% from previous year.

12.2. Composition (nutrient, phytochemical) and quality characteristics comparison

Table 16 compares the chemical composition of selected seeds (e.g. Chia Seed, Flaxseed, and Pumpkin Seed) that would compete with Sacha Inchi Seed in the North American markets either as a food ingredient, dietary supplement ingredient or medicinal ingredient. The nutrients and phytochemicals shown in the table include amino acids, fatty acids, minerals, sterols, and vitamins.

Table 15 Composition (nutrient, phytochemical) comparison – seeds that compete with sachachi

	CS	FS	PS	SIS
Amino Acids (% of protein)	about 21% of seed is protein	about 20% of seed is protein	about 31-51% of seed is protein	about 27% of seed is protein
Alanine	4.686	4.4	2.34	3.6
Arginine	9.52	9.2	9.32	5.5
Aspartic Acid	8.156	9.3	5.28	11.1
Cystine	1.443	1.1	0.673	2.5
Glutamic Acid	13.806	19.6	10.4	13.3
Glycine	4.493	5.8	2.83	11.8
Histidine	2.736	2.2	1.38	2.6
Isoleucine	3.513	4.0	2.30	5.0
Leucine	6.393	5.8	4.09	6.4
Lysine	4.513	4.0	2.20	4.3
Methionine	0.39	1.5	1.24	1.2
Phenylalanine	5.12	4.6	3.14	2.4
Proline	4.59	3.5	2.02	4.8
Serine	5.103	4.5	3.17	6.4
Threonine	3.636	3.6	1.84	4.3
Tryptophan	0.00	1.8	1.53	2.9
Tyrosine	2.97	2.3	2.21	5.5
Valine	5.58	4.6	2.82	4.0
Total Amino Acids	86.648	91.8	58.783	97.6
Fatty Acids (% of total fatty acid fraction)	about 30% of seed is fatty oil	about 42% of seed is fatty oil	about 50% of seed is fatty oil	about 54% of seed is fatty oil
Saturated				
Myristic (C14:0)	0.10		0.18	
Saturated fatty acids <C16:0		NMT 1.0		
Palmitic (C16:0)	6.7	3.0-8.0	16.41	3.8-4.1
Heptadecanoic (C17:0)	0.2			0.1
Stearic (C18:0)	3.0	2.0-8.0	11.14	2.7-3.3
Arachidic (C20:0)	0.3	NMT 1.0		0.1
Behenic (C22:0)	0.1			
Lignoceric (C24:0)	0.2			
Monounsaturated				
Palmitoleic (C16:1 <i>n</i> -7)	0.1	NMT 1.0	0.16	<0.1
<i>cis</i> -10 Heptadecanoic (C17:1)	0.1			<0.1
Oleic (C18:1 <i>n</i> -9)	6.9	11.0-35.0	18.14	NLT 8.9
Gadoleic (C20:1 <i>n</i> -11)				0.2-0.3
Gondoic (C20:1 <i>n</i> -9)	0.1			
Erucic (C22:1 <i>n</i> -9)			0.76	

	CS	FS	PS	SIS
Fatty Acids (% of total fatty acid fraction)	about 30% of seed is fatty oil	about 42% of seed is fatty oil	about 50% of seed is fatty oil	about 54% of seed is fatty oil
Polyunsaturated				
Linoleic (LA) (C18:2 <i>n</i> -6)	18.8	11.0-24.0	52.69	NLT 32.1
Linolenic (C18:3)		35.0-65.0	1.27	NLT 44.7
α -Linolenic (ALA) (C18:3 <i>n</i> -3)	58.7			
γ -Linolenic (GLA) (C18:3 <i>n</i> -6)	0.1			
Eicosadienoic (C20:2 <i>n</i> -6)	0.1			
Eicosatrienoic (C20:3 <i>n</i> -3)	0.1			
Docosatetraenoic (C22:4)	0.1			
Minerals (mg/kg = μg/g)				
Aluminium			9.21	
Arsenic			0.45	
Barium			1.16	
Calcium	6798.0	2360.0	346.0	2406.0
Chromium	5.0		3.0	
Cobalt	2.5		0.29	
Copper	17.0	10.0	15.4	12.9
Iron	99.0	50.0	106.0	103.5
Magnesium	3800.0	4310.0	5690.0	3210.0
Manganese		30.0	49.3	
Molybdene	2.5		0.805	
Nickel	2.5		0.53	
Phosphorus	7800.0	6220.0	15700.0	
Potassium	8091.5	8310.0	5790.0	5563.5
Selenium	0.06		0.08-0.4	
Sodium	121.5	270.0	6.9	15.4
Strontium			1.83	
Sulphur	2900.0			
Zinc	44.0	40.0	113.0	49.0
Vitamins (mg/100g)				
Vitamin A (IU)	44 IU		16 IU	
Vitamin B1 (thiamine)	0.7	0.53	0.273	
Vitamin B2 (riboflavin)	0.2	0.23	0.153	
Vitamin B3 (nicotinic acid)	7.2	3.21	4.987	
Vitamin B5 (pantothenic acid)		0.57	0.750	
Vitamin B6 (pyridoxine)	0.1	0.61	0.143	
Vitamin C (ascorbic acid)	5.4	0.50	1.9	
Vitamin K (phylloquinone)			7.3	
Folic acid (μ g/100g)		112	0	
Biotin (μ g/100g)		6		

	CS	FS	PS	SIS
Tocopherols and tocotrienols (mg/kg of fatty oil fraction)	about 30% of seed is fatty oil	about 42% of seed is fatty oil	about 50% of seed is fatty oil	about 54% of seed is fatty oil
Total tocopherols				2390
gamma + delta tocopherols				min 1900
beta + gamma tocopherols			338-540	
alpha-Tocopherol		7	78-126	0
beta-Tocopherol				0
delta-Tocopherol		10		1250
gamma-Tocopherol		552		1140

Legend and sources of data shown in tables

CS	Chia Seed	EFSA (2009) ¹⁹⁷ (Note: values are average of multiple data points)
FS	Flax Seed	(1) Morris DH (2007) ¹⁹⁸ (amino acids, tocopherols in oil fraction) (2) European Pharmacopoeia, 7th Edition (fatty acids in oil fraction)
PS	Pumpkin Seed	(1) EMA (2011) ¹⁹⁹ (amino acids, fatty acids, minerals, tocopherols) (2) USDA National Nutrient Database (vitamins)
SIS	Sacha Inchi Seed	(1) Gutiérrez LF et al. (2011) ²⁰⁰ (minerals) (2) Hamaker BR et al. (1992) ²⁰¹ (amino acids) (3) Norma Técnica Peruana (NTP 151.400 2009) (fatty acids, tocopherols) (4) Follegatti-Romero et al. (2009) ²⁰² (tocopherols in oil fraction)

Table 16. Quality specifications comparison of seeds that compete with sachu inchi seed

	CS	FS	HS	PS	SIS
Foreign matter	No standard	NMT 10% of seeds with a dull coat and NMT 1.5% of other foreign matter	Does not contain bract	NMT 1%	No standard
Swelling Index	No standard	NLT 4	No standard	No standard	No standard
Loss on drying	4-9% (91-96% dry matter)	NMT 8.0%	NMT 9.0%	NMT 12.0%	6.37% (fresh); 0.0% (dry)
Total ash	4-6%	NMT 5.0%	NMT 7.0%	NMT 7%	2.69% (fresh); 2.87% (dry)
Acid-insoluble ash	No standard	No standard	NMT 2.0%	No standard	No standard
Crude fibre	18-30%	28%	No standard	No standard	11.30% (fresh); 12.07% (dry)
Fat / Fatty oil	30-35%	41%	No standard	30-53%	51.40% (fresh); 54.90% (dry)

197 European Food Safety Authority (EFSA) (2009). Scientific Opinion: 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.

198 Morris, DH. (2007). *Flax - A Health and Nutrition Primer*, 4th Edition. Flax Council of Canada. 2007.

199 European Medicines Agency (EMA) and Committee on Herbal Medicinal Products (HMPC). (2011). Draft - Assessment report on *Cucurbita pepo* L., semen. London, UK: EMA.

200 Gutiérrez, L.F., L.M. Rosada and A. Jiménez (2011). Chemical composition of Sacha Inchi (*Plukenetia volubilis* L.) seeds and characteristics of their lipid fraction. *Grasas y Aceites*; 62(1):76-83.

201 Hamaker, B.R. and others. (1992). Amino acid and fatty acid profiles of the Inca Peanut (*Plukenetia volubilis*). *Cereal Chem*; 69(4):461-463.

202 Follegatti-Romero, C.R. Piantino and others (2009). Supercritical CO₂ extraction of omega-3 rich oil from Sacha inchi (*Plukenetia volubilis* L.) seeds. *J. of Supercritical Fluids*;49:323-329.

	CS	FS	HS	PS	SIS
Protein	20-22%	20%	No standard	31-51%	24.21% (fresh); 25.86% (dry)
Carbohydrates	25-41%	29%	No standard	No standard	4.03% (fresh); 4.3% (dry)
Cadmium		NMT 0.5 ppm		NMT 0.3 ppm	
Lead		NMT 5.0 ppm		NMT 10 ppm	
Mercury		NMT 0.1 ppm			

Legend and sources of data shown in table

CS	Chia Seed	European Commission (2009) ²⁰³
FS	Flax Seed	(1) European Pharmacopoeia (2012) ²⁰⁴ (2) Morris DH (2007) ²⁰⁵
HS	Hemp Seed	Japanese Pharmacopoeia (JP XVI 2011) ²⁰⁶
PS	Pumpkin Seed	(1) World Health Organization (2009) ²⁰⁷ (2) European Medicines Agency (2011) ²⁰⁸
SIS	Sacha Inchi Seed	Pascual B and Mejía M (2000) ²⁰⁹

12.3. Ease of application comparison

Sacha inchi seeds and the other oilseeds discussed in this chapter (chia, flax, hemp and pumpkin) have considerably different organoleptic (appearance, colour, odour and taste) and physical characteristics (size and shape). However the main commercial product form for all of these is packaged whole seeds for eating as a snack food or for adding to other foods such as cereals, baked goods, trail mixes, yoghurts and smoothies. Even though these seeds are of different sizes and shapes, the equipment needed for filling whole seeds, for example into 16 oz. bags, is generally the same and adjustable as is the equipment for mixing and packaging of nut mixes or trail mixes that contain a range of different whole dried fruits, seed and nuts. Therefore no specialized packaging equipment should be necessary to accommodate the addition of sachu inchi seed packing for companies already packing other seeds and nuts into bags or cartons.

In the case of companies making coated snack products, e.g. caramel covered or chocolate covered seeds, fruits and nuts, sachu inchi seeds should not require new or specialized equipment or processes. These companies are already working with a range of shapes, sizes and textures of the various seeds, nuts and fruits that are coated or admixed into a complex mixture in bars.

12.4. Price comparison

Table 18 provides a typical average bulk ingredient pricing structure comparison at three tiers (distributor price, wholesale price and retail price) for chia, flax, hemp, pumpkin, sachu inchi and walnut in the United States natural foods channel. The prices shown are generic or typical catalogue prices for certified organic

203 European Commission (EC). (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. Official Journal of the European Union.

204 European Directorate for the Quality of Medicines (EDQM). (2012). European Pharmacopoeia, 7th Edition (PhEur. 7.1). Strasbourg, France: EDQM; 3364-3365.

205 Morris, D.H. (2007). Flax - A Health and Nutrition Primer, 4th Edition. Flax Council of Canada.

206 Japanese Pharmacopoeia Committee (2011). Cannabis Fructus. In: The Japanese Pharmacopoeia, Sixteenth Edition (JP XVI). Tokyo, Japan: Japanese Ministry of Health, Labour and Welfare; page 1661.

207 World Health Organization (WHO) (2009). WHO Monographs on Selected Medicinal Plants, Volume 4. Geneva, Switzerland: WHO; 83-91.

208 European Medicines Agency (EMA) and Committee on Herbal Medicinal Products (HMPC). (2011). Draft - Assessment report on Cucurbita pepo L., semen. London, UK: EMA.

209 Pascual, B. and M. Mejía (2000). Extracción y caracterización de aceite de Sachu Inchi (*Plukenetia volubilis* L.). Anales Científicos UNALM; Vol. XLII:143-158.

bulk ingredients which were current as the time of this study (April 2013). They do not take into account any special pricing for high volume or large customer contract pricing whereby the seller may take a lower margin in consideration of overall business.

Table 17. Price comparisons (US\$/lb): organic chia, flax, hemp, pumpkin, sachu inchi, walnut

Description	Pack sizes (lb)	Distributor price (US\$/lb)	Wholesale price (US\$/lb)	Retail price (US\$/lb)
Chia seed, black Origin: non known	25	6.37	8.47	12.69
Flax seed Origin: Canada or the United States	25	1.05	1.39	2.09
Flax seed, golden Origin: Canada or the United States	25	0.92	1.22	1.85
Hemp seed, raw, shelled Origin: Canada	5	6.52-8.73	8.67-11.62	12.99-17.45
Pumpkin seed Origin: China	27.5	2.32	3.09	4.65
Pumpkin seed Origin: the United States	27.5	2.76	3.67	6.05
Sachu inchi seed, roasted Origin: Peru	10		9.40 ²¹⁰	
Sachu inchi seed, roasted Origin: Peru	20		14.99 ²¹¹	19.99
Sachu inchi seed, raw powder Origin: Peru	10		12.97 ²¹²	14.97
Walnut, shelled halve and pieces Origin: not known	25	6.83	9.09	13.65

Sources: Most of the price information in table 18 was provided confidentially by an information provider at a major independent national distributor of natural, organic and specialty foods and related products. Pricing for sachu inchi seed was not available from the same source. Thus they are not calculated on the same basis or margins.

Note: 1.0 lb = 0.453597 kg.

210 Great Lakes International Trading Inc. (2013). Wholesale / Distributor Price List: <http://www.glit.com/wholesale.pdf>

211 Nuts.com: <http://www.nuts.com/nuts/peanuts/sachu-inchi.html>

212 Sunburst Superfoods: <http://www.sunburstsuperfoods.com/organic-sachu-inchi-powder/>

12.5. Recommended uses comparison

Table 18. Recommended uses comparison for sachu inchi seed competitive products

Substance	Canada	United States
Chia Seed	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Source of alpha-linolenic acid (ALA) for the maintenance of good health • Source of linoleic acid (LA) for the maintenance of good health • Source of omega-3 fatty acids for the maintenance of good health • Source of essential fatty acids for the maintenance of good health • Natural source of fibre and omega-3 fatty acids • Source of antioxidant 	<p>Oral: DSP component with Nutrient Content Claim statements:</p> <ul style="list-style-type: none"> • Provides [x] mg omega-3 fatty acids per serving • Supports healthy digestion with [x] grams of fibre per serving • Gluten-free source of fibre providing [x] grams per serving <p>Oral: Conventional food ingredient</p>
Flaxseed	<p>Oral: NHPD medicinal ingredient:</p> <ul style="list-style-type: none"> • Source of essential fatty acids for the maintenance of good health • Source of omega-3 fatty acids for the maintenance of good health • Source of alpha-linolenic acid (ALA) for the maintenance of good health • Source of omega-6 fatty acids for the maintenance of good health • Source of linoleic acid (LA) for the maintenance of good health • Used in Herbal Medicine as a bulk-forming laxative • Used in Herbal Medicine to promote bowel movement by increasing bulk volume and water content • Used in Herbal Medicine to provide gentle relief of constipation and/or irregularity • Used in Herbal Medicine to help reduce blood lipid levels in adults • Provides antioxidants for the maintenance of good health <p>Oral: Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> • Stabilizing agent and Thickening agent (Flaxseed mucilage) <p>Oral or Topical: Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> • Flavour enhancer (Dry Flaxseed) 	<p>Oral: DSP component with Nutrient Content Claim statements:</p> <ul style="list-style-type: none"> • Provides [x] mg essential fatty acids per serving • Provides [x] mg omega-3 fatty acids per serving <p>Oral: Conventional food ingredient</p>
Pumpkin Seed	<p>Oral: NHP medicinal ingredient:</p> <ul style="list-style-type: none"> • Traditionally used in Herbal Medicine for the relief of lower urinary tract symptoms related to benign prostatic hyperplasia or related to an overactive bladder, after serious conditions have been excluded by a medical doctor <p>Oral: Non-medicinal NHP ingredient:</p> <ul style="list-style-type: none"> • Flavour enhancer (Dried or powdered Pumpkin Seed) 	<p>Oral: DSP component with structure / function claim statements:</p> <ul style="list-style-type: none"> • For prostate and urinary tract health • Helps to maintain healthy bladder function <p>Oral: Conventional food ingredient</p>

Substance	Canada	United States
Sacha Inchi Seed	Oral: NHP medicinal ingredient. <ul style="list-style-type: none"> • Source of essential amino acids for the maintenance of good health • Source of essential fatty acids for the maintenance of good health 	Oral: DSP component with Nutrient Content Claim statements: <ul style="list-style-type: none"> • Provides [x] mg of essential amino acids per serving • Provides [x] mg of essential fatty acids per serving

Sources: Health Canada Natural Health Products Directorate (NHPD) Natural Health Products Ingredients Database (NHPID), Health Canada Food and Drug Regulations, U.S. Food and Drug Administration (FDA) Dietary Supplement notification letters, and various FDA and USDA regulations.

12.6. Regulatory status comparison

Table 19. Regulatory status comparison for sachu inchi seed competitive products

Substance	Canada	United States
Chia Seed	Oral: NHP medicinal ingredient but also found as a conventional food ingredient	Oral: DSP component but also found as a conventional food ingredient
Flaxseed	Oral: NHP medicinal ingredient but also permitted as a conventional food ingredient	Oral: DSP component and also permitted as a conventional food ingredient
Pumpkin Seed	Oral: NHP medicinal ingredient but also permitted as a conventional food ingredient	Oral: DSP component and also permitted as a conventional food ingredient
Sacha Inchi Seed	Oral: NHP medicinal ingredient	Oral: While food products and DSPs already exist in the United States market, their legal status is uncertain, whether affirmed as GRAS for use in food products or whether considered as an Old Dietary Ingredient (ODI) for use in DSPs

Sources: Health Canada Natural Health Products Directorate (NHPD) Natural Health Products Ingredients Database (NHPID), Health Canada Food and Drug Regulations, U.S. Food and Drug Administration (FDA) Dietary Supplement notification letters, and various FDA and USDA regulations.

Chapter 8 Commercialization channels

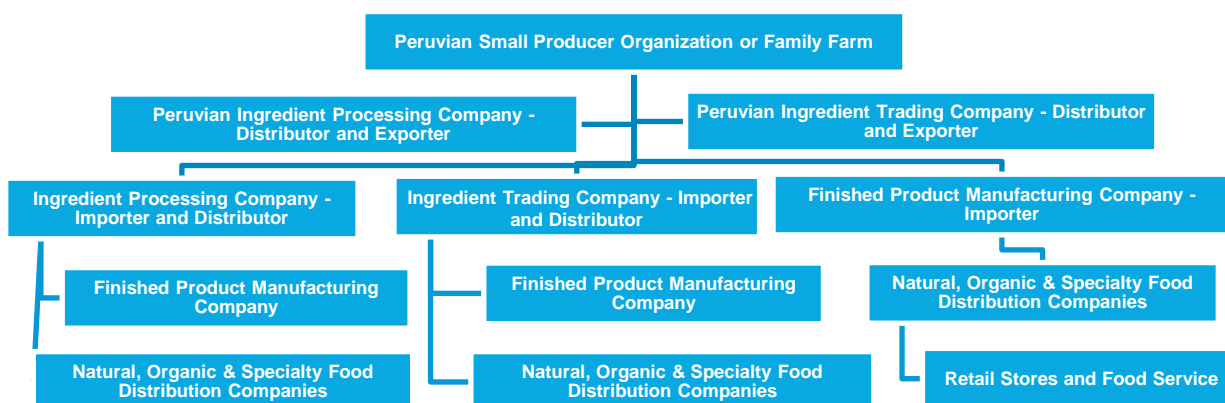
1. Trade channels

Based on the interviews conducted for this study with Peruvian producers and exporters and with North American importers, the Peruvian natural ingredients that are the subject of this report (dried golden berries, Peruvian mesquite powder, sacha inchi seeds, seedcake powder and fatty oil) are being imported at this time mainly by:

- Trading companies who may re-pack (into various size and pack options) and resell the bulk ingredients without additional processing or value-adding. Some may even resell the bulk ingredients in their original bags, boxes or drums without repacking or relabelling. Trading companies resell the ingredients to finished product manufacturing companies (both contract packagers and brand owners with their own manufacturing capacity) as well as to wholesale distribution companies who then sell on to retail grocery stores, cooperatives, produce markets that have bulk bins (for example for consumers to buy dried fruits, flours, seed, nuts, oils by weight) and food service accounts (e.g. bars, cafeterias, caterers, coffee shops, hotels, restaurants).
- Ingredient distribution companies with processing and other value-adding capabilities (e.g. analytical testing and documentation, custom blending, custom formulation, drying, encapsulation, extraction, fermentation, granulation, microbial reduction, milling and micronization, particle sizing and density adjustment, private label, etc.). Bulk ingredient distributors basically compete for the same customers in the same channels that are listed above for trading companies.
- Finished product manufacturing and marketing companies with high enough demand to justify importing directly from exporters. Some finished product marketing companies have developed relationships directly with producer organizations or with Peruvian export trading companies for certain higher demand ingredients. The finished product marketing company may have their own processing and packaging equipment or they may have their products made by a designated contract packaging company.

Figure 25 illustrates a typical trade channel for any of the Peruvian natural ingredients that are the subject of this study. The first importer may be a processing company and distributor, a trading company and distributor, or a finished product manufacturing company (whether the brand holder with own packaging capabilities or a designated contract manufacturer).

Figure 25. Typical trade channel for Peruvian natural ingredients



While the trade of bulk oils, bulk dried fruits and bulk dried powders may occur separately through certain specialized distributors (e.g. specialty oils suppliers or bulk dried fruit wholesalers or bakery flour distributors), there is a new breed of natural ingredient importer / trader / distributor that aims to be a one-stop shop for a wider range of sustainable superfood ingredients linked together by principles of ethical trade and natural health.

These companies are not just selling ingredients they are selling a new way of doing business, i.e. ethical trading. Here are some examples of the ways that selected bulk natural ingredient distribution companies in America are describing themselves in their marketing materials and websites:

- **Ciranda Organic Ingredients** positions itself as a supplier of certified organic and fair trade certified ingredients to the organic food and personal care industries; 'As an importer and distributor of certified organic foods, Ciranda is naturally dedicated to ecological and environmental safety and sustainable food production': <http://www.ciranda.com/content/ciranda-organic-ingredients>
- **Essential Living Foods (ELF)** states that its mission is to improve the health of the planet, its people, and their communities by working in close collaboration with small farms and indigenous groups to supply customers with the purest, most nutritious superfoods. ELF donates 1% of profits back to their supplier communities and states that they are dedicated to fair, ethical, and holistic business practices: <http://essentiallivingfoods.com/>
- **Marroquin Organic International** states that they provide customers in the food, beverage, nutraceutical, pet, and cosmetic industries with a reliable supply-chain for the quality organic and non-GMO ingredients they need to innovate and grow: <http://www.marroquin-organics.com/>
- **Mother Jungle Herbs Inc.** positions itself as the leading supplier of South American raw organic superfoods and botanical extracts: <http://www.motherjungleherbs.com/>
- **Mountain Rose Herbs** states that it has become known for its uncompromising commitment to organic agriculture and has always put an emphasis on conducting business in an ethical, responsible, clear, and ecological way: <http://www.mountainroseherbs.com/>
- **PIA Ingredients** states that they reach out to farmers and growers by building long term relationships through fair trade practices, which in turns helps them to assemble a consistent supply of ingredients: <http://www.piaingredients.com/>
- **Pure Ground Ingredients** states that its goal is to provide a diverse range of organic and fair trade ingredients: <http://www.puregroundingredients.com/>
- **RFI Ingredients** states that by capitalizing on natural, organic and science-driven ingredients, existing expertise and global network of manufacturing facilities, they do more than just sell ingredients...they offer turnkey products using their Field to Formula® vertically-integrated model: <http://www.rfiingredients.com/>

2. Recommended trade channels and distribution strategy

Unless the Peruvian producer or exporting company is well-funded enough to operate their own sales and marketing divisions in the United States and Canada as well as storage and distribution warehousing in order to offer just-in-time shipping, the recommended strategy is to align your company with a like-minded importer / trader or importer / processing and distribution company, one that has an already established network of customers for unique natural ingredients and one that has the capacity to hold inventory and offer good payment terms to their customers.

One interview respondent for this study emphasized that a big problem, even for the interested importing trading companies is late shipments from Peru. Finished product manufacturing companies rate their suppliers on service and quality, especially on-time shipping of the right quantities of the specified qualities. If a supplier ships late and/or short on too many occasions, they may become disqualified as a supplier.

It is also very important to have knowledgeable technical sales representatives who are readily available to provide customer service and technical support to customers when needed. This includes troubleshooting with your customer's product development, manufacturing and quality control professionals when there are technical issues to solve during production. Providing this level of service is very difficult and almost impossible to do well from another country. Foreign companies that have succeeded in bulk ingredient distribution in the United States have generally hired experienced technical sales professionals and have also invested in holding inventories in American warehouses. Some have either established American sales divisions or have invested in or acquired existing United States ingredient processing and/or distribution companies.

Given the fact that Peru is a non-GMO country and that the prioritized biodiversity products are generally being marketed in North America as organic, non-GMO, allergen-free, raw and vegan superfoods, the American distributors who are specialising in ingredients that link these attributes of sustainability, health, safety and ethics are the ones to target for business development and distribution strategy. They are already interested in these ingredients and may already have the capacity to market and sell your ingredients through to the right audience.

At the same time, especially for biodiversity ingredients that are linked to a particular origin like the Peruvian Amazon or Peruvian Andes, the finished product marketing companies want supply chain transparency and access to the producer groups in order to develop their own relationships with the producer communities – even in the context of buying the ingredients from an American importer / trading company. The finished product marketing companies want to market the stories about the people and the places behind the ingredients. More and more this is requiring the development of trust-based trade relationships throughout the supply chain, which is not easy.

One of the American companies interviewed for this study indicated that it has been difficult so far to be allowed direct access to the actual producer community in Peru. There may be concerns that American buyers might try to go around the established trade relationships in order to buy direct from source. However, most United States brands using these ingredients are still small- to medium- sized companies that do not have the staff, experience or resources necessary to import all of their ingredients directly from countries of origin. These companies do need to rely on American traders or ingredient processing companies from whom they can buy smaller quantities as needed and also enjoy more favourable terms of payment by comparison to being the importer.

Chapter 9 Price

1. Price developments and factors influencing price

As one example, in the case of golden berries, Peruvian producers and exporters interviewed for this study commented that it is difficult to compete with Ecuadorian golden berry exporters on price because Ecuador uses the United States dollar as its currency. On the other hand it is also difficult to compete with Colombia on price because of their significantly larger scale of golden berry production with economies of scale. While there is genuine interest from potential new product development professionals in the United States for Peruvian ecotype golden berries, the Peruvian price is still significantly higher than typical market prices from neighbouring Ecuador and Colombia. Product developers thinking of using dried berries in products like breakfast cereals and power bars may have cost ceilings for certain ingredients like dried fruits depending on the percentage used in the total formulation and the target margin for the proposed new product.

One Peruvian producer and exporter of golden berries stated that United States buyers of comparable dried fruits for use in cereal products such as muesli or power bars do not want to pay more than about US\$ 5.00 kg (=US\$ 2.27 lb). Comparable dried berries like cranberries and raisins are generally available to buyers within that price limitation. Current export pricing from Peru however ranges between US\$ 10.00 to US\$ 15.00 kg (US\$ 4.54 US\$ 6.80 lb) with an average customs value of about US\$ 12.00 kg (US\$ 5.44 lb). It was suggested by Peruvian exporters that export prices of Ecuadorian and Colombian golden berries are presently significantly lower although no prices from these neighbouring countries were made available.

It can also be seen in the comparative price tables provided in this study that the selected competitive natural ingredients, in most cases, are significantly lower cost than the Peruvian ingredients that could be substituted in new product developments. The reasons for the price disparity can be fairly straight forward. For example, in the case of Peruvian golden berries, if they are to compete as components of breakfast cereals, nutrition bars or fruit and nut mix products, against California raisins and/or Wisconsin cranberries, they will not be able to compete on a basis of price or availability. The United States is a major producer of raisins and cranberries at a scale that Peruvian golden berries are not likely to reach any time soon. Golden berries would have a better chance of competing on price and availability against other imported berries like goji berries which are imported entirely from China. So there must be another case made for new entries or substitutions of dried golden berries that justifies a premium price by comparison to competing commodities like raisins and cranberries but also a convincing argument supporting a premium price over golden berries that originate from Ecuador or Colombia. If, in the future, Peru should invest in a significant scaling up of golden berry cultivation and production technology, it could be possible to gain economies of scale necessary to compete with Colombia which presently owns 90% of the global market. It is uncertain if the companies themselves can fund this level of growth. Governmental prioritization for investment and development support to entrepreneurs who have the know-how and interest to scale up golden berry cultivation areas and processing plants could be considered.

The North American market is demanding more and more assurances of food safety, quality control, country of origin traceability and transparency, organic and non-GMO verification, allergen-free verification, kosher, and ethical or fair trade verification. All of these attributes, if assured through independent third-party inspections and certifications, indeed drive up the costs of the ingredients and correspondingly the final products. At the moment, there is evidence that the market for healthy products with multiple certifications is growing in the United States and Canada – so long as the certifications satisfy the main drivers of authenticity, transparency, safety, purity, quality, absence of contamination, simple, wholesome, super nutritious, and ethical, etc.

Based on the interviews conducted with American companies, the most important certifiable standards for companies to implement, which will most certainly add cost to the products, are: Organic Certified, Non-GMO Verified, Gluten-Free Certified and Kosher Certified. While some companies were ambivalent about kosher certification, they recognize that it is an important market access requirement in the United States and Canada. Some respondents added that Vegan Verified as well as Raw Verified are also important for their customers.

Additionally, the successful marketing of these Peruvian natural ingredients still requires considerable customer education, technical support and routine analytical testing, all of which add costs to the ingredients.

It is difficult so far to provide useful information on price developments for Peruvian mesquite flour and/or sacha inchi seeds and oil. These Peruvian ingredients are so relatively new to the North American market that most wholesale distribution companies do not yet list these in their catalogues nor stock them as regular items in inventory. Just a few specialty distributors are carrying these goods and selling them mainly to micro- to small- sized natural product companies for use in new product launches. Most of the retail packaged finished products that contain these ingredients have only been in the market a short time. The long-term success or failure of these new retail products will play a role in determining future demand. In the case of roasted sacha inchi seeds, two ingredient distribution companies were identified offering bulk prices that ranged considerably, from US\$ 9.40 lb for a 500 lb minimum order in 10 lb box size from Great Lakes International Trading Inc. up to US\$ 14.99 lb for a 20 lb case size from Nuts.com. Until there is steady demand for roasted sacha inchi seeds from finished product companies and correspondingly more distributors begin to keep it in stock, considerable price differences and fluctuations between competing distributors can be expected.

One American company stated that in order for these ingredients to ultimately succeed in the United States and Canadian markets much more research needs to be carried out by research institutes, universities and companies. It is not only a matter of selling ingredients that can be substituted with other ingredients on the basis of price, availability, functionality or sensory characteristics (appearance, colour, odour, texture, taste). It is also a matter of sales representatives having the tools they need to succeed, for example concise scientific documentation and reports to provide to their prospective customers that support the uses and claims for the specified ingredient. Technical sales representatives need to provide detailed analytical data on the nutritional and phytochemical composition of the ingredient, testing results showing consistent compliance with an established quality specification, evidence that the ingredient is indeed safe for the intended uses in humans at the recommended serving sizes (in food products) or dosages (in medicinal products), and clear evidence that the ingredient in its various forms have governmental approval or authorization for use. Investing in the compilation of sales support data is a factor that impacts the cost of the ingredient.

2. Costing (price strategy)

The cost and price structure and strategy will vary depending on the market channel.

Using golden berries as an example, one of the major natural and organic food wholesale distribution companies sells dried organic golden berries to retail stores in 11 lb bags or boxes (= 5 kg). The retail stores may fill the berries into bulk bins or they may re-pack the berries into 1 lb bags. Some golden berry exporters are offering the dried berries in 4.5 kg or 5 kg vacuum sealed bags as well as 20 kg bags packed in cardboard boxes.

It is possible that the American distribution company is buying direct from a South American exporter (in either 5 kg or 20 kg units), but it is more likely that they are buying just-in-time from a trading company holding inventory in the States who is the first importer. Here is a possible pricing structure in this scenario:

- **Distributor price** is about US\$ 7.03 lb (=US\$ 3.19 kg);
- **Wholesale price** is about US\$ 9.35 lb (=US\$ 4.24 kg); this distributor's wholesale prices are generally calculated at a 25% margin or 33% mark up;
- **Suggested retail price** is about US\$ 14.05 lb (=US\$ 6.37 kg); in this scenario the retailers margin is about 33.5% or 50% mark up.

Another example is the type of organic natural ingredient distributor that sells bulk botanical ingredients to small-to-medium sized natural product manufacturers as well as to buying clubs, cooperatives and grocery stores with bulk bins, retail herb shops, natural medicine clinic dispensaries, and even directly to

consumers through internet sales. Using Mountain Rose Herbs® (Eugene, Oregon)²¹³ as an example, here is their price structure for Peruvian mesquite powder:

- 4 oz price (= 0.1134 kg) = US\$ 3.50 unit US\$ 14.00 lb
- 8 oz price (= 0.2268 kg) = US\$ 6.25 unit US\$ 12.50 lb
- 1 lb price (= 0.4536 kg) US\$ 11.00 lb
- 5-9 lb price (= 2.268-4.082 kg) US\$ 9.90 lb – 10% discount off 1 lb price
- 10-24 lb. price (= 4.54-10.89 kg) US\$ 9.35 lb – 15% discount off 1 lb price
- 25+ lb price (= 11.34+ kg) US\$ 8.25 lb – 25% discount off 1 lb price

Another Oregon wholesale distribution company (Azure Standard)²¹⁴ offers Peruvian mesquite powder at two price brackets:

- 1 lb price (= 0.4536 kg) US\$ 12.60 lb
- 24 lb price (= 10.89 kg) = US\$ 275.10 unit US\$ 11.46 lb – 9% discount off 1 lb price

The price structure for organic Peruvian mesquite powder at Sunburst Superfoods²¹⁵ is:

- 1 lb price (= 0.4536 kg) US\$ 12.97 lb
- 5 lb price (= 2.268 kg) = US\$ 59.85 unit US\$ 11.97 lb – 7.7% discount off 1 lb price
- 10 lb price (= 4.54 kg) = US\$ 109.70 unit US\$ 10.97 lb – 15.4% discount off 1 lb price

213 Mountain Rose Herbs®: <http://www.mountainroseherbs.com/wholesale.html>

214 Azure Standard: <http://www.azurestandard.com/shop/product/6581/>

215 Sunburst Superfoods: <http://www.sunburstsUPERFOODS.com/organic-mesquite-powder/>

Chapter 10 Promotion

1. Price developments recommendations for product promotion

Natural ingredients promotion

The relevant trade shows for producers, processors and suppliers of natural ingredients to attend and/or exhibit at are the following:

- **Engredea:** <http://www.engredea.com/>
Engredea (occurs annually in Anaheim, California) brings together the community of leading suppliers and manufacturers to source new ingredients, packaging, technologies, equipment, and services in the global nutrition industry. Engredea is co-located with Natural Products Expo West, the largest exhibition in the United States for finished natural products.
- **SupplySide MarketPlace:** <http://marketplace.supplysideshow.com/>
The SupplySide® Marketplace (occurs annually in New York City, New York) in 2013 featured 350+ global exhibitors offering more than 5,000 ingredients. Target audience are professionals in the following industries: Dietary Supplement, Food and Beverage, Cosmetic, Personal Care, Animal Nutrition, Pharmaceutical and Sports Nutrition.
- **SupplySide West:** <http://west.supplysideshow.com/>
SupplySide® West (occurs annually in Las Vegas, Nevada) brings together the suppliers and buyers that drive the dietary supplement, food, beverage, personal care and cosmetic marketplace. Leaders from the executive management, R&D, QA/QC and marketing teams participate in this show each year.

Finished products promotion

The relevant trade shows for manufacturers and marketers of finished natural products to attend and/or exhibit at are the following:

- **Canada Health Food Association Expo East:** <https://www.chfa.ca/events/chfa-east-2012/>
CHFA East (occurs annually in Toronto, Ontario) is Canada's largest conference and trade show for the natural health and organics industry. With over 650 exhibitors, it's the place to meet the industry's top manufacturers, distributors and brokers, face-to-face. For retailers, this event is the East Coast's biggest showcase of innovative new products and educational seminars.
- **Canada Health Food Association Expo West:** <https://www.chfa.ca/events/expo-west-2012/>
CHFA West (occurs annually in Vancouver, British Columbia) is one of the largest conference and trade show for the natural health and organics industry in Canada. With over 500 exhibitors, it's the place to meet the industry's top manufacturers, distributors and brokers, face-to-face. For retailers, this event is the West Coast's biggest showcase of innovative new products and educational sessions.
- **Natural Products Expo East:** <http://www.expoeast.com/>
Natural Products Expo West (occurs annually in Baltimore, Maryland) is the East Coast's premier tradeshow and conference for the natural, organic and healthy living industry. In 2012, the show brought together over 21,000 attendees and 1,550 exhibits from more than 96 countries.
- **Natural Products Expo West:** <http://www.expowest.com/>
Natural Products Expo West (occurs annually in Anaheim, California) is the world's largest and premier tradeshow for the natural, organic and healthy products industry. Since 1981, Natural Products Expo West has been the leading independent voice and industry event. In 2012, Natural Products Expo West hosted over 60,000 industry members and over 3,000 exhibits showcasing products in the categories of natural and specialty foods, organic, supplements, health and beauty, natural living and pet products.

Cosmetic products promotion

The relevant events and trade shows for manufacturers and marketers of natural cosmetic ingredients and products to attend and/or exhibit at are the following:

- **Cosmoprof North America:** <http://www.cosmoprofnorthamerica.com/>
Cosmoprof North America – the only all-encompassing business-to-business beauty trade show event in North America! organized by product categories, there are four pavilions that cover the entire spectrum of the beauty industry; (1) Cosmetics and Personal Care Pavilion, (2) Packaging, Contract Manufacturing & Private Labels, (3) Wellness and Spa and (4) Professional Hair, Nails & Tools. Strong international participation solidified by the presence of country pavilions give a global perspective on emerging trends.
- **Sustainable Cosmetics Summit:** <http://www.sustainablecosmeticssummit.com/>
The Sustainable Cosmetics Summit is a series of international summits that focuses on the leading issues the beauty industry faces concerning sustainability and ecological products. The aim of the summit is to encourage sustainability in the beauty industry by bringing together key stakeholders and debate these major issues in a high-level forum.

2. Buyer list

2.1. Selected natural ingredient distribution companies

AMAZON FOREST INC.

102 – 106 Hillcrest Avenue, Ledgewood, New Jersey 07852, United States
Tel.: +1 973-584-3900 / Fax: +1 973-584-3902
E-mail: sales@amazonforest.net
Web: <http://www.amazonforest.net/>

ANDEAN NATURALS

393 Catamaran Street, Foster City, California 94404, United States
Tel.: +1 888 547-9777 / Fax: +1 707 202-2838
E-mail: info@andeannaturals.com
Web: <http://www.andeannaturals.com/>

BI NUTRACEUTICALS

2550 El Presidio Street, Long Beach, California 90810, United States
Tel.: +1 310 669-2100 / Fax: +1 310 637-3644
Web: <http://www.binutraceuticals.com/>

BOTANIC INNOVATIONS LLC

1540 S. River Street, Spooner, Wisconsin 54801, United States
Tel.: +1 715 635-7513 / Fax: +1 715.635.7519
Web: <http://www.botanicinnovations.com/>

CIRANDA ORGANIC INGREDIENTS

221 Vine Street, Hudson, Wisconsin 54016, United States
Tel.: +1 715-386-1737 / Fax: 715-386-3277
E-mail: info@ciranda.com
Web: <http://www.ciranda.com/>

DAMIANA SUPPLY

Mr. Sammy Mizrachi, Manager
Miami, Florida, United States
E-mail: sales@damianasupply.com
Tel.: +1 786 266 1615
Web: <http://www.damianasupply.com/>

ECUADORIAN RAINFOREST LLC

25 Main Street, Building 6, Belleville, New Jersey 07109, United States
Tel.: +1 973-759-2002 / Fax: +1 973-759-3002
E-mail: info@intotherainforest.com
Web: <http://www.intotherainforest.com/>

ESSENTIAL LIVING FOODS

3550 Hayden Avenue, Culver City, California 90232, United States
Tel.: +1 310 319 1555 / Purchasing: ext. 232 / Fax: +1 310 319 1557
E-mail: info@essentiallivingfoods.com
Web: <http://essentiallivingfoods.com/>

GLOBAL AGRICULTURAL TRADING (GAT)

16601 Ventura Blvd., Suite 400, Encino, California 91436, United States
Tel.: +1 877 609 6006 / Fax: +1 877 609 6006
E-mail: Contact@GAT-Global.com
Web: <http://gat-global.com/>

GREAT LAKES INTERNATIONAL TRADING INC.

858 Business Park Drive, Traverse City, Michigan 49686, United States
Tel.: +1 231 947-2141 / Fax: +1 231 947-0628
E-mail: glit@glit.com
Web: <http://www.glit.com/>

HIGH QUALITY ORGANICS (HQO)

12101 Moya Blvd., Reno, Nevada 89506, United States
Tel.: +1 775 971-8550
E-mail: info@hqorganics.com
Web: <http://www.hqorganics.com/>

JEDWARDS INTERNATIONAL INC.

39 Broad Street, Quincy, Massachusetts 02169, United States
Tel.: +1 617 472-9300 / Fax: +1 617 472-9359
E-mail: Sales@Bulknaturaloils.com
Web: <http://www.bulknaturaloils.com/>

MARROQUIN ORGANIC INTERNATIONAL

303 Potrero Street, Suite 18, Santa Cruz, California 95060, United States
Tel.: 831-423-3442 / Fax: 831-423-3432
E-mail: info@marroquin-organics.com
Web: <http://www.marroquin-organics.com/>

MESQUITEFLOUR.COM / SKELETON CREEK

Aravaipa Canyon, Arizona, United States
E-mail: jeau@mesquiteflour.com
Web: <http://www.mesquiteflour.com/>

MOTHER JUNGLE HERBS

Dante Mazzi, Chief Operations Officer
Mailing Address: PO Box 426, Buellton, California 93427, United States
Warehouse Address: 181 Industrial Way, Suite B, Buellton, California 93427, United States
Tel.: +1 805 350 3154
E-mail: dante@motherjungleherbs.com
Jose Barragan, Sales / Executive Director
Tel.: +1 805 350 3154 / +1 951 587 0502
E-mail: jose@motherjungleherbs.com
Web: <http://www.motherjungleherbs.com/>

MOUNTAIN ROSE HERBS

Mailing Address: PO Box 50220, Eugene, Oregon 97405, United States
 Warehouse Address: 4060 Stewart Road, Eugene, Oregon 97402, United States
 Tel. (International): +1 541 741-7307 / Fax: +1 510 217-4012
 Web: <http://www.mountainroseherbs.com/>

NP NUTRA

15171 S. Figueroa Street, Gardena, California 90248, United States
 Tel.: 1-310-694-3031 / Fax: 1-310-606-2069
 E-mail: admin@npnutra.com
 Web: <http://www.npnutra.com/>

NUTS.COM

125 Moen Street, Cranford, New Jersey 07016, United States
 Tel.: +1 800-558-6887
 E-mail: care@nuts.com
 Web: <http://www.nuts.com/driedfruit/wholesale.html>

NUTRACEUTICALS INTERNATIONAL GROUP

348 Evelyn Street, Paramus, New Jersey 07652, United States
 Tel.: +1 201 399 233 / Fax: +1 201 483 6087
 Web: <http://nutraintlgroup.com/>

PIA INGREDIENT CORPORATION

2420 Industry Street, Oceanside, California 92054, United States
 Fax: +1 760 439-8908
 E-mail: lori.le@pia-ingredients.com
 Web: <http://piaingredients.com/>

PURE GROUND INGREDIENTS

Kevin Lindseth, Owner
 P.O. Box 7172-313, Stateline, Nevada 89449, United States
 Tel.: +1 775 843-6415
 E-mail: kevin@puregroundingredients.com
 Web: <http://www.puregroundingredients.com/>

RAW DEAL INC.

Barry Steinlight, President
 Mailing Address: PO Box 412, Allamuchy, New Jersey 07820, United States
 Warehouse Address: 4 Gold Mine Road, Flanders, New Jersey 07836, United States
 Tel.: +1 973-347-6400 / Fax: +1 973-347-5999
 E-mail: barrys@raw-deal.net
 E-mail: info@raw-deal.net
 Web: <http://www.raw-deal.net/>

RFI INGREDIENTS

300 Corporate Drive, Suite 14, Blauvelt, New York 10913, United States
 Tel.: +1 845 358 8600 / Fax: +1 845 358 9003
 E-mail: rfi@rfiingredients.com
 Web: <http://www.rfiingredients.com/>

RICEPLEX GLOBAL INC.

PO Box 388, New Gretna, New Jersey 08224, United States
 Wholesale inquiries: Michael Belini
 Tel.: +1 609 516-4187
 E-mail: mbelini@riceplex.com
 Web: <http://www.riceplex.com/Super-Fruits-and-Organic-Snacks.html>

SKY HEALTH NATURALS / VMG VALUE MANUFACTURING GROUP

Rodney Grisso, Owner
PO Box 1263, Cobb, California 95426, United States
Tel.: +1 707.928.1994
E-mail: rodney.grisso@skyhealthnaturals.com or rodney.grisso@valuemfg.com
Web: <http://skyhealthnaturals.com/>

TEAWOLF

25 Riverside Drive, Pine Brook, New Jersey 07058, United States
Tel.: +1 973-575-4600 / Fax: +1 973-575-4601
E-mail: info@teawolf.com
Web: <http://teawolf.com/>

UHTCO CORPORATION

Mr. Jorge L. Urena and Martha E. Urena, Founders and Managers
2378 Sequoia Way, Oakville, Ontario L6M 4V5, Canada
Tel.: 905 616.4265 / Fax: 905 248.3845
Web: <http://www.uhtco.ca/>

Z NATURAL FOODS

5407 N Haverhill Road #336, West Palm Beach, Florida 33407, United States
Tel.: 561-242-1880 / Fax: 561-290-1509
Web: <http://www.znaturalfoods.com/>

2.2. Selected natural ingredient extraction and processing companies

A.M. TODD BOTANICAL THERAPEUTICS

1717 Douglas Avenue, Kalamazoo, Michigan 49007, United States
Tel.: +1 269-343-2603 / Fax: +1 269-343-3399
E-mail: BotanicalSales@amtodd.com
Web: <http://www.amtodd.com/botanicals.php>

AVOCA INC. (Division of Pharmachem Laboratories)

PO Box 129, 841 Avoca Farm Road, Merry Hill, North Carolina 27957, United States
Tel.: +1 252-482-2133 / Fax: +1 252-482-8622
E-mail: avocainc@avocainc.com
Web: <http://www.pharmachemlabs.com/divisions/avoca>

BIO-BOTANICA® INC.

75 Commerce Drive, Hauppauge, New York 11788-3942, United States
Tel.: +1 631.231.5522 / Fax: +1 631.231.7332
Web: <http://www.bio-botanica.com/>

FRUTAROM USA

9500 Railroad Avenue, North Bergen, New Jersey, United States
Tel.: +1-201-861-9500 / Fax: +1-201-861-8711
E-mail: info@frutarom.com
Web: <http://www.frutarom.com/>

iTi TROPICALS

30 Gordon Avenue, Lawrenceville, NJ 08648, United States
Tel.: +1 609 987 0550 / Fax: +1 609 482 4333
Web: <http://www.ititropicals.com/>

MOORE INGREDIENTS LTD (Division of A.M. TODD)

9047 Sutton Place, Hamilton, Ohio 45011, United States
Tel.: +1 513.881.7144 / Fax: +1 513.881.7145
Web: www.mooreganics.com

NATUREX INC.

375 Huyler Street, South Hackensack, New Jersey 07606, United States
 Tel.: +1 201 440-5000 / Fax: +1 201 342-8000
 Web: <http://www.naturex.com/>

VALENSA INTERNATIONAL

2751 Nutra Lane, Eustis, Florida 32726, United States
 Web: <http://www.usnutra.com/>

2.3. Selected contract manufacturer and private label companies

ESSENTIAL LIVING FOODS

3550 Hayden Avenue, Culver City, California 90232, United States
 Tel.: +1 310.319.1555 ext. 211
 E-mail: info@essentiallivingfoods.com
 Web: <http://essentiallivingfoods.com/pages/private-label>

LIEF ORGANICS

29013 Avenue Penn, Valencia, California 91355, United States
 Tel.: +1 661 775-2500
 E-mail: info@lieforganics.com
 Web: <http://lieforglabs.com/>

NEXGEN PHARMA

17802 Gillette Avenue, Irvine, California 92614, United States
 Tel.: +1 949 863-0340
 1835 East Cheyenne Road, Colorado Springs, Colorado 80905, United States
 Tel.: +1 719 579-9650
 Web: <http://www.nexgenpharma.com/>

NUTRI-FORCE NUTRITION

14620 NW 60th Avenue, Miami Lakes, Florida 33014, United States
 Tel.: +1 800.455.3396 / Fax: +1 305 629 9994
 Web: <http://www.nutriforce.com/>

PARAGON LABORATORIES

20433 Earl Street, Torrance, California 90503, United States
 Fax: +1 310 370-7354
 E-mail: sales@ParagonLabsUSA.com
 Web: <http://www.paragonlabsusa.com/>

VITALITY WORKS®

8500 Bluewater Road NW, Albuquerque, New Mexico 87121, United States
 Tel.: +1 505-268-9950 / Fax: +1 505-268-9952
 Web: <http://www.vitalityworks.com/>

2.4. Selected finished product manufacturing and marketing companies

ADVANTAGE HEALTH MATTERS INC. / ORGANIC TRADITIONS® / HEALTH MATTERS

5787 Steeles Avenue West, West North York, Ontario M9L 2W3, Canada
 Tel.: 416-742-1011 / Fax: 416-742-8528
 E-mail: orders@advantagehealthmatters.com
 Web: <http://advantagehealthmatters.com/C-106/OrganicTraditions.aspx>

AGI'S RAW FOODS

2255 N. University Pkwy., Provo Utah 84604, United States
 Tel.: 801-687-8406
 E-mail: agisrawfoods@hotmail.com

Web: <http://www.agisrawfoods.com/products.php>

AKEA LLC

900 Ridgefield Drive, Suite 170, Raleigh, North Carolina 27609, United States

Tel.: 919.981.6110 x1 / Fax: 919.981.6111

E-mail: akeacare@akealife.com

Web: <http://goodlifewith.akealife.com/>

ANCIENT SUN INC. / WILDBAR®

E-mail: info@wildbar.info

Web: <http://www.wildbar.info/>

ANDEAN DREAM, LLC

P.O. Box 411404, Los Angeles, California 90041, United States

Tel.: +1 310 281-6036

E-mail: info@andeandream.com

Web: <http://www.andeandream.com/>

ANDEAN TREASURES INTERNATIONAL INC.

1000 Ponce De Leon Boulevard Suite 302, Coral Gables, Florida 33134, United States

Web: <http://andean treasures.com/>

BEACHBODY LLC / SHAKEOLOGY®

3301 Exposition Blvd., 3rd Floor, Santa Monica, California 90404, United States

Web: <http://www.shakeology.com/>

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Tel.: +511 348-8737

Web: <http://blamacperu.com/>

BLUE MOUNTAIN ORGANICS DISTRIBUTION, LLC / LOVE RAW FOODS

P.O. Box 898, Floyd, Virginia 24091, United States

Tel.: +1 540 745-5129

E-mail: wholesale@bluemountainorganics.com

Web: <http://www.bluemountainorganics.com/loverawfoods/>

CASA DE MESQUITE LLC / CASA DE FRUTA

10021 Pacheco Pass Highway, Hollister, California 95023, United States

Tel.: +1 408 842 7282 / Fax: +1 408 842 0248

E-mail: info@casadefruta.com

Web: <http://www.casadefruta.com/mesquite.php>

DIVINE FOODS INC. / PRANA BAR

445 Corporate Drive, Suite B, Escondido, California 92029, United States

Fax: 760 781-1042

Web: <http://www.pranabarstore.com/Organic-Goldenberry-Goji.html>

DR. BO'S NATURAL HEALTH AND BEAUTY PRODUCTS

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E-mail: info@drbo.com

Web: <http://www.drbo.com/>

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980 Adelaide St South Unit 27, London, Ontario, N6E1R3, Canada

Tel.: 519-434-6208

Web: <http://www.dremerald.com/Home-Page.html>

EARTH CIRCLE ORGANICS

355 Crown Point Circle, Ste. D, Grass Valley, California 95945, United States
 Tel.: 530-273-3663 / Fax: 530-273-3223
 E-mail: info@earthcircleorganics.com
 Web: <http://www.earthcircleorganics.com/>

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 E-mail: info@earthsourceorganics.com
 Web: <http://www.righteouslyrawchocolate.com/>

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140 58th Street, Suite 6E, Brooklyn, New York 11220, United States
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 E-mail: info@chocolatebar.com
 Web: <http://chocolatebar.com/>

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 Web: <http://www.extremehealthusa.com/>

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 Fax: +1 866 527.2081
 Web: <http://www.gnosischocolate.com/>

GOOD SUPERFOOD LLC / GOOD CACAO

Paul Frantellizzi, Founder and CEO
 Boise, Idaho, United States
 Web: <http://www.goodcacao.com/>

GOPAL'S HEALTHFOOD INC. / NATURE'S GIFT COOKIES

Stefan Knuppel, CEO and Owner
 800 CR 125, Sidney, Texas 76474, United States
 Tel.: +1 254.259.2299 / Fax: +1 254.259.2294
 Web: <http://gopalshealthfoods.com/wholesale/cookies/natures-gift>

HARMLESS HARVEST

145 Sixth Avenue, 7th Floor, New York, New York 10013, United States
 Tel.: +1 347 688-6286 / Fax: +1 877 398-8807
 Web: <http://www.harmlessharvest.com/>

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Dr. Jameth Sheridan (D.H.M.), co-founder

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Tel.: +1 760-747-8822
Web: <https://healthforce.com/>

HEALTHFUL ORGANICS INTERNATIONAL INC.
495 Woodward Avenue, Hamilton, Ontario L8H 6N6 Canada
Tel.: 905 543 8777 / Fax: 905 543 8444
Web: <http://healthfulorganics.com/>

HERBS AMERICA COMPANY / MACA MAGIC®
P.O. Box 446, Murphy, Oregon 97533, United States
Tel.: +1 541- 846-6222 / Fax: +1 541- 846-9488
E-mail: info@macaroot.com
Web: <http://www.herbs-america.com/>

INCA LIFE PRODUCTS LLC
Ms. Diana Rabanal
8800 NW 5th Street, Pembroke Pines, Florida 33024, United States
Web: <http://www.incalifeperu.com/>

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Consumer Relations Dept, Kao Brands Company
2535 Spring Grove Ave, Cincinnati, Ohio 45214, United States
Web: <http://www.johnfrieda.com/en-US/Home>

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8101 Biscayne Blvd #609, Miami, Florida 33138-4668, United States
Tel. (Miami): 305.751.7341 / Tel. (New York City): 212.333.4355 / Fax: 305.751.7344
E-mail: kopali@kopali.com
Web: <http://kopali.net/products/fruits/>

LESLIE'S ORGANICS, LLC / COCONUT SECRET
298 Miller Avenue, Mill Valley, California 94941, United States
Tel.: +1 415 383-9800 / Fax: +1 415-383-9804
E-mail: info@coconutsecret.com
Web: <http://www.coconutsecret.com/>

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Web: <http://www.levelground.com/>

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Web: <http://www.livingintentions.com/>

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Heidi Nevala, President
Minneapolis, Minnesota, United States
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Web: <http://www.linkedin.com/in/heidinevalanautraherbs>

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9100 Van Horne Way, Richmond, British Columbia V6X 1W3 Canada
Web: <http://us.naturespath.com/qia>

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 Tel.: +1 512.266.6100
 Web: <http://www.navajoskincare.com/>

NAVITAS NATURALS

936 B Seventh St. Box # 141, Novato, California 94945, United States
 Tel.: +1 415 883 8116
 Web: <http://navitasnaturals.com/>

NEW SPIRIT NATURALS

615 West Allen Avenue, San Dimas, California 91773, United States
 Tel.: +1 909 592-4445 / Fax: +1 909 599-4035
 E-mail: eservice@newspirit.com
 Web: <http://www.newspirit.com/>

NEW WORLD NATURALS

Dr. Nita Bishop, N.D.,
 112 North Alder / Box 417, Granite Falls, Washington 98252, United States
 Tel.: 425-830-9594 / Fax: 360-691-6451
 E-mail: drnita@newworldnaturals.org
 Web: <http://www.newworldnaturals.org/ChocOmega.php>

NORTH AMERICAN HERB & SPICE

PO Box 4885, Buffalo Grove, Illinois 60089, United States
 Tel.: +1 847-473-4700 / Fax: +1 847-473-4780
 E-mail: info@p-73.com
 Web: <http://www.p-73.com/>

NOW FOODS

244 Knollwood Drive, Suite 300, Bloomingdale, Illinois 60108, United States
 Tel.: 888-669-3663
 Web: <http://www.nowfoods.com/>

NP NEW PHARMA INC. / EPA MAX

3307 NW 74 Avenue, Miami, Florida 33122, United States
 Victor G. Farinas, Director and President
 Web: <http://www.newpharmainc.com/>

ORGANIC LIVES ENTERPRISES

PO Box 48592, Vancouver, British Columbia V7X 1A3, Canada
 Tel.: +1.778.588.7777
 E-mail: info@organiclives.org
 Web: <http://www.organiclives.org/>

ORGANIC VEGAN SUPERFOODS, LLC

5200 NW 43rd Street, Suite 102-305, Gainesville, Florida 32606, United States
 Tel.: +1 352 448.1695
 E-mail: contact@organicvegansuperfoods.com
 Web: <http://organicvegansuperfoods.com/>

PRANA

160 Saint-Viateur E, suite #500, Montreal, Quebec H2T 1A8, Canada
 Web: <http://pranana.com/en/>

QUINOA PERU FOODS

Vancouver, British Columbia, Canada
 Tel.: +1 604-839-5971
 E-mail: ruynoya@quinoaperufoods.com

Web: <http://www.quinoaperufoods.com/>

RAINFOREST HERBAL PRODUCTS

Marvin Zeifman (Canada)

Daniel Castro (Peru)

Calle Porta 639 Miraflores, Lima 18, Perú

Tel. (Canada): +1 905 597 7347 / Fax (Canada): +1 289 597 7348

Tel. (Peru): +511 243 4668 / 444 2033

E-mail (Canada): marvinzeifman@rainforestproduct.com

E-mail (Peru): dany@rainforestproduct.com

Web: <http://www.rainforestproduct.com/>

RAWGANIQUE.COM

Box 81, Denman Island British Columbia V0R1T0, Canada

Tel.: +1 250 335-0050 Ext 1

E-mail: rawganique.com@gmail.com

Web: <http://www.rawganique.com/Food/wild-raw-mesquite-powder.htm>

RAWPOWER.COM

PO Box 1358, Coeur d'Alene, Idaho 83816, United States

Tel.: +1 208-676-9065

Web: <http://www.rawpower.com/>

RAW ONE FOOD / SANDESH ONE CORPORATION

Sandesh Taylor, President

1904 Coolidge Street, Hollywood, Florida 33020-2426, United States

Tel.: +1 954 922-1315

Web: <http://www.rawonefood.com/>

RICH NATURE LABS

9700 Harbour Place Suite 128, Mukilteo, Washington 98275, United States

Tel.: +1 888-708-8127 / Fax: +1 425-493-1803

E-mail: info@richnature.com

Web: <http://richnature.com/>

SACHA INCHI CORPORTION

120 Promenade Circle, Thornhill, Ontario L4J 7W9, Canada

Tel.: 416 304-9809 / Cel: 647 202-0617

E-mail: Jacqui@sachainchicorporation.com

Web: <http://www.sachainchicorporation.com/>

SACHA VIDA

Carlos Campos, Founder and CEO

E-mail: info@sachavida.com

Web: <http://sachavida.com/>

SALVE SISTER LLC

Mary Ashby Brown, Founder

E-mail: info@salvesister.com

Web: <http://www.salvesister.com/>

SAMBAZON

Ryan Black, CEO and Co-Founder

1160 Calle Cordillera, San Clemente, California 92673, United States

E-mail: info@sambazon.com

Web: <http://sambazon.com/>

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10853 Venice Blvd, Suite 2, Los Angeles California 90034, United States

Web: <http://www.terramazon.com/>

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Tel.: +1 604 945 3133

Web: <http://shopca.myvega.com/>

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Fax: +1 450.678.0022

Web: <http://www.neolia.com/>

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754 West Pioneer Boulevard. Suite 101 Mesquite, Nevada 89027, United States

E-mail: support@sunwarrior.com

Web: <http://www.sunwarrior.com/>

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10 Underwood Place, Suite 9, Clifton, New Jersey 07013, United States

Tel.: +1 973-246-4113 / Fax: +1 973-767-1180

E-mail: CustomerService@SunburstSuperfoods.com

Web: <http://www.sunburstsUPERFOODS.com/>

SUNFOOD SUPER FOODS

1830 Gillespie Way, Suite 101, El Cajon, California 92020, United States

Tel. (International): +001-619-596-7979 / Tel. (in the United States): +1 619 596 7979/ Fax: 619 596 7997

E-mail: support@sunfood.com

Web: <http://www.sunfood.com/>

THEO CHOCOLATE

3400 Phinney Avenue North, Seattle, Washington 98103, United States

Tel.: 206 632.5100 / Fax: 206 632.0413

E-mail: info@theochocolate.com

Web: <https://www.theochocolate.com/>

TOTAL IMAGE FITNESS™

Don M. Hartwell, President

#1-3419 12St. N.E., Calgary, Alberta T2E 6S6, Canada

Tel.: 403 277.7214 / Fax: 403 277.7952

E-mail: don@totalimagefitness.ca

Web: <http://www.totalimagefitness.ca/sacha-inchi-oil>

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David Kaplan, Founder

16 A Pamaron Way, Novato, California 94949, United States

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Web: <http://www.royalhimalayan.com/>

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1370 Miners Drive, Lafayette, Colorado 80026, United States

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E-mail: info@twomomsintheraw.com

Web: <http://www.twomomsintheraw.com/>

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Tel.: 905 616.4265 / Fax: 905 248.3845

Web: <http://www.uhtco.ca/>

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E-mail: denniswerner@ultimatesuperfoods.com
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VITAMINS BECAUSE LLC

3930 S Suncoast Blvd, Homosassa, Florida 34448, United States
Fax: +1 352 628-6743
Web: <http://www.doctorvitaminstore.com/>

WONDER FOOD COMPANY, INC. / COCO KEENO

Maria Mouchati, Founder and CEO
42-335 Washington Street, Suite F-24, Palm Desert, California 92211, United States
Tel.: +1 760.218.7801
Web: <http://wonderfoodco.com/>

YOGA EARTH

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Tel.: +1 888 327-8450.
E-mail: community@yogaeearth.com
Web: <http://www.yogaeearth.com/shop/>

ZOCALO GOURMET

12407-B Mukilteo Speedway, Suite 245, Lynnwood, Washington 98087, United States
Tel: +1 425 398-9761
E-mail: info@culinarycollective.com
Web: <http://www.zocalogourmet.com/>

2.5. Selected finished product distribution companies

ADVANTAGE HEALTH MATTERS INC.

5787 Steeles Avenue West, West North York, Ontario M9L 2W3, Canada

Tel.: 416-742-1011 / Fax: 416-742-8528

E-mail: orders@advantagehealthmatters.com

Web: <http://advantagehealthmatters.com/>

AZURE STANDARD

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Tel.: 541-467-2230 / Fax: 541-467-2210

E-mail: info@azurestandard.com

Web: <http://www.azurestandard.com/>

ECOMAX NUTRITION

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Tel.: 514-344-7008 / Fax: 514-344-3757

E-mail: ecomaxjc@bellnet.ca

Web: <http://www.ecomaxnutrition.com/>

NATURE'S BEST

PO Box 2248, Brea, California 92821-2248, United States

Web: <http://www.naturesbest.net/>

SELECT NUTRITION

Division of UNFI

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Web: <http://www.selectnut.com/>

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