

THE NORTH AMERICAN MARKET FOR NATURAL PRODUCTS

PROSPECTS FOR ANDEAN AND AFRICAN PRODUCTS



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The North American Market for Natural Products: Prospects for Andean and African Products

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Survey of natural products market in the United States and Canada, with a special focus on selected South American and African products – presents a general overview of the North American market for natural products; highlights prospects for Peruvian and South American products in this market; gives legal definitions of natural products; outlines market access requirements in terms of regulations, quality standards, product presentation, packaging, and labelling; outlines different distribution channels, and reviews the qualifications required by North American buyers of their suppliers; provides examples of companies in the natural products market, illustrating their approach in developing their market niche and businesses; appendices include a list of importers/wholesalers of natural ingredients, producers of essential oils, and herb farms.

Descriptors: **Medicinal plants, Medicinal teas, Essential Oils, Spices, Market Access, Quality Standards, Packaging, Labelling, United States, South America, Canada, Peru, Africa, Case Studies.**

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English, Spanish (separate editions)

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Foreword

In this United Nations Decade of Biodiversity (2011-2020), there is increasing focus on the role of trade in safeguarding biodiversity as well as contributing to poverty reduction.

Trade in natural products has important economic benefits for some of the world's most marginalized people. There is also an environmental benefit in this trade. The sustainable collection and certified sale of natural products offers local people an incentive to preserve biodiversity rich areas like the Amazonian rainforest and provides an alternative to destructive practices like slash and burn agriculture and logging.

Consumers in the developed and emerging economies are driving this trade. Demand is increasing for products free of synthetic ingredients. There is a new trend in 'superfoods' derived from plants like maca and camu camu – these are species found only in particular regions of the Andes and Amazon and so are a unique biodiversity asset for the developing world. There is also a strong sentiment from consumers to help poor producers through trading under fairer terms.

The North American market continues to offer great opportunities for exporters in this segment, despite the economic recession. However, it is a demanding marketplace.

The market requires suppliers to compete in several areas: quality, price and more recently 'sustainability' certification. A fourth area of competitive advantage for exporters is having the knowledge and capacity to meet the array of regulations, standards, product specifications, supplier qualifications and so on.

This technical paper provides the exporter with guidance in these four key areas of competition.

Two accompanying papers provide more in depth guidance on how to make claims about natural products in marketing and how to label products correctly.

ITC's mandate is to provide practical guidance to exporters in developing countries in accessing international markets. This document along with others in our Sustainability Market Guides series provides small and medium sized enterprises as well as micro enterprises with guidance in this exciting new market and so will help strengthen their competitiveness and foster greater sustainability in the supply chain.



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Sustainability Market Guides

This is part of a series of Sustainability Market Guides produced under ITC's Trade, Climate Change and Environment Programme (TCCEP), financed by the Government of Denmark.

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

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

2010-2011

1. Claim Statements for Natural Products – The United States Market
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2012 (published and forthcoming)

6. The North American Market for Natural Products
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Acronyms

| | |
|---------|---|
| AHPA | American Herbal Products Association |
| CFR | Code of Federal Regulations |
| CGMP | Current good manufacturing practices |
| DSC | USP Dietary Supplements Compendium |
| DSHEA | Dietary Supplement Health and Education Act of 1994 |
| DSP | Dietary supplement product |
| FCC | Food Chemicals Codex |
| FDA | Food and Drug Administration |
| FLO | FairTrade Labelling Organizations International |
| FTF | Fair Trade Federation |
| FWF | FairWild Foundation |
| GACP | Good agricultural and collection practices |
| GAP | Good agricultural practices |
| GMP | Good manufacturing practices |
| GRAS | Generally recognized as safe |
| HS Code | Harmonized System tariff code |
| IFOAM | International Federation of Organic Agriculture Movements |
| ILO | International Labour Organization |
| IMO | Institute for Market Ecology |
| ITC | International Trade Centre |
| MSDS | Material safety data sheet |
| NHP | Natural health product |
| NHPD | Natural Health Products Directorate |
| NHPR | Natural Health Products Regulations of 2003 |
| NOP | National Organic Program |
| NTFP | Non-timber forest products |
| OTC | Over-the-counter |
| PhEur | European Pharmacopoeia |
| UNCTAD | United Nations Conference on Trade and Development |
| USDA | United States Department of Agriculture |
| USP | United States Pharmacopeia |
| WCO | World Customs Organization |
| WHO | World Health Organization |

Executive summary

Natural products in the North American market have experienced strong market growth in the last decade as consumers increasingly demand nutritional and cosmetic products derived from natural sources.

Key trends predicted for the coming year include the continuing acceptance of exotic foods and flavours. Sustainability brands, antibiotic- and hormone-free ingredients, and local and organic goods will continue to gain market share, as consumers seek these green and ethical attributes in their foods and cosmetics to fit a more 'wellness' lifestyle approach.

This publication provides key information about the natural products market and technical details of how to access markets, with a special focus on selected South American and African products.

The report begins by giving an overview of the market (section 1) and characterizing the main market channels that exist within North American natural products markets. The section discusses how one plant ingredient can have different market channels. For example flax seed oil could be used in all market channels (including uses as a dietary supplement, food or functional food market, pet foods, and cosmetics and body care). This section also identified the prospect for dietary/herbal supplements, and for 'superfoods', and interesting oils, as well as sustainable and ethical ingredients from South American and African sources.

Section 2 provides legal definitions of natural products.

Section 3 provides a description of products according to official trade and botanical classifications.

Section 4 outlines the requirements for access to each market channel and the requirements in terms of regulations, standards, product presentation, and application forms. The report also provide hands-on guidance to exporters wishing to gain access to North American markets, giving technical details needed for the various standards, and regulations relating to the importation, production, quality and certification that are sought by both the United States and Canadian markets.

Section 5 discusses prices for natural ingredients.

Section 6 outlines different distribution channels.

Section 7 gives background to the qualifications required by North American buyers of their suppliers.

Section 8 sets out packaging and labelling requirements for the North American markets.

Section 9 provides guidance to exporters on how to strengthen their marketing in the supply chain. Case studies identify companies in the natural products market, and what approach they take to developing their market niche and business. Information on trade fairs is given, especially as an approach for gaining access to new buyers, servicing existing clients, and developing strategic relationships.

The report concludes that this is a time of high interest, opportunity and growth in North American natural product markets. However, it is no longer enough to be a supplier of an ingredient that has a desirable functionality or application. Both consumers and government regulators are looking at these products more closely, especially with respect to safety requirements, sustainability and eco-social demands. To reach the market and be successful in the long-term will require suppliers to score well in all these areas.

1. Market overview

1.1. The natural products market

The North American natural products market is made up of the following groups:

- Dietary supplements,
- Foods and functional foods,
- Natural cosmetic products, and
- Over-the-counter (OTC) drug products (botanical drugs).

However, certain botanicals may fulfil requirements and find use in applications in more than one group. It is therefore common to find a particular botanical, e.g. camu camu, may be used in dietary supplements, foods, as well as cosmetic products.

Dietary supplements

The official definition of dietary supplements (in the United States of America) and natural health products (in Canada) is found in section 2. This report refers to these products as 'dietary supplements', and would include products such as vitamins and minerals, herbal remedies, traditional medicine products such as traditional Chinese medicine products, probiotics, and other products like amino acids and essential fatty acids.

Foods and functional foods

Generally, functional foods or health foods have no specific regulatory definitions, but instead have marketing defined definitions. Functional foods (also known as 'nutraceuticals') are broadly defined as foods and food components that provide a health benefit beyond basic nutrition, according to the Institute of Food Technologists. They can include fruits that are thought of as having special health-promoting properties, such as camu camu, with their high content of vitamin C, yogurts that contain live cultures of probiotics, botanicals such as spices or herbs that may be considered foods yet which also are health promoting, such as green tea.

Natural cosmetic products

Botanicals are increasingly being found in cosmetic products, especially ones that have claims of being natural. Examples include shea butter lotions, creams and shampoos or face creams with essential fatty acids (from sacha inchi, or camu camu) included in the formulation.

OTC drug products

This report is not focused on pharmaceutical or OTC drug products as they have very different regulatory specifications and marketing channels than the rest of the botanical groups covered in this report.

1.2. Growth to date and trends in the market

The last decade has seen strong growth in the botanicals market. This is driven by two factors: regulatory change and rising consumer demand.

In 1994, the United States introduced the Dietary Supplement Health and Education Act of 1994 (or DSHEA). It clarified the rules about how United States companies could market these products. In Canada, certain herbal products were already regulated as medicines in the 1990s, but a new framework came into effect in 2004 that required all natural health products (NHPs) to be authorized and licensed, including traditional herbal medicinal products, modern phytopharmaceutical products, homoeopathic medicines, essential fatty acids, vitamins, minerals and probiotics.

Soon after the passing of the DSHEA, echinacea became the first big herbal superstar. Demand for echinacea boomed. Americans and Canadians began to look for other existing natural alternatives to take care of their health and happiness. Following echinacea came others such as St John's wort, ginkgo and ginseng.

Several years later negative media coverage arose concerning the potential negative side effects of the use of these herbs, scaring consumers away from parts of the herbal supplement market.

In the following segments, recent growth trends are as follows:

Dietary supplements

The United States retail sales of dietary supplements exceeded US\$ 9 billion in 2009, up 8% from 2008. From 2005 to 2009 the market grew by a total of 26%. In Canada, the supplement retail industry was expected to exceed Can\$ 2.75 billion in value by the end of 2010.¹ Today, although the dietary supplement market remains strong, its growth, while steady, has slowed considerably.

In Canada, the use of new ingredients in the natural-ingredients market continues to rise; however, market access barriers are greater due to the Canadian requirement of pre-market licensing of finished NHPs. In the United States, while the botanical dietary supplement market grew fast in the mid 1990s, the development and implementation of regulations that govern the manufacture, labelling and sale of these dietary supplements has caused this growth to slow considerably.

DSHEA provides the regulatory framework for herbal dietary supplements in the United States and the federal enforcing agency is the Food and Drug Administration (FDA). Each Food and Drug Branch (FDB) of each of the fifty states also has enforcement authority. FDA requires notification but does not require premarketing authorization or product licensing as does the Canadian NHP regulations through the Canadian Food and Drug Act. In the United States, this resulted in a surge of herbal medicine or dietary supplement companies making outrageous claims about what their products could do for consumers, quickly followed by negative media and consumer scepticism. Today, consumers are regaining interest in dietary supplements because the FDA has increased its regulation of claims, and regulations such as the GMPs have been developed to help govern the quality of dietary supplements.

Indeed, according to a recent report from market research company Packaged Facts, dietary supplements in the United States have proven to be recession-proof, as the older, baby-boomer generation in the United States has favoured dietary supplements over prescription drugs and precautionary medical procedures as a way to stay healthy.

The key market prospect areas for dietary supplements continues to be for improving conditions associated with ageing, as well as those that have feel-good properties (those that when taken make the consumer feel better). Any natural cosmetics, cosmeceuticals and/or dietary supplements that promise anti-ageing or age-reversing benefits are popular, particularly if the natural ingredients have scientifically documented beneficial activity. The baby-boomer generation is still the largest segment of the population, and as they age and experience more age-related health problems, they will continue to seek dietary supplementation for improving their health. Part of the reason for this is that they, as well as other Americans, are losing their confidence in their ability to pay for healthcare.

With an estimated 68 million American adults trying to lose weight, the weight-loss industry represents a huge potential market for certain natural ingredients (albeit a very controversial and fast changing market). Determining the potential value of, and opportunities within, the weight-loss market for ingredient producers is complicated as a significant number of products in this sub-sector are sold through non-traditional channels such as radio and television infomercials (direct sale via telephone call-ins), commercial e-mail (spam), tabloid advertisements, direct mail, internet websites, weight-loss franchises and direct marketing through multi-level companies. Natural ingredients sold mainly to manufacturers of weight-loss products are a high-risk prospect as this sub-sector is more frequently subjected to punitive regulatory action and lawsuits which can rapidly and adversely affect the market demand for an ingredient.

¹ Packaged Facts. Nutritional Supplements in the U.S., 4th Edition. August 2010, www.packagedfacts.com.

One of the top sellers in the United States and Canadian market is DHA and other omega-3 fatty acids. DHA products are normally made from fish or algae, however, new food or supplement products that provide good sources of omega-3 fatty acids will find a large and growing market prospect, especially if produced at a competitive price with respect to comparable oils. Among the Peruvian natural products, sachu inchi seed oil is showing the most potential, however, issues around source, stability and pricing have not yet been fully resolved.

Foods and functional foods

Recently there has been strong growth in 'functional foods'. This market is growing and products of this type are often termed 'superfoods'. The market is expected to continue to grow. Leatherhead Food International predicts the United States functional food market to grow to about US\$ 8.61 billion by 2015, a 21% jump from 2009 levels. Revenues generated by Canadian companies in the health and wellness market which includes dietary supplements reached almost Can\$ 3.0 billion in 2007, with an extra Can\$ 545 million in exports, according to Statistics Canada.

The United States is the world's most valuable functional food and beverages market, estimated to be US\$ 115 billion in retail value, or one quarter of the global sales in health and wellness, according to market research firm Euromonitor International. The key opportunities for new products identified by companies interviewed for this report are for those that can be considered superfoods, especially those that qualify in a regulatory sense to be sold as food in the United States.

To qualify for the market for intended use as a food ingredient, these products need to be 'generally recognized as safe' (or GRAS).

Another emerging area for natural products is 'beauty foods', or food that promises beauty benefits, usually related to hair, skin and nails. In both the United States and Canada, these foods are marketed in a similar way to functional foods, using existing food regulations. The global market for beauty foods was estimated by the management consultant firm Kline Group to be worth US\$ 1.5 billion in 2007. Europe and Japan currently lead the market for beauty foods, with 55% and 41% respectively of the market, whilst the United States represents only 3% of the market.

Further key trends, as forecast by Packaged Facts, in their *Food Flavors and Ingredients Outlook 2011* include:

Flavours from around the globe – ethnic foods and flavours will continue to be a key area of growth, providing interest without taxing smaller food budgets.

Sustainability – there will be a greater use of natural, organic, local and antibiotic-and-hormone-free ingredients, as well as foods connected with sustainability.

Wellness overhaul – food will get more attention as health and wellness activities will be better integrated into peoples' overall lifestyles. One area that demonstrates Americans' attitude to health issues and food is the strong growth in the gluten-free food market.

Plethora of produce – there will be an increased interest in vegetable consumption for health reasons.

Flavour and ingredient crossovers – there will be more 'crossover products' with savoury ingredients in sweet dishes, and sweet ingredients into savoury dishes.

Satisfying sweets – agave syrup, due to its low-glycemic appeal, will continue to grow in popularity, as well as extracts made from the stevia leaf. Superfruits such as blueberries and pomegranates will also grow in popularity.

Natural cosmetic products

According to Organic Monitor, an organic food marketing company, the North American natural cosmetics market has surpassed the US\$ 5 billion mark. Although the market has more than 600 brands, very few

are dominating, and a two-tier market has developed with large brands (such as Burt's Bees and Bare Escentuals) occupying the first tier, and small-to-medium sized brands occupying the second tier.² The natural personal care or cosmetic market now outperforms the overall personal care markets around the world. In the United States the natural personal care category is growing at double-digit levels, with the highest growth coming from those brands that could be considered 'truly natural'.

The natural cosmetics market is shifting towards the increasingly green values being adopted by society, leading to more growth in the 'truly natural' cosmetic product brands. Much of what is driving growth of these brands is the reformulation of 'natural-inspired' brands, as well as placement in mass-market retailers such as Target, Wal-Mart, and drug stores. Leading 'truly natural' brands include Burt's Bees (Clorox) and Tom's of Maine (Colgate-Palmolive). These developments are in the context of health and wellness trends in society which are leading consumers to seek out companies and products that accept responsibility for social issues and the environment. Other trends include increased consumer spending on certified-natural cosmetics, as well as demand of lower-priced private label brands (those made by one company to be sold under another company's brand).³

The third-largest market for natural cosmetic products is Brazil where the market for natural cosmetics grew at double-digit levels. Growth here is not surprising as there is already a culturally-ingrained acceptance of herbs and plants as well as a burgeoning middle-class which has spending available for this type of product.⁴

Pet foods

Pet foods represent another growing market segment for natural products. According to Packaged Facts, the overall pet market grew 4% in 2010. Retail sales of pet foods reached US\$ 18.4 billion in 2010.

Among the fastest growing areas of the pet foods market is the health-oriented market, including cat and dog treats (especially those that have a health benefit), refrigerated/frozen raw foods, cat and dog supplement and nutraceutical treats.

An important contributor to the rise in market share of organic and natural pet foods is the 2007 recall of 60 million cans and pouches of pet food, following an incident where 471 cats and dogs were poisoned, with 104 reported dead. Following this event, the Nutrition Business Journal recorded a 27% spike in United States animal nutrition sales in 2007, and in 2008 consumer sales of natural and organic pet foods rose 18% reaching US\$ 1.2 billion.

Other incidents with conventional brands have also contributed to the rise in market share of organic and natural pet foods. These include a recall in 2008 of the Wegmans retail chain's private label dog and cat foods after a salmonella threat was uncovered, and a recall in 2010 of several brands from the large supermarket chain Kroger after toxic chemicals were found in pet-food corn filler.

Even though pet ownership has remained constant, the natural and organic pet food market is growing by 12-15% annually, thereby taking market share from conventional and private label brands.

The 2007 recall in pet foods also affected the Canadian pet food market. Canadian consumers are now placing a higher degree of importance on the trustworthiness and transparency of a pet food company and/or brand. The Canadian pet food market generated revenue of approximately Can\$ 1.1 billion in 2008. The market is seen as a stable market with opportunity for growth and new trends.⁵ Natural products might enter pet foods as healthy ingredients in a standard pet food, or in the faster-growing nutraceutical pet snack industry.

² North American natural cosmetics market passed the US\$ 5 billion mark, <http://www.organicportal.info/index.php/home-mainmenu-1/news-mainmenu-2/1-latest/784-news-north-american-natural-cosmetics-market-passed-the-usd-5-billion-mark.html>.

³ Natural cosmetics a global trend setter, <http://www.organic-market.info/web/Fairs + Conferences/BioFach - Vivanness/cosmetics/214/215/0/8309.html>.

⁴ Mills, Nancy, Natural Products Outperform the Overall Personal Care Market: More Double-digit Growth on the Global Horizon. Kline:: http://www.klinegroup.com/reports/emailings/newsletters/consumer/november2010/timely_trends.asp.

⁵ The Canadian Pet Food Market, <http://Globaltrade.net>.

1.3. Sustainable and ethical segment

Foods, supplements and cosmetic ingredients that fit the sustainable growing or ethical product area will grow in popularity. Certifications, such as fair trade, combined with organic, is an area of high market growth. This not only provides opportunities for producers, but in the case of fair trade or other social certifications, guarantees of higher prices or premiums in the market, along with good working conditions for farmers or farm workers in the supply chain. According to FLO, the United States saw over €757 million in retail sales of fair trade certified products in 2008, and over €851 million in 2009 (representing 7% growth). By comparison, Canada had €123 billion of retail sales in 2008 and €201 billion in 2009 (representing 66% growth). The top-five sellers of fair trade certified goods in 2009, in terms of estimated value, were the United Kingdom, the United States, France, Germany and Canada.

Essentially, we are entering a time where being a hot new ingredient is not enough. New ingredients that have the most promising market prospects are those that are exciting in their functionality while also having other requirements such as proof or third-party certification that they are produced in a sustainable manner, which increasingly includes more equitable trade relationships for the farmer.

1.4. Peruvian and South American prospects for the United States and Canadian markets

There is still a stable market in North America for certain established herbs, such as uña de gato. However, the products that have the most promise for the current and coming trends in the North American markets are those considered as 'functional food products', superfoods, or more specifically, those that can be considered GRAS (generally recognized as safe) in the United States or as foods under the Novel Foods Regulation (under the Canadian Food and Drugs Act).

Although many of these products in their more simple forms have long histories as foods, the respective food safety agencies in both Canada and the United States require companies to establish the safety of foods before they enter the marketplace (to learn more about this see section 2 Legal Definitions).

For example, even though food and drink company Harmless Harvest markets a camu camu juice which is the same as that consumed in South American regional markets, a review of the safety of the fruit juice was made (called a 'self-affirmation') by a GRAS panel of experts (organized by the company), and is kept on-file at the company in case the FDA has questions.

As uña de gato does not have a history of food use, it would not be appropriate for use in foods, unless a company was to establish safety through scientific methods. Therefore, a functional food beverage made with uña de gato would not be allowed in the United States or Canada unless a company were to take the extra effort and expense to establish this.

The main destinations for biodiversity-based products from Peru in 2010 were North America (40%), Europe (44%) and Asia (15%), according to the country's promotion body, PromPeru. Oceania, Africa and other destinations accounted for only 1.68%. The top priority biodiversity products from Peru are listed in Table 1. This shows that top-selling exports from Peru are tara, annatto, cochineal, quinoa, Brazil nuts, and giant corn.

Table 1. Peruvian exports by product group and product (2010)

| Product groups | Product | FOB value (US\$ '000) | % |
|--|-------------|-----------------------|---------|
| Exotic fruits | Camu camu | 597. | 0.19% |
| | Lucuma | 630 | 0.20% |
| | Goldenberry | 148 | 0.05% |
| | Others | 720 | 0.23% |
| | SUB-TOTAL | 2,095 | 0.66% |
| Grains and nuts | Brazil nut | 15,043 | 4.73% |
| | Giant corn | 9,536 | 3.00% |
| | Quinoa | 13,553 | 4.26% |
| | Amaranth | 1,863 | 0.59% |
| | Purple corn | 1,877 | 0.59% |
| | Sacha inchi | 1,047 | 0.33% |
| | SUB-TOTAL | 42,920 | 13.48% |
| Nutraceutical & medicinal plant | Maca | 6,156 | 1.93% |
| | Cat's claw | 1,376 | 0.43% |
| | Yacon | 633 | 0.20% |
| | Others | 958 | 0.30% |
| | SUB-TOTAL | 9,123 | 2.87% |
| Industrial | Annatto | 11,089 | 3.48% |
| | Tara | 43,0845 | 13.54% |
| | Cochineal | 208,709 | 65.57% |
| | Others | 1,270 | 0.40% |
| | SUB-TOTAL | 264,153 | 82.99% |
| TOTAL | | 318,291 | 100.00% |

Source: PromPerú.

For simplicity, the most promising Peruvian botanicals are categorized below as both 'super fruits', and 'superfoods'. Furthermore, many of these products will find a market in the growing natural cosmetic market. The emphasis here is on super fruits/foods as this is seen as a growing area that also includes functional foods, but may more accurately indicate the use of the product in a more natural form such as a nut, rather than a beverage with an extract, a typical functional food form.

Figure 1. Case study: Culinary Collective

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 Lynnwood, WA 98087, United States
 Tel: 1-425-398-9761
 Fax: 1-425-398-9765
 URL: <http://www.culinarycollective.com>

The Culinary Collective, founded in 1998, imports finished product and bulk ingredients from both Spain and Peru and is growing at an annual rate of about 20%. Betsy Power, co-founder, is optimistic about growth in the speciality food market, as consumers become more concerned about the quality and origins of the food they eat. There is a consistent trend towards heritage, organic, fair trade and gluten-free, all of which can be found in Peruvian products. The company has approximately 125 products, the majority of which (about 100) are imported from Spain within their Matiz España division. The company has been working in Peru for only three years, yet, according to Ms Power, they are reaching a tipping point for the acceptance of Peruvian products in the market. They are also establishing consistent supply and product quality from their vendors. They currently have 18 products from Peru under their Zócalo brand, with a focus on what they call Heritage products including ajis (Peruvian peppers) such as aji amarillo, aji limo, and aji panca (<http://www.zocalogourmet.com/products/herbspices.html>) all in paste, powder and pod formats; herbs, including huacatay (black mint); flowers and grains including, kaniwa, amaranth (kiwicha), quinoa, Lima bean, mesquite (algarroba), purple corn (maize morado), and sweet potato; and beans, such as pussac punay.

The main market for Culinary Collective products is the speciality food stores such as Whole Foods Market and high-end retailers. Of the heritage products that the Culinary Collective carries, Betsy Power believes the kaniwa grain has great potential; however, the largest sellers thus far are the aji pastes, sweet potatoes, and purple corn flours.

Integral to the company's mission is their work with small-scale famers, producers with local ownership and fair-trade practices and with products that are native to their region. Consistent supply is also crucial. The company uses strict social and environmental criteria in their sourcing practices, embodied in the Rooted Foods Seal of Transparency (www.rootedfoods.org). The company has tried to work through government agencies to help source products and find famers and producers but they have had the most success by networking via their existing vendors. Two of their biggest challenges are obtaining and maintaining a consistent supply and consistent pricing. On the market side, Ms Power reports consumer education to be the biggest challenge, as they are working with so many products that are new to North American consumers.

Producers can contact Culinary Collective via e-mail: info@culinarycollective.com.

Super fruits:

Camu camu (*Myrciaria dubia*): the camu camu fruit has a high content of Vitamin C as well as flavonoids. Harmless Harvest describes the taste of its pulp as a 'tart and raw mouth feel that gives way to surprising woody green notes'. Camu camu may find a place in the North American markets as a juice, super food, functional food and dietary supplement (for its Vitamin C content, antioxidants, and anti-inflammatory properties), and potentially also in cosmetics (the seed oil or fruit pulp extract), or as a natural colour or flavour.

Cupuaçu (*Theobroma grandiflorum*) – research is incomplete on the potential healthful properties of cupuaçu. However, it is known to contain antioxidants its main interest may be for being a relative of chocolate, as it is closely related to cacao/chocolate (*Theobroma cacao*), and is a popular juice drink in certain areas of South America. Cupuaçu may find a place in the North American markets for its use as a juice, super food, functional food and dietary supplement (for its antioxidants), and perhaps also in cosmetics (the fruit pulp extract), or as a natural flavour.

Lucuma (*Pouteria lucuma*) – Lucuma may find a place in the North American markets for its use as a juice, super food (for its nutritive content, including fibre, vitamins and minerals), functional food and dietary supplement (for its antioxidants), and perhaps in cosmetics (the fruit pulp extract), or as a natural flavour. It is also being promoted as a diabetic-friendly alternative sweetener.



Camu camu fruit, source:
MANCHAMANTELES/PromPerú.



Cupuaçu, source:
<http://seekingsustenance.wordpress.com/2010/03/07/bacuri-cupuaçu>.



Lucuma, source:
MANCHAMANTELES/PromPerú.

Superfoods:

Sacha inchi (*Plukenetia volubilis*) – The primary interest for sacha inchi is for its content of omega-3 fatty acids. Sacha inchi may find a place in the North American markets for its use as a super food (as the nut), functional food and dietary supplement (for its omega-3 fatty acid content), and perhaps in cosmetics (the oil).

Maca (*Lepidium meyenii*) – Although maca has been on the United States and Canadian markets for years as a ‘sexual health enhancer’, its more long-term sustainable market lies in its use as a food. As most Peruvians know, maca can be used to make a wide variety of foods and is a very nutritional. Maca may find a place in the North American markets for its use as a super food (as a powder), functional food (in various potential forms), and will continue to have a market as a dietary supplement.

Chia (*Salvia hispanica*) – The primary interest for chia seed is for its content of omega-3 fatty acids. Chia may find a place in the North American markets for its use as a super food (as the seeds or oil), functional food and dietary supplement (for its omega-3 fatty acid content), and the oil may find a role in cosmetics.



Maca, source: MANCHAMANTELES /PromPerú.



Sacha inchi, source: MANCHAMANTELES /PromPerú.



Chia, source: <http://deborahsmall.wordpress.com/2008/07/23/gathering-thistle-chia/>.

Other prospects:

Peruvian products have a lot of potential in North American markets, as many are considered traditional foods therefore have an easier time proving safety when they enter the market.

Yacón (*Smallanthus sonchifolius*) – The yacón plant is a source of alternative sweetener ingredients that are diabetic friendly, or low-glycemic, and safely within the food category so will find a receptive market in both Canadian and the United States. Although legally they are not sold as ‘sweeteners’, as this requires rigorous food safety proof for food additives in both markets, they are often sold as natural ingredients that impart sweetness.

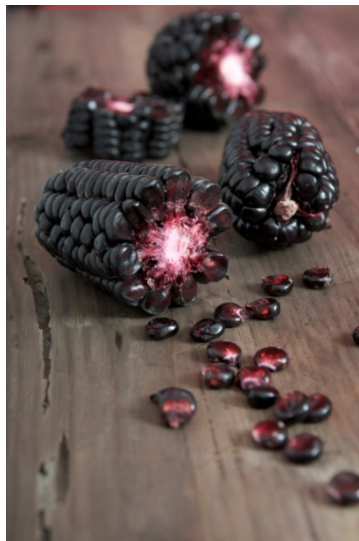
Purple corn extract (*Zea mays*) – The market for antioxidants has become much tougher in the North American markets as there is much competition among a proliferation of products. The antioxidant products expected to show the most promise will have other qualities or be relatively inexpensive for the antioxidant power they contain. Purple corn extract shows strong potential in this area not only as an extract but also as a food, food colouring and juice ingredient.

Quinoa (*Chenopodium quinoa*) and amaranth (*Amaranthus caudatus*) and canigua (*Chenopodium pallidicaule*) – ‘Ancient grains’ make very effective superfoods, and the prospect of having a food that can be a substitute for rice or pasta and contains superior nutritional benefits (such as protein and other micronutrients), will find growing receptivity in the United States and Canadian markets. Another exploding area is the gluten-free market, which has seen a 28% compound annual growth rate between 2005 and 2008, according to Packaged Facts. In 2009, ConAgra Mills announced their line of ancient grains to replace white rice, potato and corn flours which are often used in gluten-free products to improve their flavour but which have poor nutritional values. The Harvard Health Letter had drawn attention to the nutritional issues pertaining to gluten-free eating just prior to their launch, criticising manufacturers for profiting from making good-tasting but nutritionally-poor gluten-free products.

Dragon’s blood (*Croton lechleri*) – An extract of *Croton lechleri* is coming to the pharmaceutical market for use in normalizing stools. On 4 November 2010, Napo Pharmaceuticals announced Phase 3 clinical trial results for the treatment of chronic diarrhoea in people living with HIV/AIDS – a potential US\$ 300 million annual market. Once approved by FDA and other governments’ health agencies, this will represent a great opportunity for Peruvian producers.



Yacon, source: MANCHAMANTELES/PromPerú.



Purple maize, source: MANCHAMANTELES/ PromPerú.



Quinoa, source: MANCHAMANTELES/ PromPerú.



Croton lechleri, source: Fragma Fotografia /PromPerú.

1.5. African prospects for the United States and Canadian markets

There are several African botanical ingredients sold in North America that are considered GRAS or have received novel food approval in Canada. One example which has received GRAS approval from the FDA and Health Canada is baobab. Other African natural products currently available in the North American market include rooibos, honeybush and other herbal teas, as well as devil's claw, which is marketed as a dietary supplement product (food) in the United States but as a natural health product (medicine) in Canada.

In turn, there are several natural products from Africa that although commonly consumed in Africa are not currently available in the United States or Canadian markets and require regulatory approval before they can be marketed and sold. Two such examples are bambara nuts and Kalahari desert truffles.

Bambara nut (*Vigna subterranean L. Verde*) is a legume belonging to the Fabaceae family and cultivated throughout southern Africa. It is a close relative of the cowpea and, although an important crop in many rural areas, it is felt to be underutilised.⁶ The nuts are high in protein and essential fatty acids and

⁶ Lyimo, M., Berling, S. and Sibuga, K. (2004) 'Evaluation of the nutritional quality and acceptability of germinated Bambara nut (*Vigna-subterranea (L) verle*) based products', *Ecology of Food and Nutrition*, 43: 181-191.

contain relatively high quantities of lysine and methionine.⁷ In addition, it is very drought resistant and is able to grow in poor soil. In Africa, the harvested pods are consumed when unripe as well as cooked.

Kalahari Desert truffles (*Kalaharituber pfeilii* (Henn.)) occur naturally and cannot be sown or commercially propagated. Truffles are edible fungi which form symbiotic relationships with the roots of a host plant. One particular species the Kalahari Desert truffle has been associated with is the water melon, *Citrullus lanatus*, a species indigenous to the Kalahari Desert region and which itself is an important natural product.⁸ The desert truffles only ripen when there has been adequate rainfall and they can range in size from 10g to 200g.⁹ In raw form they have a creamy, marbled appearance and turn yellow after several days of air exposure. As well as being considered a delicacy, the desert truffles are also nutritious with higher fat, potassium and phosphate concentrations than many other vegetables. These truffles are not comparable in price to those sold in Europe and North America but are increasing in popularity on the local and regional market.

Bitter aloe or Cape aloe (*Aloe ferox* (Mill.)) is a leaf succulent originating in the dry regions of Africa, Asia and southern Europe. *Aloe ferox* is indigenous to South Africa whereas other species of aloe such as *Aloe vera* is naturalised in various regions and is cultivated widely in the United States of America.¹⁰ These two species have been identified as having high commercial value for cosmetic and wellness products, and are harvested for the bitter sap which has several medicinal properties. Due to high demand in the international natural products market, all species of aloe with the exception of *Aloe vera* are regulated by CITES to control international trade for conservation purposes (Grace, 2008). There is a strong history of traditional therapeutic use of aloe species both topically and orally. Uses range from treatment of digestive disorders through to wounds and burns. There is also increasing interest in the use of aloe as a functional food ingredient in health products. Although the *Aloe vera* and *Aloe ferox* have similar properties, it is reported that the sap of *Aloe ferox* is more bitter than that of *Aloe vera* and shows a higher amino acid content. *Aloe ferox* continues to be harvested in the wild, whereas *Aloe vera* is often cultivated outside its natural range.

Aloe is included in both the United States Pharmacopeia and Health Canada's Compendium of botanical monographs. The USP official monograph (<http://www.usp.org/standards/pending/>) includes several aloe species in its description including *Aloe barbadensis* (Miller), *Aloe vera* (Linne), *Aloe ferox* (Miller), *Aloe africana* (Miller) and *Aloe spicata* (Baker). An alternative name for *Aloe vera* is Curacao aloe, whereas Cape aloe refers to *Aloe ferox*. According to Health Canada's ingredient monograph, aloe latex can be consumed to promote bowel movement. Health Canada also presents a monograph for topical application to help relieve minor burns including sunburn, and to assist in the healing of minor wounds and skin irritations.

Superfoods:

Africa's wealth of plant diversity offers a large range of plant species with properties that position them alongside established superfoods such as goji berries and acai. The **baobab tree (*Adansonia digitata* L.)** is distributed across Africa and produces fruit which contains a naturally dry fruit powder. The fruit powder is consumed as a health ingredient in a range of food and beverage products and is classified as a 'superfruit' due to its impressive nutritional profile. It is exceptionally high in dietary fibres (more than 50% total dietary fibre) which play an important role in gut health. Calcium, potassium and magnesium are also found in significant volumes in the fruit, as are vitamin C and antioxidants. Baobab can be purchased in raw natural powder form as a health ingredient and it is found in formulated consumer products such as smoothies, cereal bars, jams and beverages.

⁷ Barimalaa, I. and Anoghalu, S. (1997) 'Effect of processing on certain antinutrients in Bambara groundnut (*Vigna subterranean*) cotyledons', *J Sci Food Agri*, 73: 186-188.

⁸ Trappe, J., Claridge, A., Arora, D. and Smit, W. (2008) 'Desert truffles of the Kalahari: Ecology, ethnomycology, and taxonomy', *Economic Botany*, 62(3): 521-529.

⁹ Taylor, F., Thamage, D., Baker, N., Roth-Bejerano, N. and Kagan-Zur, V. (1995) 'Notes on the Kalahari desert truffle, *Terfezia pfeilii*', *Mycology Research*, 99 (7): 874-878.

¹⁰ Rodriguez, E., Martin, J. and Romero, C. (2010) '*Aloe vera* as a functional ingredient in foods', *Critical Reviews in Food Science and Nutrition*, 50: 305-326.

Oils:

Demand for exotic oil ingredients has increased globally in recent years as consumers demand unusual products and industry incumbents look to differentiate themselves from competition. Many plant oils also have specific active and functional properties that are particularly valuable to cosmetic products that focus on natural ingredients.

African nut oils that have cosmetic application (discussed in more detail earlier in the report) include: marula, Kalahari melon seed, baobab, mongongo and mafura. Other cosmetic ingredients from Africa already traded in significant volumes include shea butter and argan oil.

The **shea tree (*Butyrospermum parkii*)** is the source of shea butter which is said to be the most widely used exotic vegetable fat, with global demand reaching €239 million in 2006. However, most demand comes from the food industry with the cosmetic market accounting for a much smaller percentage.¹¹ Generally the price of shea butter is related to the price of cocoa butter as it can be used as a cocoa butter substitute. Much shea butter comes from Ghana and Uganda.

The Global Shea Alliance works to establish industry standards for quality and sustainable sourcing, and promote shea worldwide (www.globalshea.com). It is a non-profit association whose mission is to facilitate an economically viable and environmentally and socially responsible shea nut and product businesses. The butter is extracted from the kernels as solid oil by hydraulic pressing or screw expellers. Shea butter has a high content of omega-3 and omega-9 fatty acids with excellent moisturising properties and can be found in a wide range of cosmetic and personal care products. Shea butter has many traditional uses such as protection from the sun and muscle relaxant. There are also reports of shea butter being used as a source of antioxidants and vitamin E.

Figure 2. Case study: Planet Botanicals

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Maine 04092, United States
Tel: 1-877-204-2075
Fax: 1-866-772-8249
URL: www.planetbotanicals.com

Planet Botanicals combines organic shea butter with various plant oils and butters from around the world to create natural skin-care products that contribute to the economic empowerment of those harvesters and cooperatives in the value chain.

Michele Gilfoil, founder of Planet Botanicals, launched the company after experiencing the nourishing effects of shea butter and meeting with the African women's cooperative which produced it. As described by Gilfoil, the mission of the company is to produce natural and fair trade personal care products that are made using sustainably sourced ingredients that provide nourishing properties to the skin. Planet Botanicals first began focussing on shea butter and has since expanded its 'Africa Collection' to include indigenous fruit oils, organic essential oils, and other botanical ingredients. The products are made with 99.5% to 100% natural ingredients, many with nearly 100% organic ingredients. In addition, the products and ingredients are fully traceable, non-GMO and made without harmful chemicals and preservatives.

Planet Botanicals works with a number of key ingredients sourced throughout Africa and elsewhere. Shea butter, which is the founding ingredient in several products, is sourced directly from a women's cooperative in Uganda and is certified organic. Marula oil is another key ingredient: it is expeller-pressed, certified organic, and sourced from southern Africa. Kalahari melon seed oil is processed in the same way as marula oil. Kigelia and moringa products are also sourced from Africa. Planet Botanicals aims to use natural and efficacious ingredients in products designed to, for example, hydrate dry and chapped skin as in the Hand And Body Balm range, which has Ugandan shea butter and African fruit oils.

Gilfoil highlights the importance of creating strong and collaborative relationships with harvesters and cooperatives, and sourcing directly from these groups. Along with the direct social impact, Gilfoil also recognises the significance of working with producers who have traditional knowledge of the species and who receive a fair and equitable share of benefits.

¹¹ CBI (2009) Natural ingredients for cosmetics: The EU market for exotic vegetable oils for cosmetics.

Argan oil is extracted from the nut of the **argan tree (*Argania spinosa*)** which is indigenous to Morocco in North Africa. It is estimated that the global demand for argan oil is more than 385 tonnes a year and continuing to rise. There are also reports of price increases as the number of argan oil applications increases (e.g. as a speciality food oil) and demand exceeds supply. Primarily, argan oil has been used as a cosmetic ingredient as it contains vitamin E which is beneficial for dry and ageing skin. It is found in a range of cosmetic products including shampoos, massage oils and body lotions.

It is expected that certain trends in the cosmetic sector will impact on the market for natural and exotic vegetable oils. Trends for particular product functions and active ingredients such as anti-ageing and anti-oxidants will bring increased interest in exotic oils, particularly given the trend for natural produce. Additionally, ethical sourcing and trading is becoming more important to consumers and industry. Organic and fair-trade certified products are continuously increasing in number, as are the number of certification bodies and options.

PhytoTrade Africa works to address the issues of ethical sourcing and sustainable harvesting at an environmental and social level. The case study on PhytoTrade Africa provides more information about the trade association and the natural products it helps to bring to market.

Figure 3. Case study: PhytoTrade Africa

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URL: www.phytotradeafrica.com

PhytoTrade Africa was established in 2001 as a natural products trade association in southern Africa with the goal of improving the lives of rural African people and the management of biodiversity through the commercialisation of indigenous plants in Africa. PhytoTrade Africa is a non-profit membership-based organization representing the private sector, development and environmental agencies, individuals and others in eight counties: Botswana, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia and Zimbabwe. The mission of PhytoTrade Africa is to alleviate poverty and protect biodiversity by developing a natural-products industry that is both economically sustainable as well as ethical and environmentally sustainable.

PhytoTrade Africa works on many levels spanning the supply chain from harvesting to consumer ready products. It is involved in research & development, developing functional, efficient and traceable supply chains, marketing and consumer awareness, and monitoring and evaluation. It was appointed as a Centre of Excellence for Access and Benefit Sharing by the SADC Secretariat in Botswana and was the first producer-driven organization in Africa to co-own a patent on natural product processing technology with an international technology company. A significant part of PhytoTrade's work revolves around regional and international regulations and ensuring member products comply with them and are of high quality. PhytoTrade Africa attained GRAS approval from the FDA in 2009 as well as approval from Health Canada for sale in Canada as a food ingredient supplier. In addition, through the adoption of the PhytoTrade Africa Members Charter, it ensures that the ingredients supplied are ethically produced in a sustainable manner and that producers receive a fair and equitable share of benefits.

Indigenous natural ingredients are harvested by PhytoTrade Africa members from these plants and trees: baobab, marula, Kalahari melons, devil's claw, mongongo, mafura, kigelia (sausage tree) and yellow plum (*Ximenia americana*). These have applications across several industry sectors including food, beverage, cosmetic and dietary supplements. In addition to its current range, PhytoTrade also has a pipeline of species that are under analysis.

PhytoTrade Africa has in-depth understanding of the processes required to create a sustainable and beneficial natural products market. Through experience and the backing of a strong and committed team, PhytoTrade aims to continue to create positive impacts on rural harvesters and biological diversity in southern Africa.

2. Legal definitions

2.1. Dietary supplements

In the United States, the classification of dietary supplement' covers those products that are (according to the Food and Drug Administration, FDA) taken by mouth and contain a 'dietary ingredient' intended to supplement the diet.

The dietary ingredients in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gencaps, liquids, herbal teas or powders.

They also exist in other forms (for example as a snack bar), but where this is the case, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of foods, not drugs, and requires that every supplement be labelled as a dietary supplement.

The regulatory framework for dietary supplements in the United States is the Dietary Supplement Health and Education Act of 1994 (DSHEA). In Canada, products that enter the medicinal and/or nutritional health market are required to be licensed prior to market entry by the Natural Health Products Directorate (NHPD), which is a branch of Health Canada. This makes entry into the Canadian supplement market more difficult because of the pre-marketing authorization requirement, rather than the post-market monitoring that is conducted by the FDA in the United States.

Depending on the type of natural health product (NHP), the evidence requirements for product-licence application submissions range from relatively easy to very difficult. A compendial or traditional pharmacopoeial NHP application is fairly easy, for instance, whilst a non-traditional application for a complex mixture is difficult in terms of the levels of evidence needed for submission.

Since the establishment of the NHPD in 2004, there have been approximately 33,000 applications reviewed (of the 43,000 submitted), and 48% have been withdrawn or refused. In addition, there has been a considerable backlog at the NHPD, since they began accepting applications. There are in fact tens of thousands that have been submitted and that have yet to be cleared by the directorate. This has led to a system where the NHPD issues an exemption number once an acceptable and complete application is submitted; companies are then allowed to sell once they have the exemption number (with the caveat that they may have to withdraw from the market once reviewed and the application is rejected due to insufficient evidence). Also due to the existing backlog, enforcement has been targeted mainly at high-risk products, for example those that are for children or pregnant women. Furthermore, companies with licensed NHPs may file complaints against unlicensed NHPs by following the necessary procedures outlined by the NHPD.

The following is an overview of dietary supplement product regulations and notification requirements by the United States FDA: <http://www.fda.gov/food/dietarysupplements/default.htm>
<http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm#what>.

And, an overview of natural health product (NHP) regulations and licensing requirements by Canada's NHPD: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/index-eng.php#a2>.

2.1.1. Foods and functional foods

'Functional foods' are broadly defined as foods and food components that provide a health benefit beyond basic nutrition, according to the Institute of Food Technologists. This definition is an unofficial marketing definition as there is no regulatory or official definition in the United States or Canada. Therefore, in order for 'functional foods' to be sold in either the Canadian or United States, they have to qualify as foods, which means fulfilling the safety requirements of ordinary foods.

In the United States, the primary regulatory bodies responsible for foods are the FDA and the United States Department of Agriculture (USDA). In Canada, the primary regulatory bodies for foods are the Food Directorate, the Canadian Food Inspection Agency (CFIA) and Agriculture and Agri-Food Canada (AAFC).

Ingredients can be marketed as components of either dietary supplement or food products. The different marketing approach can be explained on the labelling. Typically a nutritional facts box or a dietary supplement facts box provides the necessary information to determine if a particular product is a dietary supplement or a food item.

It is sometimes difficult to discern the difference between foods and supplements because some supplements often come in similar forms to foods, such as snack bars or beverages. Nonetheless, food products are required to bear a nutrition facts box on the information panel of the label whilst dietary supplement products are required to bear a supplement facts box on the information panel.

Furthermore, these various products may be mixed together in a natural products store or other retail outlet, further complicating the proper categorization of the products. To further confuse the distinction, there is no regulatory or legal distinction between what constitutes a food and a functional food. Therefore, there are no sanctioned or uniformed differences between the two types of products. Manufacturers label the product as a food or supplement according to their own specifications, basing their distinctions on the product form and the intended use of the product. There are, however, certain functional food products with labels that bear 'authorized health claims,' 'qualified health claims,' and/or 'nutrient content claims.'

The table below serves as a guideline to the differences between each type of product.¹²

Table 2. Key differences between dietary supplements, foods and functional foods

| | Dietary supplement | Food | Functional food |
|---------------------------------|--|--|--|
| Key labelling difference | Supplement facts box | Nutrition facts box | Nutrition facts box |
| Product forms | Typical forms are tablets, capsules, softgels, herbal teas, liquids, and powders. Also may be in bar or drink form. Not allowed to take the form of conventional food. | Conventional food forms, including: beverages, prepared meals, bars, yogurts, baked goods, etc. | Conventional food forms, including: beverages, prepared meals, bars, yogurts, baked goods, etc. |
| Claims | Structure/function claims and use requires specific FDA notification and label disclaimer. May also have a health claim or nutrient content claim. | May have certain specified health claims or nutrient content claims. Structure/function claims allowed except on USDA-regulated foods. | May have health claims or nutrient content claims. Structure/function claims allowed except on USDA-regulated foods. More likely than conventional foods to have structure/function claims |

2.1.2. Pet foods

The FDA regulates pet foods and treats, in a similar manner to other animal feeds. That is, there is no regulation by the FDA for pet foods, but they do require that the ingredients are safe and have an appropriate function in foods. Ingredients that are clearly normal food, such as meat, poultry and grains are considered safe and need no further regulation. Other ingredients – such as sources of minerals, vitamins or other nutrients, flavourings and preservatives or processing aids – may be generally recognized as safe (GRAS) for their intended use (See the FDA's Code of Federal Regulations Title 21 CFR 582 and 584) or must have approval as food additives (See 21 CFR 570, 571 and 573). The Government of Canada's enhanced animal health safeguards, implemented in July 2007, make it illegal for specified risk materials (SRMs) to be fed to any animal, including dogs and cats. Members of the pet food association of Canada (PFAC) take a strong stand in supporting this legislation and have fully complied with it by removing specified risk materials from their pet food. The labelling and advertising of pet food is regulated by the Consumer Packaging and Labelling Act and the Competition Act, both of which are administered by Industry Canada.

¹² See ITC publications *Labelling of Natural Products for the United States Market* (2011), ITC, Geneva and *Claim Statements for Natural Products in the United States Market* (2011), ITC, Geneva.

For more information on pet food regulation in the United States:

<http://www.fda.gov/animalveterinary/products/animalfoodfeeds/petfood/ucm2006475>.

Packaged Facts estimates total United States retail sales of pet supplements and nutraceutical treats at more than US\$ 1 billion in 2010, reflecting a compound annual growth rate (CAGR) of 4% during the five-year period beginning in 2006. Sales growth stalled in 2009 and 2010 as the recession took hold and held on, in a slow-down attributable almost entirely to a downturn on the equine side.

As a result, the small-animal category, including products for dogs and cats, gained ground between 2006 and 2010, increasing from 45% to 52% of the market share and surpassing equine as the larger category. In 2011 the United States retail sales of pet supplements and nutraceutical treats were expected to pick up with much faster growth in the small animal area than in equines. Nutraceutical treats will be the fastest area of product growth.¹³

2.1.3. Cosmetics and body care

In the United States, the two most important laws pertaining to cosmetics marketed in the United States are the [Federal Food, Drug, and Cosmetic Act](#) (FD&C Act) and the [Fair Packaging and Labelling Act](#) (FPLA). In Canada, Health Canada's Cosmetics Program regulates the cosmetics industry via a variety of acts and regulations.

For more on the regulation of cosmetics in the United States:

<http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074162.htm>.

For more on the regulation of cosmetics in Canada:

<http://www.hc-sc.gc.ca/cps-spc/person/cosmet/index-eng.php>.

Figure 4. Case study: Dr. Bronner's Magic Soaps

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Fax: 1-760-745-6675
E-mail: gero@drbronner.com
URL: www.drbronner.com

Dr. Bronner's Magic Soaps, founded in 1948, is the best selling brand of natural soaps in the United States.

It is a 'mission-driven' company that has at its core philosophy 'constructive capitalism', defined as 'where you share the profit with the workers and the Earth from which you made it'. In earlier years the company practised its philosophy mostly through responsibility to its staff and by spending half of its after-tax income on charities and environmental causes. In 2003, Dr. Bronner's started to take responsibility for its agricultural supply chain (for coconut, palm, olive and several essential oils). It has shifted to using organic raw materials and has become a fully-committed fair trade company, with some 95% of its agricultural raw materials now certified organic and fair trade.

To be close to its suppliers, create long-term relationships and know the origin of its raw materials, Dr. Bronner's started, or partnered in, four major farming and processing projects. The largest, the Serendipol organic and fair trade project in Sri Lanka (see http://www.drbronner.com/coconut_oil_from_sri_lanka.html) was initiated in late 2005 as a cooperation between Dr. Bronner's Magic Soaps and Sri Lankan partners. The mission of Serendipol (Pvt) Ltd. is to produce coconut oil and other coconut products that are environmentally sustainable and socially responsible along the entire value chain, as documented by third party organic and fair trade certification. Serendipol started production at its Kuliapitiya factory in June of 2007, and as of early 2011 they employed more than 160 people. As the guardian of the supply chain, Serendipol must ensure that fair prices are paid to farmers and fair wages to farm and production workers: the latter enjoy unusually good working conditions and benefits for this industry.

¹³ Packaged Facts. Pet Supplement and Nutraceutical Treats in the U.S., 3rd Edition. January 2011. www.packagedfacts.com.

The coconuts are supplied by more than 400 family-owned farms in Sri Lanka, from farms that are typically 5-10 hectares (with a few larger than 50 hectares). Supporting farmers with improving soil fertility and productivity is one of the key elements in the company's strategy. In Sri Lanka, this includes extension services and supply of compost at cost. Serendipol now exports more than 1,200 tonnes per year of virgin coconut oil to the United States and Europe, for use in cosmetics and the food industry. The price paid by its customers includes a fair trade premium of 10%, administered by a fair trade committee, on the cost of coconuts and labour. This fair trade fund has now financed a large number of projects, with an initial focus on improving local health care and education systems. In 2011 it will spend some US\$ 250,000 on community development, including several rural electrification projects. The project has been certified organic and Fair for Life Social & Fair Trade by IMO since 2007.

Dr. Bronner's also produces organic/fair trade palm oil at a small-holder project with 300 farmers in Ghana and cooperates closely with its supplier of olive oil in Occupied Palestinian Territory and peppermint oil in India. Jojoba oil collected from the wild in Mexico, and bees wax from Zambia will soon be added to its list of sustainable raw materials. The company's ultimate goal is to obtain virtually all of its raw materials from organic/FT sources and positively affect the lives of some 20,000 people in the course of doing business. According to Gero Leson, director of special operations for Dr. Bronner's: 'When we look for producing partners, we look for those that are interested in a long-term relationship in an area where our working and trading relationship can facilitate positive rural development.'

3. Product descriptions

3.1. Customs and trade statistics classification

The Harmonized Commodity Description and Coding System, generally referred to as 'Harmonized System' or simply 'HS', is a multipurpose international product nomenclature developed by the World Customs Organization (WCO). It comprises about 5,000 commodity groups, each identified by a six-digit code, arranged in a legal and logical structure and it is supported by well-defined rules to achieve uniform classification. The system is used by more than 190 countries and economies as a basis for their customs tariffs and for the collection of international trade statistics. Over 98% of the merchandise in international trade is classified in terms of the HS.¹⁴

For this market brief, the COMTRADE database, United Nations Statistics Division, was referenced for trade statistics. The database of the United States Department of Commerce and Census Bureau was also utilized. In the trade data of the United States Census Bureau, up to 10 digits are used. Most of the natural ingredients that are used in the United States cosmetics and dietary supplement industries are not commodities and do not have their own exclusive HS Code. Therefore, most are grouped within a general six-digit product code.

The United States Census Bureau's merchandise trade statistics measure goods traded between the United States and other countries. They are the official source of information about United States imports, exports and the balance of merchandise trade. As a leading economic indicator and a major component of the Gross Domestic Product (GDP), these statistics provide critical information to a wide and varied group of users in the public and private sectors. Sources for import statistics include:

- The United States Customs Service (Customs) Automated Broker Interface (ABI),
- Paper import entry summaries (Appendix A), and
- Paper or electronic applications for foreign trade zone admission.

Sources for export statistics include:

- Automated Export System (AES),
- Paper Shipper's Export Declarations (SEDs), and
- Canadian data provided by Statistics Canada.

¹⁴World Customs Organization. What is the Harmonized System (HS)? Available at: <http://www.wcoomd.org/hsharmonizedsystem.htm>.

Export declarations, either paper or electronic, are required for shipments to all countries except Canada. They are completed by exporters (United States principal parties of interest) or their duly authorized agents who in turn submit them to the exporting carrier who then has the responsibility to submit them to customs at the time of exportation.¹⁵

3.2. Expanded definitions of selected high-demand natural ingredients

American ginseng root (*Panax quinquefolius* L.) is a perennial plant, native to cool and shady hardwood forests of central, eastern, and northern North America. Harvested in the autumn, the root is separated from the rhizome and dried at low temperature. According to the Pharmacopoeia of the People's Republic of China (PPRC 2005), the dried root must contain not less than 2.0% of the total amount of ginsenosides Rg₁, Re and Rb₁,¹⁶ and according to the United States Pharmacopoeia, not less than 4.0% of total ginsenosides (Rg₁, Re, Rb₁, Rc, Rb₂, and Rd).¹⁷ The supply is produced mainly in Canada (Ontario & British Columbia), followed by the United States (Wisconsin) and also China. It is used mainly as a dietary supplement in the form of herbal teas, chewing chips, fluid extracts, and powdered root or extract in capsules or tablets. Ginseng oil and extracts are used in a range of cosmetic products including bath oils, facial cleansers, hair care products (conditioners and shampoos), moisturizing creams, perfumes, skin lotions, soaps, and sunscreens.

Asian ginseng root (*Panax ginseng* C.A. MEYER) is a perennial plant, native to the montane forests of central eastern Asia. Cultivated mainly in China, the Republic of Korea, and Japan, the supply is imported mainly from China and the Republic of Korea. According to the United States Pharmacopoeia, the dried roots must contain not less than 0.2% of ginsenoside Rg₁ and not less than 0.1% of ginsenoside Rb₁.¹⁸ Its uses as a component of dietary supplements and cosmetics products are comparable to those of American ginseng root (see above).

Cat's claw bark (*Uncaria tomentosa* (WILLD.) DC), also known by its Peruvian names uña de gato and garabato amarillo¹⁹ and by its indigenous Asháninka name savéntaro,²⁰ is a woody vine native to Peru and other tropical areas of Central and South America. The plant is usually cut at the base and the vine is pulled down from the canopy to harvest the stem bark.²¹ According to the United States Pharmacopoeia, cat's claw consists of the inner bark of the stems of *Uncaria tomentosa* that contain not less than 0.3 percent of pentacyclic oxindole alkaloids as the sum of speciophylline, uncarine F, mitraphylline, isomitraphylline, pteropodine, and isopteropodine.²² Extracts of cat's claw bark are used mainly as dietary supplements for supporting or improving immune system functions, as well as in medicinal products for arthritic conditions, and to a lesser extent in liquid preparations for topical application, sometimes in combination with other Andean botanicals such as dragon's blood croton (*Croton lechleri* MÜLL. ARG.).

Cayenne fruit (*Capsicum annuum* L. var. *minimum* (MILLER) HEISER and small fruited varieties of *Capsicum frutescens* L., also known as capsicum, chilies, chili pepper, and paprika), is an annual (perennial in the tropics), native to tropical South America, now cultivated in tropical zones worldwide.²³ According to the European Pharmacopoeia, the dried ripe fruits must contain minimum 0.4% of total

¹⁵ Foreign Trade Division, Bureau of the Census. U.S. Merchandise Trade Statistics: A Quality Profile. Washington, DC: Methods Research & Quality Assurance Branch, Foreign Trade Division, Bureau of the Census. December 19, 2002.

¹⁶ Chinese Pharmacopoeia Commission. Radix Panacis Quinquefolii (Xiyangshen). In: *Pharmacopoeia of the People's Republic of China*, English Edition 2005. Beijing, China: People's Medical House. 2005.

¹⁷ United States Pharmacopoeial Convention. American Ginseng. In: *United States Pharmacopoeia 34th Revision—National Formulary 29th Edition* (USP 34-NF 29). Rockville, MD: United States Pharmacopoeial Convention, Inc., 2011.

¹⁸ United States Pharmacopoeial Convention. Asian Ginseng. In: *United States Pharmacopoeia 34th Revision—National Formulary 29th Edition* (USP 34-NF 29). Rockville, MD: United States Pharmacopoeial Convention, Inc... 2011.

¹⁹ Gupta MP (ed). 270 Plantas Medicinales Iberoamericanas. Bogotá, Columbia: CYTED-SECAB 1995;486–487.

²⁰ Reinhard KH. *Uncaria tomentosa* (Willd.) D.C.: cat's claw, uña de gato, or savéntaro. *J Alt Comp Med*. 1999;5(2):143–151.

²¹ United States Fish and Wildlife Service (USFWS). Cat's claw (*Uncaria tomentosa* and *U. guianensis*)—Proposal for Inclusion in Appendix II. *Federal Register*. April 18, 2002;67(75):19224–19225.

²² United States Pharmacopoeial Convention. Cat's Claw. In: *United States Pharmacopoeia 34th Revision—National Formulary 29th Edition* (USP 34-NF 29). Rockville, MD: United States Pharmacopoeial Convention, Inc. 2001.

²³ Wichtl M (ed.), Brinckmann J and Lindenmaier M (translators & editors). *Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis* (English 3rd Edition). Stuttgart, Germany: Medpharm Scientific Publishers. 2004.

capsaicinoids.²⁴ The supply is cultivated in the southwestern United States, and is also imported from Mexico, China, India and tropical African countries. Capsicum oleoresin and purified capsaicin are both used as components of analgesic creams and lotions. Capsicum extracts are used as components of cosmetics including dry hair care, dry skin care, insect repellent, sun care, and varicose vein products. The powdered fruit (in capsules or tablets), oleoresin, and tincture forms are used in dietary supplement products.²⁵

Ginger rhizome (*Zingiber officinale* ROSCOE) is a perennial, cultivated plant, native to tropical southeastern Asia (no longer found in the wild). The main suppliers are India, China, Nigeria, Indonesia, and Tanzania but some of the supply also comes from the United States (Hawaii), Costa Rica, Dominican Republic, Peru and Jamaica. According to the United States Pharmacopeia, the dried rhizome (scraped or unscraped) must contain no more than 0.18% shogaols and not less than 0.8% gingerols and gingerdiones. Ginger tincture must contain no more than 0.034% 6-shogaol and not less than 0.10% of gingerols.²⁶ Ginger is widely used in dietary supplement products (United States) and natural health products (Canada) in the form of juice (in syrup base), herbal tea, oleoresin, and powdered rhizome or extract (in capsules or tablets), for promoting healthy digestion, preventing morning sickness and motion sickness, and for joint health (arthritic conditions). Ginger is also used as a secondary component in a wide range of categories including laxatives and liver tonics. Ginger essential oil and ginger aqueous infusions are used as components of cosmetics including creams, detergents, lotions, perfumes and soaps.

Green tea leaf (*Camellia sinensis* (L.) O. KUNTZE), a cultivated shrub, is considered native to China. The supply is imported mainly from China, India, Japan and other tropical or subtropical regions.²⁷ Green tea leaf is widely used in dietary supplement products (e.g. herbal teas, dry extracts in tablets or capsules) and as a component of cosmetics including deodorant sticks, eye gels, facial masks, facial moisturizers, hand and body lotions, shampoos, conditioners and hair rinses, soaps, sunscreens, and toothpastes.

Liquorice root (*Glycyrrhiza glabra* L. *G. inflata* BATALIN, and *G. uralensis* FISCHER ex DC) is a perennial mainly collected in the wild and cultivated to a minor extent. The world supply is produced mainly in Asian countries including China, Afghanistan, Azerbaijan, Iran, Pakistan, Syria, Turkey, Turkmenistan, Kazakhstan, and Uzbekistan, as well as small amounts from European countries (e.g. Italy). According to the United States Pharmacopeia, dried liquorice (roots, rhizomes, and stolons) must contain not less than 2.5% of glycyrrhizic acid (according to European Pharmacopeia, not less than 4.0%). Powdered liquorice extract must contain not less than 6.0% of glycyrrhizic acid, and liquorice fluid extract has no minimum requirement.²⁸ Liquorice is widely used in dietary supplement and natural health products, particularly as a component of tonic formulas (liver, stomach), digestive-aids, laxatives, and especially upper respiratory tract, cough and sore-throat formulas. It is used in the form of teas, tinctures, fluid extracts, and powdered root or dry extract in capsules or tablets. Liquorice extract is also used as a component of cosmetics including bath mixtures, douches, hand creams, hair care products (shampoo and conditioner), skin creams and gels, lotions, moisturizers, ointments, and skin-lightening creams.

Linseed (Flaxseed) oil is obtained by cold expression from ripe seeds of *Linum usitatissimum* L.²⁹ Canada is the world's leading producer of flaxseed accounting for 80% of world production. Other major producers include China, the United States and India.³⁰ Flaxseed oil is widely used in dietary supplement

²⁴ European Pharmacopoeia Commission. Capsicum (Capsici fructus). In: *European Pharmacopoeia 7.0*. Strasbourg, France: European Directorate for the Quality of Medicines. 2011.

²⁵ Blumenthal M, Brinckmann J, Dinda K, Goldberg A, Wollschlaeger B. *The ABC Clinical Guide to Herbs*. Austin, TX: American Botanical Council. 2003.

²⁶ United States Pharmacopoeial Convention. Ginger; Powdered Ginger; Ginger Tincture. In: *United States Pharmacopeia 34th Revision—National Formulary 29th Edition (USP 34-NF 29)*. Rockville, MD: United States Pharmacopoeial Convention, Inc., 2011.

²⁷ Wichtl M (ed.), Brinckmann J and Lindenmaier M (translators & editors). *Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis (English 3rd Edition)*. Stuttgart, Germany: Medpharm Scientific Publishers. 2004.

²⁸ United States Pharmacopoeial Convention. Licorice, Powdered Licorice, Powdered Licorice Extract, Licorice Fluidextract. In: *United States Pharmacopeia 34th Revision—National Formulary 29th Edition*. Rockville, MD: United States Pharmacopoeial Convention, Inc., 2011.

²⁹ European Pharmacopoeia Commission. Linseed Oil, Virgin (Lini oleum virginale). In: *European Pharmacopoeia 7.0*. Strasbourg, France: European Directorate for the Quality of Medicines. 2011.

³⁰ Agriculture and Agri-Food Canada. Flaxseed. *Agriculture and Agri-Food Canada Bi-weekly Bulletin*. August 30, 2002; Volume 15, Number 17.

products as a source of essential fatty acids (EFAs). Flaxseed extracts and/or oil are also used as components of cosmetics including body milks, facial creams, moisturizing and emollient hand creams, softening massage oils. It can be used in almost any cosmetic product as an active principal or as a carrier in the oily phase. Flaxseed powder is also used in supplements as well as food products.

Maca root (*Lepidium meyenii* WALP), is a herbaceous, perennial, cultivated crop, found only on the Andean central sierra of Peru (in Junín and Pasco), in the puna agro-ecological zone at approximately 4,000m altitude.³¹ Powdered maca root, maca root dry extract (in capsules or tablets), maca fluid extracts, and roasted maca (powder or granules for making coffee- or tea-like drinks) are marketed as herbal dietary supplements, mainly for enhancing fertility or treating sexual dysfunction. However, maca is a food that has been consumed by Peruvians since ancient times, and its use as a food is also re-emerging in Peru, as well as spreading to the North American market.

Maté leaf (*Ilex paraguariensis* ST.- HIL.), also known as Paraguay tea or yerba maté, is an evergreen tree or shrub, cultivated between latitudes 30° and 20° in the southern hemisphere. The supply is imported from Brazil, Argentina, Paraguay,³² Uruguay, Antigua and Barbuda, and Peru. Maté leaf contains 0.3–2.4% caffeine, according to the *German Drug Codex* (DAC): not less than 0.6% (green maté) and 0.4% (roasted maté).³³ Maté is mainly used in herbal dietary supplement products for fatigue, but also as a diuretic component of weight-loss programmes, in herbal tea, as a fluid extract or in tincture forms. Maté extract is also used as a component of cosmetic skin care preparations.

Neem leaf / seed oil (*Azadirachta indica* J. JUSS.), is considered to be native to Burma and northeast India, and is now cultivated in many semi-arid and sub-humid areas of Asia, Africa, Australia, South America, and the southern United States.³⁴ The dried leaf or extract are used as components of herbal dietary supplements taken orally (in capsules, tablets, and teas) to improve skin conditions (e.g. acne, haemorrhoids, psoriasis) and for lowering blood sugar levels (glycemic control). Neem seed oil is used as a component of cosmetics applied topically for acne, athlete's foot, candida, dandruff, eczema, fungus, head lice, herpes, psoriasis, etc., and as a component of hand and body lotions, face creams, oral hygiene products (mouth freshener, mouthwash, toothpaste), and soaps.

Psyllium husk is the cleaned, dried seed coat, separated by winnowing and thrashing, from the seeds of *Plantago ovata* FORSKAL, *Plantago psyllium* L., or from *Plantago indica* L.³⁵ Psyllium is widely used as a dietary fibre supplement, as an over-the counter (OTC) bulk-forming laxative, and as a supplement taken to reduce the risk of coronary heart disease as part of a diet low in saturated fat and cholesterol.

3.3. Expanded definitions of selected high-demand natural ingredients from Africa

3.3.1. Herbal teas from Africa

Herbal teas are infusions made from roots, flowers, leaves, seeds or twigs of plants. They are increasingly recognized as health drinks with beneficial properties with studies showing that tea is linked to a reduced risk of several cancers and the development of cardiovascular diseases.³⁶

Some herbal teas from South Africa have made the transition from limited local use to commercial product and export, and many other herbal teas have the potential to follow suit.³⁷ Rooibos and honeybush are two

³¹ Hernández B, León. Maca. In: *Neglected Crops: 1492 from a different perspective*. Rome: Food and Agriculture Organization (FAO) of the United Nations (UN). 1994.

³² Wichtl M (ed.), Brinckmann J and Lindenmaier M (translators & editors). *Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis* (English 3rd Edition). Stuttgart, Germany: Medpharm Scientific Publishers. 2004.

³³ Bundesvereinigung Deutscher Apothekerverbände (ABDA). *Geröstete Mateblätter; Grüner Mateblätter*. In: *Deutscher Arzneimittel-Codex (DAC) Ergänzungsbuch zum Arzneibuch, Band II*. Stuttgart: Deutscher Apotheker Verlag. 2004.

³⁴ Schmidt L, Jøker D. *Azadirachta indica* A. JUSS. Danida Forest Seed Centre Seed Leaflet. September 2000;No. 12.

³⁵ United States Pharmacopeial Convention. *Psyllium Husk*. In: *United States Pharmacopeia 34th Revision—National Formulary 29th Edition*. Rockville, MD: United States Pharmacopeial Convention, Inc., 2011.

³⁶ Shikanga, E., Combrinck, S. and Regnier, T. (2010) South African *Lippia* herbal infusions: Total phenolic content, antioxidant and antibacterial activities. *South African Journal of Botany* 76:567-571.

³⁷ Joubert, E., Gelderblom, W., Louw, A and de Beer, D. (2008) South African herbal teas: *Aspalathus linearis*, *Cyclopia* spp. and *Athrixia phylicoides* – A review. *Journal of Ethnopharmacology* 119: 376-412.

herbal teas from South Africa that are currently in high demand and exported in significant quantities. An emerging key trend in the tea sector is to be natural, with the more beneficial, novel and unusual ingredients attracting most consumer attention. Trends for traceable, organic and fair trade ingredients are also becoming more prominent and Africa offers a lot of exotic herbal and botanical ingredients for the United States market that possess these qualities.³⁸

Rooibos (*Aspalathus linearis* N.L. BURM) is a flowering shrub belonging to the Fabaceae family and is indigenous to the mountains of South Africa's northern and Western Cape.³⁹ It is a polymorphic species and various wild forms exist with characteristic morphology and distribution. Rooibos is commonly consumed as a tea with rising international demand, partly attributed to its health properties.⁴⁰ It has no caffeine, little tannin, and high levels of polyphenol antioxidants. Today, rooibos is mainly cultivated on large farms and it is estimated that small-scale farmers produce around 2% of the total output. The demand for rooibos tea by the international market has increased to such a level that it now exceeds local market demand.⁴¹ Cultivation practices have evolved significantly but many of the processing techniques continue to follow traditional methods.



Rooibos, source: <http://www.food-info.net/uk/qa/qa-fp118.htm>.

It is the needle-like leaves that are harvested, fermented, dried and sold as rooibos tea. Recently, the South African Rooibos Council lobbied for and acquired UTZ certification standards for rooibos to ensure sustainability in the growing and sourcing of rooibos. The plant is harvested in the summer, 18 months after planting, and taken to processing plants where the leaves are bruised between rollers to activate the fermentation required to enhance the flavour of the tea. It is during fermentation that the leaves turn red and develop the typical aroma. The tea is then sterilised with steam and dried.

Non-fermented tea is also available and is known as green rooibos, where more antioxidants are preserved. Studies have found that the anti-mutagenic activity of rooibos is comparable to that of extracts from *Camellia sinensis*, traditional tea, and highlights the beneficial health effects. Although rooibos is primarily used as an ingredient in tea, it is also seen in a wider range of products including other beverages and cosmetic products. Use in the cosmetic industry can be attributed to its high antioxidative capacity. There is continued research into the effects of rooibos tea on several conditions including stress and cancer.

Hibiscus (*Hibiscus sabdariffa* LINNE) belongs to the Malvaceae family and is commonly known in some parts of the world as roselle, red sorrel or karkadé. It is widely grown in Africa, as well as Southeast Asia and some tropical countries of America.⁴² *Hibiscus sabdariffa* is an erect annual herb with thick, red, fleshy flower calyces which are used to prepare hot and cold beverages and are reported to have several health benefits. The flowers contain anthocyanins, flavonoids, and polyphenols and the tea is consumed to provide antioxidative protective effects against hypertension, inflammatory diseases



Hibiscus, source: <http://www.naturephoto-cz.com/hibiscus:hibiscus-photo-3858.html>.

³⁸ May, J. (August 2010) Emerging Ingredient Trends in Foods and Drinks: Growth opportunities in flavours and formulation by product category. *Business Insights: Ingredients*.

³⁹ Erickson, L. (2003) Rooibos Tea: Research into Antioxidant and Ant mutagenic Properties. *HerbalGram* (59):34-45.

⁴⁰ Gerz, A. and Bienabe, E. (2006) Rooibos tea, South Africa: The challenge of an export boom. *Royal Tropical Institute, Origin-based Products: Lessons for pro-poor market development*: 53-63.

⁴¹ Van der Merwe, J., Joubert, E., Richards, E., Manley, M., Snijman, P., Marnewick, J. and Gelderblom, W. (2006) A comparative study on the antimutagenic properties of aqueous extracts of *Aspalathus linearis* (rooibos), different *Cyclopia* spp. (honeybush) and *Camellia sinensis* teas. *Mutation Research* 611: 42-53.

⁴² Sayago-Ayerdi, S., Arranz, S., Serrano, J. and Goni, I. (2007) Dietary fibre content and associated antioxidant compounds in Roselle Flower (*Hibiscus sabdariffa* L.) beverages. *Department of Nutrition, Faculty of Pharmacy, Universidad Complutense de Madrid*.

and cancer.⁴³ Several other folk medicine uses are reported including treatment for high blood pressure, liver disease and fever.⁴⁴ Hibiscus is cultivated in African countries such as Egypt and Sudan. However, it is reported that southern regions of Africa are more suitable for its cultivation.⁴⁵

In addition, *Hibiscus sabdariffa* is regarded as the predominant commercially available anthocyanins food colorant source, making it popular as a natural food colouring agent. After harvesting, once the flower has dropped, the red calyces are dried, usually in May. Across the world, different harvesting methods are used: either the entire plant is cut or only ripe calyces are removed. Generally harvesting takes place every 10 days until the end of the growing season which is from December through to January. On average, the drying ratio is 10:1. The United States and Germany are said to be major importers of hibiscus, where the dried calyx is used as the base for many herbal teas.⁴⁶ Hibiscus is listed as one of the top 10 fastest growing ingredients in hot drinks in 2008-2009, seeing a 1.97% increase in use during 2009.⁴⁷



Lemon grass, source:

http://www.agroviet.gov.vn/en/Pages/news_detail.aspx?NewsId=405&Page=1.

Lemon grass (*Cymbopogon citratus* DC.) belongs to the Gramineae family and is a tall, coarse grass with a strong lemon flavour.⁴⁸ Lemon grass is widely cultivated in the tropics and subtropics and *Cymbopogon citratus* is cultivated in Uganda, Zambia and in small quantities in South Africa despite the fact it is native to southern India, Ceylon, Indonesia and Malaysia.⁴⁹ Ideal climatic conditions for lemon grass cultivation are in frost-free areas and at an optimum altitude of 750m above sea level. Lemon grass is used in cooking, medicinal teas and cuisines in Africa, the Middle East and Southeast Asia. The leaves are consumed as a tea to treat fevers and stomach ailments⁵⁰ and when dried, lemon grass can be marketed as a health tea or blended with other herbal teas. An essential oil is also extracted from fresh stalks and leaves by steam distillation. This is listed by the FDA as a food additive which has received GRAS approval.

Lemon verbena

(*Aloysia triphylla* (L'Herit) Britton), native to South American countries (Uruguay, Paraguay, Argentina, Chile and Brazil), is a deciduous perennial shrub that can reach up to 5 meters. It is widely cultivated in South America but has also been introduced to Africa where it is now also farmed in South Africa, Morocco and Algeria. It is a member of the Verbenaceae family and grows naturally as well as being cultivated. The leaves and flowering tops are used to make an infusion that is consumed as an herbal tea with aromatic, digestive, and antispasmodic properties, and it has been used traditionally to treat colds, fever and spasms.⁵¹ Antioxidant activity has been recorded in the leaves and has been



Lemon verbena, source: <http://www.highlandgardens.co.uk/lemon-verbena-583-p.asp>.

⁴³ Lin, T-L., Lin, H-H., Chen, C., Lin, M., Chou, M. and Wang, C. (2007) *Hibiscus sabdariffa* extract reduces serum cholesterol in men and women. *Nutrition Research* 27:140-145.

⁴⁴ Ali, B., Al Wabel, N. and Blunden, G. (2005) Phytochemical, pharmacological and toxicological aspects of *Hibiscus sabdariffa* L.: A review. *Phytotherapy Research* 19: 369-375.

⁴⁵ Aziz, E. and Badran, N. (2007) Effect of cobalt and nickel on plant growth, yield and flavanoids content of *Hibiscus sabdariffa* L. *Australian Journal of Basic and Applied Sciences* 1 (2): 73-78.

⁴⁶ ASNAPP, <http://www.herbs.org/africa/hibiscus.html>. Accessed 5 May 2011.

⁴⁷ May, J. (August 2010) Emerging Ingredient Trends in Foods and Drinks: Growth opportunities in flavours and formulation by product category. *Business Insights: Ingredients*.

⁴⁸ Ojo, O., Kabutu, F., Bello, M. and Babayo (2006) Inhibition of paracetamol-induced oxidative stress in rats by extracts of lemongrass (*Cymbopogon citratus*) and green tea (*Camellia sinensis*) in rats. *African Journal of Biotechnology* 5(12).

⁴⁹ AFF (Dept. of Agriculture, Forestry and Fisheries) (2009) Essential oil crops: Production guidelines for lemongrass. *Directorate Plant Production, Republic of South Africa*.

⁵⁰ Ojo, O., Kabutu, F., Bello, M. and Babayo (2006) Inhibition of paracetamol-induced oxidative stress in rats by extracts of lemongrass (*Cymbopogon citratus*) and green tea (*Camellia sinensis*) in rats. *African Journal of Biotechnology* 5(12).

⁵¹ Carnat, A., Carnat, AP., Fraise, D. and Lamaison, J. (1999) The aromatic and polyphenolic composition of lemon verbena tea. *Fitoterapia* 70: 44-49.

linked with flavonoids and phenolic compounds.⁵² Iridoid glycosides and potassium have also been identified in the infusion.

The essential oil of lemon verbena has associated pharmacological properties and the quantity of citral in the infusion is said to be linked to the aromatic character of the lemon verbena tisane and the implied digestive impact. Due to the essential oil composition and the lemon flavour, it is often used as an ingredient in jams, sorbets and drinks. Lemon verbena infusion has a comparable antioxidant capacity to other commercial drinks such as green tea and pomegranate.⁵³ One study estimates that the cost of manufacturing lemon verbena extract by supercritical fluid extraction is US\$ 26.96/kg and that through this process the optimum amount of active constituents is retained in the extract. According to the British Pharmacopeia (2011) lemon verbena leaf has a minimum acteoside content of 2.5%, expressed as ferulic acid as the drug dries. After grinding it has a characteristic odour reminiscent of lemon. Lemon verbena is listed in the FDA's list of food additives as a substance used in conjunction with flavours and as an additive for which a petition has been filed and a regulation issued.

Makoni (*Fadogia aencylantha* SCHWEINF.) is a herb from the Rubiaceae family, growing predominantly in the open woodland and grasslands of the Eastern Highlands of Zimbabwe as well as Mozambique. Makoni is a low growing woody perennial plant and is dormant between July and October until the rains arrive. Leaves are harvested between April and July when they turn yellow and are then fermented and dried.



Once the leaves have dried, the tea is ready for consumption. Makoni tea is harvested from the wild and is mainly processed by local producers. However, commercial cultivation of Makoni tea is possible and would increase yields significantly. It is consumed as a tea in Zimbabwe and is associated with several health benefits as it is caffeine free and has a high content of zinc. Among several traditional and medicinal uses, Makoni tea is said to boost the immune system and is taken as a treatment for stomach ailments. It has also been used to stimulate appetite and for muscle toning.⁵⁴

Makoni, source: http://www.zimbabweflora.co.zw/speciesdata/species.php?species_id=156110.

Fever tea/lemon bush (*Lippia javanica* BURM.F. SPRENG) is a highly aromatic woody shrub that belongs to the Verbenaceae family and can reach a height of 5 metres. There are five indigenous species of *Lippia* in South Africa⁵⁵ and *Lippia javanica* is distributed in Zimbabwe, South Africa, east Africa and Ethiopia.⁵⁶ The Verbenaceae family includes many plants that are known for their anti-tumour, anti-inflammatory and antioxidant properties.⁵⁷ Although there are five *Lippia* species indigenous to southern Africa, *Lippia javanica* and *Lippia scaberrima* infusions are used for medicinal purpose and sold



Fever tea/lemon bush, source: <http://www.plantzafrica.com/plantklm/lippiajavan.htm>

⁵² Pereira, C., Meireles, M. (2006) Evaluation of global yield, composition, antioxidant activity and cost of manufacturing of extracts from Lemon Verbena (*Aloysia triphylla* (L'Herit.) Britton) and mango (*Mangifera indica* L.) leaves. *Journal of Food Processing Engineering* 30: 150-173.

⁵³ Abderrahim, F., Estrella, S., Susin, C., Arribas, S., Gonzalez, M. and Condezo-Hoyos, L. (2011) The antioxidant activity and thermal stability of Lemon Verbena (*Aloysia triphylla*) infusion. *Journal of Medicinal Food* 14 (5): 517-527.

⁵⁴ Global Facilitation Unit for Underutilised Species. Makoni (*Fadogia aencylantha*).

⁵⁵ Mokoka, N. N. (2005) Indigenous knowledge of Fever Tea (*Lippia javanica*) and effect of shade netting on plant growth, yield and compound composition. M. Inst. Agrar. Agronomy, University of Pretoria.

⁵⁶ Lukwa, N. et al (2009) *Lippia javanica* (Burm F) Spreng: its general constituents and bioactivity on mosquitoes. *Tropical Biomedicine* 26(1): 85-91.

⁵⁷ Hanson, A. (2009) Bioactivity and microbial content of *Lippia multiflora* leaves, a herbal tea from Ghana. *MSc in Food Science: Stellenbosch University*.

as natural caffeine-free teas.⁵⁸ It is known locally as 'fever tea' and is claimed to have fever- and pain-relieving properties.⁵⁹ Studies have been conducted to assess the propagation potential of *Lippia* and it has been concluded that plants can be relatively easily introduced and existing wild populations can be managed to provide a reliable supply. During commercial processing, whole shoots are often harvested by stripping the leaves which allows the coppice shoot to sprout. The leaves of *Lippia javanica* contain stearic, palmitic, myristic, oleic, arachidic, behenic and lignoceric acids.⁶⁰ The plant has several medicinal uses in Africa including treatment of fever and influenza.

Large quantities of antioxidant compounds have been reported in the aerial parts of *Lippia* species and the consumption of *Lippia* infusions as a health herbal tea has been validated by the antioxidant and antibacterial activities. However, it should be noted that different species have different levels of activity, with *L. javanica* having the highest antioxidant activity levels.



Honeybush. source:
<http://organicjar.com/2009/1156/>.

Honeybush (*Cyclopia intermedia*) is indigenous to South Africa and belongs to the Fabaceae family. It is a short, woody leguminous shrub grown on mountain slopes between the eastern and western Cape regions of South Africa. The leaves and stems are used to prepare honeybush tea.

Although honeybush is now cultivated, in the early 1980s it was mainly collected from wild populations to satisfy local demand. However, with growing interest from Japan and Germany in particular, larger quantities of a higher quality were required which led to commercial cultivation.⁶¹ After harvesting, the plant is cut and fermented at higher temperatures in an oven or in a curing heap, and then left to dry. During this process the plant material changes colour from green to brown due to oxidization of the phenolic compounds.⁶² Both the leaves and the

stems are used to manufacture the tea. An alternative to the fermentation heap method is a baking oven where the product is first immersed in water and then fermented at temperatures greater than 60 degrees Celsius. This method prevents moulds and results in a high quality product. The tea is used for its restorative properties: soothing coughs and alleviating bronchial complaints including pneumonias and tuberculosis).⁶³ Some studies have indicated antioxidative properties, chemo preventative potential and immune enhancing effects.

The **resurrection plant** (*Myrothamnus flabellifolia*) belongs to the Myrothamnaceae family and is a woody shrub. The shrub reaches between 0.5m and 1.5m tall and is found growing in mountainous and rocky regions throughout southern Africa.⁶⁴ Populations are also found in coastal regions of Namibia as well as in South Africa, Botswana, Zimbabwe and other east African areas.

⁵⁸ Shikanga, E., Combrinck, S. and Regnier, T. (2010) South African *Lippia* herbal infusions: Total phenolic content, antioxidant and antibacterial activities. *South African Journal of Botany* 76:567-571.

⁵⁹ Olivier, D., Shikanga, E., Combrinck, S., Krause, R., Regnier, T. and Dlamini, T. (2010) Phenylethanoid glycosides from *Lippia javanica*. *South African Journal of Botany* 76: 58-63.

⁶⁰ Mokoka, N. N. (2005) Indigenous knowledge of Fever Tea (*Lippia javanica*) and effect of shade netting on plant growth, yield and compound composition. M. Inst. Agrar. Agronomy, University of Pretoria.

⁶¹ Du Toit, J. and Joubert, E. (1998) The effect of pretreatment on the fermentation of Honeybush tea (*Cyclopia maculate*) *Journal of the Science of Food and Agriculture* 76: 537-545.

⁶² McKay, D. and Blumberg, B. (2007) A review of the bioactivity of South African herbal teas: Rooibos (*Aspalathus linearis*) and Honeybush (*Cyclopia intermedia*). *Phytotherapy Research* 21: 1-16.

⁶³ Kamara *et al.*, 2003

⁶⁴ Moore, J., Lindsey, G., Farrant, J. and Brandt, W. (2007) An overview of the biology of the desiccation-tolerant resurrection plant *Myrothamnus flabellifolia*. *Annals of Botany* 99: 211-217.



Myrothamnus flabellifolia, source: http://www.myro.ch/en/info_auf_pflanze.html.

The plant has a strong powers of revival after complete desiccation hence the reference to resurrection. The resurrection ability is often seen as a symbol of hope in African tradition and the plant is widely used in South African traditional medicine and teas with decoctions reportedly used for cough, influenza, kidney disorders and haemorrhoids.⁶⁵ Herbal tea made from the leaves is called resurrection tea and there are reports of high tannin (polyphenol) concentrations. Mastication of the leaves is used to treat skin irritations and mucosal irritations by topical application. *Myrothamnus flabellifolia* contains high concentrations of polyphenols and it is suggested that these are responsible for some of the observed medicinal effects.

3.3.2. Medicinal herbal products (dietary supplement) from Africa

Devil's claw (*Harpagophytum procumbens* DC.) belongs to the Pedaliaceae family and is indigenous to the deep sandy soils of the Kalahari Desert in southern Africa, with supplies coming from Namibia, South Africa and Botswana. It is a perennial herb with a succulent taproot and creeping stems which grow from a primary tuber.⁶⁶ Secondary tubers are also present and are harvested as they contain harpagoside, an iridoid glycoside, which has shown to be effective in the treatment of conditions such as osteoarthritis, kidney inflammation and tendonitis.⁶⁷ Devil's claw is predominantly used as a medicinal product for reducing inflammation, particularly associated with osteoarthritis⁶⁸ and joint and lower back pain. It is also used to treat loss of appetite and digestive complaints and can be found in several personal care and cosmetic products.⁶⁹ During harvesting, which is primarily wild harvesting, the primary tuber is left intact in the soil and only the secondary tubers are removed. After harvesting, any holes dug in the soil must re-filled and the mother tuber left undisturbed. In 2009 Namibia exported approximately 10,000kg of devil's claw to the United States.

According to Health Canada's Natural Health Product Monograph, varying doses are recommended for different uses: 0.6-1.5g dried secondary tubers per day is recommended for the stimulation of appetite; 0.6-4.5g for the relief of digestive disturbances; and 0.6-7.5g for the relief of joint pain associated with osteoarthritis.

According to the British Pharmacopeia (2011) devil's claw root contains a minimum of 1.2% of harpagoside as a dried drug. The devil's claw dry extract is produced from the herbal drug using either water or a hydroalcoholic solvent and has a minimum of 1.5% of harpagoside as a dried extract. Devil's claw is not currently consumed as a food ingredient and is not GRAS approved. It is marketed as a dietary supplement product (food) in the United States but as a natural health product (medicine) in Canada. Health Canada includes devil's claw as a medicinal ingredient in the monograph for multiple-ingredient joint-health products. Here a minimum daily dose of 600mg is recommended and a minimum of 2-3 months' use is suggested to see the beneficial effects.

⁶⁵ Anke, J., Petereit, F., Englehardt, C. and Hensel, A. (2008) Procyanidins from *Myrothamnus flabellifolia*. *Natural Product Research* 22(14): 1237-1248.

⁶⁶ Baghdikian, B., M. C. Lanhers, et al. (1997). An analytical study, anti-inflammatory and analgesic effects of *Harpagophytum procumbens* and *Harpagophytum zeyheri*. *Planta Medica* 63: 171-176.

⁶⁷ Wegener, T. (2000). Devil's Claw: From African traditional remedy to modern analgesic and anti-inflammatory. *Herbalgram (The Journal of the American Botanical Council and the Herb Research Foundation)* 50.

⁶⁸ Under U.S. regulations dietary supplements are foods and not medicines. Thus dietary supplements cannot legally be labeled or marketed for reducing inflammation or treating osteoarthritis. That would make the product a drug. In Canada however, where natural health products (NHPs) are medicinal products, these disease treatment claims would be legal. Just not for 'dietary supplement products.'

⁶⁹ Vlachojannis, J., Roufogalis, B.D., Chrubasik, S., (2008). Systematic review on the safety of *Harpagophytum* preparations for osteoarthritic and low back pain. *Phytotherapy Research* 22: 149-152.

3.3.3. Cosmetic oils from Africa

Marula (*Sclerocarya birrea* A. rich.) is indigenous to southern Africa and is found in a range of habitats including mixed deciduous woodland, wooded grassland, and open dry savannas.⁷⁰ The trees are recorded in east and south tropical Africa, through to southern Africa and Madagascar, and can reach 17m in height. The deciduous trees are generally considered to belong to the Anacardiaceae family with edible fruit flesh which is used in several traditional recipes including beer-making.⁷¹ Marula fruits are high in vitamin C and the kernels are rich in protein. The trees have an average fruit yield of 550-1000kg per year⁷² and the fruits contain a hard stone which surrounds two or three edible seeds rich in oil. The oil has been used for centuries in Africa as a moisturiser and to protect against dry skin. The oil is clear, pale yellow in colour and with high stability. It contains a high proportion of mono-unsaturated fatty acids and antioxidants.⁷³

Marula oil has also been compared to olive oil and sweet almond oil although it has higher stability and has shown to have richer moisturising properties, possibly due to the fatty acid and tocopherol composition. Marula oil hydrates the skin, heals skin tissue, reduces redness and conditions the hair. It is currently wild harvested although increasing demand could lead to increased use of commercial cultivation practices: it readily germinates and can be propagated efficiently. There are several cosmetic and personal care products on the market that use marula oil as an ingredient.

Kalahari melon (*Citrullus lanatus* THUNB.) is native to the western Kalahari region of Namibia and Botswana. They are adapted to drought conditions and are also found in parts of Zimbabwe and Zambia. Kalahari melon is a creeping annual herb that belongs to the Cucurbitaceae family.⁷⁴ The flesh of the Kalahari melon is pale yellow or green, unlike the common watermelon, and is bitter in taste. Kalahari melons are currently wild harvested and the seeds are collected from the fruit flesh. As well as being edible, protein rich and used in cooking, the seeds are pressed for oil and used in cosmetic preparations. They are rich in clear, yellow oil which has a history of use as a cosmetic ingredient and is used to moisturise and provide regenerating and restructuring properties. The oil consists of glycosides of linoleic, oleic, palmitic and stearic acid which provides the properties that make it excellent for soap-making, moisturising and conditioning.⁷⁵



Kalahari melon, source: PhytoTrade Africa.

Baobab (*Adansonia digitata* L.) belongs to the Bombacaceae family and is known as 'The tree of life'. The tree can grow up to 24m in height with the trunk reaching 25m in diameter. The deciduous tree is distributed throughout Africa and grows predominantly in arid and semi-arid conditions with annual rainfall between 300-800mm. Baobab fruits are harvested from wild populations by collecting fallen fruits. The hard shell of the fruit is cracked open and the naturally dry, off-white, fruit pulp is separated from the

⁷⁰ Gouwakinnou, G., A. Lykke, et al. (2011). Local knowledge pattern and diversity of use of *Sclerocarya birrea*. *Journal of Ethnobiology and Ethnomedicine* 7(8).

⁷¹ Leakey, R. R. B. (1999). Potential for novel food products from agroforestry trees: a review. *Food Chemistry* 66: 1-14.

⁷² Mariod, A., B. Matthaus, et al. (2010). Fatty acids, tocopherols, phenolics and the antimicrobial effect of *Sclerocarya birrea* kernels with different harvesting dates. *Journal of American Oil Chemical Society* 87: 377-384.

⁷³ Ojewole, J. A. O., T. Mawoza, et al. (2009). *Sclerocarya birrea* (Anacardiaceae): A review of its phytochemistry, pharmacology and toxicology and its ethnomedicinal uses. *Phytotherapy Research* 24 (5): 633-639.

⁷⁴ Anhwange, B., B. Ikyenge, et al. (2010). Chemical analysis of *Citrullus lanatus* (Thunb.) *Cucumeropsis mannii* (Naud.) and *Telfairia occidentalis* (Hook F.) seed oils. *Journal of Applied Science Research* 6(3): 265-268.

⁷⁵ Nyam, K. L., C. P. Tan, et al. (2009). Optimization of supercritical CO₂ extraction of phytosterol-enriched oil from Kalahari melon seeds. *Food Bioprocess Technology*.

seeds.⁷⁶ The pulp is edible and is highly nutritious with high levels of calcium, dietary fibres, vitamin C, antioxidants, potassium and magnesium.⁷⁷ Oil from the seed is rich and golden and is used in cosmetics for its emollient properties and to treat certain skin conditions on the face, body and scalp.⁷⁸

Figure 5. Case study: Baobab Foods Inc. – sourcing ‘superfruit’ from southern Africa

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URL: www.baobabfoods.com

Baobab Foods Inc was established in 2011 and operates as the exclusive North American importer and distributor of baobab fruit powder serving the United States and Canada. David Bruck, CEO, states that the inspiration behind Baobab Foods was the opportunity to introduce Americans and Canadians to the baobab superfruit which has been dubbed ‘The King of Superfruits’ by *Fast Company* magazine.

Baobab Foods have partnered with Afriplex, a South African company who is a leading international supplier of wellness products from Africa, and who has many years of experience of supplying baobab to the regional and, more recently, the international market.

Bruck observes that through marketing efforts there is increasing consumer awareness of baobab fruit powder and its unique nutritional attributes, and that the number of baobab products on shelves is increasing. Baobab Foods are currently offering Baobest™ Fruit Bars and Baobest™ Fruit Powder, both of which are certified organic by Ecocert and Kosher. At the Natural Products Expo West in March 2011, Baobest™ fruit powder was named one of the show’s top-five products by *Delicious Living Magazine*.

Baobab Foods is an innovative company who have seen the great potential that lies with this superfruit from Africa. They say they are continually expanding and diversifying product lines and are working with a network of partners to create innovative baobab products, ranging from new drink solutions through to baobab-infused ingredients and cereals.

Through their partners and suppliers in Southern Africa, Baobab Foods use best-practice forestry techniques to ensure that the harvesting of baobab is sustainable and managed ethically. Bruck highlights that by adding value to the baobab fruits, and hence the trees, communities are encouraged to protect the local resource and conserve the species.

Mongongo / manketti (*Schinziophyton rautanenii* Schinz.) is a deciduous fruit tree which occurs in Zambia, Angola, Namibia, Botswana, Zimbabwe and Mozambique, and belongs to the Euphorbiaceae family.⁷⁹ The tree can reach 20m in height and is found on seasonal drylands with varying climatic conditions with the mongongo season lasting from April to September.⁸⁰ Within southern Africa, mongongo trees grow in large groves on the well-drained sands of the Kalahari Sands Plateau. The fruits are edible, as are the kernels which are rich in protein and oil. The oil has a large proportion of linoleic and eleosteraic acid which contributes to skin protection properties including hydration and regeneration. The oil is used in various personal care products including massage oils, shampoos for dry and fragile hair and in soap-making. Mongongo is primarily collected from the wild but there are reports of previous domestication efforts.

⁷⁶ Osman, M. (2004). Chemical and nutrient analysis of Baobab (*Adansonia digitata*) fruit and seed protein solubility. *Plant foods for human nutrition* 59: 29-33.

⁷⁷ Chadare, F. J., A. R. Linnemann, et al. (2009). Baobab Food Products: A review on their composition and nutritional value. *Critical Reviews in Food Science and Nutrition* 49: 254-274.

⁷⁸ Athar, M. and S. Nasir (2005). Taxonomic perspective of plant species yielding vegetable oils used in cosmetics and skin care products. *African Journal of Biotechnology* 4(1): 36-44.

⁷⁹ Juliani, R., A. Koroch, et al. (2007). Mungongo cold pressed oil (*Schinziophyton rautanenii*): A new natural product with potential cosmetic applications. *Acta Horticulturae* 756: 407-412.

⁸⁰ Lee, R. (1973) Mongongo: The ethnography of a major wild food resource. *Ecology of Food and Nutrition* 2: 307-321

Mafura (*Trichilia emetica* Vahl) belongs to the Meliaceae family and is an evergreen, slow growing hardwood tree that can reach a height of 30m. Mafura is distributed throughout southern Africa at low altitudes and in areas not affected by frost. The species is also found along rivers and the coast where rich alluvial soils are dominant.⁸¹ The seeds are soft and rich in oil, bright red, and held in bunches in the fruit capsules.



Trichilia emetic seed, source:
PhytoTrade Africa.

Each tree bears a large number of seeds with an average yield of oil, approximately 20 litres of oil per tree. The pressed seed yields an oil which is a solid butter and can be used for soap making, cosmetics and hair care products due to its emollient and hydrating properties. *T. emetica* is currently wild harvested but there is potential to increase industry interest in the product as a replacement for other commonly used edible fats.⁸²

Ximenia oil (*Ximenia americana* L., *X. caffra*) is obtained from the *Ximenia americana* deciduous shrub which is also known as the yellow plum. It is widespread across southern Africa and grows in bushveld and generally at low altitudes. The fruit is edible with a sour taste and is often used to make jelly and contains vitamin C.⁸³

The fruits are wild harvested and the nuts are removed ready for decortication and pressing of the kernels. The seeds yield between 60%-70% oil which is edible and is characterised by long-chain fatty acids. The oil contains ximenynic acid, an active component, which is said to have anti-inflammatory properties and is an effective treatment for dry skin conditions.⁸⁴ In addition, the seed oil contains oleic, linoleic, linolenic, and erucic acid. The oil has traditionally been used as an emollient, to soothe chapped skin and as a hair oil and conditioner.

4. Market access

4.1. Sanitary and safety regulations

4.1.1. Good agricultural and collection practices (GACPs)

As a prerequisite for the production of pharmacopoeial-quality natural ingredients that are made from medicinal herbs & extracts, the implementation of good agricultural and collection practices (GACPs) specific to medicinal plants is highly advisable.

In December 2006, The Botanical Raw Materials Committee of the American Herbal Products Association (AHPA) in cooperation with the American Herbal Pharmacopoeia (AHP) released their guidance document entitled: Good Agricultural And Collection Practice For Herbal Raw Materials (available on the internet at http://www.ahpa.org/portals/0/pdfs/06_1208_AHPA-AHP_GACP.pdf). It is meant to be used by companies (members or not) as a guideline for their own farming operations and/or for their suppliers who cultivate or collect wild medicinal and aromatic plants. The United States Pharmacopoeia's publication, the USP Dietary Supplements Compendium (DSC)⁸⁵ (see section 4.2.1), contains references for good agricultural practices, as well as information on post-harvest handling. Additionally, in 2003 the World Health Organization (WHO) published its publication, WHO Guidelines On Good Agricultural And Collection Practices (GACP)

⁸¹ Komane, B., Olivier, E., Viljoen, A. (2010). *Trichilia emetica* (Meliaceae) – A review of traditional uses, biological activities and phytochemistry. *Phytochemistry Letters* 4 (1): 1-9

⁸² Khumalo, L. W., L. Majoko, et al. (2002). Characterisation of some underutilised vegetable oils and their evaluation as starting materials for lipase-catalysed production of cocoa butter equivalents. *Industrial Crops and Products* 16: 237-244

⁸³ Rezanka, T., Sigler, K., (2007). Identification of very long chain unsaturated fatty acids from Ximenia oil by atmospheric pressure chemical ionization liquid chromatography- mass spectroscopy. *Phytochemistry* 68 (6): 925-34

⁸⁴ Saeed, A. and S. Bashier (2010). Physio-chemical analysis of Ximenia americana L seed oil and structure elucidation of some chemical constituents of its seed oil and fruit pulp. *Journal of Pharmacognosy and Phytotherapy* 2(4): 49-55.

⁸⁵ United States Pharmacopoeial Convention. USP Dietary Supplements Compendium (DSC). Rockville, MD: United States Pharmacopoeial Convention, Inc. 2011.

For Medicinal Plants, intended to become an international standard for producers of botanical raw materials.⁸⁶

In Canada, there has been a move to create good agriculture and collection practices (GACP), which cover safety, quality assurance and traceability for the Canadian herb, spices, wild collected products, hemp and natural health products industry. The Canadian Herb, Spice And Natural Health Products Coalition (CHSNC) is one of more than 20 national industry groups involved in the Canadian On-Farm Food Safety Working Group (COFFS) (<http://www.onfarmfoodsafety.ca>) and provides training and workshops for herb and spice producers across Canada.⁸⁷ The Canadian Horticultural Council (CHC) has an on-farm food safety (OFFS) programme called CanadaGAP. More about this programme and GACP can be found at www.canadagap.ca or by visiting: <http://www.saskherbspice.org/gacp-overview.html>

GAPs are especially relevant for minimizing the microbiological load of conventionally grown as well as organically grown medicinal plants because there really are no acceptable decontamination methods for medicinal plants. There are practically no methods which reduce microbial counts without, at the same time, adversely affecting a medicinal herb's active constituents. For example, pasteurization and autoclaving are not generally suitable; dry heat can only be used for a few select herbs; ethylene oxide (ETO) forms toxic reaction products such as ethylene chlorohydrin and ethylene glycol (and ETO has been banned in the EU since 1990); ionizing irradiation (banned in Germany) also causes measurable changes in the chemistry composition of the botanical.⁸⁸ Additionally, the use of ozone also causes significant undesirable changes in composition and quality, particularly in the case of volatile oil herbs like chamomile flowerhead. In the United States, the treatment of botanical dietary ingredients with irradiation or with ETO is not allowed under current federal regulations. However, herbs and spices that will be used in small amounts solely for flavouring or aroma of food products can be sterilized using these methods. In Canada the NHPD will, under certain conditions, allow the use of irradiation as a microbial reduction or sterilizing procedure (except for vitamins and probiotics that are generally sensitive to this process). For certified organic products, steam treatment is the only acceptable and viable technology for microbial reduction. According to the European Pharmacopoeia general monograph entitled Herbal Drugs: 'If a decontaminating treatment has been used, it is necessary to demonstrate that the constituents of the plant are not affected and that no harmful residues remain. The use of ethylene oxide (ETO) is prohibited for the decontamination of herbal drugs.'⁸⁹ Instead, the development and implementation of GAPs for the hygienic production and handling of botanical raw materials should be implemented in order to minimize the microbiological load during growing, harvesting, drying, packing and storage stages.^{90,91}

In addition to the above mentioned GAP and GACP guidance, a new certifiable standard for sustainable wild resource management has been released called the FairWild Standard, which is intended to increase the sustainability of wild collection of medicinal and aromatic plants, see section 4.3.2.

4.1.2. Good manufacturing practices (GMPs) for cosmetics and dietary supplements

Cosmetic GMPs

In the United States there are no regulations setting forth specific GMP requirements for non-drug cosmetics, for example for products such as Super Lustrous™ lipstick by Revlon. In contrast, the law

⁸⁶ World Health Organization. WHO Guidelines on Good Agricultural Practices (GACP) for Medicinal Plants. Geneva, Switzerland: World Health Organization. 2003. Available at: <http://whqlibdoc.who.int/publications/2003/9241546271.pdf>

⁸⁷ Canadian Herb, Spice and Natural Health Products Coalition (CHSNC). Good Agriculture and Collection Practices (GACP): Safety, Quality Assurance and Traceability for the Canadian Herb, Spice and Natural Health Products Industry. Available at: <http://www.saskherbspice.org/CHSNC/gacp.html>

⁸⁸ Wichtl M (ed.). Rückstände auf pflanzlichen Drogen. In: Teedrogen und Phytopharmaka: Ein Handbuch für die Praxis auf wissenschaftlicher Grundlage. Stuttgart, Germany: Wissenschaftliche Verlagsgesellschaft mbH. 2002;XXXII–XXXIV.

⁸⁹ European Pharmacopoeia Commission. Monograph: Herbal Drugs (Plantae medicinales). In: European Pharmacopoeia 7.0. Strasbourg, France: European Directorate for the Quality of Medicines. 2011.

⁹⁰ The European Medicines Agency (EMA) Committee on Herbal Medicinal Products. *Guideline on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin*. London, United Kingdom: EMA. 20 February 2006. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003362.pdf

⁹¹ Máthé Á, Franz C. Good agricultural practice and the quality of phytomedicines. *Journal of Herbs, Spices & Medicinal Plants* 1999;6(3):101–105.

requires strict adherence to GMP requirements for cosmetics that are classified as drugs, such as the medicated shampoo, Nizoral Anti-Dandruff Shampoo. There are regulations specifying minimum current GMP requirements for drugs⁹² and failure to follow these causes a cosmetic drug to be termed 'adulterated' under the FD&C Act, sec. 501(a)(2)(B). Title 21 of the Code of Federal Regulations can be viewed at:

<http://www.gpo.gov/fdsys/pkg/CFR-2010-title21-vol4/pdf/CFR-2010-title21-vol4-chapl-subchapC.pdf>.

The FDA's Good Manufacturing Practice Guidelines for cosmetics can be viewed at:

<http://www.fda.gov/cosmetics/guidancecomplianceregulatoryinformation/goodmanufacturingpracticegmpguidelinesinspectionchecklist/default.htm>

In Canada, cosmetics are regulated under the Cosmetic Regulations of the Food and Drug Act:

<http://laws.justice.gc.ca/en/F-27/C.R.C.-c.869>.

As in the United States, the Canadian government gives guidance on cosmetic GMPs:

http://www.hc-sc.gc.ca/cps-spc/person/cosmet/info-ind-prof/gmp_cosmet-bpf-eng.php.

Dietary supplement GMPs in the United States

On June 25, 2007, the FDA published its final rule entitled Current Good Manufacturing Practice (CGMP) In Manufacturing, Packing, Labelling Or Holding Operations For Dietary Supplements.⁹³ The date by which the final rule was required to be adhered to by companies depended on the size of the respective company: large companies had to comply by June 2008; companies with less than 500 employees had until June of 2009; and small companies with less than 20 employees were required to come into compliance by June 2010. The final CGMPs are available at: <http://edocket.access.gpo.gov/2007/07-3039.htm>.

The regulation establishes the minimum CGMPs necessary for activities related to manufacturing, packaging, labelling, or holding dietary supplements to ensure the quality of the dietary supplement. Foreign firms that export finished dietary supplement products to the United States must satisfy the requirements of this regulation. However, the small number of foreign products in the FDA dietary supplement sales database suggests that relatively few foreign firms do so. The foreign firms that will be most affected by this regulation are suppliers of natural ingredients for use in dietary supplement products. Although suppliers of dietary ingredients are not directly covered by the regulation, the need of manufacturers to meet the ingredient specifications required by the regulation will indirectly affect foreign suppliers (as well as domestic suppliers). The requirements include provisions related to:

- The design and construction of physical plants that facilitate maintenance;
- Cleaning;
- Proper manufacturing operations;
- Quality control procedures;
- Testing final product or incoming and in-process materials;
- Handling consumer complaints; and
- Maintaining records.

GMPs in Canada

The Natural Health Products Regulations (NHPR) in Canada contains GMP requirements. In order to help manufacturers, packagers and labellers of natural health products (NHPs) in Canada and elsewhere to adhere to these GMP requirements, the following guidance document is provided by Health Canada:

<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf-eng.php>.

⁹² Title 21 of the Code of Federal Regulations (CFR), parts 210 and 211

⁹³ Department of Health and Human Services, Food and Drug Administration. Current Good Manufacturing Practice in Manufacturing, Packaging, Labelling or Holding Operations for Dietary Supplements. Final Rule. *Federal Register*. June 25, 2007;72(121):34752-34958. Available at: <http://www.gpo.gov/fdsys/pkg/FR-2007-06-25/pdf/07-3039.pdf>

Before a site licence is issued by the NHPD, manufacturers, packagers, labellers and importers must demonstrate that they adhere to the GMP practices. Distributors are also supposed to follow the GMPs but are not required to hold a licence. The GMPs are divided into Chapter 1 and Chapter 2. Chapter 2 provides only GMP requirements for homeopathic facilities. Chapter 1 is subdivided into:

- Places (premises and equipment);
- People (personnel and quality assurance);
- Processes (sanitation programme and operations); and
- Products (specifications, stability, samples, records, recall reporting and sterile products).

4.1.3. Registration of foreign facilities under the Bioterrorism Act in the United States

The United States Congress responded to the events of 11 September 2001 by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which President Bush signed into law on 12 June 2002.

On 19 March 2003, the FDA released guidance documents addressing food and cosmetic security preventive measures, including the registration of foreign suppliers of ingredients with the FDA. The FDA designed these guidance documents as a way to help United States product manufacturers minimize the risk of tampering or other malicious, criminal or terrorist actions. In the United States, natural ingredients, including medicinal herbs and extracts, and/or oral use natural products made from natural ingredients are predominantly regulated as dietary supplements, therefore a sub-set of food regulations rather than drug regulations. In turn, external use natural products are regulated as non-drug cosmetics or cosmetic drugs. Therefore, natural ingredients used in both cosmetics and/or dietary supplements are covered by the Bioterrorism Act and these new FDA guidelines.

The rule also requires importers to provide prior notice of imports to FDA and the Bureau of Customs and Border Protection that includes:

- Identification of the submitter, including name and firm;
- Entry type and US Customs System (ACS) entry number, or other United States Customs identification number for the import;
- Identification of the articles, including complete FDA product code, the common or market name, the quantities, and the lot or code numbers;
- Identification of the manufacturer;
- Identification of the grower;
- Country of origin;
- Identification of the shipper;
- Anticipated date, time and location of arrival;
- United States Customs entry process information;
- Identification of the importer, owner, and consignee; and
- Identification of the carrier

The American Herbal Products Association (AHPA) provides a webpage to outline what is needed for registration of food shipments under the Bioterrorism Act:

<http://www.ahpa.org/Default.aspx?tabid=238>.

Three relevant Guidance for Industry documents, concerning importers and exporters of natural ingredients, are available from the FDA to download:

– Importers and Filers: Food Security Preventive Measures Guidance is available to download at:

<http://www.fda.gov/Food/FoodDefense/Bioterrorism/PriorNotice/default.htm>.

– Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance is available to download at: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125340.htm>.

– Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance is available to download at:

<http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm>.

Additionally, other relevant information concerning the Agricultural Bioterrorism Protection Act of 2002 can be obtained at the Agricultural Bioterrorism web page of the Animal and Plant Health Inspection Service (APHIS) of the USDA: http://www.aphis.usda.gov/programs/ag_selectagent/.

4.1.4. Phytosanitary certificates

A phytosanitary certificate documents the origin of a shipment and confirms inspection in the country of origin by a member of that country's national plant protection organization. This helps to ensure that the shipment is free of injurious plant pests and diseases. These certificates are only needed for plants and unprocessed or unmanufactured plant products.

The certifying country usually charges a fee for providing these certificates. Phytosanitary certificates are governed under the International Plant Protection Convention, a multilateral treaty acknowledged by the World Trade Organization as the source for international standards for phytosanitary measures affecting trade. Phytosanitary certificates are recognized as an internationally accepted form of pest risk mitigation.

As of 22 January 2002, the United States Department of Agriculture (USDA) began consistently and routinely enforcing an existing requirement that shipments must be accompanied by a phytosanitary certificate of inspection, or similar documentation approved by USDA. All plants, roots, bulbs, seeds, and other plant products must be accompanied by a phytosanitary certificate issued by the plant health officials where the product originated in order to be considered for entry into the United States.⁹⁴

To learn more about the Phytosanitary Certificate requirements in the United States, visit the USDA website: http://www.aphis.usda.gov/import_export/plants/plant_exports/pcit.shtml.

The USDA also gives answers to a list of frequently asked questions regarding phytosanitary certification: http://www.aphis.usda.gov/import_export/plants/plant_exports/faqs.shtml.

Canadian Food Inspection Agency (CFIA) Policy on the Issuance of Phytosanitary Certificates can be seen here: <http://www.inspection.gc.ca/english/plaveg/protect/dir/d-99-06e.shtml>.

4.1.5. Food colours

FDA separates colour additives into two categories. These are colours that the agency certifies (derived primarily from petroleum and known as coal-tar dyes) and colours that are exempted from certification (obtained largely from mineral, plant, or animal sources). Only approved substances may be used to colour foods, drugs, cosmetics, and medical devices.

FDA requires domestic and foreign manufacturers of certain colours to submit samples from each batch of colour produced. FDA scientists test each sample of these colours to confirm that each batch of the colour is within established specifications. These certified colours are listed on labels as FD&C, D&C or external D&C. Using the uncertified versions of colour additives that require certification is illegal in foods, drugs, cosmetics, and medical devices. Below is a link for the Color Certification programme on the FDA website: <http://www.fda.gov/ForIndustry/ColorAdditives/ColorCertification/default.htm>.

⁹⁴ The Animal and Plant Health inspection Service (APHIS). Information for Commercial and Non-Commercial Importers of Nursery Stock, Plants, Roots, Bulbs, Seeds, and Other Propagative Plant Products. Plant Protection and Quarantine. Washington, DC: The Animal and Plant Health inspection Service (APHIS). January 2002.

The Color Certification programme is self-supporting because the law requires manufacturers to pay FDA a user fee for each pound of colour the agency certifies. In 2000, FDA certified more than 13 million pounds of colour additives.⁹⁵

In Canada, food colourings are regulated by the Food and Drugs Act (FDA) as food additives. A list of permitted colours as food additives are listed in Table III of section B.16.100 of the Food and Drug Regulations: <http://www.hc-sc.gc.ca/fn-an/consult/feb2010-food-aliments-col/lett-eng.php>.

4.1.6. Hazard Analysis & Critical Control Points (HACCP)

HACCP is a management system from the FDA for food safety in which the analysis and control of biological, chemical and physical hazards apply to raw material production, procurement and handling, as well as manufacturing, distribution and consumption of the finished product. The FDA provides specific HACCP guidelines for dairy, juice, retail and food service, and seafood. Although they have been voluntary guidelines, with the passage of the FSMA (see below), HACCP plans for all levels of food production will become a legal requirement.

See the FDA guidance page on HACCP here:

<http://www.fda.gov/food/foodsafety/hazardanalysiscriticalcontrolpointshaccp/default.htm>.

4.1.7. Food Safety Modernization Act (FSMA)

A United States law, signed by President Obama in January 2011, gives the FDA the right to order recalls and greater access to companies' safety records, as well as requiring companies to put into plan detailed food safety plans.

The new law was introduced mainly due to the number of outbreaks of food borne illness that hit the United States in recent years. The new law will strengthen public health and safety by requiring biennial registration of all food manufacturing facilities, adopting a risk-based approach to inspection, as well as improving the safety of imported food and food ingredients.

Many of the new requirements of this act did not take effect immediately but there were a few significant ones that did.

They were: FDA's enhanced inspectional authority; mandatory recall authority, which gives the FDA the authority to request a recall; authority to require import certifications for food, as the FSMA requires refusal of admission for any imported food that fails to meet the certification requirements or other assurance that the food meets FDCA requirements; the FDA's expanded authority to order an administrative detention; and employee protection, which provides whistleblower protections for employees who provide information on the violation of the FSMA.

Other important requirements include: the registration of food facilities, which go into effect on the earlier date of FDA's issuance of implementing regulations; and hazard analysis and risk-based preventive controls, which requires food facilities to have in place numerous HACCP-like controls; produce safety, which prompt the establishment of new science-based minimum standards for the safe production and harvesting of raw agricultural commodities that the FDA has determined could be a risk to human health; the protection against intentional adulteration, which result in the issuance of regulations to protect against the intentional adulteration of food; and the foreign-supplier verification programme, which will require United States importers to verify through risk-based foreign-supplier verification activities that imported food is produced in compliance with all applicable requirements pertaining to hazard analysis and standard for product safety, as well as not being adulterated or misbranded.

⁹⁵ U.S. Food and Drug Administration. Cosmetics and Colors Fact Sheet. Washington, DC: U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Cosmetics and Colors Fact Sheet. 30 July, 2001.

See the FDA Guidance Page on the FSMA at: <http://www.fda.gov/food/foodsafety/fsma/default.htm>.

4.1.8. GRAS affirmation of food and functional food ingredients

GRAS is the acronym for the phrase 'generally recognized as safe', which applies under sections 201(s) and 409 of the Federal Food, Drug and Cosmetic Act (the Act), to substances intentionally added to foods or food additives. These substances are 'subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having adequately shown to be safe under the conditions of its intended use.' However, GRAS substances are not required to go through an FDA premarket review process and approval, therefore companies need to make their own decisions as to whether a substance is GRAS or not before going to market.

Even though the GRAS regulations have been in place since the 1970s, there continues to be a lot of confusion by marketers about the regulations, especially in emerging markets such as natural foods. Originally, when the term 'GRAS' was coined by the FDA, the body created a process by which companies could petition the FDA to allow food ingredients to become affirmed as GRAS. However, in 1997, the FDA announced that they would be no longer devoting resources to the petition process and they were replacing it with the GRAS notification process that is now in place. This was done in order to increase the ease with which companies could make a GRAS determination and then have the assurance of an FDA review before going to market. Through this process a company may send a GRAS notice to the FDA, who would then respond either that they do not agree with the reasoning given about the ingredient being affirmed as GRAS, or that they 'have no questions': the FDA does not provide a 'yes' or 'approved' answer to GRAS notices. Companies are free to market the ingredient with or without submitting a notice, as the GRAS notification process is a voluntary process. However many companies will prefer to wait to get an answer from the FDA before marketing due to legal and safety issues.

After submitting a GRAS notification, the FDA can take up to 180 days to respond. The notification should include a GRAS exemption claim, which is a succinct description of the substance, the applicable conditions of use, and the statutory basis for the GRAS determination (either through scientific procedures or through common use in food). Most notifiers choose to submit notices based on scientific procedures. It is important to note that in order for an ingredient to be deemed GRAS, it requires a group of qualified experts to agree based on data that is generally available to the public. Furthermore, the assessment of safety depends on the characteristics of the substance and the estimated dietary intake.

Companies may prepare notifications themselves, but usually they will hire a group of experts to help them do this as a GRAS panel. This group of experts usually consists of approximately two or three individuals who are qualified in the field to review the data and make a determination (such as a toxicologist, a food scientist, a pharmacologist and a chemist). If a company wants a GRAS notice for a new or proprietary ingredient, they will have to complete safety studies first, and ideally have those studies published in the public domain. Some companies will hire a full service laboratory to do the safety studies and GRAS notification for them, such as Covance (www.covance.com).

Another option is for a company to create a GRAS panel and accompanying documentation, but instead of notifying the FDA, to keep this information in-house and go to market (as no premarket approval is required by the FDA). This is possible because there is no requirement by the FDA that they are notified of a company's decision (and reasoning) why a particular product is GRAS. Instead, companies are only required to make sure a product is GRAS, and they only need to share their reasoning of how and why they have determined this if the FDA requests evidence. The costs of creating a GRAS panel usually depends on the consulting fees for the qualified experts, and the costs of the safety studies can vary widely depending on how novel the ingredient is, its scope of use, and if there is already pre-existing published information available.

See the FDA's GRAS Notice Inventory web page here:
<http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm>.

4.1.9. New Dietary Ingredients (NDIs)

A NDI is defined as 'a dietary ingredient that was not marketed in the United States before October 15, 1994'. Each supplement manufacturer or distributor is responsible for establishing that the dietary ingredients in its dietary supplements comply with the NDI notification requirements. While some trade associations and other industry groups have published lists of 'old dietary ingredients', these lists have not been verified by FDA and are not backed by evidence that the ingredients listed were actually marketed prior to October 15, 1994.

The FDA's Draft Guidance for Industry on New Dietary Ingredient Notifications is available at: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm257563.htm#i-intro>.

4.2. Quality requirements

The quality of natural ingredients is judged by the quality control (QC) unit of each product manufacturing company based on a set of written specifications. According to GMP regulations, the QC unit of a company may not release a natural ingredient for production in a batch until the ingredient has been tested and has been found to be in conformity with its written specifications.

Some cosmetics and dietary supplement companies, particularly those whose products are regulated as drugs in other countries, have developed internal ingredient specifications that are based on pharmacopoeial standards monographs. For an ingredient to be labelled as pharmacopoeial-grade (e.g. senna USP (United States Pharmacopoeia)), the ingredient must be assayed and documented to conform to all of the qualitative and quantitative standards that appear in the relevant monograph.

4.2.1. Quality requirements in the United States

For many high-demand natural ingredients such as botanical raw materials, extracts and essential oils, official pharmacopoeial standards are published in the United States Pharmacopeia Dietary Supplements Compendium (DSC).

The Dietary Supplement Health and Education Act of 1994 (DSHEA) amended the Federal Food, Drug and Cosmetics Act (FD&C Act) named the United States Pharmacopeia (USP) and National Formulary (NF) as official compendia for dietary supplement ingredient quality standards.

At the same time, compliance with USP-NF standards was made voluntary for industry. Nonetheless, the amendments provide that if a herbal dietary supplement covered by the specifications of an official compendium is represented as conforming to the specifications of an official compendium and fails to conform to such specifications, it shall be deemed misbranded. Thus, compliance with a USP monograph becomes mandatory only in cases where the product label designates an ingredient as USP-grade. In the case of botanical drugs, The FD&C Act recognizes the USP as the official compendium for drug quality standards. Thus, compliance with pharmacopoeial standards is mandatory for botanicals that are used as active pharmaceutical ingredients.

4.2.2. Quality requirements in Canada

Licensed natural health products (NHPs) must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.⁹⁶ For active ingredient specifications, pharmacopoeial standards currently accepted by the NHPD are the British Pharmacopoeia (BP), European Pharmacopoeia (PhEur) and United States Pharmacopeia (USP).⁹⁷ All ingredient (medicinal and non-medicinal) and finished product specifications should as a minimum meet the standards described in the publications

⁹⁶ Health Canada Natural Health Products Directorate (NHPD). *NHPD Compendium of Monographs*, Version 2.1. Ottawa, ON: Natural Health Products Directorate. November 2007. Available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/compendium_mono_v2-1-eng.pdf

⁹⁷ Health Canada Natural Health Products Directorate (NHPD). *NHPD Evidence for Quality of Finished Natural Health Products*, Version 2.0. Ottawa, ON: Natural Health Products Directorate. June 2007. Available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/eq-paq-eng.pdf

referred to in Schedule B to the Food and Drugs Act, or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

For some natural ingredients that do not have official standards published in the European or United States Pharmacopoeias, other authoritative monographs are also utilized by industry for quality control standards. These include those of the American Herbal Pharmacopoeia (AHP) and the British Herbal Pharmacopoeia (BHP), as well as monographs of the World Health Organization (WHO).

These standards can provide valuable guidance to producers that may facilitate increased trade if the natural ingredients are documented to be in compliance, especially through independent laboratory certificates of analysis. A certificate of analysis document for each lot number of the natural ingredient should state which specific set of pharmacopoeial standards were used for testing (e.g. USP-NF or PhEur) and report the results of all tests, thereby showing that the ingredient conforms with the monograph. In this case the natural ingredient can be labelled and traded as pharmacopoeial-grade (e.g. cat's claw USP), and command a premium over lower commercial grades. The certificate of analysis must also be signed and dated by a qualified person of the QC unit, or by the responsible chemist at the independent testing laboratory.

4.2.3. The United States Pharmacopeia-National Formulary (USP-NF) & Health Canada's Natural Health Products Directorate (NHPD) Compendium of Monographs

The United States Pharmacopeia (USP) is a non-profit organization with the mission to provide standards for medicines and foods, thereby ensuring their quality and safety. It was formed in 1820 and officially recognized by federal law in 1848. Today the USP is combined with the National Formulary (NF), which was established by the American Pharmaceutical Association in 1888 to provide standards for 'unofficial preparations', which refers to remedies that were not included in the USP but were commonly used by pharmacists. In 1975 the NF was purchased by the USP and its information incorporated into a single publication, forming the USP-NF. Later, in 2006, the USP purchased the Food Chemicals Codex (FCC) from the National Academy of Science, Institute of Medicine, which is a compendium of standards for the purity and identity of food ingredients.

The USP has recently produced a dedicated Dietary Supplements Compendium (DSC). It is a substantial first work that includes approximately 400 official monographs extracted from the USP 32-NF 27 and more than 150 monograph from the Food Chemicals Codex (FCC) sixth edition, as well as further information that is pertinent to dietary supplements.

Health Canada's NHPD Compendium of Monographs provide pre-cleared information (PCI) that support the safety, efficacy and quality of a medicinal ingredient or Natural Health Product (NHP) that NHPD has reviewed and has determined to be acceptable. In terms of quality requirements, each monograph provides information on compliance with specifications outlined in pharmacopoeial monographs. The NHPD expressly lists monographs of the BP, PhEur, and USP to be acceptable quality standards for medicinal ingredients used in NHPs.

In Canada there are two places to gain guidance on what is on the marketplace: one is the Licensed Natural Health Products Database; the other is Health Canada's Compendium of Monographs. The Licensed Natural Health Products Database contains information about natural health products that have been issued a product licence (and therefore are allowed to be sold on the Canadian market) by Health Canada. Products with a licence have been assessed by Health Canada and found to be safe, effective and of high quality under their recommended conditions of use. The types of products found in the database include:

- Vitamin and mineral supplements;
- Herb and plant-based remedies;
- Traditional medicines like traditional Chinese medicines or Ayurvedic (Indian) medicines;

- Omega 3 and essential fatty acids;
- Probiotics;
- Homeopathic medicines; and
- Many everyday consumer products, like certain toothpastes, anti-perspirants, shampoos, facial products and mouthwashes.

The Compendium of Monographs includes botanicals, as well as vitamins, minerals, and product monographs. The botanical monographs can be accessed online and include those in the following table:

Table 3. Botanical monographs available from Health Canada’s Compendium of Monographs

| | |
|-----------------------------|-------------------------------|
| Alfalfa* | European Pennyroyal* |
| Aloe – Oral* | Evening Primrose Oil* |
| Aloe – Topical* | Fennel, Bitter* |
| Angelica* | Fennel, Sweet* |
| Arginine, L-* | Fenugreek – Oral* |
| Arnica | Fenugreek – Topical* |
| Ashwagandha* | Feverfew* |
| Astragalus* | Figwort* |
| Avens* | Flaxseed* |
| Beta-Carotene* | Flaxseed oil* |
| Bilberry – Buccal* | Frankincense – Buccal |
| Bilberry – Oral* | Frankincense – Oral* |
| Biotin* | Frankincense – Topical |
| Birch, Weeping* | Garlic |
| Birch, White* | Gentian* |
| Black Cohosh* | Ginger* |
| Black Horehound* | Ginkgo Biloba* |
| Blessed Thistle – Oral* | Ginseng, American* |
| Blessed Thistle – Topical* | Ginseng, Panax* |
| Boldo* | Globe artichoke* |
| Borage Oil* | Goldenseal – Buccal* |
| Burdock – Oral* | Goldenseal – Oral* |
| Burdock – Topical* | Grape Seed Extract* |
| Calendula – Buccal* | Green Tea Extracts |
| Calendula – Oral* | Ground Ivy – Oral* |
| Calendula – Topical* | Ground Ivy – Topical* |
| California poppy* | Hamamelis Water – Buccal* |
| Caraway* | Hamamelis Water – Ophthalmic* |
| Cascara Sagrada* | Hamamelis Water – Topical |
| Catnip* | Hawthorn-Crataegus laevigata* |
| Cayenne – Oral* | Hawthorn-Crataegus monogyna* |
| Cayenne – Topical | Heal-all – Buccal* |
| Chamomile, German – Buccal | Heal-all – Oral* |
| Chamomile, German – Oral* | Heal-all – Topical* |
| Chamomile, German – Topical | Hops* |
| Chamomile, Roman* | Horse Chestnut* |
| Chaste tree* | Horseradish* |
| Cranberry* | Hyssop* |
| Cranberry, dried extract* | Juniper* |
| Curcumin* | Lemon Balm* |
| Dandelion* | Licorice* |

| | |
|--|----------------------------|
| Dandelion Juice* | Linden, European* |
| Deglycyrrhizinated licorice – Buccal* | Linden, Large-leaf* |
| Deglycyrrhizinated licorice – Oral* | Linden, Small-leaf* |
| Devil's claw* | Lungwort – Oral* |
| Echinacea Angustifolia* | Lungwort – Topical |
| Echinacea pallida* | Milk Thistle* |
| Echinacea purpurea* | Mugwort* |
| Eleuthero* | Passionflower* |
| Peppermint* | St. John's Wort – Topical* |
| Propolis – Buccal | Stinging Nettle* |
| Propolis – Oral* | Stinging Nettle Juice* |
| Propolis – Topical | Thuja – Oral* |
| Psyllium – Plantago afra* | Thuja – Topical |
| Psyllium – Plantago arenaria* | Thyme – Buccal* |
| Psyllium – Plantago ovata* | Thyme – Oral* |
| Rosemary – Oral* | Thyme – Topical* |
| Rosemary – Topical* | Turmeric – Oral* |
| Saw Palmetto* | Turmeric – Topical |
| Saw palmetto, liposterolic extract* | Valerian* |
| Senna* | Witch Hazel – Buccal* |
| Skullcap* | Witch Hazel – Oral* |
| St. John's Wort – Oral* | Witch Hazel – Topical* |
| St. John's Wort – Oral – Hydroalcoholic Extract* | |

See the Licensed Natural Health Products Database at:

<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/lnhpd-bdpsnh-eng.php>.

See Health Canada's Compendium of Monographs at:

<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/index-eng.php>.

4.2.4. Notes on African botanicals and official monographs

The United States Pharmacopeia and Health Canada's Compendium of Monographs include several species with African origin which are part of North America's natural product industry. Examples of those natural products of interest include: aloe, acacia, myrrh, pygeum, palm kernel oil, sesame oil, frankincense, senna and devil's claw.

The USP Official Monographs describe acacia as the 'dried gummy exudates from the stems and branches of *Acacia senegal* (Linne)' and other acacia species found in Africa, primarily in Sudan. It is used in food and beverage products, as well as an additive, and more recently in dietetic food and health sectors. Along with listing acacia as a single ingredient, acacia syrup is also included in the monograph.

As listed in the USP Official Monographs, myrrh is the 'oleo-gum resin obtained from the stems and branches of *Commiphora molmol* (Engler) and other related species of *Commiphora* other than *Commiphora mukul* (Family: Burseraceae)'. The *Commiphora* genus is a spiny shrub or small tree found in Africa and Asia with gum exuding from the stem which has several medicinal properties. Uses include treatment of minor skin ailments, and it has also been recommended for gum disease, toothache, sprains and bruises. The USP monograph includes both oral and topical preparations.

Pygeum is listed in the dietary supplements section of the USP. It consists of extracts of the bark of *Prunus africana* and is used to alleviate discomfort suffered by patients of an enlarged prostate. According to the monograph, pygeum contains not less than 9% of extractable matter. *Prunus africana* is an evergreen tree found in mountain areas of tropical Africa and Madagascar. Pygeum extract and capsules are also included in the monograph involving pulverized pygeum using solvents to extract the active ingredient.

Prunus africana is also listed in the American Herbal Pharmacopoeia which states that due to the demand for the herbal drug and timber, pygeum is threatened with habitat loss and overharvesting.⁹⁸

Palm kernel oil is an edible oil from the kernel of the oil palm, *Elaeis guineensis* (Jacq.) (Fam. Arecaceae) and is listed in the USP Official Monographs National Formulary (USP-NF) section. The palm is native to west Africa and bears a fruit which has an oily fleshy outer layer and a single oil rich seed. Oil is extracted from both the fruit pulp and the kernel and both have applications in the food industry. Palm kernel oil and palm oil are both widely used but there are many controversial issues relating to social and environmental impacts of this ingredient. There is currently significant activity to find alternatives to these oils that are acceptable to industry. According to the British Pharmacopoeia (2011), fractionated palm kernel oil is a white, solid, brittle fat which is odourless and almost insoluble in water and ethanol, and is often used as an ingredient in cosmetics.

Sesame oil, included in the USP-NF, is the refined fixed oil from the seed of a cultivated variety of *Sesamum indicum* (Linne) (Fam. Pedaliaceae) which originated in sub-Saharan Africa. Asia grows the majority of the sesame seeds on the market today, with Africa producing about a quarter. The seeds are rich in oil and have a high content of iron, magnesium, and calcium, along with vitamin B1 and vitamin E. It is also said they have high antioxidant content. According to the British Pharmacopoeia (2011), refined sesame oil may contain a suitable antioxidant and it appears as a clear, light yellow liquid (almost colourless).

Senna (*Senna alexandrina*) has several synonyms including *Cassia acutifolia* and *Cassia angustifolia* as listed in Health Canada's monograph. According to the American Herbal Pharmacopoeia, senna is one of the primary botanical laxatives used worldwide. The fruit and leaves are rich in anthraquinone glycosides which stimulate intestinal peristalsis.⁹⁹ Health Canada's monograph reports oral administration of the fruit and leaf and doses for standardized extracts are calculated as sennoside B at 15-30mg per day. With regards to dry, powdered, decoction and infusion preparations, the recommended dose is 0.5-3g per day. Senna has been used traditionally as a stimulant laxative and Health Canada reports use to promote bowel movement by direct action on the large intestine. According to the USP-NF, senna leaf contains not less than 2.5% of anthraquinone glucosides, calculated as sennosides, on the dried basis. Senna pods are the dried ripe fruit and contain not less than 3.4% anthraquinone glucosides (*Alexandrian senna*), calculated as sennosides, on the dried basis.

Frankincense (*Boswellia sacra* (Flueck.)), according to Health Canada's monograph, has several traditional applications including use as an astringent, diuretic, to promote circulation and relieve urinary disorders. The stem bark resin can be taken orally as a dry preparation at a dose between 3-8g per day. The same dose applies to topical application which can be used to promote the healing of injuries, promote tissue regeneration and relieve gum, mouth and throat complaints.

4.3. Emerging and established product certifications/labels

4.3.1. USDA National Organic Program Import Requirements for Agricultural Products and the Canadian Organic Products Regulations

The USDA National Organic Program (NOP) Standards require all agricultural products (including botanical raw materials & extracts) sold, labelled or represented as organic in the United States to be certified by a USDA accredited certifying agent. However, in lieu of organic certification by a USDA accredited certifying agent, imported organic agricultural products (including medicinal herbs, extracts and essential oils) may be sold in the United States if they have been certified and recognized through:

- A USDA recognition of conformity assessment (by independent certifying agents that are accredited by foreign governments) or
- An equivalency determination (organic certification programmes of foreign governments).

⁹⁸ Upton, R., Graff, A. *et al.* (2011) American Herbal Pharmacopoeia. Botanical Pharmacognosy. *American Herbal Pharmacopoeia*. CRC Press.

⁹⁹ Upton, R., Graff, A. *et al.* (2011) American Herbal Pharmacopoeia. Botanical Pharmacognosy. *American Herbal Pharmacopoeia*. CRC Press.

For the USDA National Organic Program's Export Arrangements and Recognition Agreements, Export Certificate Procedures and Accompanying Documentation, Import Authorizations, and Imported Organic Agricultural Products, visit: <http://www.ams.usda.gov/nop/NOP/Trade.html>.

On 25 March, 2002, an equivalency agreement was announced for the sale of plant-based United States - certified organic products into Japan. Under the agreement, Japan recognizes the United States National Organic Program as equivalent as a system of oversight, enforcement and standards. Therefore, organic plant-based food products certified by a USDA-accredited agency can be used by any JAS-certified company, including importers, manufacturers, and distributors. There is a stipulation in the agreement, however, that alkali-extracted humic acid, lignin sulfonate, and potassium bicarbonate are not allowed to be used in processed organic food product exported to Japan.

In June of 2009, The United States Department of Agriculture (USDA) and the Canadian Food Inspection Agency (CFIA) announced the signing of an organic equivalency agreement whereby each country would recognize each other's officially certified organic products.

Although Canada has had an organic standard since 1999, it was officially codified into law by the Organic Products Regulations in 2006. As of 30 June, 2009, the Organic Products Regulations have required mandatory certification to the revised National Organic Standard for agricultural products that are designated as organic in international or inter-provincial trade. To learn more, visit: <http://www.inspection.gc.ca/english/fssa/orgbio/orgbioe.shtml>.

India's organic programme, the National Program for Organic Production (NPOP) has established recognition of conformity assessment with the United States for export of organic products into the United States. In July 2010, equivalency requirements for the Australian Standard (AS 6000) were approved by the standards committee.

4.3.2. FairWild® certification

FairWild is an eco-social or fair-trade or fair-deal standard that is specifically aimed at medicinal and aromatic plants that are wild-collected. The FairWild Foundation (FWF) is based in Weinfelden, Switzerland, with its secretariat based at TRAFFIC International in Cambridge, United Kingdom. The FairWild Foundation mission is to aim to provide a worldwide framework for implementing a sustainable, fair and value-added management and trading system for wild-collected natural ingredients and products thereof. FWF does this by (1) encouraging sustainable and fair business practices and focus on influencing consumer choice; (2) informing, advising and assisting those involved in the wild plant trade; (3) providing advice on the application of the FairWild Standard and supply chain certification; and by (4) providing advice on the application of standards for sustainable and fair management of trade in conservation, trade policy, and other regulations.

The FairWild standard has no restrictions on the geographical scope, type of producer group, or the botanical ingredient, as long as that ingredient is wild-harvested. FWF provides the following price and premium definitions:¹⁰⁰

- The FairWild Price that is paid by the buyer to the wild collection enterprise is based on cost calculations but it is always above the normal market prices for conventional wild crops. In general, the FairWild price is at least 5% to 10% higher than prices paid for same product collected conventionally in the region.
- The FairWild Premium Fund amount is negotiated between seller and buyer on a case-by-case basis appropriate for the specific situation and scale. It is usually paid out by the final buyer (e.g., the finished-product manufacturer) to the wild-collection enterprise (even when there are other companies in between). If it is paid by an intermediate buyer (e.g., a wholesale distribution company) or by other value-adding companies in the supply chain (e.g., an extraction house), this amount will usually be charged upstream to the final buyer (e.g., finished-product manufacturer).

¹⁰⁰ FairWild Foundation. FairWild® Certification Guidance for Industry: Frequently Asked Questions on Costs, Fees, Funds, and Pricing. 2009. Available at: <http://www.fairwild.org/certification-overview>.

In order to access the FairWild standards, see the following links:¹⁰¹

FWF FairWild Standard:

<http://www.fairwild.org/publication-downloads/fairwild-standard-ver-20/FairWild-Standard-V2.pdf>.

FWF FairWild Standard and Performance Indicators

<http://www.fairwild.org/publication-downloads/fairwild-standard-ver-20/FairWild-Standard-Indicators-V2.pdf>.

4.3.3. Fairtrade International (FI), Fairtrade Canada (formerly TransFair Canada), Fair Trade USA (formerly Transfair USA)

In North America, the most well known fair trade standard is that of the Fairtrade Labelling Organizations International, now called Fairtrade International (FI).

From December 31, 2011, Fair Trade USA (FTUSA) decided to resign its membership of the Fairtrade International (FLO) system effective December 31, 2011.

According to a report in <http://www.thenews.coop/topics/Ethics>, the main point of contention between FLO and FTUSA was a difference of opinion about whether to include hired labour plantations in Fairtrade, particularly for coffee.

At the time of publication of this paper, no details were available on transition planning and the consequent operational changes.

The following information relates to FLO standards for natural products. It is still not clear how these will change under the new FI label.

In order to be certified Fairtrade by FLO, producers must be organized in certain types of producers' organizations (that FLO allows), and there must be a standard for the particular product to be certified. For example, the FLO's Fairtrade Standard for Tea for Hired Labour covers six botanicals – chamomile flower (*Matricaria recutita*, Asteraceae), Hibiscus flower (*Hibiscus sabdariffa*, Malvaceae), peppermint leaf (*Mentha × piperita*, Lamiaceae), rooibos herb (*Aspalathus linearis*, Fabaceae), spearmint leaf (*Mentha spicata*, Lamiaceae), and tea leaf (*Camellia sinensis*, Theaceae). In addition to the standards, which include social criteria, FLO publishes a periodically updated minimum price and premium information (<http://www.fairtrade.net/793.html>) that specifies the product, type, quality, form, characteristics, country/region, certification scope, price level, unit, quantity, currency, Fairtrade Minimum Price, Fairtrade Premium and date of validity, where applicable. Key requirements among fair trade certifications are the payment of a Fairtrade Minimum Price, and a Fairtrade Premium (definitions follow).^{102 103}

- Fairtrade Minimum Price (where it exists) is the lowest possible price that may be paid by buyers to producers for a product to become certified against the Fairtrade standards.
- Fairtrade Premium is an amount paid to producers in addition to the payment for their products. The Fairtrade Premium is intended for investment in the producers' business and community (for small farmers' organizations or contract production projects) or for the socio-economic development of the workers and their communities (for hired labour situations).

The TransFair USA Almanac 2009 report showed that United States imports of Fairtrade Certified (FLO Certified) herbs from Egypt grew by 73% over 2008, and imports of Fairtrade spices grew by 240%. According to the Fairtrade Labelling Organizations International Annual Report 2009-2010, there were 827 FLO-certified producer organizations in 60 countries, which represented an 11% increase over 2008.

¹⁰¹ FairWild Foundation. FairWild Standard Version 2.0. 2010. Weinfelden, Switzerland: FairWild Foundation. 2010.

¹⁰² Fairtrade Labelling Organizations International (FLO). Fairtrade Minimum Price and Fairtrade Minimum Premium Table. Current Version 31.05.2010. Bonn, Germany. 2010. Available at: <http://www.fairtrade.net/793.0.html>.

¹⁰³ Fairtrade Labelling Organizations International (FLO). Generic Fairtrade Trade Standards. Current Version 15.08.2009. Bonn, Germany: FLO 2009. Available at: http://www.fairtrade.net/generic_trade_standards.html.

Moreover, consumers spent an estimated €3.4 billion on Fairtrade products in 2009, an increase of 15% over 2008.¹⁰⁴

In order to access the FLO standards for producers, see the following links:

FLO Fairtrade Standards for Herbs & Spices for Small Producers' Organizations:¹⁰⁵

http://www.fairtrade.net/fileadmin/user_upload/content/2009/standards/documents/Herbs_and_Spices_SPO_Dec_10_EN.pdf

FLO Fairtrade Standard for Herbs and Herbal Teas & Spices for Small Producers' Organizations

http://www.fairtrade.net/fileadmin/user_upload/content/2009/standards/documents/2011-08-11_SPO_HerbsHerbalTeasSpices_SR_EB.pdf

FLO Fairtrade Standard for Tea for Hired Labour

http://www.fairtrade.net/fileadmin/user_upload/content/2009/standards/documents/2011-08-23_EN_Tea_HL_SS_EB.pdf

4.3.4. Fair for Life Social & FairTrade Certification

The second most well-known fair trade standard in North America is Fair For Life Social & FairTrade Certification. This certification was developed in 2006 by the Swiss Bio-Foundation, in conjunction with IMO (Institute for Market Ecology) as a brand-neutral, third-party certification programme for social accountability and fair trade and as a complement to existing fair trade certification systems. The certification combines strict social and fair trade standards with adaptability to local conditions and a wide variety of products and botanicals. Recently, there have even been standards developed for tourism, mining, and artisan production (i.e. handicrafts). The certification is based on several sets of baseline standards — such as ILO conventions, FLO Fairtrade standards, SA8000, and IFOAM Social Criteria — and requires continuous improvement of social and fair trade conditions beyond the minimum requirements.

As its requirements apply throughout the chain of custody, and also have strict multi-ingredient labelling rules, this fair trade certification is usually thought of as more like organic certification in its process than the FLO fair trade certification. The following are some of the key features of Fair For Life Social And FairTrade Certification programme:

- No restriction on the type of agricultural product or production system, including many niche market but nonetheless important raw materials, multi-ingredient products, and wild-crafted (many herbs and medicinal plants). There are separate criteria for sustainable wild-harvesting of plants. Non-food products – including handicrafts, textiles, toys, mining products and tourism – can also be certified. Production systems allowed include smallholder cooperatives and small farmers under contract by processors and traders (contract production), plantations and processors.
- Physical audit of the ultimate buyer of FairTrade materials and products, usually a company in the developed world, for verification of their fair trade practices and own social responsibility.
- Buyer and supplier cooperate closely and negotiate a fair price for all sales – not just a few fair trade consignments. Farmers always receive a fair and sustainable price for their products that covers, at a minimum, cost of production and a reasonable premium for value added organic production. Additionally, a FairTrade premium is paid either directly to the farmers as additional premium or into a premium fund for community projects.
- Transparent system of FairTrade premium payment and use. The importer agrees on a FairTrade premium with the FairTrade supplier. It may be paid directly to the farmers and/or used by a fund for community for local development projects, such as, sanitary installations in the village, healthcare,

¹⁰⁴ Annual Report 2009-10. Bonn, Germany: FLO; 2010. Fairtrade Labelling Organizations International website. Available at: www.fairtrade.net/fileadmin/user_upload/content/2009/resources/FLO_Annual-Report-2009_komplett_double_web.pdf.

¹⁰⁵ Fairtrade Labelling Organizations International (FLO). Fairtrade Standards for Herbs and Spices for Small Producers' Organizations. Current Version 08.12.2010. Bonn, Germany: FLO. 2010. Available at: <http://www.fairtrade.net/716.html>.

education projects, and livestock programmes to ensure nutritional and ecological balance. IMO audits payment and use of the premium to ensure that this extra premium money is fully paid to the farmers (as premium in addition to the FairTrade price) or used for intended social community projects. The buyer may be involved in the decision on how the FairTrade premium is spent. FairTrade premium use and certifications are published on the www.fairforlife.net website.

- Rigorous chain of custody requirements throughout the whole system ensure traceability and transparency, and greater control.
- No licence fee is leveraged on participants in the supply chain. Certified entities incur only the actual costs of inspection and certification. For efficiency, FairTrade inspections may be combined with audits for organic or other ecological standards (organic textiles, FSC, GlobalG.A.P., bird-friendly, etc.). The IMO's 'fair for life – Social & FairTrade certified by IMO' certification seal and the 'for life – Social Responsibility certified by IMO' seal may be used on certified products.
- Certification provides maximum transparency for buyers and consumer through annual audits by qualified inspectors. Each operation will be measured against a list of published criteria. The performance rating of all certified operations are published on the IMO website, together with an assessment of their social impact in their host communities.
- Good environmental performance is assessed in detail, and additional good agricultural practices (GAP) criteria must be met if an operation is not certified according to organic or GAP standards.
- Requirements for physical audit of key handlers to help keep the focus of the supply chain on producers, transparency, and handlers' own commitment to social responsibility within the company and a FairTrade sourcing policy.

See the Fair for Life Social & FairTrade Certification web page here:

http://www.fairforlife.net/logicio/pmws/indexDOM.php?client_id=fairforlife&page_id=become&lang_iso639=en.

Figure 6. Case study: Discovery Organics

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URL: <http://www.discoveryorganics.ca>

Discovery Organics is a fresh organic-produce importer and distributor serving the United States and Canada. Annie Moss and Randy Hooper identify the fair trade market as a key area of upcoming growth. Currently, they see the largest growth at the natural-food-store level, but their expectation is that the conventional supermarkets will jump into the fast growing produce sector, as they have in other areas (coffee and other grocery areas recently.)

Randy Hooper, managing director, who also manages sourcing in Latin America, believes that fair trade sales are growing in North America but primarily to consumers who are also motivated to buy organic and local produce, whereas in Europe the market is more sophisticated and there are many more dedicated fair trade consumers who buy fair trade first, whether organic or conventional.

Hooper also believes that the organic sector will continue to grow as consumers link organic farming methods to being a positive for the environment, especially as wilder weather linked to climate change converts many sceptics.

Domestic fair trade also has great potential, according to Hooper. He sees the indigenous population of North America in the same light as small farmers in Latin America, hoping that the same rules could be applied, giving First Nations people some equitable return on crops grown on their tribal land.

Discovery Organics sees its job as not only a distributor for but also a partner with farms. That partnership ranges from working together on crop planning, seed selection and marketing information, to coordinated freight, packaging and compliant labelling.

Discovery has been buying from fair trade growers in Peru, Chile and Mexico for three years and now has many paid employees working on those countries. After visiting several dozen farmers and cooperatives, with often 200-500 hopeful smallholders coming to meetings, Hooper usually finds that the first question is always about payment – growers are so used to being ripped off completely or paid poorly and late. 'I always tell them that their best protection is to become fair trade certified, and have solid, signed contracts in place.' Although not a guarantee, fair trade companies are required to pay at profitable prices, on time, or risk losing their certification and ability to sell fair trade. One example is a cooperative, Agrovida, in Peru, which was not paid for three entire mango crops produced by the town of Little Pedregal, twice by local 'coyotes' and once by a European company with forged documentation. This kind of experience is very common, according to Hooper.

Discovery Organics has offices in Trujillo, Peru (shared with Fairtrasa) and in Mexicali, Mexico. Their employees have a range of backgrounds, from establishing co-ops to managing irrigation systems.

4.3.5. Rainforest Alliance Certified

The Rainforest Alliance Certified label has become a mainstream label for eco-social products in North America. The standards are managed by the Sustainable Agriculture Network (SAN) and include standards for protecting wildlife, wild lands, workers' rights, and local communities.¹⁰⁶

See the Rainforest Alliance standards at:

http://www.rainforest-alliance.org/agriculture/documents/sust_ag_standard.pdf.

4.3.6. The Fair Trade Federation

The Fair Trade Federation (FTF) is a trade association whose mission is to strengthen and promote North American organizations which are committed to fair trade. The Federation is part of the global fair trade movement, building equitable and sustainable trading partnerships and creating opportunities to alleviate poverty. Companies which become members of the Fair Trade Federation must comply with their principles of fair trade, and once they are members can use the Fair Trade Federation label on products. Traditionally, companies that use these labels on their products are small artisans of handicrafts, as until very recently there were no standards for fair trade handicraft production available by a third-party certifier. The Fair Trade Federation also provides much needed assistance in marketing these crafts to the various Alternative Trading Organizations (ATOs) that base their sourcing on FTF member products.

To apply to the FTF, visit this link: <http://www.fairtradefederation.org/ht/d/sp/i/203/pid/203>.

4.3.7. Whole Foods Market's Whole Trade™ Guarantee programme

Whole Foods Market is one of the largest natural product retail food chains in the United States and Canada. Whole Foods has created their own programme which is a type of Supplier Qualification programme that they encourage their suppliers to comply with. It is designed to be a guarantee to their customers about their commitment to ethical trade, the environment and quality products, and may be a sign of what qualification programmes may begin to look like for other retail store chains. In order for a product to meet the Whole Trade™ Guarantee, the products must: meet Whole Foods Market's high quality standards, provide more money to producers, ensure better wages and working conditions for workers, and utilize sound environmental practices.

To learn more about the Whole Foods Whole Trade™ Guarantee Programme, visit:

<http://www.wholefoodsmarket.com/products/whole-trade.php>.

4.3.8. GlobalG.A.P.

GlobalG.A.P. (formerly EUREPGAP) began in 1997 as an initiative of retailers aiming to agree on standards for the development of good agricultural practices (GAP) in order to ensure food safety. Today, GlobalG.A.P. is a private sector body that sets voluntary standards for the certification of agricultural products worldwide. The GlobalG.A.P. standard is primarily designed to reassure consumers about how

¹⁰⁶ Sustainable Agriculture Network. *Sustainable Agriculture Standard* April 2009. San José, Costa Rica: Rainforest Alliance. 2009. Available at: http://www.rainforest-alliance.org/agriculture/documents/sust_ag_standard.pdf.

food is produced on the farm by minimising detrimental environmental impacts of farming operations, reducing the use of chemical inputs and ensuring a responsible approach to worker health and safety as well as animal welfare. GlobalGAP acts as a practical approach to GAP anywhere in the world. The standards have the following key aspects:

- Technical production standards: to ensure sustainable agriculture by means of integrated pest management and integrated crop management, so as to minimize the impact of residues on man and the environment;
- Hygienic standards: to prevent chemical, microbiological or physical contamination of the harvested crops taking place;
- Working environment: to ensure workers health and to prevent social abuse of workers; and
- Traceability: to ensure that, if a problem occurs, the product is traceable to the farm where it was grown.

Figure 7. Selected ecological and social sustainability certification marks visible in the botanicals trade



4.3.9. UTZ CERTIFIED

UTZ CERTIFIED is most well-known for its certification of coffee, but it is now expanding into other product commodities to include certification programmes for palm oil, cocoa, and tea. Soon they will also offer a programme for cotton and rooibos. The key elements of the UTZ certification is the adherence to the UTZ Code of Conduct, which includes a set of economic, social and environmental criteria for responsible production (for producers), and traceability through the supply chain. The UTZ CERTIFIED organization is responsible for maintaining the code of conduct, the certification and training of certification bodies, and for ensuring that approved certification bodies carry out the annual inspections required for certification.

UTZ claims the added value of certification to be: recognition for the better grower, efficient farm management, transparent supply chain, and market access. According to the 2010 Annual Report, UTZ CERTIFIED coffee saw growth of 7.66% for the volume certified in tonnes, and 7.94% in the volume certified in 60 kilo bags; more than 70,000 tonnes of certified cocoa was produced in 2010, which was a large increase from 5,400 tonnes in 2009. UTZ CERTIFIED tea is much lower in volume, with approximately 17,280 tonnes in 2010, however this is a more recent programme with the first tea gardens only being certified in 2009.¹⁰⁷

See the UTZ codes of conduct here: <http://www.utzcertified.org/index.php?pageID=114>.

4.3.10. Community Trade programme from The Body Shop¹⁰⁸

The Community Trade programme is an internal company programme of responsible sourcing and buying practices to which the Body Shop adheres. It was begun in 1987 as one of the first examples of fair trade, striving to produce benefits to the company, their customers, and their suppliers. All the Body Shop

¹⁰⁷ UTZ CERTIFIED Good Inside Annual Report 2010.

¹⁰⁸ <http://www.thebodyshop.com/en/ww/services/pdfs/AboutUs/CTPrinciples.pdf>.

suppliers are asked to sign its code of conduct which supports the company's Ethical Trading Initiative, which was developed to help improve conditions for workers along the supply chain.

The Body Shop also uses Community Trade ingredients in their products. Spending on Community Trade has increased in recent years (in gifts and accessories). The Body Shop works with over 25,000 farmers from producers worldwide that supply them with 20 of their naturally derived ingredients, and 60 different gifts and accessories.

The types of ingredients produced in the Community Trade programme include: organic alcohol, aloe vera, babassu oil, bananas, coconut oil, beeswax, bergamot, purple corn, Brazil nut oil, chamomile, cocoa, honey, marula oil, olive oil, peppermint, seaweed, shea nut oil, soya, tea tree oil, sugar cane, and sesame oil. Beyond just being an internal programme, The Community Trade programme is verified by the third-party certifier, IMO.

Body Shop Community Trade commitments:

- We will work towards predictable and long-term trading relationships with communities.
- We will guarantee a living wage for our community trade suppliers and their workers.
- We will support initiatives in the supplier's community that contribute to sustainable development.

Community Trade activities:

- Including Community Trade ingredients, gifts and accessories in new product development wherever appropriate and possible.
- Aligning corporate and personal objectives to the success of the Community Trade programme.
- Ensuring that our demand is appropriate and sustainable by assessing the capacity of each supplier, and working where possible to manage the business level placed to that which the supplier can support.
- Benchmarking our Community Trade Supplier Guidelines against the highest external standard, e.g. Smallholder Guidelines of the Ethical Trade Initiative and Fairtrade Labelling Organization.
- Undertaking regular participatory audits, and providing all suppliers with clear information and feedback to assist in maximising long-term benefits.
- Working with suppliers to access the market place in order to reduce community dependency on The Body Shop.
- Creating in-store communication to raise awareness of the benefits of Community Trade to our customers.
- Engaging with the wider fair trade community to share best practice and address common issues.

5. Prices

Most of the thousands of natural ingredients that are used in cosmetic and/or dietary supplement products in the United States are not commodities (with some exceptions e.g. flaxseed oil), and therefore CIF or wholesale pricing information is not readily or publicly available. Most producers do not publish their price schedules (with certain exceptions), and most prefer to prepare price quotations on a case-by-case basis in response to serious inquiries. Some raw material suppliers such as Nutraceuticals International (a dietary supplement raw material supplier; <http://www.nutraceuticalsintl.com/>) or George Uhe (<http://www.uhe.com/>) do provide a product list with pricing on wholesale/bulk raw materials that may be faxed or e-mailed to clients.

Quotes may be dependent on a number of factors including the desired grade and quality, any unique specifications (e.g. a stock item that may require additional processing steps in order to meet a customer's unique particle size or density requirement), the single-order quantity, the annual contract quantity and the total value of business conducted with the customer over a period of time etc. Other customer specific conditions could potentially include whether the total shipment could be sent directly to the customer's

warehouse or whether it must be stored at a consolidation warehouse thus allowing the customer to take draws from the contract on a just-in-time basis or according to a predetermined delivery schedule.

With some rare exceptions, the internet is not yet a reliable source for obtaining commercial prices for natural ingredients. However, buyers and sellers can register with online services like Green Trade (<http://www.greentrade.net>) and ITC's Organic Link (<http://www.intracen.org/exporters/organic-products/exporters/>) for trading organic natural ingredients. In general, however, internet vendors often publish only consumer and retail pricing schedules, for example, for quantities less than 1 kg, which is not useful information for the buyer. Some suppliers that provide low quantity pricing on the internet may also offer commercial quantities with industrial price quotes prepared upon request from serious buyers.

The Market News Service for Medicinal Plants and Extracts is a quarterly publication available from the International Trade Centre (ITC) (<http://www.msonline.org/>). It provides indicative pricing of selected high-demand medicinal herbs and extracts from several major world markets including: Africa, China and other East Asian countries, Europe, India and other Asian countries, North America and South America. Tables 4, 5, 6, 7 are extracts from the December 2010 and 2008 issues of the Market News Service providing indicative pricing of top-selling botanical ingredients in the United States market.¹⁰⁹

In some cases many natural ingredients that are used in cosmetics, dietary supplements and/or natural health products are also classified as spices (e.g. cayenne fruit or ginger rhizome). Indicative tonne pricing for such natural ingredients may also be obtained from the ITC's Market News Service for Spices & Culinary Herbs, a bi-monthly publication that includes quotes for a range of herbs in selected markets in Asia, Europe, the Middle East and the United States. Indicative price information for essential oils can be found in the Market News Service's Essential Oils And Oleoresins Report, a quarterly report on essential oils and oleoresins worldwide. Other useful MNS bulletins include Market News Service for Gum Arabic and Gum Resins, a quarterly report.

Members of the Herb Growing & Marketing Network can list available crops on the Herbworld Online message board, providing date of availability, price, quantity, etc. There are other such online directories, such as the Swiss Import Promotion Programme's (SIPPO) Market Place Exporters Directory: <http://www.osec.ch/internet/osec/en/home/import/market.html>, or trading portals like Alibaba.com http://www.alibaba.com/Agriculture_p1.

Table 4. Botanical raw materials (indicative bulk prices), December 2010

| Product | Botanical Name | Grade | Cultivated or wild | Origin | Price USD/kg | Basis |
|-----------------------|----------------------------|-------------|--------------------|---------------|--------------|------------|
| American ginseng root | <i>Panax quinquefolius</i> | Medium | Cultivated | Minnesota | 88-110 | FOB SF |
| American ginseng root | <i>Panax quinquefolius</i> | Small legs | Cultivated | Minnesota | 44 | FOB SF |
| Coriander fruit | <i>Coriandrum sativum</i> | Not known | Cultivated | Canada | 1.61 | Spot NY |
| Echinacea herb* | <i>Echinacea purpurea</i> | PhEur-grade | Cultivated | Pacific NW | 5.95 | FOB Pac NW |
| Echinacea root* | <i>Echinacea purpurea</i> | PhEur-grade | Cultivated | Pacific NW | 22.04 | FOB Pac NW |
| Peppermint leaf* | <i>Mentha x piperita</i> | PhEur-grade | Cultivated | United States | 8.15 | FOB Pac NW |
| Slippery elm bark* | <i>Ulmus rubra</i> | USP-grade | Wild | United States | 30.42 | FOB USA |

* Certified organic

Notes: Quality Standards: Standards for the above listed medicinal plants are published in the United States Pharmacopeia and National Formulary (USP-NF). Some also has quality standards published in the Farmacopeia Herbolaria de los Estados Unidos Mexicanos (FHEUM) and/or in the European Pharmacopoeia (PhEur).

¹⁰⁹ Brinckmann J. Market News Service for Medicinal Plants & Extracts Nr. 7. Geneva, Switzerland: International Trade Centre. March 2008; June 2010.

Table 5. Botanical raw materials (indicative bulk prices) for select Peruvian botanicals from 2008¹¹⁰

| Product | Source | Price USD/kg | Destination |
|--|--------|--------------|----------------|
| Cat's claw bark (<i>Uncaria tomentosa</i>) powder | Peru | 9.5 | FOB Peru |
| Maca hypocotyle (<i>Lepidium meyenii</i>) – conventional powdered | Peru | 4.9-7.1 | FOB Peru |
| Maca hypocotyle (<i>Lepidium meyenii</i>) – conventional powdered | Peru | 10.0-15.9 | FOB New Jersey |
| Maca hypocotyle (<i>Lepidium meyenii</i>) – conventional gelatinized powdered | Peru | 9.9 | FOB Peru |
| Maca hypocotyle (<i>Lepidium meyenii</i>) – certified organic gelatinized powdered | Peru | 10.3-12.95 | FOB Peru |

Table 6. Botanical extracts (indicative bulk prices), December 2010

| Product | Standard | Price USD/kg | Basis |
|--|---|--------------|---------|
| Black cohosh rhizome dry extract (<i>Actaea racemosa</i>) | min 2.5% triterpene glycosides as 27-deoxyactein | 65-105 | FOB USA |
| Echinacea herb dry extract (<i>Echinacea purpurea</i>) | min 24% ginkgoflavoneglycosides; 2.6-3.2% bilobalide; 2.8-3.4% ginkgolides A, B & C | 35-40 | FOB USA |
| Ginkgo leaf dry extract (<i>Ginkgo biloba</i>) | min 24% ginkgoflavoneglycosides; 2.6-3.2%; bilobalide; 2.8-3.4% ginkgolides A,B & C | 175-275 | FOB USA |
| Saw palmetto fruit extract (EU standard) (<i>Serenoa repens</i>) | min 85% and max 95% fatty acids | 85-105 | FOB USA |

Notes: (1) Black Cohosh rhizome prices rose over the last quarter due to a late harvest which was a result of a severe winter in the south-east, early snow, and a low stock of the harvest from the previous year. (2) Echinacea angustifolia root is low in supply. Although some companies obtain it from cultivation, most of the supply is wild harvested in the mid-western and mid-southern United States. Some companies are switching to Echinacea pallida or Echinacea purpurea as a result. (3) The 2010 harvest of saw palmetto berry was poor, causing the market price to double.

Table 7. Botanical raw materials (indicative bulk prices), December 2010

| Product | Botanical name | Grade | Cultivated or wild | Origin | Price USD/kg (FOB) | Basis |
|-------------------------|----------------------------|--------------------------|--------------------|--------------|--------------------------------|-------|
| Food / Beverage | | | | | | |
| Rooibos | <i>Aspalathus linearis</i> | Conventional/ Organic | Cultivated | South Africa | 2.27 – 2.50/ 3.20 – 3.60 | FOB |
| Hibiscus | <i>Hibiscus sabdariffa</i> | Conventional/ Organic | Cultivated | Africa | 1.50 / 2.00 – 3.00 | FOB |
| Lemon verbena | <i>Aloysia tryphilla</i> | Conventional/ Organic | NA | South Africa | 8.50 – 11.55/ 11.55 – 17.30 | FOB |
| Honeybush (tea bag cut) | <i>Cyclopia intermedia</i> | Conventional | Cultivated | South Africa | 8.67 | FOB |
| Lemongrass | <i>Cymbopogon</i> | Conventional/ Organic | Cultivated | Zambia, | 5.55 / | FOB |

¹¹⁰ Brinckmann J. Market News Service for Medicinal Plants & Extracts Nr. 26. Geneva, Switzerland: International Trade Centre. March 2008.

| | | | | | | |
|-----------------------------|--------------------------------------|--------------------------|------------|-------------------------|------------------------------|-------------------------|
| (tea bag cut) | <i>citratius</i> | Organic | | Uganda, South Africa | 7.35 | |
| Devil's claw | <i>Harpagophytum procumbens</i> | Conventional/ Organic | Wild | Namibia | 3.50 – 5.80 / 4.70 – 8.00 | FOB |
| Baobab fruit powder | <i>Adansonia digitata</i> | Conventional/ Organic | Wild | Southern Africa | NA | NA |
| Aloe bitter crystal lump | <i>Aloe ferox</i> | Conventional | Cultivated | South Africa | 8.18 | Not including export |
| Aloe liquid gelly | <i>Aloe ferox</i> | Conventional | Cultivated | South Africa | 13.33 | NA |
| Cosmetic | | | | | | |
| Crude marula oil | <i>Sclerocarya birrea</i> | Conventional/ Organic | Wild | Southern Africa | 43.50/ 65.16 | FOB |
| Crude KMS oil | <i>Citrus lanatus</i> | Conventional | Wild | Namibia | 21.70 | FOB |
| Crude Ximenia oil | <i>Ximenia americana</i> | Conventional | Wild | Southern Africa | 36.50 | FOB |
| Crude mongongo oil | <i>Schinziophyton rautanenii</i> | Conventional/ Organic | Wild | Zambia | 21.70/ 29.00 | FOB |
| Crude mafura butter | <i>Trichilia emetica</i> | Conventional/ Organic | Wild | Mozambique | 8.70 / 14.50 | FOB |
| Crude baobab oil | <i>Adansonia digitat</i> | Conventional/ Organic | Wild | Southern Africa | 29.00 / 43.50 | FOB |

6. Distribution channels

6.1. The natural product supply chains

The botanical product supply chain always starts with the producer, a wild harvester or farmer, except in rare cases where a product is produced through plant tissue culture. There are a range of different models for supply chains; including direct-to-consumer, direct, less direct and indirect. These are summarized in Figure 28. The only truly direct supply chains are those where consumers have direct access to the produce of farms, such as at a farmers' market, or in community supported agriculture (CSA) (see direct-to-consumer example in Figure 28). In international trade, a supply chain that is considered direct would be a situation where a manufacturer buys from a producer and then sells to a retailer, which then sells to a consumer. An example of this is Dr Bronner's Magic Soaps which buys most its ingredients direct from producers (for example olive oil from the Occupied Palestinian Territory), they import the ingredients into the United States, use them to produce soaps, package them for wholesale, sell to retailers and distributors who then sell to consumers. This is a case of a company that has a mission-driven approach in sourcing its ingredients direct from fair trade certified sources.

Buyers of cosmetic and/or dietary supplement products purchase natural ingredients from a range of different supplier types. Smaller manufacturers will often purchase their natural ingredients from wholesale distribution companies that may offer value-adding capabilities such as cutting and sifting, particle sizing, granulation, blending, as well as laboratory analysis with analysis certification. On the other hand, many wholesale distribution companies may purchase the ingredients from primary producers, re-package the ingredients into smaller containers, and re-label them so as not to disclose their sources.

Figure 8. Typical supply chains

| |
|---|
| <p>Direct-to-consumer Producer > Consumer</p> <p>Direct Producer > Manufacturer > Retailer</p> <p>Less direct Producer > Processor > Manufacturer > Distributor > Retailer</p> <p>Indirect Producer > Processor > Exporter/Port > Importer/Port > Distributor > Contract Manufacturer > Retail > Consumer</p> |
|---|

In many cases, natural product brand holders have no production capabilities and so their products are manufactured entirely by a contract manufacturing company. The contracting company can specify both the grade and quality of natural ingredients for their products, as well as the ingredient supplier to be used. More often, however, the contract manufacturer is entrusted to purchase the natural ingredients based on their own criteria and relationships. In such cases, it may be more important for the natural ingredient producer to develop a relationship with the contract manufacturer than with the natural product brand holder.

Less-direct supply chains and indirect supply chains can have many kinds of intermediaries between the producer and point of sale. Figure 28 has a list of possible intermediaries and a description of their roles.

Table 8. Supply chain roles – brief definitions

| Name | Definition |
|-----------------------------|---|
| Producer | A farmer or other producing agent for agricultural produce. |
| Processor | A business engaged in processing agricultural products and preparing them for market. |
| Distributor | A business that buys non-competing products or product-lines, warehouses them, and resells them to retailers or direct to the end users or customers. |
| Exporter | A business (or person named in the customs export declaration) that sells its goods to a business or party in another country. |
| Importer | A business (or party making the import declaration) that is liable for the payment of duties (if any) on the imported goods. |
| Manufacturer | A business engaged in manufacturing one or more products. |
| Contract manufacturer | A manufacturer that can be contracted to manufacture products by another company, like a brand holder |
| Brand holder | A company that owns and markets a specific brand. |
| Co-packer (contract packer) | A company that is a contract manufacturer for other companies but which also can package products in final or semi-final packaging. |
| Retailer | A business which sells goods to the consumer, as opposed to a wholesaler or supplier which normally sells their goods to another business. |

Further distinctions can be made regarding supply chains. There are a number of vertically-integrated natural product companies in the United States. Several of these own and operate their own farms or have contract-grower arrangements for some of their natural ingredient supply requirements. Examples of vertically-integrated cosmetic and/or herbal dietary supplement companies in the United States include: Amway Corporation, which owns Trout Lake Farm (four farm locations: Washington, California, Mexico, Brazil); Eclectic Institute (which operates a 90-acre organic herb farm); Herb Farm (which operates an 85-acre organic herb farm); Young Living (which operates a 1,600-acre organic herb farm on two locations); and Gaia Herbs (which operates a 250-acre organic herb farm). Please refer to the Herb Farms section of appendix III for details.

Figure 9. Case study: RFI ingredients

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RFI is a manufacturer of innovative natural ingredients for the food, functional food, and dietary supplement industries. The company, formed in 1989, specializes in the supply of ingredients and proprietary formulations developed by its global partnerships and in-house applications laboratory. The company has a network of global partners that enables them to capitalize on worldwide seasons and economic fluctuations. With manufacturing operations in North America, South America and China, they are able to source ingredients from an extensive area. RFI also operate Atlantic Coast Functional Foods (ACFF), a separate company that concentrates on selling functional foods in the Asian market.

In Latin America, RFI has an exclusive relationship with a raw material and extraction facility located in Brazil. RFI does foster relationships with growers directly, but more often it is their global partner companies that maintain these relationships. 'The largest area of growth potential we are seeing is for the 'superfoods'.' Says Paulo Altaffer, VP of Business and Product Development for RFI. 'We are always actively looking for good sources of fruits, nuts, oils, botanicals that have health benefits, and are safe to use as foods...'

Other United States natural product companies also own and operate foreign farms, have joint ventures with foreign farms, or contract foreign growers for specific crops. For example, New Chapter, a manufacturer and marketer of dietary supplement products (e.g. Supercritical Therapy® brand), operates Luna Nueva Farm in La Tigra in Costa Rica: a 74-acre certified organic and biodynamic ginger and turmeric farm. Another example is Guayakí Sustainable Rainforest Products, which handles maté leaf organically grown and certified on a 20,000-acre Guayakí Rainforest Reserve in Paraguay.

A variety of retail stores sell natural products in the United States with over 3,000 natural food vendors. One of the most popular is the Whole Foods Market chain which began in 1980 with one store and now has over 300 stores in North America and the United Kingdom. It is important to realize that Whole Foods Markets does the majority of its buying through a large natural products distributor called UNFI. UNFI is the leading independent US distributor of natural, organic and speciality foods and related products (which includes dietary supplements and natural cosmetics). Other natural products, such as cosmetics and organic clothing, can be found in a variety of stores and superstores. These generally buy via distributors with only a minority going directly to producers. Fair trade stores throughout North America focus their buying on members of the Fair Trade Federation or the World Fair Trade Organization.

It is also important to realize that some of the leading cosmetic and dietary supplement consumer products in the United States market are actually manufactured in Europe. These European natural products are re-labelled for the United States market and distributed either by the foreign company's United States sales and marketing division, through a subsidiary or by a company that has obtained exclusive sales and marketing rights in the United States. For example, EuroPharma™ (<http://www.europharmausa.com/>) distributes European-made natural personal care products and natural medicines. Where European natural products are being distributed in the United States, the natural ingredient producers and exporters in developing countries need to develop relationships with the product manufacturer located in Europe rather than with the product vendors in the United States.

6.2. Successful models for foreign natural ingredient suppliers in the United States market

Due to the high level of competition, it is difficult to succeed in the United States market for natural ingredients without maintaining a strong presence inside the United States (sales, marketing, warehousing, technical support, etc...). Selling into the United States market from abroad puts businesses at a severe disadvantage for many reasons such as:

- Buyers' expectations of readily available technical support and samples, as needed, from the ingredient vendor's scientific and technical affairs staff.

- Buyers' preference to take product delivery of contracted ingredients, as needed, on a just-in-time basis.
- Buyers' expectation that a vendor can quickly remedy a problem, for example by immediately shipping a new batch load of the same ingredient.

Vendors who do not have their natural ingredients warehoused inside the United States and ready-for-shipment may lose out on both spot-buying opportunities as well as on fixed annual contracts awarded by just-in-time buyers.

Models of successful foreign vendors of natural ingredients generally include those who have set up, at a minimum, sales and marketing offices in one or more locations in the United States staffed by United States industry veterans. Foreign companies who staff their United States sales and marketing offices with personnel from the company's country of origin may be less successful than those who can afford to attract and hire experienced United States staff. These United States staff typically already have a successful track record and their own valuable connections to key industry buyers and decision makers (such as new product development, quality control, and research and development managers) involved in ingredient selection, vendor qualification, and approval steps along with the purchasing manager.

In the area of raw material sales, it is increasingly the case that buyers expect raw material suppliers to also offer full-service options. Many of these additional services, such as formulation, application assistance, and product concept support, are expected free of charge.

Some successful foreign natural ingredient vendors operating in the United States, particularly European and Asian companies, also keep sufficient inventories ready-to-ship, either at a consolidation warehouse/shipping service company or they may lease or own their own warehouse and shipping facilities in the United States.¹¹¹ If inventories run too low prior to the next ocean container arrival, some vendors will airfreight a less-than-container-load purchase order directly to the customer in order not to risk losing the business. Some of the more successful foreign vendors also have scientific and technical staff working in their United States offices in order to assist customers with product development and to help troubleshoot when there are ingredient problems at any stage of production.

Foreign ingredient vendors who do not have the resources available to maintain their own warehousing and/or sales & marketing operations inside the United States may also succeed by developing a strategic relationship with an appropriate, well-positioned American company. A common arrangement is to grant the American company exclusive rights to distribute their brand of natural ingredients to the United States market. There are many examples of full-service United States -owned wholesale distribution companies whose catalogues are dominated by the offerings of several different foreign natural ingredient suppliers. For example, **RFI Ingredients** (<http://www.rfiingredients.com/>) offers natural ingredients for the food, functional food, dietary supplement and pet food industries by incorporating the business catalogues of partners (for example **Grupo CentroFlora** for botanical extracts produced in Brazil). Another example of an American master distributor of foreign-made natural ingredients is **P.L. Thomas & Co. Inc.** (<http://www.plthomas.com/>), the United States sales representative for botanical natural ingredients produced by **Galilee Herbal Remedies** of Israel. Entering into such an exclusive partnership should not be done without much scrutiny and careful thinking, as some producers find themselves in relationships with distributors that do not fulfil promises of marketing and do not meet sales goals, or are otherwise difficult to work with. Additionally, the producer may be expected to do a lot of work in the relationship and when sales contacts are made then are legally obliged to work through their exclusive partner, regardless of the performance of that partner.

6.3. Succeeding in the supply chain – finding the right partner or adding value

Once a company has a better understanding of who they are and what role they play in the supply chain, they generally have two broad options for increasing business. These options include to identify better with

¹¹¹ Either at a consolidation warehouse / shipping service company or they may lease or own their own warehouse and shipping facilities in the United States.

customers who purchase their products and to find ways to add more value to their products to capture more margin for each unit sold.

The first option, to identify more (or better) customers to buy their products, can result in increased volume of products sold and cash-flow. Although companies generally try to find as many customers for their products as possible, many do not consider that finding the right partner and investing in this relationship may be a more valuable use of time. The majority of natural products buyers buy on price and do not invest much in supplier relationships, presuming that distributors do a good job with supplier relations, representation and can assist them in transactions (for example importing, marketing, sending samples, understanding and communicating quality, and sometimes more elaborate activities such as formulation assistance or labelling support). However, there are examples of companies (such as the mission-driven companies mentioned above) that take time to work with their suppliers/producers and assist them in reaching the quality they need for the market, as well as assist in how to present or prepare the product in a manner the buyer needs.

According to Gero Leson from Dr. Bronner's Magic Soaps, 'We invest a lot of time and resources in developing the relationships with our producers. Dr Bronner's is a mission-driven company that not only has ideals for our own behaviour but also for determining what kind of suppliers we work with and how we treat them. Part of how we satisfy these principles in our mission is by being fair trade certified and also fully committing to working with fair trade partners, and investing in those relationships.'

Figure 10. Case study: Harmless Harvest – sourcing 'superfruits'

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When Harmless Harvest started their business a couple years ago, they were trying to find non-timber forest products (NTFP) fruits that could be made into a beverage, with a supply that is scalable. They also wanted a fruit that could show consistency in production, as well as meet a profile of product attributes they had compiled to help them in their search. Harmless Harvest worked with Swiss fragrance and flavour manufacturer Givaudan to receive initial advice, and once they narrowed their search down to a list of about 20 different fruits, they received lists of producers from NGOs operating in Brazil and Peru.

The next challenge they faced was finding fruits that met the desired attributes and that had a fresh/frozen fruit supply. They found that most processors were using freeze drying and this was not good enough for some fruits, as the freeze drying process altered the flavour profile (e.g. the forest woodiness that is part of the cupuaçu is lost on freeze drying). One fruit that stood out and met all their conditions was camu camu, so they went into further development with this fruit. They found it had a unique flavour, texture and fragrance, had an interesting profile of nutrients, was very quick growing, was high yielding, and grew in poor soils/habitats. Another challenge was that they found that there were differences in the sub-species of camu camu depending on location. They realized that they would need to do a self-affirmation for GRAS. Also, as they were trying to figure out the best source for the fruit, it was realized that wild camu camu had not been managed well, so they began working with Dr Chuck Peters from the New York Botanical Garden (an expert on wild harvesting) to help them devise a sustainability plan. They report that it has been difficult to find out on their own how much camu camu is coming from real agroforestry and how much is just coming from people chopping down the forest.

Harmless Harvest reports that for their uses, once camu camu is harvested, it needs to be pulped, pasteurized, and then it can be hand-sealed and placed in a freezer. Justin Guilbert, president of Harmless Harvest, said: 'A small community can do this, and if communities could have assistance with buying pulpers and freezers, they could be making a lot more money for the high quality fruit, and get access to the market.'

Harmless Harvest has been also interested in cupuaçu, and has found a cosmetic partner who has been investing in cupuaçu seed oil for its use in cosmetics (the seed oil has hydrating properties). As this company had been building up a supply for the seed, they could increase the return for their investment by selling pulp to Harmless Harvest. They are also looking for other sources and have turned to their NGO partners to help them in this.

Guilbert thinks camu camu could be the next big superfruit, and says this is reflected by the retailers. He said that the image of acai was hurt in a big boom and bust that happened with products that became popular for their outrageous weight loss claims.

Guilbert warns: 'The key to making camu camu a successful and sustainable botanical is to give people the full explanation of its benefits to prevent a big surge and fall in demand. That way it doesn't become, for example, the next weight loss sensation, and then once people try it and are disappointed they lose all interest in it. People need more information to base their decisions on, and the marketing story should reflect this whole story.' Guilbert estimates that this year they will use about 40 tons of pulp, and this could go up to 120 tons depending on the demand.

The second method of enhancing trade from the supplier perspective is to add more value to the products that are offered, for example by offering higher quality processing, or services that a buyer might value.

The demand for quality varies from buyer to buyer. It is important to find out what the specific supplier qualifications are that a buyer is looking for in a producer. Large and smaller companies will usually have supplier-qualification programmes (see section 7.0, Supplier qualifications), or at least a list of product specifications (see section 4.2, Quality requirements). Along with quality standards, companies also have requirements for certifications, such as organic, fair trade, halal or kosher, in addition to food safety and hygiene related certifications, such as HACCP or GlobalGAP (see section 4.3, Emerging product certifications/labels).

A second strategy of adding value to agricultural products is through processing. Figure 30 shows how the fruit camu camu can be further divided (through minimal processing) into its pulp and seed parts. Those parts can be further divided into advanced processed products (which adds another level of value) such as oil from the seed, the extract, natural colour (also an extract, but with different processing or specifications) or they can be frozen (fresh frozen pulp).

7. Supplier qualifications

The information required by buyers from suppliers can vary. The more established, larger manufacturers or brandholder companies in North America have supplier-qualification programmes requiring suppliers to qualify before they can sell to the manufacturer. In some cases, the buyer's purchasing department is not authorized to make a purchase until after the Quality Control (QC) unit has inspected and qualified the production site(s) in the country of origin. For an example of a supplier qualification document, see appendix X.

Figure 11. Case study: Aveda – buyer qualification and Andean sourcing

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Aveda has been in operation since 1978 and is now owned by Estee Lauder. The company has both a global supply relations package as well as a coding package that it sends to new potential suppliers. According to Cindy Angerhofer, Ph.D. executive director of botanical research and aroma for Aveda: 'Generally, we are here to help suppliers, especially if they produce an ingredient we are focused on, but they really need to work through the supplier qualifications on their own. It is important they share at least three separate samples, a MSDS with us, and have some idea of safety of the product (such as REACH documentation, AMES and in vitro testing). Also, sustainability is important to us, as well as a high quality, consistent supply of material, and that the material is within the new guidelines for the Convention on Biological Diversity.'

Angerhofer reports that Aveda is actively looking at Peru as a resource for ingredients. Right now the company buys Brazil nut oil from CANDELA (Comercio Alternativo de Productos No Tradicionales y Desarrollo en Latinoamerica). The company is especially always looking for aromas, essential oils, or other fragrances. It is also interested in biological materials that have traditional-medicine skin or hair applications. It buys a lot of organically certified materials, and fair trade as a concept is important to the company but it is still looking into certifications in this area and others.

Angerhofer reports the company is looking at sachu inchi right now, as well as chia seeds, as sources of essential fatty acids (omega-3 fatty acids) but that this type of product is always challenging because the omega-3 fatty acids are so unstable.

Aveda has summaries about some of their ingredient-buying stories on its website, including those of lippia from Brazilian communities, babassu from Brazil, and uruku from the Amazon (Brazil). For example, Brazilian urukum (Bixa orellana) is from a plant that produces a pod that is filled with seeds that give off a bright red pigment when squeezed. A local tribe, the Yawanawa, use this pigment as a shield from the sun, to protect from mosquitoes, and as an expression of health and beauty. In the mid-1980s the village of Nova Esperanca successfully began a fight to regain their cultural lands and heritage. In 1992, Aveda's founder, Horst Rechelbacher and an anthropologist, May Waddington started a partnership to create an urukum tree plantation, that could help the Yawanawa to sustain themselves. Aveda's research chemists also discovered the red pigment was perfect for developing a superior red lip colour. The partnership with Aveda reportedly has created jobs within the community and a means for cultural survival, while preserving the land and protecting it from the threat of loggers and rubber-tappers. Aveda has helped the community to build a solar energy system, a school and a dispensary to treat malaria. Aveda has also helped the Yawanawa gain organic certification and develop partnerships with a pharmaceutical facility that processes the urukum.

Section 4 on market access gives more details on some of the quality requirements sometimes required by buyers. To qualify as a supplier, the buyer's quality control (QC) unit may carry out a GACP inspection if the supplier is a producer of botanical raw materials, or a GMP inspection if the supplier is a producer of value-added extracts or oils. Questionnaires may be used if a physical inspection cannot be carried out. Copies of valid certification documents and inspection reports may be requested by the buyer. For each ingredient, the buyer will have detailed written specifications. For Canada, specification requirements for natural health product active ingredients and finished products are defined in the NHPD Compendium of Monographs. For the United States, specification requirements for dietary supplement components and finished products are defined in FDA's CGMPs for dietary supplements. Buyers may have additional requirements beyond those required in the national regulations. Below are other potential requirements of a supplier-qualification programme.

Material safety data sheets (MSDS) – These are information forms that state the properties of a given substance (the raw material) which are considered important in workplace safety including: procedures for handling or working with that substance in a safe manner; physical data (melting point, boiling point, flash point, etc); toxicity; health effects; first aid; reactivity; storage; disposal; protective equipment; and spill-handling procedures. Formats vary by country.

In Canada the Workplace Hazardous Materials Information System (WHMIS) establishes the requirements for MSDS (administered by Health Canada under the Hazardous Products Act, Part II, and the Controlled Products Regulations).

Normally, for an agricultural raw material product, an MSDS is not required.

Toxicology/Safety testing – In the United States, companies are legally required to assure the safety of their products. Even though this burden lies on the product manufacturer/brandholder, many manufacturers pass on this responsibility to their suppliers. If the raw material is an agricultural product (without proprietary processing), testing is not normally required (as the ingredient is already established on the market) unless it is a new product. In this case the buyer might ask a supplier for safety testing or references.

In Canada, companies are required to have a licence to sell their products in the Canadian market. The application for this licence requires proof of safety, quality and efficiency. Although this is a requirement on the manufacturer/brandholder, the more sophisticated supplier would do well to have safety data available (even a bibliography of references from published sources) to assist the buyer. Types of safety testing might include: skin sensitization, ocular irritation, skin toxicity and irritation, acute oral toxicity, phytotoxicity, photoallergenicity, mutagenicity, carcinogenicity, and reproductive toxicity.

Identity & Quantitative Compositional Breakdown – This includes: the Latin name of the plant; part(s) of the plant used (e.g. flower, leaf, root, fruit pulp); identity of any solvents used in extraction; ratio of solvent to botanical prior to extraction; and the recent yield after extraction. In the case of a multicompositional mixture, the full disclosure of components within the mixture is required.

Certifications – Proof of relevant certification such as a transaction certificate and/or FLO.

Status (if listed on Redlist, by the IUCN or in CITES) – In the case of botanicals, buyers will often want to know if the botanical is listed on either the Redlist (The World Conservation Union Redlist of Threatened Species (see www.redlist.org)), IUCN (the International Union for Conservation of Nature), or in CITES (the Convention on International Trade in Endangered Species of Wild Fauna and Flora, (see www.cites.org)).

Pricing schedule – Some buyers will ask to see a pricing schedule with pricing in price per kilogram, including the manufacturer and distributor price (if applicable). Some buyers will also want to know production costs in the case of fair trade certified produce.

Raw material specifications – A certificate of analysis and specifications is normally required for dietary supplements (herbal medicines) including acceptable ranges for each specification. Physical descriptions are also necessary, including the description of the odour and colour, as are special handling or shipping requirements.

Analytical test method for all tests appearing on the certificate of analysis – If the product is a processed botanical product (such as extraction), and carries a specification sheet, the methods for determining reference standards and testing should be disclosed.

Microbiological analysis – Buyers typically set an upper limit for the acceptable colony forming units per gram or millilitre (ml), as determined by aerobic count or most probable number. Micro-organisms that are often restricted are gram negative bacteria *Staphylococcus aureus*, *Candida albicans*, *Enterococcus species*, or *Aspergillus niger*. Products with high water content often require microbiological testing (except for fresh produce) as they may be more susceptible to microbiological contamination.

Trace contaminants/Impurities – this might include: heavy metals, pesticides, iodine, 1,4-dioxane, ethylene oxide, residual catalysts, processing aids, and reaction by-products (residual monomers).

Pigments – If the product is a processed natural pigment, buyers can ask for proof of compliance to national regulations.

Environmental impact – If the product is a harvested botanical (especially those harvested from wild environments), information on the sustainability of harvesting may be requested. In the case of a processed product, there may be requirements for information relating to biodegradability (or other degradation pathways), aquatic toxicity, volatile organic compounds (VOC) content, accumulation and persistence, treatability in a public owned treatment plant, bioconcentration and adsorption.

Lot samples – Most buyers require samples from separate production lots in order to test internally and assess average quality.

8. Packaging and labelling

8.1. Packaging and labelling into the United States

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

In addition to legal requirements for the packaging and labelling of imported ingredients, importers are likely to have their own additional packaging and labelling requirements, for example that the seller's lot number, the buyer's item code number, and the purchase order number are stencilled on each sack or drum. The importer 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.

Labelling requirements include:

- English name of the ingredient;
- English name of country of origin;
- Name and address of the producer;
- Gross weight;
- Net and tare weights;
- Vendor's lot number (must match lot number on packing list); and
- Any other information requested by the buyer (e.g. buyer's item code).

If the imported natural ingredient is certified organic, the following USDA National Organic Program regulations may also apply:

§ 205.307¹¹² Labelling of non-retail 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))'.

a) Non-retail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

- 1) The name and contact information of the certifying agent which certified the handler which assembled the final product;*
- 2) Identification of the product as organic;*
- 3) Special handling instructions needed to maintain the organic integrity of the product;*
- 4) The USDA seal;*
- 5) 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.*

b) Non-retail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable.

8.1.1. Ingredient nomenclature

Dietary supplement law requires product ingredients labelling to be consistent with the standard common names (SCN) as defined in the American Herbal Products Association's publication Herbs Of Commerce.¹¹³

Cosmetic ingredients must use nomenclature found in the International Cosmetic Ingredient Dictionary and Handbook published by the Cosmetic Toiletries And Fragrance Association (CTFA).¹¹⁴

8.1.2. Country-of-origin marking requirements

Every article of foreign origin entering the United States must be legibly marked with the English name of the country of origin unless an exception from marking is provided for in the law. The marking must be legible, of an adequate size, and clear enough, to be read easily by a person of normal vision. The marking should be located in a conspicuous place, where it can be seen with a casual handling of the article. Abbreviations that unmistakably indicate the name of a country, such as 'Gt. Britain' for Great Britain or 'Luxemb' for Luxembourg, are acceptable. Variant spellings which clearly indicate the English name of the country of origin, such as 'Brazil' for Brazil and 'Italie' for Italy are acceptable. However, it is always preferable to spell out the country's name in full, because any abbreviation may be a cause for confusion. However, 'E.C.' or 'E.U.' for European Community or European Union, respectively, are not acceptable abbreviations since they do not indicate the individual country of origin of the goods.

¹¹² United States Federal Register.

¹¹³ McGuffin M, Kartesz JT, Leung AY, Tucker AO (eds.). American Herbal Products Association's Herbs of Commerce, 2nd Edition. Silver Spring, MD: American Herbal Products Association. 2000.

¹¹⁴ Weaver K. Cosmetic Labelling Regulations. NPI Watch. 10 January 2003.

The best form of marking is one which becomes a part of the article itself, such as branding, stencilling, stamping, printing and moulding. Other forms of marking, such as adhesive labels, also will be acceptable if it is certain that the marking will remain legible and conspicuous until the article reaches the ultimate purchaser in the United States. When tags are used, they must be attached in a conspicuous place and in a manner which assures that, unless deliberately removed, they will remain on the article until it reaches the ultimate purchaser.¹¹⁵

8.1.3. Food and Drug Administration

To ensure that FDA is notified of all regulated products imported into the United States, the importer, or his/her representative, must file an entry notice and an entry bond with the United States Customs Service (Customs) pending a decision regarding the admissibility of the product. FDA inspection and enforcement procedures for imports rely on coordination with Customs. FDA is notified by Customs of the entry and makes a decision as to the article's admissibility. If FDA does not wish to examine the entry, the product is allowed to proceed into United States commerce.

8.1.4. United States Department of Agriculture

USDA regulatory activities are enforced by the Animal and Plant Health Inspection Service (APHIS), the Food Safety Inspection Service (FSIS), and Agricultural Marketing Service (AMS), among other agencies. In addition, the United States Customs Service participates by the detaining of imports when USDA requirements have not been met. APHIS is responsible for enforcing regulations governing the import and export of plants and animals and certain agricultural products. APHIS import requirements depend on both the product and the country of origin. Plants and plant materials usually must be accompanied by a phytosanitary certificate issued by an official of the exporting country (see section 4.1.4 for more information on phytosanitary certificates).

For USDA National Organic Program regulations, visit:

<http://www.ams.usda.gov/nop/NOP/NOPhome.html>.

8.1.5. United States Customs Service

The US Customs Service cooperates with a number of other federal agencies and a licence or permit from the responsible agency is necessary to import a range of products including plants and plant products.

8.2. Packaging and labelling into Canada

For requirements on packaging and labelling, as well as all other import questions, the Canadian Food Inspection Agency has made available the Automated Import Reference System (AIRS) which is convenient for those wanting to know the most accurate and up-to-date information on import requirements. AIRS uses a question-and-answer approach to guide the user through a series of questions about the Harmonized System (HS) codes, origin, destination, end use and miscellaneous qualifiers of the product they wish to import.

See the Canadian Food Inspection Agency Automated Import Reference System (AIRS) web page here:

<http://www.inspection.gc.ca/english/imp/airse.shtml#>.

There is also a guidance document provided by Health Canada for good importing practices. For foods, labelling of the product shall have a written product description that is available and current for each product. The following information may apply:

- Common name of the product,
- Brand name,
- Net quantity declaration,

¹¹⁵ U.S. Customs Service. Marking of Country of Origin on U.S. Imports. Acceptable Terminology and Methods for Marking. Washington, DC: U.S. Customs Service.

- Product variety,
- Grade,
- Product specifications and characteristics,
- Container size,
- Copy of the Canadian label,
- List of ingredients,
- Packaging material,
- Final use of the product,
- Origin of the product,
- Labelling instructions when further labelling is required, and
- Handling and storage instructions when special requirements exist. (Examples include the following: do not store with non-food items; keep refrigerated; keep frozen; store at room temperature.)

For labelling of licensed natural health products, please refer to the Health Canada NHPD Labelling Guidance Document here:

<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/labelling-etiquetage-eng.php>.

If a natural health product (NHP) will be imported into Canada, the product licence applicant must provide the NHPD with an attestation that the NHP will be manufactured, packaged, labelled, imported, distributed and stored in accordance with good manufacturing practices (GMPs) for NHPs. Furthermore the foreign NHP manufacturing site must be inspected and listed under the site licence of the importing firm.¹¹⁶

9. Sales promotion

9.1. Trade fairs

Natural ingredient producers and exporters in developing countries should consider exhibiting at relevant supply expos in the United States in order to establish contacts with product manufacturers' buyers or to investigate the possibility of securing a business arrangement, exclusive or otherwise, with a suitable importing and ingredient distribution company or broker. It may be possible to obtain the latter without exhibiting, but by only attending the trade fair and making appointments in advance for private meetings with targeted potential business partners. Meetings with purchasers should be firmed up in advance and should take place away from the show floor if possible. Ingredient distributors generally have only their sales and marketing personnel in the exhibition booth while their purchasing agents may be meeting with their vendors privately at other locations.

Visiting the trade fair can also provide the exporter with valuable market information by attending educational seminars, trade association meetings, industry receptions, and by walking the show floor. Whether visiting or exhibiting, the natural ingredient producer should be prepared with professionally produced material in English to provide an overview of capabilities and a list of offerings.

If the costs of trade fair exhibition are beyond the means of an individual ingredient producer, it may be possible to organize a cooperative exhibition including several producers from the same region under one umbrella. In some cases, this is partially organized or funded by the export promotion agencies in the country of origin or even by United States trade development organizations that may have funding available to cover expenses for producers from developing countries to participate in study tours in the United States in order to meet potential buyers and/or to attend trade shows.

¹¹⁶ Natural Health Products Directorate (NHPD). Natural Health Products Regulations. Canada Gazette. June 18, 2003. Available at: <http://gazette.gc.ca/archives/p2/2003/2003-06-18/html/sor-dors196-eng.html>.

Figure 12. Case study: Mountain Rose Herbs

PO Box 50220
 Eugene, OR 97405, United States
 Tel: 1-800-879-3337
 Fax 1-510-217-4012
 International Calls: 1-541-741-7307
 E-mail: shawn@mountainroseherbs.com, Procurement@mountainroseherbs.com
 URL: www.mountainroseherbs.com

Mountain Rose Herbs have been in business since 1987. Around the year 2001, the company changed its sourcing practices from being dependent on many distributors to sourcing directly from producers. They are importing approximately 12-14 containers every month. They have farm managers for each major world region they work with, to liaise with the farmer and to help establish procurement procedures with the farms.

According to company vice-president Shawn Donnille, the change has made a huge difference to their business. He says they have much more influence on almost every step of production including harvesting, processing and cleaning practices, which makes a big difference with the quality of the herbal product. They are getting many requests for tonnage quantities, which is not their main business, and they are starting to experience a lot of shortages, as they are having a hard time keeping up with demand. Another difficulty for them is finding new farmers to work with. The absence of a listing of producers around the world means they have to spend time finding and investigating new farms. When asked what would be the best ways for farms to find a company such as his own, Donnille replied that the best way is just to have the farmers e-mail or call them directly. Donnille says that he often tells farmers that the best way to reach the market is to go to one of the herbal trade association websites, such as The American Herbal Products Association (AHPA), and to just cold call all of their members.

Their two biggest selling products out of the South American region are maca powder (certified organic) and lemon grass (certified organic), and they would like to find more good producers of both of these products. Other herbs they carry from the region are yacon, catuaba, marapuama, cat's claw, acerola and pau de arco. Donnille says that only one of the three producers they buy from – when they need to buy for example, cat's claw – might have stock for them to buy so that they are often out of stock on these items. Another popular selling product from the region is acai, although they do not have a good direct source for this yet, and camu camu they are still looking into. Donnille says that the 'superfruits' are very trendy but feels the herbs are a steady market that is here to stay.

The following trade fair is one of the main events of interest to producers of natural ingredients for the United States natural cosmetics and dietary supplements market and for natural product manufacturers' buyers:

SupplySide International Trade Show and Conference

Virgo Publishing – Health & Nutrition Division, P.O. BOX 40079, Phoenix, AZ 85067-0079, United States

For exhibiting information, contact Todd Willis at 480-990-1101, ext. 1171.

URL: <http://www.supplysideshow.com/>

SupplySide is produced by the publishers of the Natural Products Insider. Insider is subscribed to by more than 10,000 professionals in the dietary supplement, food and cosmetic industries. SupplySide is the world's largest event for healthy and innovative ingredients, specifically focused for manufacturers, marketers and formulators of foods, beverages, supplements and cosmeceuticals.

Another trade fair is Engredea. Now co-located with Natural Products Expo East and West, Engredea features exhibitors of natural ingredients. However, although these are much larger shows than SupplySide, they are not specifically focused on ingredients. Buyers of ingredients from Canadian companies will often attend the United States shows, either SupplySide West or Engredea, and now there are Expo East and West (and Quebec) trade shows specific to Canada, provided by the Canadian Health Food Association (CHFA). Another show of note is the Fancy Food Show, which is a speciality food show (including gourmet foods) that focuses on finished products and ingredients. There are two key Fancy Food Shows: one in the summer on the East coast (Washington DC, June) and one in the winter in California (San Francisco, January).

Table 9. Approximate booth fees at the top American trade shows (2011-2012 pricing)

| | Natural Products Expo West | Supply Side West | Fancy Food Show (summer) | Institute for Food Technologists (IFT) |
|------------------------------------|---|---|--|--|
| Main audience of show | Retailers attend to find finished product | Buyers attend to find ingredient suppliers | Retailers attend to find finished product | Food developers attend to find food ingredients |
| Contact for exhibiting info | 1.303.390.1776 tradeshows@newhope.com | Todd Willis at (480) 990-1101 ext. 1171 or twillis@vpico.com | Jennifer Carney (212) 482-6440 Ext.121 jcarney@nasft.org | Phone: +1-312-782-8424 Fax: +1-312-782-8348 E-mail: info@ift.org |
| Example booth size | 100 square foot (10' x 10') | 100 square foot | 100 square foot | 100 square foot |
| Booth price | US\$ 4,995 | US\$ 4,550 | US\$ 3,400 | US\$ 3,195 |

9.2. Internet

Increasingly, internet sales are becoming a more important venue for commerce, including natural products and even some ingredients or raw materials. One of the world's most popular online marketplaces for a wide variety of products is eBay (www.ebay.com). On eBay, one can also find and sell natural ingredients, such as food products and cosmetics. A new website from eBay that is dedicated to being 'people positive' is World Of Good (<http://worldofgood.ebay.com/>). This features a variety of natural products but not usually raw material ingredients on their own.

A few raw material suppliers also carry retail or bulk product lines, and some make these speciality product lines available on the internet. For example, see the online site of Essential Living Foods: <http://www.essentiallivingfoods.com/products/index.html>, which features superfoods from South America, specifically Peru.

Certainly, doing business on the internet is also not without serious risks. There are risks in receiving payments from credible customers, risks in shipping product to international locations, and risk associated with trying to build a business online that is able to effectively attract customers.

9.3. Certified supplier networks

Ingredient suppliers who are certified to a specific standard may also have alternative trading networks established specifically for their products. For example, fair trade certified suppliers may have special trade assistance available to them to link them with buyers who are interested in certified ingredients. The Fairtrade Labelling Organizations International (FLO)/Transfair and the Institute for Marketecology (IMO)/Fair for Life are the two most well-known fair trade certifications in North America. Producers who are certified at origin are sometimes matched with buyers through the respective certification body or labelling initiative. The Fairtrade Labelling Organizations International (FLO) gives various kinds of support to producers, including market assistance. Please see: http://www.fairtrade.net/support_for_producers.html

Producers who have Fair for Life Social & FairTrade certified by IMO certification also receive support from IMO in complying with the market, and their profiles are given at the Fair for Life website which is used by buyers to link up with appropriate producers: www.fairforlife.net.

For organically certified companies, both buyers and sellers can register with online services like Green Trade (<http://www.greentrade.net>) to find buyers or suppliers of ingredients. Additionally, many certifiers of organic companies, just as in fair trade, also carry lists of their certified producers which some buyers will use when sourcing ingredients. For example, IMO has an updated list available at: http://www.imo.ch/imo_certified_operations_en,1221,998.html, and CCOF has its list at: <http://www.ccof.org/directories.php>.

There are a number of 'mission-driven' companies in the natural products industry (notably AlterEco, Sambazon, Traditional Medicinals, Frontier Natural Product Co-op, Equal Exchange, Guayaki) that focus

on finding producers with similar principles such as sustainability and fair trade. Producers lucky enough to find a buyer dedicated to maintaining a long-term relationship also have the responsibility to make sure the mission-driven principles are being upheld at farm level. Certification is one of the easiest ways to identify such 'mission-driven' buyers.

The Fair Trade Federation (FTF) is a membership organization for producers and manufacturers of fair trade products. It also provides assistance to 'alternative trading organizations' (ATO) that are looking for products (usually handicrafts) produced by a fair trade process. Another example within fair trade or socially-responsible trading is Whole Foods Market's Whole Trade Program. To qualify for the Whole Foods Market's Whole Trade Program, a supplier needs to be certified by either Transfair/FLO, Fair for Life/IMO, or Rainforest Alliance, as well as meet specific quality expectations by Whole Foods Market. Products in the Whole Trade Program enjoy certain promotional benefits by Whole Foods Market, as well as occasional preferential buying opportunities.

9.4. Concluding remarks

In summary, this is an exciting time for botanicals in the North American markets. North American consumers are increasingly health- and wellness-conscious and as a result are interested in exotic new foods and flavours. However, it is rarely enough for ingredients to add a new application or functionality and on top of that these ingredients are now finding stricter scrutiny among government regulations and safety requirements and sustainable and eco-social demands. To reach the market and maintain popularity, ingredients will have to prove efficacy through clinical research and score well in all of these areas. Although it may sound like the barriers have become too high for many botanicals, those that have traditional food use will be the most likely to fulfil these demands.

Appendix I Importers/wholesalers of natural ingredients

ALOECORP

100 Technology Drive, Suite 325
Broomfield, Colorado 80021, United States
TEL: 1-303-635-2200
FAX: 1-303-635-2300
URL: <http://www.aloecorp.com/>

AMAX NUTRASOURCE, INC.

1770 Prairie Road, Eugene, OR 97402, United States
TEL: 1-541-688-4944
FAX: 1-541-688-4866
14291 East Don Julian Road
City of Industry, CA 91746, United States
TEL: 1-626-961-6600
FAX: 1-626-961-2890
E-mail: info@amaxnutrasource.com
URL: <http://www.amaxnutrasource.com/>

AVOCA, INC.

A subsidiary of Pharmachem Labs, Inc.
State Road 1502
Merry Hill, Bertie, NC 27957, United States
TEL: 1-201-246-1000
FAX: 1-201-246-8105
E-mail: sales@pharmachemlabs.com
URL: <http://www.pharmachemlabs.com/>

BIO-BOTANICA

75 Commerce Drive
Hauppauge, NY 11788-3942, United States
TEL: 1-631-231-5522
FAX: 1-631-231-7332
URL: <http://www.bio-botanica.com/>

DESERT KING INTERNATIONAL

[Manufacturing Plants: Chile & Mexico]
7024 Many Circle
San Diego CA, 92154, United States
FAX: 1-619-429-5001
URL: <http://www.desertking.com/>

DRACO NATURAL PRODUCTS, INC.

[Manufacturing Plant: DRACO CHINA,
Shanghai, People's Republic of China]
539 Parrott Street, San Jose, CA 95112, United States
TEL: 1-408-287-7871
FAX: 1-408-287-8838
E-mail: info@DracoHerbs.com
URL: <http://www.dracoherbs.com/index.htm>

FRUTAROM, INC.

9500 Railroad Ave.
North Bergen, New Jersey 07047, United States
TEL: 1-201-861-9500
FAX: 1-201-861-4323
E-mail: usa@frutarom.com
URL: <http://www.frutarom.com/index.html>

IMPROVE U.S.A., INC.

215 Dalton Drive, Suite D
DeSoto, Texas 75115, United States
TEL: 1-972-230-9155
FAX: 1-972-230-8824
E-mail: ImproveUSA@Aloewholesale.com
URL: <http://www.aloewholesale.com>

INDENA USA, INC.

[Manufacturing Plant: Indena S.p.A. – Milan,
Italy 20139 Milan, Italy Viale Ortles, 12]
East Coast: 1719 Route 10 East, Suite 311
Parsippany, New Jersey 07054, United States
TEL: 1-973-401-0077
FAX: 1-973-401-0078
West Coast: 1001 Fourth Avenue Plaza,
Suite 3714, Seattle, WA 98154, United States
TEL: 1-206-340-6140
FAX: 1-206-340-0863
E-mail: elke@indenausa.com
URL: <http://www.indena.it/>

LINNEA USA

435 McCartney Street
Easton PA 18042, United States
TEL: 1-610-253-7950
FAX: 1-610-253-7970
E-mail: sales@linnea-worldwide.com
URL: www.linnea-worldwide.com

MARTIN BAUER Inc.

300 Harmon Meadow Boulevard, Suite 510
Secaucus, New Jersey 07094, United States
TEL: 1-201-659-3100
FAX: 1-201-659-3180
E-mail: welcome@martin-bauer-group.us
URL: www.martin-bauer-group.us

SABINSA CORPORATION

121 Ethel Road West, Unit #6
Piscataway, New Jersey 08854, United States
TEL: 1-732-777-1111
FAX: 1-732-777-1443
E-mail: Info@sabinsa.com
URL: <http://www.sabinsa.com>

SYMRISE Inc.

300 North Street
Teterboro, NJ 07608, United States
TEL: 1-201-288-3200
FAX: 1-201-462-2200
URL: <http://www.symrise.com/en/home.html>

VALENSA INTERNATIONAL

2751 Nutra Lane
Eustis, Florida 32726, United States
TEL: 1-352-357-2004
FAX: 1-352-483-2095
E-mail: usncustomerservice@usnutra.com
URL: <http://www.usnutra.com>

YAKIMA CHIEF, INC. CO2 EXTRACTION

555 West South Hill Road;
P.O. Box 209; Sunnyside, Washington 98944,
United States
TEL: 1-509-839-9022
FAX: 1-509-839-5570
URL:
<http://www.yakimachief.com/facilities/CO2extract.html>

WILD FLAVORS

1261 Pacific Avenue
Erlanger, Kentucky 41018, United States
URL: <http://www.wildflavors.com>

Appendix II Essential-oil producers

AROMA CREATIONS, INC.

24691 State Route 20
Sedro-Woolley, Washington 98284-8012, United States
TEL: 1-360-854-9000
FAX: 1-360-856-4384
E-mail: info@aromacreations.com
URL: <http://www.aromacreations.com>

B&G FARMS

18,000 acre peppermint leaf farm
12088 Road 11 Sw
Royal City, WA 99357-9508, United States
TEL: 1-509-346-2294

CITRUS AND ALLIED ESSENCES, LTD.

3000 Marcus Avenue
Lake Success, NY 11042, United States
TEL: 1-718-343-0030
FAX: 1-516-354-1262
E-mail: info@citrusandallied.com
URL: <http://www.citrusandallied.com>

I.P. CALLISOIN & SONS

Peppermint oil & Spearmint oil
600 Stewart Street, Suite 2000
Seattle, WA 98101, United States
TEL: 1-206-441-7752
FAX: 1-206-728-9041
E-mail: info@ipcallison.com
URL: <http://www.ipcallison.com>

LABBEEMINT

Mint oil
P.O. Box 130
Harrah, WA 98933, United States
TEL: 1-509-848-2022

THE LEBERMUTH COMPANY

TEL: 1-574-259-7000
FAX: 1-574-258-7450
E-mail: info@lebermuth.com
URL: <http://www.lebermuth.com>

WM. LEMAN COMPANY

Peppermint oil & Spearmint oil
P.O. Box 100
Bremen, Indiana 46506-0100, United States
TEL: 1-219-546-2371
FAX: 1-219-546-5762
E-mail: info@wmlleman.com

YOUNG LIVING ESSENTIAL OILS

1,800 acres of organic farmland in Utah and Idaho, and 70,000 square feet of greenhouse
URL: <https://www.youngliving.org>

Appendix III Herb farms and wild collectors

ALOECORP

Largest aloe vera farm in US
100 Technology Drive, Suite 325
Broomfield, Colorado 80021, United States
TEL: 1-303-635-2200
FAX: 1-303-635-2300
URL: <http://www.aloecorp.com>

AMERICAN BOTANICALS

Broad range of wild collected medicinal herbs
24750 Highway FF, Eolia, Missouri 63344,
United States
TEL: 1-573-485.2300
FAX: 1-573-485.3801
URL: <http://www.americanbotanicals.com>

AROMATICS INC.

Large scale cultivation of catnip, peppermint,
spearmint and other herbs
PO Box 13093, Salem, Oregon 97309, United
States
TEL: 1-503-363-9494
FAX: 1-503-363-3395
E-mail: aromatics@msn.com

B&G FARMS

18,000 acre peppermint leaf farm
Royal City, Washington, United States

BOSTON JOJOBA COMPANY

940 acre jojoba farm in Arizona
URL: <http://www.bostonjojoba.com/visit.asp>

CACHALOT, EL NINO, & MILLA VERDE FARMS

Largest commercial jojoba plantation in United
States
Desert Whale Jojoba Company, Inc.
P.O. Box 41594, 2101 EastBeverly Dr.
Tucson, AZ 85717, United States
TEL: 1-520-882-4195
FAX: 1-520-882-7821
URL: <http://www.desertwhale.com>

CHARLESTON TEA PLANTATION

127-acre tea leaf farm owned by the
R.C. Bigelow Tea Co.
6617 Maybank Highway, Charleston, SC, United
States
TEL: 1-843-559-0383
URL: <http://www.bigelowtea.com>

DESERT HERB COMPANY, INC.

Organic & commercial medicinal & culinary
herb cultivation
PO Box 125, 1003 Ranch Road
Chamberino, New Mexico 88027, United States
TEL: 1-505-882.2425
FAX: 1-505-882.1910
E-mail: tjfarm1@juno.com

ELECTIC INSTITUTE FARM

90 acre organic medicinal herb farm (40
herbs; echinacea, ginkgo, goldenseal, hops)
36350 S.E. Industrial Way
Sandy, Oregon 97055, United States
TEL: 1-503-668-4120
FAX: 1-503-668-3227
URL: <http://www.eclecticherb.com>

AIA HERB FARM

250 acre organic medicinal herb farm
(50 herbs; echinacea, feverfew, valerian)
108 Island Ford Road
Brevard, NC 28712, United States
URL: <http://www.gaiaherbs.com>

HERB PHARM FARM

85 acre organic medicinal herb farm; 110
herbs: black cohosh, echinacea, valerian)
PO Box 116, Williams, OR 97544, United States
TEL: 1-800-348-4372
E-mail: info@herb-pharm.com
URL: <http://www.herb-pharm.com/pharmfarm.html>

KAUAI ORGANIC FARMS, INC.

45 acre organic medicinal herb farm
(ginger rhizome, noni fruit, turmeric rhizome)
PO Box 1338 Kilauea, HI 96754, United States
TEL: 1-808-651-1777
FAX: 1-808-828-1343
E-mail: neal@kauaiorganicfarms.com
URL:
<http://www.kauaiorganicfarms.com/index.html>

LAVENDERFARMS.COM

A group of five lavender flower farms in
Washington State
URL:
<http://www.lavenderfarms.com/olympic/oly.htm>

LAVENDER HILL

100 acre organic lavender flower estate in
Southern Oregon
TEL: 1-541-857-8168
E-mail: LAVENDERHILLInc@aol.com
URL: <http://www.lavenderhillfarm.com>

PACIFIC BOTANICALS

114 acre organic medicinal herb farm
plus wild collected herbs
4350 Fish Hatchery Road
Grants Pass OR 97527, United States
TEL: 1-541-479-7777
FAX: 1-541-479-5271
E-mail: info@pacificbotanicals.com
URL: <http://www.pacificbotanicals.com>

PLANTATION MEDICINALS, INC.

Large scale cultivation & wild collection
(echinacea, saw palmetto)
PO Box 128, 1401 County Road 830
Felda, Florida 33930, United States
TEL: 1-941-675.2984
FAX: 1-941-675.4591

Pu'u'ala FARM AND RANCH

1,000 acre organic medicinal herb farm
(kava root & leaf, neem leaf, noni fruit)
Honokaa, HI 96727
PO Box 4175, Hilo, HI 96720, United States
TEL: 1-888-315-4100
FAX: 1-808-935-8854
E-mail: orders@puuuala.com

PURCELL JOJOBA INTERNATIONAL

1,200 acre jojoba farm in Bouse, Arizona
142 Front Street, Avila, CA 93424, United States
TEL: 1-805-595-7275
FAX: 1-805-595-9238
URL: <http://www.purcelljojoba.com>

SAN FRANCISCO HERB & NATURAL FOOD CO.

Echinacea, peppermint, spearmint cultivation
Central Oregon
E-mail: info@herbspicetea.com
URL: <http://www.herbspicetea.com>

SAW PALMETTO BERRIES CO-OP OF FLORIDA

Saw palmetto fruit collection
1206 Kings Way Naples, Florida 34104, United States
TEL: 1-239-775-4286
FAX: 1-239-775-9818
URL: <http://www.sawpalmetto.com>

STRATEGIC SOURCING, INC.

Large range of cultivated and wild collected medicinal herbs; some certified organic
115 Snow Ridge Road, Banner Elk, NC 28604, United States
TEL: 1-828-898-7642
FAX: 1-828-898-7647
E-mail: efletcher@strategicsourcinginc.net

TROUT LAKE FARM, LLC

1,200 acre organic herb farm (catnip, echinacea, feverfew, nettle, skullcap) plus wild collected herbs
42 Warner Road, Trout Lake, WA 98650, United States
TEL: 1-509-395-2025
FAX: 1-509-395-2645
E-mail: herbs@troutlakefarm.com
URL: <http://www.troutlakefarm.com>

US NUTRACEUTICALS, LLC

Wild collected black cohosh, goldenseal, saw palmetto, slippery elm, witch hazel
2751 Nutra Lane, Eustis, Florida 32726, United States
TEL: 1-352-357-2004
FAX: 1-352-483-2095
E-mail: usncustomerservice@usnutra.com
URL: <http://www.usnutra.com>

VAN DRUNEN FARMS

Certified organic and conventionally farmed cranberry, fennel, garlic, mint, orange peel, parsley, rosemary, sage, thyme
300 West 6th St., Momence, Illinois 60954, United States
TEL: 1-815-472-3100
FAX: 1-815-472-3850
URL: <http://www.vandrunenfarms.com/>

WILD FLAVORS, Inc.

1261 Pacific Avenue
Erlanger, Kentucky 41018
TEL: 1-888-WILD-Flavors
URL: <http://www.wildflavors.com>

WISCONSIN CULTIVATED GOLDENSEAL

Goldenseal root farm
2204 9th Avenue
Athens, WI 54411, United States
TEL: 1-715-257-7899
E-mail: golden_seal@hotmail.com

WISCONSIN GINSENG & HERB CO-OP

Cooperative of 90 American ginseng farmers
P.O. Box 581, Marathon, WI 54448, United States
TEL: 1-715-443-3723
FAX: 1-715-443-3723
E-mail: info@ginsengherbco-op.com
URL: <http://www.ginsengherbco-op.com>

YAKIMA CHIEF, INC. HOP GROWERS

Cooperative of hop farmers
555 West South Hill Road;
P.O. Box 209; Sunnyside, WA 98944, United
States
TEL: 1-509-839-9022
FAX: 1-509-839-5570
URL:
<http://www.yakimachief.com/about/history.html>

YOUNG LIVING FARM

1,600 acre organic herb farm (lavender, lemon
balm, peppermint, clary sage)
Mona, Utah and St. Maries, Idaho
URL:
http://www.youngliving.com/en_US/company/farms/

Appendix IV Wholesale distributors

ACTA HEALTH PRODUCTS

Botanical Extracts
1131 N. Fair Oaks, Sunnyvale, CA 94089, United States
TEL: 1-415-459-4393
FAX: 1-415-459-3491
E-mail: inquiry@ActaProducts.com
URL: <http://www.actaproducts.com>

AMERICAN INGREDIENTS, INC.

Botanical Raw Materials & Extracts
2929 East White Star Avenue
Anaheim, CA 92806-2628, United States
TEL: 1-714-630-6000
FAX: 1-714-630-6655
E-mail: Sales@amer-ing.com
URL:
<http://www.pharmachemlabs.com/divisions/american-ingredients/>

AMERICAN MERCANTILE CORPORATION

Botanical Raw Materials & Extracts
1310 Farmville Road, Memphis, TN 38122-1001, United States
TEL: 1-901-454-1900
FAX: 1-901-454-0207
URL: <http://www.americanmercantile.net>

ASHANINKA IMPORTS INC.

Botanical Raw Materials & Extracts from Brazil, Mexico, and Peru
P.O. BOX 770065, MIAMI FL 33177 0065, United States
TEL: 1-305-971-3008
FAX: 1-305-971-3224
E-mail: info@ashaninka.com
<http://www.ashaninka.com/raw/rawmat/rawmaterials.html>

AYUSH HERBS, INC.

Indian Botanical Raw Materials & Extracts [from Ayush Herbs Pvt Ltd., H.P India]
2115 112th Avenue NE,
Bellevue, Washington 98004, United States
TEL: 1-425-637-1400
FAX: 1-425-451-2670
URL: <http://www.ayush.com>

BDS NATURAL PRODUCTS

Botanical Raw Materials & Extracts
1904 ½ East Dominguez Street
Carson, California 90810, United States
TEL: 1-310-518-2227
FAX: 1-310-518-2577
E-mail: info@bdsnatural.com
URL: <http://www.bdsnatural.com>

BI NUTRACEUTICALS

Botanical Raw Materials & Extracts
2550 El Presidio Street
Long Beach, CA, 90810, United States
TEL: 1-310-669-2100
FAX: 1-310-637-3644
E-mail: botan@botanicals.com
URL: <http://www.botanicals.com>

CHEMCO INDUSTRIES, INC.

OptiPure® Brand Botanical Extracts
6984 Bandini Blvd.
Los Angeles, CA 90040, United States
TEL: 1-323-721-8300
FAX: 1-323-721-9600
URL: <http://www.optipure.com>

COGNIS CORP USA

Botanical Extracts and Derivatives
5051 Estecreek Drive
Cincinnati, OH 45232-1446, United States
TEL: 1-513-482-3000
FAX: 1-513-482-5503
URL: <http://www.cognis.com/cognis.html>

ESSENTIALLY PURE INGREDIENTS

Artichoke Extract, Garlic, Kava Extract, Soy
21411 Prairie Street
Chatsworth, CA 91311, United States
TEL: 1-818-739-6046
FAX: 1-818-739-6042
E-mail: Customerservice@essentiallypure.com
URL: <http://www.essentiallypure.com>

EXTRACTS PLUS, INC.

3275 Corporate View Drive
Vista, CA 92083, United States
TEL: 1-760-597-0200
FAX: 1-760-597-0734
URL: <http://www.extractplus.com>

FAMARCO LIMITED, INC.

B&K INTERNATIONAL
Botanical Raw Materials
1381 Air Rail Avenue
Virginia Beach, VA 23455, United States
TEL: 1-757-460-3573
FAX: 1-757-460-2621
E-mail: info@famarco.com
URL: <http://www.famarco.com/catalog/>

GCI NUTRIENTS, INC.

Botanical Raw Material & Extracts (Chinese, Indian Ayurvedic, South American)
1501 Adrian Road
Burlingame, CA, United States
TEL: 1-650-697-4700
FAX: 1-650-697-6300
URL: <http://www.gcinutrients.com>

GENI, INC.

Ayurvedic Herbal Extracts
1250 E. Conner Street
Noblesville, IN, 4606, United States
Tel: 1-317-776-3600
Fax: 1-317-776-3650
E-mail: info@geniherbs.com
URL: <http://www.geniherbs.com>

GEORGE UHE COMPANY

Essential oils & natural extracts
12 Route 17 North, PO Box 970
Paramus, NJ 07653-0970, United States
TEL: 1-201-843-4000
FAX: 1-201-843-7517
E-mail: global@uhe.com
URL: <http://www.uhe.com>

GILROY FOODS

Capsicum, Garlic, Onion, Black Pepper
1350 Pacheco Pass Hwy.
Gilroy, CA 95020, United States
TEL: 1-408-289-5060
FAX: 1-408-846-3073
E-mail: purchasing@gilroyfoods.com
URL:
<http://www.gilroyfoodsandflavors.com/index.jsp>

GLOBAL MARKETING ASSOCIATES

Chinese & European Botanical Extracts
3536 Arden Road
Hayward, CA 94545-3908, United States
TEL: 1-510-887-2462
FAX: 1-510-887-1882
E-mail: global@gmaherbs.com
URL: <http://www.gmaherbs.com>

GOOD HOPE BOTANICALS, INC.

Botanical Raw Materials
1805-B South McDowell Blvd, Petaluma, CA
94954, United States
TEL: 1-707-763-2809
FAX: 1-707-763-2832
E-mail: kim@goodhopebotanicals.com
URL: <http://www.goodhopebotanicals.com>

G.S. HALY COMPANY

Tea leaf (green, black, oolong)
156 Arch Street
Redwood City CA 94062, United States
TEL: 1-650-367-7601
FAX: 1-650-367-0291
E-mail: gshaly@pacbell.net
<http://www.gcinutrients.com>

GUAYAKI SUSTAINABLE RAINFOREST PRODUCTS

Certified organic maté leaf
684 Clarion Court
San Luis Obispo, CA 93401, United States
TEL: 1-805-546-8111
FAX: 1-805-545-8111
E-mail: info@guayaki.com
URL: <http://www.guayaki.com>

HERB TRADE CERTIFIED ORGANICS

Certified Organic Botanical Raw Materials
12101 Moya Blvd.
Reno, Nevada 89506-2600, United States
TEL: 1-973-817-8500
FAX: 1-775-971-8551
E-mail: info@organicherbtrade.com

KALUSTYAN CORPORATION

Botanical Raw Materials
855 Rahway Avenue Union, New Jersey, 07083,
United States
TEL: 1-908-688-6111
FAX: 1-908-688-4415
URL: <http://www.kalustyan.com>

MAFCO WORLDWIDE CORPORATION USA

Licorice root & extracts
Third Street & Jefferson Avenue
Camden New Jersey. 08104, United States
TEL: 1-856-964-8840
FAX: 1-856-541-8925
E-mail: jswanson@mafcolicorice.com
URL: <http://www.mafcolicorice.com>

MARTIN BAUER, INC.

Extracts (by Finzelberg & Plantextrakt)
[Headquarters: Martin Bauer GmbH & Co. KG,
Dutendorfer Strasse 5-7, 91487
Vestenbergsreuth Germany]
2 Sylvan Way
Parsippany, New Jersey 07054-3806, United
States
TEL: 1-973-683-1411
FAX: 1-973-683-0177
E-mail: info@plantextrakt-inc.com
URL: <http://www.martin-bauer.com>

MB NORTH AMERICA, INC.

Botanical Raw Materials
 [Headquarters: MB Holding GmbH & Co. KG,
 Dutendorfer Strasse 5-7, 91487
 Vestenbergsgreuth Germany]
 2780 Skypark Drive, Suite 225
 Torrance, California 90505, United States
 TEL: 1-310-534-7100
 FAX: 1-310-534-8001
 E-mail: info@mb-northamerica.com
 URL: <http://www.the-nature-network.com/en/the-nature-network.html>

ORCAS INTERNATIONAL, INC.

Ayurvedic & Chinese herbal extracts
 230 Route 206, Building 4, Suite 3
 Flanders, New Jersey 07836, United States
 TEL: 1-973-252-7100
 FAX: 1-973-252-7104
 E-mail: orcas@orcas-intl.com
 URL: <http://www.orcas-intl.com>

PHARMACHEM LABORATORIES, INC.

Botanical Powders & Extracts
 265 Harrison Avenue
 Kearny, NJ 07032, United States
 TEL: 1-201-246-1000
 FAX: 1-201-246-8105
 E-mail: sales@pharmachemlabs.com
 URL: <http://www.pharmachemlabs.com>

PHARMLINE, INC.

Botanical Extracts
 41 Bridge Street, PO Box 291
 Florida, New York 10921, United States
 TEL: 1-845-651-4443
 FAX: 1-845-651-6900
 E-mail: info@pharmlineinc.com
 URL: <http://www.pharmlineinc.com>

P.L. THOMAS & CO., INC.

Botanical Raw Materials & Extracts
 119 Headquarters Plaza
 Morristown, NJ 07960, United States
 TEL: 1-973-984-0990
 FAX: 1-973-984-5666
 E-mail: info@plthomas.com
 URL: <http://plthomas.com>

RFI INGREDIENTS

Botanical Raw Materials & Extracts
 300 Corporate Drive, Suite 14
 Blauvelt, NY 10913, United States
 TEL: 1-845-358-8600
 FAX: 1-845-358-9003
 E-mail: rfi@rfiingredients.com
 URL: <http://www.rfiingredients.com>

SAMPAC ENTERPRISES

Chinese Botanical Raw Materials & Extracts
 434 N. Canal St., Unit 16
 South San Francisco, Ca. 94080, United States
 TEL: 1-650-876-0808
 FAX: 1-650-876-0338
 URL: <http://www.sampacent.com>

SAN FRANCISCO HERB & NATURAL FOOD CO.

Botanical Raw Materials
 47444 Kato Road, Fremont, CA 94538, United States
 TEL: 1-510-770-1215
 FAX: 1-510-770-9021
 E-mail: info@herbspicetea.com
http://www.herbspicetea.com/categories/hundred_pound_orders.html

STARWEST BOTANICALS

Botanical Raw Materials & Extracts
 11253 Trade Center Drive
 Rancho Cordova, CA 95742, United States
 TEL: 1-916-853-9354
 FAX: 1-916-853-9673
 E-mail: info@starwest-botanicals.com
 URL: <http://www.starwest-botanicals.com>

STAUBER PERFORMANCE INGREDIENTS

Botanical Raw Materials & Extracts
 4120 N. Palm Street
 Fullerton, CA 92835, United States
 TEL: 1-714-441-3900
 FAX: 1-714-441-3909
 E-mail: sales@stauberusa.com
 URL: <http://www.stauberusa.com>

STRYKA BOTANICS CO., INC.

Botanical Raw Materials & Extracts
 239 Homestead Rd
 Hillsborough, NJ 08844, United States
 TEL: 1-908-281-5577
 FAX: 1-908-281-5392
 E-mail: info@stryka.com
 URL: <http://www.stryka.com>

TRIARCO INDUSTRIES, INC.

Botanical Raw Materials & Extracts
 400 Hamburg Turnpike
 Wayne, New Jersey 07470, United States
 TEL: 1-973-942-5100
 FAX: 1-973-942-8873
 E-mail: info@triarco.com
 URL: <http://www.triarco.com>

WHOLE HERB

Botanical Raw Materials

19800 8th Street East

Sonoma, CA 95476, United States

TEL: 1-707-935-1077

FAX: 1-707-935-3447

URL: <http://www.wholeherbcompany.com/>

Appendix V Trade associations

AMERICAN HERBAL PRODUCTS ASSOCIATION (AHPA)

8630 Fenton Street, Suite 918
Silver Spring, MD 20910, United States
TEL: 1-301-588-1171
FAX: 1-301-588-1174
E-mail: ahpa@ahpa.org
URL: <http://www.ahpa.org>

AMERICAN SPICE TRADE ASSOCIATION (ASTA)

2025 M Street, NW, Suite 800
Washington, DC 20036, United States
TEL: 1-202-367-1127
FAX: 1-202-367-2127
E-mail: info@astaspice.org
URL: <http://www.astaspice.org>

ASSOCIATION FOR HAWAIIAN 'AWA (kava)

P.O. Box 636
Pepe'ekeo, HI 96783, United States
TEL: 1-808-969-7079

CAPE COD CRANBERRY GROWERS' ASSOCIATION (CCCGA)

3203-B Cranberry Highway
East Wareham, MA 02538, United States
URL: <http://www.cranberries.org>

CONSULTANTS ASSOCIATION FOR THE NATURAL INDUSTRY (CANI)

P.O. Box 689, Clovis, CA, 93613, United States
TEL: 1-559-325-7192
FAX: 1-559-325-7195
E-mail: info@cani-consultants.com
URL: <http://www.cani-consultants.com>

COUNCIL FOR RESPONSIBLE NUTRITION

1828 L Street, NW, Washington, DC, 20036, United States
Tel: 1-202-776-7929
Fax: 1-202-872-9594
E-mail: webmaster@crnusa.org
URL: <http://www.crnusa.org>

CROP-SPECIFIC TRADE ASSOCIATIONS AMERICAN JOJOBA ASSOCIATION

c/o Arizona Dept. of Agriculture
1688 West Adams
Phoenix, AZ 08007, United States
TEL: 1-602-542-0968
FAX: 1-602-542-0969

GINSENG BOARD OF WISCONSIN

TEL: 1-715-845-7300
E-mail: ginseng@ginsengboard.com
URL: <http://www.ginsengboard.com>

HERB GROWING & MARKETING NETWORK

E-mail: herbworld@aol.com
URL: <http://www.herbworld.com/newgpf/index.htm>

HOP GROWERS OF AMERICA

P.O. Box 9218
Yakima, WA 98909, United States
TEL: 1-509-248-7043
FAX: 1-509-248-7044
E-mail: doug@usahops.org
URL: <http://www.usahops.org>

IDAHO MINT GROWERS ASSOCIATION

55 SW 5th Ave #100
Meridian, ID 83642, United States

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS (ICMAD)

1220 W. Northwest Highway
Palatine, IL 60067-1803, United States
TEL: 1-847-991-4499
FAX: 1-847-991-8161
E-mail: info@icmad.org
URL: <http://www.icmad.org>

INTERNATIONAL JOJOBA EXPORT COUNCIL

4250 North Civic Center Blvd., 4th Floor, Scottsdale, Arizona 85251-3900, United States
TEL: 1-480-545-7000 x115
E-mail: info@ijec.net
URL: <http://www.ijec.net>

INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENTS ASSOCIATIONS (IADSA)

Rue de l' Association 50
B-1000 Brussels, Belgium
TEL: +32 2 209 1155
FAX: +32 2 223 3064
E-mail: secretariat@iadsa.be
URL: <http://www.iadsa.org>

THE INTERNATIONAL ALOE SCIENCE COUNCIL

E-Mail: iasc@airmail.net
URL: <http://www.iasc.org>

INTERNATIONAL ASSOCIATION OF COLOR MANUFACTURERS

1620 I Street, NW, Suite 925
Washington, DC 20006, United States
TEL: 1-202-293-5800
FAX: 1-202-463-8998
E-mail: info@iacmcolor.org
URL: <http://www.iacmcolor.org>

INTERNATIONAL FEDERATION OF ESSENTIAL

OILS AND AROMA TRADES (IFEAT)
6 Catherine Street, London, WC2B 5JJ, United Kingdom
TEL: +44 20 7836 2460
FAX: +44 20 7836 0580
E-mail: IFEATAdministrator@fdf.org.uk
URL: <http://www.ifeat.org>

INTERNATIONAL HERB ASSOCIATION (IHA)

P.O. Box 5667
Jacksonville, FL 32247-5667, United States
URL: <http://www.iherb.org>

ORGANIC TRADE ASSOCIATION (OTA)

PO Box 547-Greenfield-MA-01302
60 Wells Street-Greenfield-MA-01301, United States
TEL: 1-413-774-7511
FAX: 1-413-774-6432
E-mail: info@ota.com
URL: <http://www.ota.com>

PERSONAL CARE PRODUCTS COUNCIL

1101 17th St., NW, Suite 300
Washington, DC 20036, United States
TEL: 1-202 331-1770
FAX: 1-202 331-1969
URL: <http://www.ctfa.org>

SEQUIM LAVENDER GROWER'S ASSOCIATION

55 Parrish Road
Sequim, WA 98382, United States
TEL: 1-360-681-8563
E-mail: morningmysts@hotmail.com

**TEA ASSOCIATION OF THE USA
TEA COUNCIL OF THE USA**

420 Lexington Ave, New York, NY 10170, United States
TEL: 1-212-986-9415
FAX: 1-212-697-8658
E-mail: info@teausa.com
URL: <http://www.teausa.com>

WASHINGTON MINT GROWERS ASSOCIATION

10542 Division South Road
Othello, Washington 99344, United States

WISCONSIN STATE CRANBERRY GROWERS ASSOCIATION (WSCGA)

PO Box 365, Wisconsin Rapids, WI 54495-0365, United States
TEL: 1-715-423-2070
FAX: 1-715-423-0275
E-mail: wiscran@wctc.net
URL: <http://www.wiscran.org>

Appendix VI Trade fairs in the United States

BIOFACH AMERICA ORGANIC PRODUCTS EXPO

New Hope Natural Media
1401, Pearl Street, Boulder, CO 80302, United States
TEL: 1-303-998-9266
FAX: 1-303-998-9525
E-mail: ssilverman@newhope.com
http://www.nuernbergglobalfairs.com/va/BFA_03/e/index.html

ENGREDEA

New Hope Natural Media
1401, Pearl Street, Boulder, CO 80302, United States
TEL: 1-303-998-9266
FAX: 1-303-998-9525
E-mail: tradeshows@newhope.com
URL: <http://engredea.com/engredea12/Public/enter.aspx>

NATURAL PRODUCTS EXPO EAST (Baltimore)

NATURAL PROUDCTS EXPO WEST (Anaheim)

New Hope Natural Media
1401, Pearl Street, Boulder, CO 80302, United States
TEL: 1-303-998-9266
FAX: 1-303-998-9525
E-mail: tradeshows@newhope.com
<http://www.expoeast.com/expoeast2011/public/enter.aspx>
<http://www.expowest.com/ew12/public/enter.aspx>

SUPPLY SIDE EAST (New Jersey)

SUPPLY SIDE WEST (Nevada)

International Trade Show and Conference

Virgo Publishing – Health & Nutrition Division
P.O. BOX 40079, Phoenix, AZ 85067-0079, United States
URL: <http://www.supplysideshow.com>

Appendix VII Trade press

AHPA REPORT

THE OFFICIAL PUBLICATION OF THE AMERICAN HERBAL PRODUCTS ASSOCIATION

Monthly newsletter for AHPA members only
8630 Fenton Street, Suite 918
Silver Spring, MD 20910, United States
TEL: 1-301-588-1171
FAX: 1-301-588-1174
E-mail: ahpa@ahpa.org
URL: <http://www.ahpa.org>

COSMETICS & TOILETRIES

362 South Schmale Road
Carol Stream, IL 60188, United States
TEL: 1-630-653-2155
FAX: 1-630-665-2699
<http://www.cosmeticsandtoiletries.com>

FDA— DIETARY SUPPLEMENT / FOOD LABELING ELECTRONIC NEWSLETTER

A free electronic newsletter from the Food and Drug Administration's Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS), in the Center for Food Safety and Applied Nutrition (CFSAN)
E-mail: FDA-DSFL@vm.cfsan.fda.gov
URL: <http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/GetEmailUpdates/default.htm>

FUNCTIONAL FOODS & NUTRACEUTICALS THE OFFICIAL PUBLICATION OF NUTRACON / SUPPLY EXPO

New Hope Natural Media
1401 Pearl Street, Suite 200
Boulder, CO 80302, United States
TEL: 1-303-998-9126
FAX: 1-303-939-8440
E-mail: customerservice@newhope.com

HERBALGRAM—THE JOURNAL OF THE AMERICAN BOTANICAL COUNCIL

PO Box 144 345
Austin, TX 78714-4345, United States
TEL: 1-512-926-4900
FAX: 1-512-926-2345
E-mail: abc@herbalgram.org
URL: <http://abc.herbalgram.org/site/PageServer>

HERBAL GREEN PAGES ONLINE

A service of the Herb Growing & Marketing Network, an herb industry trade association
E-mail: herbworld@aol.com
URL: <http://www.herbalgreenpages.com>

HSC INDUSTRY NEWS

Daily Electronic Industry Newsletter for natural product industry executives
Health Strategy Consulting LLC, United States
319 Hope Street
Providence, Rhode Island 02906, United States
TEL: 1-401-270-0760
FAX: 1-401-272-0706
E-mail: aismail@health-strategy.com
URL: http://www.health-strategy.com/newsletter.php?letter_id=109&page_action=browse

JOURNAL OF HERBS, SPICES & MEDICINAL PLANTS

The Haworth Press, Inc., 10 Alice Street,
Binghamton, New York 13904-1580, United States
TEL: 1-607-722-5857
FAX: 1-607-722-6362
E-mail: getinfo@haworthpressinc.com
URL: <http://www.haworthpressinc.com/store/product.asp?sku=J044>

MARKET NEWS SERVICE FOR MEDICINAL PLANTS & EXTRACTS

A quarterly report promoting international trade in medicinal plants & extracts with regional reviews including North America
International Trade Centre UNCTAD/WTO
Palais des Nations, CH-1211
Geneva 10, Switzerland
TEL: + 41 22 730 0111
FAX: + 41 22 733 4439
E-mail: itcreg@intracen.org
URL: <http://www.mnsonline.org>

NATURAL PRODUCTS INDUSTRY INSIDER THE OFFICIAL MAGAZINE OF SUPPLYSIDE®

Virgo Publishing, Inc.
PO Box 40079, Phoenix, AZ 85067-0079, United States
TEL: 1-480-990-1101
FAX: 1-480-990-0819
URL: <http://www.naturalproductsinsider.com>

NATURAL PRODUCTS INDUSTRY INSIDER NEWSLETTER — Virgo Publishing, Inc.

A free e-mail newsletter.
PO Box 40079, Phoenix, AZ 85067-0079, United States
TEL: 1-480-990-1101
FAX: 1-480-990-0819
E-mail: NPI@vpico.com
URL: <http://www.naturalproductsinsider.com>

NEW FARM NEWSLETTER

Monthly free e-mail newsletter of the Rodale Institute featuring farmer-to-farmer knowhow on the latest organic and regenerative practices for fruit, grain, herb and vegetable crops

URL: <http://www.newfarm.org>

NUTRACEUTICALS WORLD

Serving the Dietary Supplement, Functional Food and Nutritional Beverages Industries
70 Hilltop Road,

Ramsey, NJ 07446, United States

TEL: 1-201-825-2552

FAX: 1-201-825-0553

E-mail: nutraceuticals@rodpub.com

URL: <http://www.nutraceuticalsworld.com>

**NUTRAINGREDIENTS-USA.COM
NEWSLETTER**

Breaking News on Nutraceuticals & Supplements for North America

Novis, La Tour du Triangle

26 Allée Jules Milhau

34000 Montpellier, France

TEL: +33 4 99 52 28 70

FAX: +33 4 99 52 28 75

E-mail: info@NutraIngredients-usa.com

URL: <http://www.nutraingredients-usa.com>

NUTRITION BUSINESS JOURNAL

Comprehensive market data and strategic analysis covering Dietary Supplements (vitamins, minerals, herbs & botanicals, sports nutrition), Natural/Organic Foods, Functional Foods, and Natural Personal Care.

4452 Park Boulevard, Suite 306

San Diego CA 92116, United States

TEL: 1-619-295-7685 ext. 13

FAX: 1-619-295-5743

E-mail: info@nutritionbusiness.com

URL: <http://www.nutritionbusiness.com>

NUTRITIONAL OUTLOOK

The Manufacturer's Resource for Dietary Supplements & Healthy Foods and Beverages
11444 W. Olympic Blvd.

Los Angeles, CA 90064, United States

TEL: 1-310-445-4200

FAX: 1-310-445-4299

E-mail: feedback@nutritionaloutlook.com

URL: <http://www.nutritionaloutlook.com>

PERFUMER & FLAVORIST

362 South Schmale Road

Carol Stream, IL 60188, United States

TEL: 1-630-653-2155

FAX: 1-630-665-2699

<http://www.perfumerflavorist.com>

**THE ROSE SHEET—TOILETRIES,
FRAGRANCES
& SKIN CARE**

F-D-C REPORTS

5550 Friendship Boulevard, Suite 1

Chevy Chase, MD 20815-7278, United States

TEL: 1-800-332-2181

FAX: 1-301-656-3094

URL: <http://www.elsevierbi.com/index.html>

**THE TAN SHEET—NON-PRESCRIPTION,
PHARMACEUTICALS AND NUTRITIONALS
F-D-C REPORTS**

5550 Friendship Boulevard, Suite 1

Chevy Chase, MD 20815-7278, United States

TEL: 1-800-332-2181

FAX: 1-301-656-3094

Appendix VIII Trade support organizations

THE CRANBERRY MARKETING COMMITTEE

245R Main Street, Wareham, MA 02571, United States

TEL: 1-508-291-1510

FAX: 1-508-291-1511

E-mail: cranberry.marketing@verizon.net

URL: <http://www.uscranberries.com>

CROP-SPECIFIC:

FAR WEST SPEARMINT OIL

ADMINISTRATIVE

COMMITTEE

100 N. Fruitland, Suite B,

Kennewick, WA 99336, United States

TEL: 1-509-585-5460

FAX: 1-509-585-2671

URL: <http://www.farwestspearmint.org>

FEDERAL GOVERNMENT:

FOREIGN AGRICULTURAL SERVICE (FAS) EXPORTING / BUYING ORGANIC PRODUCTS

URL:

<http://www.fas.usda.gov/aqx/organics/organics.asp>

FOREIGN AGRICULTURAL SERVICE (FAS) U.S. TRADE INTERNET SYSTEM

URL: <http://www.fas.usda.gov/gats/default.aspx>

GINSENG BOARD OF WISCONSIN

TEL: 1-715-845-7300

E-mail: ginseng@ginsengboard.com

URL: <http://www.ginsengboard.com>

HOP ALLIANCE

912 Coach Court, Yakima Wa. 98908, United States

TEL: 1-509-969-0092

FAX: 1-509-965-0719

E-mail: dbakos@aol.com

IDAHO MINT COMMISSION

URL: <http://www.idahomint.org>

INTERNATIONAL TRADE CENTRE (ITC) UNCTAD/WTO

Palais des Nations, CH-1211

Geneva 10, Switzerland

TEL: +41 22 730 0111

FAX: +41 22 733 4439

E-mail: itcreg@intracen.org

URL:

<http://www.intracen.org/exporters/biodiversity/>

<http://www.intracen.org/exporters/market-news-service/>

www.standardsmap.org

OREGON HOP COMMISSION

20209 Main Street, P.O. Box 9

St. Paul, OR 97137, United States

TEL: 1-503-633-2922

FAX: 1-503-633-2924

E-mail: cchop@oda.state.or.us

URL: <http://hop.oda.state.or.us/ohc.html>

OREGON MINT COMMISSION

PO Box 3366, Salem 97302-0366, United States

TEL: 1-503-364-2944

MARKET ACCESS PROGRAM (MAP)

United States Department of Agriculture (USDA),

Foreign Agricultural Service (FAS),

Marketing Operations Staff, Box 1042

1400 Independence Avenue S.W.

Washington, DC 20250-1042, United States

TEL: 1-202-720-4327

URL:

<http://www.fas.usda.gov/mos/programs/map.asp>

OFFICE OF THE UNITED STATES TRADE UNITES STATES CENSUS BUREAU FOREIGN TRADE STATISTICS

URL: <http://www.census.gov/foreign-trade/>

UNITED STATES DEPARTMENT OF AGRICULTURE

FOREIGN AGRICULTURAL SERVICE (FAS)

URL: <http://www.fas.usda.gov>

Appendix IX Other useful addresses

BUYERS GUIDES

ALLURED'S FLAVOR AND FRAGRANCE MATERIALS ONLINE

A comprehensive international directory of materials used in the creation of flavours and fragrances, including all known suppliers
URL: <http://64.78.48.186/ffm/>

BUYERS GUIDE TO SUPPLIERS OF NUTRACEUTICALS AND FUNCTIONAL FOOD INGREDIENTS

Institute of Food Technologists
This Buyer's Guide includes the 900 companies that exhibited at IFT FOOD EXPO®. Company descriptions, products, and full contact information are included.
URL: <http://buyersguide.ift.org/cms/?pid=3001&categoryid=1>

CTFA INTERNATIONAL BUYERS GUIDE

Comprehensive, worldwide listing of cosmetic raw materials and their suppliers
CTFA Publications Orders
TEL: 1-301-953-2614
FAX: 1-301-206-9789
E-mail: publications@ctfa.org
URL: <http://www.ctfa-buyersguide.org/jsp/BGSearchPage.jsp>

HERBAL GREEN PAGES ONLINE

Herb Growing & Marketing Network
E-mail: herbworld@aol.com
URL: <http://www.herbalgreenpages.com/>

NUTRACEUTICALS WORLD INTERNATIONAL BUYERS' GUIDE

Serving the Dietary Supplement, Functional Food and Nutritional Beverages Industries
70 Hilltop Road, Ramsey, NJ 07446, United States
TEL: 1-201-825-2552
FAX: 1-201-825-0553
E-mail: nutraceuticals@rodpub.com
<http://www.nutraceuticalsworld.com/buyersguide/>

NUTRITIONAL OUTLOOK BUYERS GUIDE

The Manufacturer's Resource for Dietary Supplements & Healthy Foods and Beverages
11444 W. Olympic Blvd.
Los Angeles, CA 90064, United States
TEL: 1-310-445-4200
FAX: 1-310-445-4299
E-mail: feedback@nutritionaloutlook.com
URL: <http://www.nutritionaloutlook.com>

ORGANIC TRADE ASSOCIATION'S ORGANIC EXPORT DIRECTORY

PO Box 547-Greenfield-MA-01302
60 Wells Street-Greenfield-MA-01301, United States
TEL: 1-413-774-7511
FAX: 1-413-774-6432
E-mail: info@ota.com
URL: <http://www.ota.com/directories.html>

ENDANGERED PLANTS & SUSTAINABILITY ORGANIZATIONS

COMMITTEE ON THE STATUS OF ENDANGERED WILDLIFE IN CANADA

COSEWIC Secretariat
c/o Canadian Wildlife Service, Environment Canada, Ottawa, Ontario K1A 0H3, Canada
TEL: 1-819-953-3215
FAX: 1-819-994-3684
E-mail: cosewic/cosepac@ec.gc.ca
URL: <http://www.cosewic.gc.ca/index.htm>

CONVENTION ON INTERNATIONAL TRADE IN ENDANGERED SPECIES OF WILD FAUNA AND FLORA (CITES)

International Environment House
15, chemin des Anémones, CH-1219
Châtelaine-Geneva, Switzerland
TEL: +41 22 917 8139
FAX: +41 22 797 3417
E-mail: cites@unep.ch
URL: <http://www.cites.org/>

NATIONAL CENTER FOR THE PRESERVATION OF MEDICINAL PLANTS

33560 Beech Grove Rd. Rutland, OH 45775, United States
TEL: 1-740-742-4401
FAX: 1-740-742-8303
URL: <http://www.ncpmh.org>

PLANT CONSERVATION ALLIANCE, MEDICINAL PLANT WORKING GROUP (MPWG)

4401 N. Fairfax Drive, Room 750
Arlington, VA 22203, United States
E-mail: plant@plantconservation.org
URL: http://www.nps.gov/plants/medicinal/working_group.htm

TRAFFIC International

219a Huntingdon Rd
Cambridge, CB3 0DL, United Kingdom
TEL: +44 1223 277427
FAX: +44 1223 277237
E-mail: traffic@trafficint.org
URL: <http://www.traffic.org/>

UNITED PLANT SAVERS (UpS)

PO Box 77, Guysville, OH 45735, United States
TEL: 1-740-662-0041
FAX: 1-740-662.0242
E-mail: info@unitedplantsavers.org
URL: <http://unitedplantsavers.org/>

**UNITED STATES FISH & WILDLIFE SERVICE
ENDANGERED SPECIES PROGRAM**

<http://www.fws.gov/endangered/>

FAIR TRADE ORGANIZATIONS

GLOBAL EXCHANGE FAIR TRADE PROJECT

Fair Trade Teas, Coffees, Chocolates
110 Capp Street, Second Floor
San Francisco CA 94110, United States
TEL: 1-415-553-4412
E-mail: storemaster@globalexchange.org
<http://www.globalexchange.org/stores/producers/>

FAIR TRADE USA

Certification for Maté leaf, Tea leaf, Coffee
1611 Telegraph Avenue, Suite 900
Oakland, CA 94612, United States
TEL: 1-510-663-5260
FAX: 1-510-663-5264
E-mail: info@transfairusa.org
URL: <http://www.transfairusa.org>

**HERBAL RESEARCH AND EDUCATION
ORGANIZATIONS**

AMERICAN BOTANICAL COUNCIL (ABC)

PO Box 144 345
Austin, TX 78714-4345, United States
TEL: 1-512-926-4900
FAX: 1-512-926-2345
E-mail: abc@herbalgram.org
URL: <http://www.herbalgram.org/>

AMERICAN HERBALISTS GUILD (AHG)

1931 Gaddis Road
Canton, GA 30115, United States
TEL: 1-770-751-6021
FAX: 1-770-751-7472
E-mail: ahgoffice@earthlink.net
URL: <http://www.americanherbalistsguild.com/>

AMERICAN NUTRACEUTICAL ASSOCIATION

5120 Selkirk Dr, Suite 100
Birmingham, AL 35242, United States
TEL: 1-205-980-5710
Fax: 1-205-991-9302
E-mail: info@ana-jana.org
URL: <http://www.americanutra.com/>

BOTANICAL SOCIETY OF AMERICA (BSA)

PO Box 299, St. Louis, MO 63166-0299, United States
TEL: 1-314-577-9566
FAX: 1-314-577-9515
E-mail: bsa-manager@botany.org
URL: <http://www.botany.org/>

**DIETARY SUPPLEMENT EDUCATION
ALLIANCE™ (DSEA)**

URL: <http://www.supplementinfo.org/>

**INTERNATIONAL COUNCIL FOR MEDICINAL
AND AROMATIC PLANTS (ICMAP)**

51 Boulevard de Montmorency
F-75016 Paris, France
E-mail: info@icmap.org
URL: <http://www.icmap.org/>

MINT INDUSTRY RESEARCH COUNCIL

P.O. Box 971
Stevenson, WA 98648, United States
E-mail: mirc@gorge.net
<http://usmintindustry.org/>

**NATIONAL INSTITUTES OF HEALTH
OFFICE OF DIETARY SUPPLEMENTS**

6100 Executive Blvd., Room 3B01, MSC 7517
Bethesda, Maryland 20892-7517, United States
TEL: 1-301-435-2920
FAX: 1-301-480-1845
E-mail: ods@nih.gov
URL: <http://dietary-supplements.info.nih.gov/>

**SOCIETY FOR MEDICINAL PLANT
RESEARCH**

[Gesellschaft für Arzneipflanzenforschung
Emmeringerstr. 11, D – 82275 Emmering]
TEL: +49 8141 613749
FAX: +49 8141 613749
E-mail: GA-Secretary@t-online.de
URL: <http://www.ga-online.org/>

**TRADITIONAL MEDICINE (TRM) ESSENTIAL
DRUGS AND MEDICINES POLICY (EDM)**

World Health Organization (WHO)
CH-1211 Geneva 27 Switzerland
FAX: +41 22 791 47 30
E-mail: trm@who.int
URL:
<http://www.who.int/medicines/publications/traditionalpolicy/en/index.html>

**WORLD HEALTH ORGANIZATION (WHO)
COLLABORATING CENTRE FOR
TRADITIONAL MEDICINE (TRM) — National
Center for Complementary and Alternative
Medicine**

NCCAM Clearinghouse, P.O. Box 7923,
Gaithersburg, MD 20898, United States
TEL: 1-301-519-3153
FAX: 1-866-464-3616
E-mail: info@nccam.nih.gov
URL: <http://nccam.nih.gov/>
<http://ods.od.nih.gov/>

REGULATORY LINKS

**UNITED STATES DEPARTMENT OF
AGRICULTURE:**

Imported Organic Agricultural Products

URL:
<http://www.ams.usda.gov/nop/NOP/TradeIssues/importedorganic.html>

National Organic Program (NOP)

<http://www.ams.usda.gov/nop/indexIE.htm>

**UNITED STATES FEDERAL TRADE
COMMISSION:**

Dietary Supplement Advertising Guide
<http://www.ftc.gov/bcp/guides/guides.shtm>

UNITED STATES FISH & WILDLIFE SERVICE:

American Ginseng Export Program
http://www.fws.gov/international/DMA_DSA/CITES/plants/ginseng.html

Exporting Goldenseal Rhizome

<http://www.ces.ncsu.edu/depts/hort/hil/hil-131.html>

The Endangered Species Program

<http://endangered.fws.gov/>

**United States Plant Species listed in the
CITES**

Appendices
http://www.fws.gov/international/DMA_DSA/CITES/plants/plants.html

**UNITED STATES FOOD AND DRUG
ADMINISTRATION:**

Color Additives
<http://www.fda.gov/food/foodingredientspackagingucm094211.htm>

**Cosmetic Good Manufacturing Practice
Guidelines**

<http://www.cfsan.fda.gov/~dms/cos-gmp.html>

Imports and Exports Guidance

<http://www.fda.gov/Food/InternationalActivities/Imports/default.htm>

Office of Cosmetics and Colors

<http://www.cfsan.fda.gov/~dms/cos-toc.html>

**Office of Nutritional Products, Labeling, and
Dietary Supplements**

<http://www.cfsan.fda.gov/~dms/supplmnt.html>

The Bioterrorism Act of 2002

<http://www.fda.gov/oc/bioterrorism/bioact.html>

UNITED STATES FOREST SERVICE

Info on Botanical Wild Collection Permits
<http://www.fs.fed.us/>

STANDARDS ORGANIZATIONS

AMERICAN HERBAL PHARMACOPOEIA

PO Box 66809, Scotts Valley, CA. 95067, United States

TEL: 1-831-461-6318

FAX: 1-831-475-6219

E-mail: ahpadmin@got.net

URL: <http://www.herbal-ahp.org/>

DEMETER ASSOCIATION, INC.

Britt Road, Aurora New York, 13026, United States

TEL: 1-315-364-5617

FAX: 1-315-364-5224

E-mail: Demeter@Baldcom.net

URL: <http://demeter-usa.org/>

NATIONAL ORGANIC STANDARDS BOARD

URL: <http://www.ams.usda.gov/nosb/index.htm>

NSF INTERNATIONAL

PO Box 130140

Ann Arbor, MI, 48113-0140, United States

TEL: 1-734-769-8010

FAX: 1-734-769-0109

E-mail: info@nsf.org

URL: <http://www.nsf.org/>

**UNITED STATES PHARMACOPEIAL
CONVENTION, INC.**

12601 Twinbrook Parkway

Rockville, MD 20852, United States

TEL: 1-301-881-0666

E-mail: dietary@usp.org

URL: <http://www.usp.org/>

**USP DIETARY SUPPLEMENT VERIFICATION
PROGRAM**

12601 Twinbrook Parkway
Rockville, MD 20852-1790, United States

TEL: 1-800-822-8772

URL:

<http://www.usp.org/USPVerified/dietarySupplements/>

Appendix X Supplier qualification document

CLICK HERE
TO E-MAIL
PACKET ▶



January 8, 2010

Re: ESTEE LAUDER RAW MATERIAL INFORMATION PACKET

To our supply base:

Attached you will find the Estée Lauder Raw Material Information Packet, which will need to be completed in its entirety in order for any material to be used by Estée Lauder Companies. **This revision should be the only one submitted and any previous copy should be discarded.**

The following information is also of particular importance:

1. Material Safety Data Sheet - must be compliant with European Union regulations including the 16 section format with risk and safety phrases, transport information & flashpoint for all liquids.
2. The Vendor is responsible for providing required Tox/Safety testing – (See page 4). It is also required by the EU Cosmetics Directive 7th Amendment that we are aware of any animal tests carried out after September 11, 2004.
3. REACh compliance must be verified through Estee Lauder raw material and chemical sheets (attached).
4. All global registry numbers, including the harmonized tariff number.
5. If material is treated with any sterilization method (such as heat, irradiation, ethylene oxide, filtration, etc.) prior to shipping to any Lauder facility, provide treatment & dose.
6. If material is secured with any tamper proof packaging, specify type used.

If you have questions regarding any information request found in this packet, please contact me at ischleno@estee.com or (631)-531-1244.

Thank you,

Ina Schlenoff

Ina Schlenoff

Raw Material Administration, Research & Development

REVISED 1/8/10 IS

RAW MATERIAL TRADE NAME: _____

CHEMIST NAME: _____

DEPT: _____

TENTATIVE CODE NUMBER: _____

**ESTÉE
LAUDER**
COMPANIES
RESEARCH PARK
125 PINELAWN ROAD
MELVILLE, NY. 11747
631-454-7000

To: Raw Material Supplier
From: Ina Schlenoff - Raw Material Administration

Re: NEW RAW MATERIAL INFORMATION PACKET

You recently introduced a new raw material to Estée Lauder Companies. In order to expedite the use of any material in our products, all of the following information is required as soon as possible.

Please note that all documentation must be supplied on corporate letterhead along with signature & title.

Material Safety Data Sheet

- Must be compliant with US, EU and Canadian regulations including the 16 section format (issued or revised within the last 3 years)
- Flashpoint must be included for all liquids
- Section 14 must be completed, which contains the following information: Proper shipping name, Hazard class, UN#, packing group

Toxicology/Safety Testing

- Please refer to page 4 for specific needs and categories of acceptable safety testing

Quantitative Compositional Breakdown to 100%

- Please include complete nomenclature (assigned CTFA/INCI names & Chemical/Common Name)
- Please include Preservative & Antioxidant percentages

Certification Regarding Source of Raw Material (pages 10-15) – Signature required

- Manufacturing flow chart listing all processing aids and extraction methods must be included

BSE Certification for Tallow Derivatives (pages 16-17)

Pricing Schedule (Cost per KILO in US dollars)

- Must include Distributor AND Manufacturer price (if applicable)

Raw Material Specifications

- Please provide ranges for all tests that appear on specification and certificate of analysis
- Please provide a description of the odor; typical or characteristic are not acceptable terms
- Please provide shelf life
- Please provide special handling or shipping requirements (page 6)

Analytical Test Methods for all tests appearing on the Certificate of Analysis

Micro Requirement for Preservation Efficacy

- Challenge tests must be submitted (for materials with >20% water content)
- Please refer to page 6 for additional information

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- Domestic or international registry numbers**
 - CAS #, EINECS #, ELINCS #
 - REACH registration Status (< 1Ton letter, Raw and Chem excel sheets attached)
 - Harmonized Tariff #
 - Canadian DSL listing, NICNAS, TSCA

*If exempt from any of these, indicate the reason
 *If registration is in process, please inform us in writing
- A separate document on company letterhead listing any trace contaminants/impurities**
 - Including heavy metals, pesticides, iodine, 1,4-dioxane, ethylene oxide, residual catalysts, processing aids, reaction by-products (residual monomers)
 - Please list concentrations
 - A letter must be included even if there are none present!
- TITANIUM DIOXIDE:** A separate document on company letterhead providing particle size analysis
- PIGMENTS:** A separate document on company letterhead listing compliance with US, EU and Japan regulations
- ESSENTIAL OILS:** A separate document on company letterhead indicating compliance with current IFRA regulations
- Environmental impact information on this ingredient or its components**
 - This would include: biodegradability or other degradation pathways; aquatic toxicity; VOC content; accumulation and persistence; treatability in a public owned treatment plant; bioconcentration and adsorption, etc.
- Three different lots (4-8 oz each) with Certificates of Analysis**
 - All tests that appear on the specifications must appear on the C.O.A
 - Please submit a separate 20 mL sample for botanical ingredients (for allergen testing)
- All global manufacturing locations; listing City, State, and Country (page 9)**
- Specify any sterilization methods and /or tamper resistant packaging used on materials prior to shipping to any EL Company facility**
- Also include: Any technical information, published literature (i.e. journal articles or industry publications), brochures, pamphlets, etc.**

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RAW MATERIAL SAFETY INFORMATION

Please confirm if any of the following safety studies have been performed and submit the full report:

**** As per the EU Cosmetics Directive 7th Amendment, if animal tests are performed after September 11, 2004- for the development or safety evaluation of a raw material- the type of test(s) & date(s) must be specified. ****

1. SKIN SENSITIZATION Yes No
 - hRIPT 100 personDate Performed:
Results:
 2. OCULAR IRRITATION Yes No
 - Ocular irritation testingDate Performed:
Results:
 3. SKIN TOXICITY and IRRITATION Yes No
 - Single dose percutaneous toxicity, LD50 determined
 - Primary skin irritationDate Performed:
Results:
 4. ACUTE ORAL TOXICITY Yes No
 - Single dose toxicity, LD50 determinedDate Performed:
Results:
 5. PHOTOTOXICITY/PHOTOALLERGENICITY Yes No
 - Phototoxicity testing
 - Photosensitization testingDate Performed:
Results:
 6. MUTAGENICITY Yes No
 - Reverse mutation testing
 - Chromosomal aberration testing
 - Micronucleus testingDate Performed:
Results:
 7. CARCINOGENICITY Yes No
Date Performed:
Results:
 8. REPRODUCTIVE TOXICITY Yes No
Date Performed:
Results:
- OTHER TESTING:
Type of testing:
Date Performed:
Results:

****INCLUDE FULL REPORTS FOR ALL TESTING MENTIONED ABOVE****

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MICROBIOLOGICAL SPECIFICATIONS

Most raw materials shall contain less than 100 COLONY FORMING UNITS per gram or ml, as determined by Aerobic Plate Count or Most Probable Number.

For references of acceptable methods for plate count determination reference the:

F.D.A. - Bacteriological Manual - 8th Edition, Revision A-1998
U.S. Pharmacopiea -33rd Edition
CTFA Technical Guidelines

No raw material may contain any of the organisms listed below as determined by Aerobic Plate Count or Most Probable Number:

Gram Negative Bacteria
Staphylococcus aureus
Candida albicans
Enterococcus species
Aspergillus niger

There are some raw materials, which do not require microbiological testing, and those will be determined by Estée Lauder and the supplier.

Micro Efficacy Studies

Water miscible raw materials may be susceptible to microbiological contamination due to their high water content and the nature of the ingredient. Any material that has over 20% water must be challenged tested or show that the material does not support microbial growth. If a preservative has been added to the raw material, then data must be submitted to support preservative efficacy claims.

Pass/ fail criteria: Bacteria must show a three-log reduction within one week following challenge.
Fungus must show at least a two-log reduction within two weeks of challenge.

Method: Either the USP or CTFA challenge test methods (or other compendium challenge methods) are acceptable procedures.

Storage and Shipping Conditions

Choose conditions for both Storage and Shipping as they may be different in some cases.

Storage: (choose one)

- Ambient Room Temperature: 68°- 85°F.
- Refrigerate: 35° - 46° F
- Red Label Room: for any raw materials with a Flash Point below 100° F
- Cool Area <68° F

Shipping: (choose one)

- Ambient Room Temperature: 68°- 85°F.
- Refrigerate: 35° - 46° F
- Red Label Room: for any raw materials with a Flash Point below 100° F

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RAW MATERIAL CERTIFICATION INFORMATION

THIS MUST BE COMPLETED FOR EACH COMPONENT:

1. **Must provide current Organic Certification (if applicable)**
2. **Must provide current Sustainability letter (if applicable)**
3. **Does this item contain any material derived from the IUCN, The World Conservation Union Redlist of Threatened Species (located on-line at <http://www.redlist.org/>) -----**

If **YES**, please provide the following information for each applicable material

- IUCN Redlist Category (vulnerable, near threatened, endangered, etc.):
- Scientific Name:
- Common Name:
- Country and Region Sourced From:

4. **Does this item contain any material derived from the CITES, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (located on-line at <http://www.cites.org/eng/app/index.shtml>) -----**

If **YES**, please provide the following information for each applicable material

- CITES Appendices I and II and III:
- Genus and Species:
- Common Name:
- Country and Region Sourced From:

INTERNATIONAL INFORMATION

AUSTRALIA:

If the material contains an extract, please provide the following information (for each extract):

- Latin name of the plant
- part(s) of the plant used (i.e., flower, leaf, root)
- identify any solvent used in extraction
- Ratio of solvent to botanical prior to extraction
- Percent yield after extraction (that is, if the process starts with 100g of plant, how many g of extract is left at the end?)

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TOXIC CHEMICAL LIST

| EPA HAZARDOUS WASTE # | CONTAMINANT | CAS # | REGULATORY LEVEL (mg/L) |
|-----------------------------|------------------------------|-----------|-------------------------------|
| D004 | Arsenic | 7440-38-2 | 5.0 |
| D005 | Barium | 7440-39-3 | 100.0 |
| D018 | Benzene | 71-43-2 | 0.5 |
| D006 | Cadmium | 7440-43-9 | 1.0 |
| D019 | Carbon tetrachloride | 56-23-5 | 0.5 |
| D020 | Chlordane | 57-74-9 | 0.03 |
| D021 | Chlorobenzene | 108-90-7 | 100.0 |
| D022 | Chloroform | 67-66-3 | 6.0 |
| D007 | Chromium | 7440-47-3 | 5.0 |
| D023 | o-Cresol | 95-48-7 | 200.0 |
| D024 | m-Cresol | 108-39-4 | 200.0 |
| D025 | p-Cresol | 106-44-5 | 200.0 |
| D026 | Cresol | | 200.0 |
| D016 | 2,4-D | 94-75-7 | 10.0 |
| D027 | 1,4-Dichlorobenzene | 106-46-7 | 7.5 |
| D028 | 1,2-Dichloroethane | 107-06-2 | 0.5 |
| D029 | 1,1-Dichloroethylene | 75-35-4 | 0.7 |
| D030 | 2,4-Dinitrotoluene | 121-14-2 | 0.13 |
| D012 | Endrin | 72-20-8 | 0.02 |
| D031 | Heptachlor (and its epoxide) | 76-44-8 | 0.008 |
| D032 | Hexachlorobenzene | 118-74-1 | 0.13 |
| D033 | Hexachlorobutadiene | 87-68-3 | 0.5 |
| D034 | Hexachloroethane | 67-72-1 | 3.0 |
| D008 | Lead | 7439-92-1 | 5.0 |
| D013 | Lindane | 58-89-9 | 0.4 |
| D009 | Mercury | 7439-97-6 | 0.2 |
| D014 | Methoxychlor | 72-43-5 | 10.0 |
| D035 | Methyl ethyl ketone | 78-93-3 | 200.0 |
| D036 | Nitrobenzene | 98-95-3 | 2.0 |
| D037 | Pentachlorophenol | 87-86-5 | 100.0 |
| D038 | Pyridine | 110-86-1 | 5.0 |
| D010 | Selenium | 7782-49-2 | 1.0 |
| D011 | Silver | 7440-22-4 | 5.0 |
| D039 | Tetrachloroethylene | 127-18-4 | 0.7 |
| D015 | Toxaphene | 8001-35-2 | 0.5 |
| D040 | Trichloroethylene | 79-01-6 | 0.5 |
| D041 | 2,4,5-Trichlorophenol | 95-95-4 | 400.0 |
| D042 | 2,4,6-Trichlorophenol | 88-06-2 | 2.0 |
| D017 | 2,4,5-TP (Silvex) | 93-72-1 | 1.0 |
| D043 | Vinyl chloride | 75-01-4 | 0.2 |

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SUPPLIER INFORMATION

Provide answers to the following questions:

1. Are samples representative of lab , pilot , experimental , or production batch ?(check one)
2. Are you a distributor or manufacturer for this material? -----
3. What is your production capacity and lead-time for this material?
4. Provide a full copy of a global (i.e., US and foreign) patent search of third party patents/patent applications relating to this material and/or its use, and highlight potential infringement issues. Also provide numbers of any patents or applications your company has filed relating to the material and/or its use.
5. Is this raw material *custom made* for and/or *exclusive* to the Estée Lauder Companies? ----

MANUFACTURER/ DISTRIBUTOR INFORMATION

1. Company: _____
2. Address: _____
3. Telephone #: _____ Fax #: _____
4. Facility Size: _____
5. Number of employees: _____
6. Affiliation (Division/Subsidiary (of)): _____
7. Chemicals to be Produced or Supplied to the Lauder Companies: _____
8. Operations performed at this facility:

| | |
|----------------|--------------------------|
| Manufacturing: | <input type="checkbox"/> |
| Re-Packaging: | <input type="checkbox"/> |
| Warehousing: | <input type="checkbox"/> |
| Distribution: | <input type="checkbox"/> |

9. Management:

| NAME | POSITION |
|------|----------|
| | |
| | |
| | |

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RAW MATERIAL SUPPLIER CERTIFICATION OF PROCESS AND ORIGIN

BACKGROUND

Raw material quality is determined and influenced not only by Standards and Specifications, but by the elimination and early identification of process and source alterations. While anticipating you will avoid such changes, we ask your agreement that we be advised as early as possible of such changes should they be unavoidable, including any change in manufacturing locations. If your proprietary needs do not permit such disclosures, which we seek in the spirit of partnering and confidentiality, simply exclude those items via an addendum to this certification.

Certification of _____ (Supplier) to Estée Lauder companies (Lauder).

Supplier certifies that the processing, final packaging, and other work as described, performed in connection of Lauder’s purchase orders will be done at the premises (list all worldwide manufacturing sites) and (if identifiable via a unique and simple reference) in accordance with the process identified below:

| <u>Lauder Item Code</u> | <u>Manufacturing Locations</u> | <u>Process ID</u> |
|-------------------------|--------------------------------|-------------------|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |

Additional List Attached

Supplier acknowledges that changes to the above, especially without prior notification (preferably in writing) to Lauder R&D (Attn: Ina Schlenoff), could jeopardize quality conformance and thereby impair the nature of our relationships.

Lauder agrees to acknowledge Supplier notifications, to not delay or withhold concurrence without reasonable cause, and to work with Supplier to maintain confidence throughout the change process.

AGREED & ACCEPTED

Supplier: _____

By: _____

Title: _____

Date: _____

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CERTIFICATION REGARDING SOURCE OF RAW MATERIAL

1. I, _____, hold the position of _____ in
(Name) (Title)
 _____ (hereinafter, "Vendor"), a company having a
(Company Name)
 principal place of business at _____. I have
(Company Address)
 conducted, or have had others conduct at my direction, a reasonable investigation, both
 internally and, where necessary, with any third party suppliers, into the source(s) of
 _____. I have obtained sufficient information to make the
(Name of Raw Material)
 statements in the following Certification truthfully and accurately.

2. I have read and understand the "Definitions of Raw Materials" attached hereto, and hereby certify the following information with respect to the ingredient identified above, the starting material and any processing aid used in its manufacture, and all ingredient components:

Definitions of Raw Material Sources

Basic Terminology

1. **Ingredient**: a substance in a cosmetic product.
2. **Starting Material** (sometimes referred to as "feedstock" or "feedsourc"): the material used in the first step of a several-step process used to create an ingredient. E.g., plant-derived stearic acid, which is the starting material for sodium stearate.
3. **Processing Aid**: any item used to process, manufacture or create an ingredient, that does not become part of that ingredient. E.g., catalysts, filters, coagulators, solubilizers.
4. **Ingredient Component**: a material that is combined with at least one other material to create another cosmetic ingredient.
5. **Fermented**: a material resulting from processes involving chemical conversion or modification by a single cell organism. E.g., yeast, cholesterol. Note: The fermentation organism and the source of all growth media components must be defined as to their individual derivation in accordance with the types of ingredients listed below.

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Types of Ingredients

1. **Petroleum Ingredient**: an ingredient in which every component is originally and solely sourced from petroleum or natural gas. E.g., ethylene oxide.
2. **Plant Ingredient**: an ingredient in which every component is originally and solely sourced from a plant (defined as any organism generally distinguished by the presence of chlorophyll, a rigid cell wall, and by the absence of the power of locomotion). E.g., spinach extract.
3. **Mineral Ingredient**: an ingredient in which every component is originally and solely sourced from a mineral (defined as inorganic chemical or substance of homogeneous structure found in nature, usually obtained from the non-living constituents of the earth's crust). E.g., iron oxide.
4. **Plant/Petroleum Ingredient**: an ingredient combining plant- and petroleum-derived components. E.g., PEG-100 stearate, where the stearate is plant-derived.
5. **Plant/Mineral Ingredient**: an ingredient combining plant-derived and mineral-derived components. E.g., calcium stearate, where the stearate is plant-derived.
6. **Animal Ingredient**: an ingredient that contains *any* component obtained by destroying an animal (defined as a living organism that requires oxygen and organic foods, is capable of voluntary movement and sensation, is incapable of photosynthesis and unlimited growth). Animals include but are not limited to *insects, shellfish or other fish, and reptiles*. E.g., stearic acid from tallow.
7. **Animal-Related Ingredient**: an ingredient in which every component is originally and solely sourced from materials produced by animals without destroying the animal. E.g., beeswax, honey, milk, eggs, and wool.

Note: In addition to identifying the ingredient type from the list above, ingredient information also must include the exact source materials for each ingredient (i.e., the specific type of plant, animal or mineral providing the starting material and any components or processing aids).

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Estee Lauder Companies Raw Material Code Number: ____ - ____

Trade Name: ____

Manufacturing Process Flowchart must be included with the following information:

1. Petroleum Ingredient (Ingredient name): _____

- a) Starting Materials: ____
- b) Country of Origin: ____
- c) Processing Aids: _____

Do any of the processing aids listed above contain animal ingredients or animal-related ingredients? Y N

If yes, please complete section 6 and/or 7 for the processing aid(s).

2. Plant Ingredient (Ingredient Name): _____

- a) Starting Materials: ____
- b) Plant Species: ____
- c) Part of Plant Used: ____
- d) Country of Origin: ____
- e) Processing Aids: ____

Do any of the processing aids listed above contain animal ingredients or animal-related ingredients? Y N

If yes, please complete section 6 and/or 7 for the processing aid(s).

g) Is this material derived from a Genetically Modified Organism?

Y N

3. Mineral Ingredient (Ingredient name): _____

- a) Starting Materials: ____
- b) Country of Origin: ____
- c) Processing Aids: ____

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- d) Do any of the processing aids listed above contain animal ingredients or animal-related ingredients? Y N
 If yes, please complete section 6 and/or 7 for the processing aid(s).

4. Plant/Petroleum Ingredient (Ingredient name):

Plant:

- a) Starting Materials: _____
 b) Plant Species: _____
 c) Part of Plant Used: _____
 d) Country of Origin: _____
 e) Processing Aids: _____

- Do any of the processing aids listed above contain animal ingredients or animal-related ingredients? Y N
 If yes, please complete section 6 and/or 7 for the processing aid(s).

- f) Is this material derived from a Genetically Modified Organism?
 Y N

Petroleum:

- g) Starting Materials: _____
 h) Country of Origin: _____
 i) Processing Aids: _____

- Do any of the processing aids listed above contain animal ingredients or animal-related ingredients? Y N
 If yes, please complete section 6 and/or 7 for the processing aid(s).

5. Plant/Mineral Ingredient (Ingredient name):

Plant:

- a) Starting Materials: _____
 b) Plant Species: _____
 c) Part of Plant Used: _____
 d) Country of Origin: _____
 e) Processing Aids: _____

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Do any of the processing aids listed above contain animal ingredients or animal-related ingredients? Y N

If yes, please complete section 6 and/or 7 for the processing aid(s).

f) Is this material derived from a Genetically Modified Organism? Y N

Mineral:

g) Starting Materials: _____

h) Country of Origin: _____

i) Processing Aids: _____

Do any of the processing aids listed above contain animal ingredients or animal-related ingredients? Y N

If yes, please complete section 6 and/or 7 for the processing aid(s).

6. Animal Ingredient (Ingredient name or Processing Aid): _____

a) Starting Materials: _____

b) Animal Species: _____

c) Part of Animal Used: _____

d) Country of Origin: _____

e) Processing Aids: _____

Do any of the processing aids listed above contain animal ingredients or animal-related ingredients? Y N

If yes, please complete section 6 and/or 7 for the processing aid(s).

7. Animal-Related Ingredient (Ingredient name): _____

a) Starting Materials: _____

b) Animal Species: _____

c) Part of Animal Used: _____

d) Country of Origin: _____

e) Processing Aids: _____

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Do any of the processing aids listed above contain animal ingredients or animal-related ingredients? Y N

If yes, please complete section 6 and/or 7 for the processing aid(s).

3. Vendor acknowledges that Estee Lauder is relying on the truth, accuracy, completeness and correctness of the foregoing statements in formulating products containing this raw material. Vendor shall indemnify, defend and hold Estee Lauder and its affiliates, their respective successors and assigns, and their respective contractors, officers, agents, employees and affiliates harmless from and against any and all claims, liabilities, obligations, demands, causes of action, damages, costs, fines or expenses, including reasonable attorney's fees suffered, paid or incurred by them resulting from or arising out of any falsity, inaccuracy, incompleteness or incorrectness of Vendor's statements in this Certification.

4. I represent that I am authorized to make the statements and accept the obligations provided herein, on behalf of Vendor.

VENDOR: _____

Signature: _____

Name: : _____

Title: _____

Date: _____

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BSE Certification for Tallow Derivatives

1. I, _____ (Name)
hold the position of _____ (Title)
in _____ (Company Name)
(hereinafter, "Vendor"), a company having the principal place of business at
_____ (Company Address).
- I have conducted, or have had others conduct at my direction, a reasonable investigation, both internally and where necessary, with any third party suppliers, into the processing and sourcing of
_____ (Name of Raw Material).
- This raw ingredient is sourced from _____ (Country of Origin).
- I have obtained sufficient information to make the statements in the following Certification truthfully and accurately.
2. I hereby certify compliance with each of the following requirements in regard to all Tallow derivatives supplied to the Estee Lauder Companies.

Requirements:

- a. That all Tallow derivatives are produced in strict compliance with the SCCNFP's opinion concerning Tallow derivatives set forth below.
- Tallow derivatives are sourced from countries where BSE is highly unlikely or unlikely.
 - The raw tallow is sourced from ruminants that are fit for human consumption, i.e., fallen stock is excluded, and any possible cross contamination is prevented.
 - The raw tallow is then submitted to Hydrolysis at > 200°C for 2 hours and corresponding pressure followed by either:
 - To obtain glycerol and fatty acids and fatty acid esters: Transesterification or Hydrolysis at least 200°C, 40 bars for 20 minutes, followed by purification to remove (insoluble) impurities; or
 - To obtain glycerol and soap: Saponification with NaOH 12M
 - Batch process: at 95°C for 3 hours or
 - Continuous processes: at 140°C, 2 bars for 8 minutes or equivalent conditions, followed by a purification to remove (insoluble) impurities.
- Moreover, other Tallow derivatives (e.g., Fatty alcohols, fatty amines, fatty amides) produced from the above mentioned and submitted to further processes are regarded as safe.
- b. The above processes are strictly certified. Accordingly, an outside auditor with recognized technical competence has certified that we comply with the SCCNFP's opinion and that certification is attached for each raw material supplied by us to you.

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- c. We agree to monitor each batch of raw material produced by us and to keep accurate records of pressure, temperature and time in accordance with the above requirements in order to document our compliance.
3. The Estee Lauder Companies **requires full compliance** with the Food and Drug Administration's (FDA) Interim Final Rule "The Use of Materials Derived From Cattle in Humans, Food and Cosmetics" (69 Federal Register 42255). This rule identifies the following prohibited cattle (bovine) materials:
- certain specified risk materials from cattle 30 months of age or older (e.g., brain, skull, eyes)
 - small intestine of all cattle
 - material from non-ambulatory disabled cattle
 - material from cattle not inspected and passed for human consumption and mechanically separated beef
 - specific risk materials from cattle tonsils and distal ileum of small intestine regardless of the age of the animal
- Tallow must be free of the prohibited cattle materials listed above, or must contain not more than 0.15 percent hexane-insoluble impurities as determined by methods specified in the regulation.
4. Vendor acknowledges that Estee Lauder is relying on the truth, accuracy, completeness and correctness of the foregoing statements in formulating products containing this raw material. Should Estee Lauder be subject to any litigation, investigation, claim, administrative proceeding or any type of action (collectively "Claims"), arising as a result of the falsity, inaccuracy, incompleteness or incorrectness of Vendor's statements, Vendor agrees to defend, indemnify and hold Estee Lauder, its agents, and affiliates, as well as their contractors, agents directors, officers and employees, from and against any and all liability, loss, damage, cost or expense (including, without limitation, reasonable attorney's fees and costs) paid or incurred by Estee Lauder arising out of or resulting from any such Claims.
5. I represent that I am authorized to make the statements and accept the obligations provided herein, on behalf of Vendor.

VENDOR _____

Signature: _____

Name: _____

Title: _____

Date: _____

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Postal address
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Palais des Nations
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The International Trade Centre (ITC) is the joint agency of the World Trade Organization and the United Nations.