

Bioscience at a Crossroads

Access and Benefit Sharing in a Time of
Scientific, Technological and Industry Change:

Botanicals



Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: Botanicals

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Front cover photographs:

Left: Maca, *Lepidium meyenii*

Centre: *Echinacea sp.*

Right: *Prunus africana* (Photo Rachel Wynberg)

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The focus of this brief is on the use of genetic resources and associated traditional knowledge in the botanicals industry, although conclusions and recommendations have broad applicability to other sectors. Note that separate policy briefs review access and benefit-sharing issues pertaining to the pharmaceutical, agriculture, industrial biotechnology, food and beverage, and cosmetic sectors. The reader is also referred to the overview brief in this series: Laird, S. and Wynberg, R. 2012. *Bioscience at a crossroads: Implementing the Nagoya Protocol on access and benefit sharing in a time of scientific, technological and industry change*. Secretariat of the Convention on Biological Diversity, Montreal. Policy briefs can be found at: <https://www.cbd.int/abs/policy-brief/default.shtml/>

INTRODUCTION

In the last decade, the botanical medicine market has grown significantly, as has the range of products containing botanicals. No longer sold primarily as single ingredients, botanicals are now often found as mixtures, in sports drinks, functional foods, cosmetics, and as natural alternatives to animal ingredients like fish oils, or artificial colourings, flavourings and preservatives.¹ The botanicals sector is diverse, with widely varying products, companies, markets, approaches to research and development (R&D), and regulatory frameworks.

Access and benefit-sharing (ABS) is a significant issue in this sector because traditional knowledge (TK) is central to product development, safety and marketing. The vast majority of products stem from European, Traditional Chinese Medicine, Ayurvedic and other medical traditions. Companies also routinely incorporate species new to the market, although demand for access has slowed in recent years due to changes in regulatory frameworks. In many regions, government oversight of the safety, efficacy, identity, purity and quality of products has increased, requiring more expensive and time-consuming research and testing than previously.² Demand for access to new species and traditional knowledge persists in this sector, however, but awareness of the Convention on Biological Diversity (CBD) and the legal and ethical obligations associated with using traditional knowledge, and bringing new species to market, is limited.³

WHAT ARE BOTANICALS?

The scope of this brief is *botanicals* – plant-based (or fungi, bacteria, algae-based) products that are used as medicines or to promote health and well-being. For the purposes of this brief, we will use the term botanicals, but around the world these products go by a range

of names, including herbal medicines, dietary herbal supplements, phytomedicines, phytoprotectants, and phytotherapeutic agents.⁴

In order to better locate botanicals in the galaxy of sectors that undertake research on and use plants, it is instructive to also discuss what botanicals are *not*. Botanicals affect the structure or function of the body, but they are distinct from *pharmaceutical drugs*. Pharmaceutical drugs, even those based on natural products, are synthetic, semi-synthetic or otherwise highly purified or chemically modified. In contrast to pharmaceuticals, the active constituents in a botanical medicine are often not identified, and its biological activity might not be well characterized.⁵

This brief also does not include traditional botanical medicines used on a local or subsistence basis, and as part of the cultures and traditions from which they arose. Botanicals included in this brief are products that are finished, labelled and sold commercially, which may, however, include some traditional medicines (e.g. the large Traditional Chinese Medicine and Ayurveda markets).

Botanicals are also not *foods*, which are consumed for their taste, aroma, and nutritive value. We include in this discussion, however, botanical products incorporated as ingredients into some *functional foods*⁶ like energy and sports drinks, bars, and other products intended to have an effect on the structure or function of the body, including promoting health or addressing health problems.⁷ Botanicals are also incorporated into *natural personal care and cosmetic products*, as we discuss in the cosmetics brief, but these products have very different intended uses.

GLOBAL MARKETS

Global nutrition industry sales – which include dietary supplements, natural and organic foods, natural personal care, household products, and functional foods – totaled more than \$300 billion in 2010 (Table 1). All of these categories might include botanicals to greater or lesser degrees, but the dietary supplements segment includes herbal supplements sold as medicines, or botanicals. In 2010, the global dietary supplement market was around \$84 billion, and is expected to grow in the coming years.⁸ A recent study estimated that by 2017, global herbal supplement, or botanicals, markets would increase to \$107 billion.⁹ Around the world, there is a growing middle class with more money and more inclination to spend on health and wellness, including natural and preventive healthcare, functional foods, and self-care.¹⁰ Unlike most sectors, the global botanicals market exhibited steady, if slowed, growth during the recent economic crisis.¹¹

Europe is the world’s largest market, led by Germany, France, Italy and the UK. Emerging economies like China, India, Brazil and Eastern Europe are projected to have faster growth than developed countries in the coming years in both consumption and production of botanicals.¹² By 2020, it is predicted that China will be the largest global producer and consumer of nutraceutical ingredients.¹³

STRUCTURE OF THE INDUSTRY

The botanicals industry varies by country, and reflects local scientific, cultural and economic contexts. Companies vary in size, nature of products, extent of R&D and overall approach. The industry includes, for example, very small family-run companies that sell a handful of products based on traditional medicine, as well as large

Table 1. Global Nutrition Industry Sales by Product Category, 2010 (\$million USD, consumer sales)¹⁴

Category	2010	% of market	2010 growth
Supplements	84.5	28%	5.4%
Natural & Organic Foods	84.1	28%	7.5%
Natural & Organic Personal Care & Household Products	31.0	10%	8.8%
Functional Foods	101,836.0	34%	4.8%
Total Nutrition Industry	301,386.0		6.1%

pharmaceutical companies that undertake extensive R&D and produce standardized phytomedicines.

In most countries, a small group of very large companies dominate the industry, with more numerous smaller companies filling niches. For example, in the US in 2011, 34 companies with sales greater than \$100 million had total revenues of \$7.27 billion; 94 companies with sales between \$20-\$100 million had total revenues of \$3.43 billion; and 727 companies with sales of less than \$20 million had revenues of \$2.06 billion. The tendency for large companies to dominate the sector is increasing as pharmaceutical, food, household product and other companies acquire small botanical firms. As Tom Aarts, an industry analyst remarks: “If the consolidation trend continues at this same rate, the majority of the nutrition industry could be owned by the pharmaceutical and food industries within five years, and the shape and colour of our industry could be much different.”¹⁵

A web of transactions and range of actors are involved in the process through which raw plant material is transformed into commercial products. These include harvesters and growers, traders, exporters, brokers, bulk ingredient and processing companies, manufacturers and marketers, distributors, and retail outlets. Over the last ten years, processing has shifted largely to cheap labour

“Most manufacturing companies outsource bulk processing, extraction and maybe tableting, mainly to China and to a lesser extent India... The Chinese extractors have had a large impact on the market, creating booms and busts. They tend to all rush into an area, to a new ingredient, drive prices up, and then scramble out. Volatility in prices for botanicals is significant anyhow, but they are exaggerating it. Booms and busts can result not only from consumer fads, or changes in regulations, or new research that shows positive or negative things about a product... booms and busts are also now the product of how many extractors are in the business of processing a species at any one time. If a lot, then the price goes down. They work on a contract basis, not only on one product, so they can go to where they can make the most margin, moving quickly from one product to another.” – Kodzo Gbewonyo, Bioresources International, Ghana

centers like China and India, with raw material harvested around the world shipped to processors for extraction and then shipped on or back to the home countries of manufacturing and marketing companies.

Access to traditional knowledge and species new to the industry is most commonly sought by intermediary or bulk ingredient companies. These companies supply a range of sectors, including botanicals, cosmetics, and food and beverage, often with the same ingredients and products. Some might develop direct relationships with communities, or receive material and knowledge via brokers and

exporters, but more often they identify new leads through the literature, internet, or word of mouth, and then ‘sell’ new ingredients or products to manufacturers. Other, usually smaller, companies enter into direct ABS partnerships with communities for use of their TK, but these direct partnerships remain an unusual exception today. As one industry manager put it: “If someone is pitching a new ingredient to us, it will usually be a US or European company that supplies ingredients – if there are any issues associated with the product, they get kicked back to the supplier in the country, or even the government.”

Saw palmetto, *Serenoa repens*.



Devil's Claw, *Harpagophytum procumbens*, Nyae Nyae Conservancy, Otjozondjupa region (Photo: Dave Cole)





Top: Capsules containing powdered Açai, *Euterpe oleracea*. Bottom: Tulsi, or holy basil, *Ocimum tenuiflorum*

PRODUCTS

A range of factors contribute to the types of botanical products on the market today. In many parts of the world, people are growing older and are living more sedentary but more stressful lifestyles.¹⁶ At the same time, a very different demographic is engaging in extreme sports and seeking performance enhancers. Others wish to maintain healthy, active and natural lifestyles as they age. In developing countries, people are moving from rural to urban and industrial environments, and so are acquiring the health problems common to developed countries; many also now have the disposable incomes of the middle class.

The main health concerns botanicals address today include: anti-aging, weight control, joint and bone health, arthritis, inflammation, digestion, immunity, stress relief, cardiovascular health, diabetes, cognition/memory, eye health, libido, female health (e.g. menopause), and male health (e.g. prostate problems).¹⁷ In some parts of the world, a consistent profile of proven species remain popular and dominate the market year after year. In Europe, this includes products such as ginkgo, St John's wort, ginseng, and garlic. In other regions, like the US, popular botanical species change more markedly in response to trends and fads.¹⁸

A major trend today is increased demand for food-based products sold for their medicinal and wellness-enhancing qualities. These include cranberry, soy, and alfalfa, as well as spices like tumeric, curcumin, oregano, ginger, and holy basil taken as tablets, capsules, powder, softgels, gelpcaps, liquid extracts, in mixtures, or as one ingredient among many in products like sports drinks or energy bars (Table 2). These food-based products are not included for their taste, aroma, or nutritive value¹⁹, and rather are intended to have medicinal activity.

Table 2. Twenty five Top-Selling Herbal Dietary Supplements in the Food, Drug and Mass Market Channel in the USA for 2011²⁰

HERB	LATIN NAME	USD\$	% CHANGE FROM 2010
Cranberry	<i>Vaccinium macrocarpon</i>	\$40,112,500	13.43
Soy	<i>Glycine max</i>	18,611,700	10.21
Saw palmetto	<i>Serenoa repens</i>	18,055,930	-3.97
Garlic	<i>Allium sativum</i>	15,218,730	-9.21
Milk thistle	<i>Silybum marianum</i>	12,834,460	14.01
Echinacea	<i>Echinacea spp.</i>	10,914,500	-14.62
Black cohosh root	<i>Actaea racemosa</i>	10,319,990	-0.53
St John's wort	<i>Hypericum perforatum</i>	8,439,300	-4.38
Ginseng	<i>Panax ginseng</i>	6,596,372	-6.94
Valerian root	<i>Valeriana officinalis</i>	5,455,633	23.02
Green tea	<i>Camella sinensis</i>	5,213,135	-8.85
Evening primrose	<i>Oenothera biennis</i>	5,018,058	4.12
Horny goat weed	<i>Epimedium spp.</i>	3,059,464	7.05
Bilberry	<i>Vaccinium myrtillus</i>	1,582,448	-11.24
Ginger	<i>Zingiber officinale</i>	1,570,807	13.04
Grape seed	<i>Vitis vinefera</i>	1,261,907	-10.96
Elderberry	<i>Sambucus nigra</i>	797,915	-14.99
Aloe	<i>Aloe vera</i>	747,787	17.31
Yohimbe	<i>Pausinystalia johimbe</i>	446,382	-8.29
Kava kava	<i>Piper methysticum</i>	336,486	6.17
Kelp	<i>Laminaria digitata</i>	333,512	41.42
Spirulina	<i>Arthospira spp.</i>	299,648	26.49
Hawthorn	<i>Crataegus spp.</i>	281,834	0.01
Cayenne	<i>Capsicum annum</i>	273,844	49.05

REGULATORY FRAMEWORK

Regulation has a large impact on botanicals markets and the demand for access to new ingredients and products. Over the last decade, regulatory frameworks for botanicals have undergone review in many countries. As the use of botanicals has expanded to include a wider range of products and applications, governments are grappling with how best to regulate them. Are botanicals active ingredients, or not? Drugs or food supplements? Does it depend on the particular ingredient, and the dosage?²¹ For a few decades, companies have successfully operated in a gray zone between various categories, but consumers increasingly demand proof of safety, product identity, and quality following a number of scares. Many consumers are also seeking products with proven efficacy. The botanicals industry has expanded to the point that it plays a significant role in public health in many countries today, and governments are trying to catch up.²²

Around the world, more comprehensive regulations, supported by clinical data needed to make health claims, and standards for good manufacturing practices (GMPs) and quality control, are increasingly the norm. In what the Nutrition Business Journal (2012) refers to as ‘regulatory creep’, Health Canada, the European Food Safety Authority (EFSA), the US Food and Drug Administration (FDA), the Japanese government and others, are focusing increasingly on safety and efficacy, and are more vigorously enforcing regulations. Governments are also raising awareness amongst consumers about adulteration and mislabeling.

The World Health Organization reported that Member States with regulations or laws governing herbal medicines increased from 25 in 1990, to 78 in 2000, to 110 in

2007.²³ The harmonization of regulations across regions like the EU, and South America²⁴, and possibly globally, is promoted as a way to streamline and provide clarity to what are now extremely inconsistent regulatory frameworks.²⁵ Regulations within the European Union, for example, are considered to be some of the most stringent in the world, while the relatively lax US regulatory environment is sometimes referred to as the “wild west”.²⁶

Josef Brinckmann, of Traditional Medicinals in the US, describes the impact of these varied regulatory environments on their company’s launch of new products. Of the 50 products they market in the US, only 5 are marketed in the EU “...because pre-marketing authorization can cost 50,000 – 100,000 Euros to develop and validate product-specific assays along with 3-year stability trials applying the new analytical method for each herbal tea product, not to mention the considerable post-marketing authorization costs to implement a pharmacovigilance monitoring and reporting system for each product.” As he said elsewhere: “...compared to the European Community, or Canada, or Australia, Japan, China or India, it’s relatively easy to break into the US market... in most countries in the world it’s difficult to expand out of the herbs that are already officially recognized because you have to go through marketing authorization, unlike in the US. It wouldn’t be very easy at all to take a dietary supplement, finished product from the US and register it in the People’s Republic of China or Japan (if it’s classified there as a medicinal product).”²⁷

RESEARCH AND DEVELOPMENT

Increasing demand from consumers for proof of safety and efficacy, industry interest in gaining control over ingredients, products, and delivery mechanisms through intellectual property rights (IPR), and expanded government oversight and regulation of this sector, has meant that in recent years, “the degree of science in supplements has gone up”, as explained one industry researcher in the US. “Companies want to have a stronger position in terms of IPR, and so are putting more science into products, and are patenting more – it is not as much of a copycat industry as it was, although that is still there... A lot of research is done through industry partnerships, or in academia and government, which form alliances with industry, and both ingredient companies and finished product companies will undertake research. The amount of evidence you have to provide is much higher, and so new products are slower in coming.”

Regulators require a range of data from companies to ensure the identity, purity, quality, strength, potency, and consistency of botanical drugs. Proving efficacy additionally requires clinical trials that are time-consuming and might run into many millions of dollars, and so are undertaken by only the largest companies. In addition to that found in large companies, advanced research is undertaken by government and academic research programs; companies will also make use of pharmaceutical company R&D on products that have been abandoned (e.g. Hoodia).

DEMAND FOR NEW INGREDIENTS AND PRODUCTS

Botanicals markets continue to demand novel ingredients and products, particularly if they are based on solid



“There are companies always looking for the next super something. But this is not a sustainable model because they will drop their commitment to the last super thing the moment the next super thing arrives. Hoodia is a good example of this – it was hot 5 years ago, and companies were putting it into weight loss products, but in typical fashion the product over-promised and under-delivered, and many were adulterated and didn’t even contain Hoodia... Demand was far higher than supply, and then the companies that made it super wrecked the market, but at the same time producers in Namibia were scaling up, and then they had no market.”

– Josef Brinckmann, Traditional Medicinals, USA

“The appeal of these ancient healing traditions, apart from being exotic (to European consumers at least), lies in the fact that the plants used have been proven – through generations of use – to be safe, and that their side effects, if any, are very well known and documented, along with maximum safety dosages. This increases consumer confidence in these ethnic botanicals’ safety and efficacy. Consumers don’t expect any nasty surprises from plants that have been used for hundreds, sometimes thousands of years, whereas synthetic drugs invariably cause side effects.”

– Joerg Gruenwald, analyze & realize ag, Germany²⁹

science. However, regulatory confusion and tightening has dampened interest. In regions like Europe, incorporation of ‘new’ species has become rare since claims cannot be made for botanicals new to the market without costly and time-consuming clinical trials. As a result, many companies sell the same portfolio of botanicals they did ten or twenty years ago, and seek growth through expansion into new countries, rather than from new products. Even in less regulated markets like the US, there is a trend towards incorporation of fewer new species. As one bulk

Açaí, *Euterpe oleracea*



ingredient supplier put it: “Regulations are tightening up, there is more science and documentation of raw material, but this means less discovery and innovation. Companies might look at different qualities of the same plant, but will introduce fewer new plants.”

In the current regulatory environment, many companies have launched existing and approved foods, like fruits and spices, as medicines in order to supply ‘new’ ingredients and products to the market. But the real drivers of new product introduction today are those companies that ‘fly under the radar’. This group tends to be comprised of small companies that hope to avoid government attention and ride off the hype created, often on the internet, for the latest ‘hot’ ingredient. In concert with extractors that opportunistically focus on popular ingredients, these companies can create large surges in demand for products and species. The danger in this approach, however, is that when the hype inevitably produces a backlash (e.g. poor quality products, containing the wrong species, and overly optimistic forecasts of effectiveness), even well-researched and -documented products introduced by more reputable companies can lose their market, with real and damaging consequences for growers and harvesters.

DEMAND FOR TRADITIONAL KNOWLEDGE

Traditional knowledge is the foundation of the botanicals industry. Unlike most sectors that demand access to genetic resources, botanical medicines continue to depend on TK. Traditional knowledge is the primary guide to new ingredient and product development, is integral to acquiring approval from regulatory agencies, and is used



Plants used in Traditional Chinese Medicine.

in marketing products to consumers by validating claims for safety and efficacy. Traditional knowledge also plays a role in selecting and breeding, or wild-harvesting, plants with particular properties, including maximizing yields of active constituents.²⁸

Traditional knowledge is accessed from literature, databases, the internet, as well as research with local communities and producers on the part of intermediary brokers, agents, or ingredient suppliers, and in a few cases marketing and manufacturing companies. Many companies today draw upon European traditional medicine because species have high levels of research to support safety and efficacy claims. Traditional Chinese Medicine and Ayurveda are also the source of many new products, supported not only by long histories of traditional use but also increasingly by extensive research.

Those companies that are aware of the CBD often voice concerns about accessing traditional knowledge ‘new’ to the market, however. They cite difficulties associated with knowing how to acquire prior informed consent (PIC) and equitably share benefits, and the costs involved in reaching an ABS agreement. For example, one researcher wondered how companies can share benefits with local communities when species and knowledge are common and widespread: “In cases where you have an endemic species with a very limited geographical range, and a few groups only have the TK, then it is potentially easier to do ABS agreements. But if you have a widely dispersed plant or TK – for example Echinacea – it is almost impossible. Can you imagine all of the European companies with Echinacea products negotiating ABS agreements with all of the North American tribes with traditional knowledge of that use? It is impossible...”

RAW MATERIAL SOURCING AND CERTIFICATION

Accessing bulk raw material, which is then traded as a commodity, does not fall within the scope of the Nagoya Protocol. However, raw material sourcing is central to the botanicals industry and it is therefore important for policy-makers to understand. Green and fair trade sourcing partnerships are also often elements of benefit-sharing packages. Much as pharmaceutical industry ABS benefit-sharing packages typically include sharing research results, technology transfer, training, and capacity-building within laboratories, in the botanicals sector, long term commitments to fair and equitable raw material sourcing in partnership with local producers or communities are a standard benefit.

Consumer awareness of green and fair trade issues associated with botanicals has grown over the last ten years, and it is difficult today to find a product without these claims attached to it.³⁰ Certification and labelling programs in this sector include organic (e.g. Soil Association, Ecocert), fair trade (Fair for Life, FairTrade, FairWild), and sustainable wild harvested (FairWild). In practice, however, very few companies have close relationships with their sources, and most rely on the claims of layers of intermediaries. Some companies even develop their own watered-down labeling schemes. The result is that consumers are overwhelmed and cannot differentiate between reputable and false claims. As one US industry representative put it: “who has the time to drill down and figure out each label?” This was echoed by a European industry analyst: “Most of all, these programs are confusing for the consumer – what is truth and what is invented – no one has any idea.”



St John's Wort, *Hypericum perforatum*

A few companies, like Traditional Medicinals, have developed internal sustainable sourcing policies that require them to ‘have long-term equitable relationships with trade partners’ and forbid purchase of ingredients anonymously from the open market.³¹ The company uses around 120 botanical ingredients, representing some 100 species, and has developed a process through which they identify species at high risk of unsustainable sourcing. They prioritize these species for more attention, more frequent relationship-building site-visits, risk-spreading (e.g. establishing two to three distinct producer groups in two to three distinct geographic zones) and more rigorous sustainability standards. Companies that undertake the complex, and time-and resource-consuming, work of forming direct partnerships with producers can provide useful guidance to policy makers seeking to better understand the ways raw material sourcing can serve as a benefit.

IMPLICATIONS OF MARKET AND RESEARCH TRENDS FOR IMPLEMENTATION OF THE NAGOYA PROTOCOL

Understanding the difference between research on genetic resources and biotrade

The research and development of botanical medicines involves a series of steps leading to their eventual commercialization. These steps include original research on genetic resources and TK, as companies look for species with particular uses, and guides to safety and efficacy. Very quickly after companies investigate new species or TK, demand shifts into the biological resource trade, or biotrade. This is because, unlike pharmaceuticals, botanicals is not a research and development-intensive industry in which it takes many years to commercialize a new product; the pace of new product launches in this industry is rapid, and usually under a year.

After a product launch, companies immediately compete with an onslaught of 'outlier' or 'cowboy' companies that begin to market the same species and TK, and, if it is successful, mainstream companies will follow. Unlike pharmaceuticals, biotech or other sectors in which new leads are held tightly within a company for a number of years, or are protected through IPR in the marketplace for a period of time, within botanical medicine copycat products emerge instantly to compete with those better researched and developed, and there is usually an associated scramble for raw materials. It is important for policy makers seeking to implement the Nagoya Protocol to understand the different phases in commercial prod-

uct development within this sector, and the differences between genetic and biological resource use.

Biotrade is central to the industry, but is distinct from ABS

Unlike pharmaceutical drugs, in which synthesis is desirable and increasingly within the reach of companies, raw materials continue to be the basis for botanical medicine products, and are integral to product identity and effectiveness. The sourcing of raw materials, the vast majority traded as commodity biological resources on international markets, is therefore a very large part of this industry. Because most companies sell many products, they source dozens of species from as many countries, relying on a complex web of suppliers. Few companies enter into direct partnerships with communities and other local groups to supply raw plant materials, although there are exceptions. The trade in raw material does not fall within the scope of the Nagoya Protocol, but sourcing partnerships have been incorporated into benefit-sharing agreements. Benefits associated with sourcing include premium prices, capacity-building, training, and commitments to purchase raw material over time.

Reluctance of companies in this sector to engage with ABS

Although regulatory trends have dampened investments in new product development, interest in new species and TK persists. However, larger companies with legal departments and the resources needed to invest in ABS agreements are generally cautious and disinclined to do so. As one industry representative noted: "The need to move new product launches quickly along often rules out complicated new scenarios like ABS agreements; companies want to launch products within a year and anything that makes that difficult means the product will most likely be reformulated." As a result, the groups undertaking bioprospecting in this sector today tend to be smaller companies, and adherence to ABS requirements can be inconsistent. Acquisitions of botanicals companies by large multi-national pharmaceutical, food, household

“People are not at all aware of the CBD in this industry. The Pure World Group commercializing maca – that came out of a complete lack of awareness about the CBD and the issues it addresses. Most companies see the CBD as something that was fashioned for the pharmaceutical industry and does not apply to them, it is for the big resource industries. At the time the CBD came out, the botanicals industry was small, at least in the US, now it is large. But most companies do not have deep pockets and do not make long-term investments. Their business strategy is based on avoiding copy-cats, and they don’t have a long term vision that would incorporate the CBD’s concerns...”

– Kodzo Gbewonyo, Bioresources International, Ghana

product and other companies with greater legal and R&D capacity, and in some cases experience with the CBD, might change the approach to ABS within this industry in the coming years, however.

Limited awareness of the CBD and Nagoya Protocol

Across the industry, awareness of the CBD is limited, although it varies significantly by region. European companies, for example, are far better informed than those in the US. One European industry researcher remarked: “It is a huge industry, and part of it is aware

of the CBD, but as in most industries people just want to make money. Most don’t know anything about it.” In the US, an industry representative said: “The level of awareness is very low, and I doubt that most would have heard of the CBD. If because of the CBD they started to have problems with a product, they would just drop that product. I don’t think many companies would use a product that meant they had to sign an ABS agreement. That would be a ‘no go’ for product development.” Another industry representative echoed this: “Companies can’t even deal with their own national regulations at this point, they certainly will not be able to take Nagoya on board.”

Left: Turmeric, *Curcuma longa*. Right: Kava, *Piper methysticum*.



THE NAGOYA PROTOCOL: RESPONDING TO SCIENTIFIC, TECHNOLOGICAL, POLICY AND MARKET CHANGE

Regulatory frameworks for botanicals are in flux around the world. As governments seek to streamline and harmonize regulations for the safety, quality and efficacy of botanical medicines, they might also address implementation of the Nagoya Protocol in order to promote the equitable and sustainable use of genetic resources. The Nagoya Protocol also offers opportunities for those in industry to better clarify their obligations and responsibilities. In particular, the Nagoya Protocol can assist with the following:

Providing legal certainty and effective and streamlined measures – Companies wishing to explore novel ingredients for the botanicals sector have been faced with an uncertain legal climate, and confusion about where to go for decision-making about ABS agreements. The Nagoya Protocol recognizes this concern and seeks to create an environment of legal certainty and mutual trust by requiring Parties to designate a national focal point on ABS and one or more competent national authorities to grant access. ABS national focal points are required to make information available on procedures for obtaining prior informed consent and reaching mutually agreed terms (Article 13). Establishment of an ABS Clearing-House (Article 14) for sharing information will also help to achieve this goal. The development of model contractual clauses (Article 19) can provide additional legal certainty and clarity and reduce transaction costs.



Korean ginseng, *Panax ginseng*

Providing clarity on scope – Many in industry have expressed concern about the inclusion of biological and other resources within the scope of ABS measures. The scope of the Protocol does not cover the commodity trade of raw materials used in the botanicals sector, local trade, or subsistence use. It specifically applies only to genetic resources within the scope of Article 15 of the CBD (Article 3) as well as to traditional knowledge



Top: Extracting *Aloe vera* sap. Bottom: Ginger, *Zingiber officinale*

associated with genetic resources. In addition, as further clarified by the Protocol (Article 2(c)), “utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.” Implementation of the Protocol within countries can further help to clarify and resolve the issue of scope.

Supporting the sharing of benefits from the use of traditional knowledge – Traditional knowledge associated with genetic resources is of interest to the botanical medicine sector and is used as a lead for new product development, in seeking regulatory approval, and for marketing. Through Parties’ implementation of Articles 7 and 12, the Nagoya Protocol can help Parties, companies and indigenous and local communities to ensure that traditional knowledge associated with genetic resources is accessed and used with the prior informed consent of indigenous and local communities and that mutually agreed terms are established. The establishment of mechanisms pursuant to Article 12 to inform potential users of traditional knowledge associated with genetic resources about their obligations, can assist companies to understand the requirements for obtaining prior informed consent and for the establishment of mutually agreed terms. The Nagoya Protocol encourages Parties to take into consideration indigenous and local communities’ customary laws and to support the development by indigenous and local communities of community protocols, minimum requirements for mutually agreed terms and model contractual clauses for benefit sharing (Article 12, Paragraph 3).

Improving monitoring of the use of genetic resources – The monitoring of botanical products presents significant challenges due to the multiple ingredients and product lines that are involved across several sectors. Through the checkpoints described in Article 17 and the internationally recognized certificate of compliance, the Nagoya Protocol can help to monitor the use of genetic resources throughout supply chains and provide evidence that

prior informed consent has been obtained, that mutually agreed terms have been negotiated, and that benefits are equitably shared.

Building the capacity of governments, researchers and companies to engage with ABS and changing scientific and technological developments – Awareness of the CBD and the Nagoya Protocol within the botanicals sector is limited, and appears to have not increased in the last few decades. Companies and academic researchers can benefit from capacity built within country governments under the Protocol. The Protocol calls for strengthening of human resources and institutional capacities to effectively implement the Protocol in developing country Parties and Parties with economies in transition. Such needs are well recognized by the Nagoya Protocol, and implementation of Articles 21 and 22 can contribute to raise awareness and build and develop capacity to effectively implement the Protocol.

Developing regional ABS approaches – Many species and traditional knowledge associated with botanicals are widely distributed across political boundaries. Implementation of Article 11 on transboundary cooperation provides important opportunities to investigate common regional or sub-regional approaches for such resources and knowledge. Consideration of the need for and modalities of a global multilateral benefit-sharing mechanism, as required by Article 10 of the Protocol, may also be of relevance in this context. These efforts should seek to dovetail where possible with existing regional efforts to harmonize regulations of safety, efficacy, and quality-control within the botanicals industry.

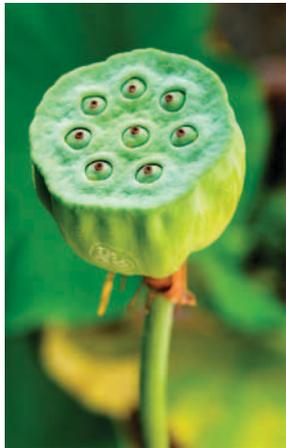


Top: Candelabra. Bottom: Nigella seeds.

ENDNOTES

- 1 Gruenwald, J. 2008. The Global Herbs and Botanicals Market, *Nutraceuticals World*, www.nutraceuticalsworld.com. Gruenwald, J. 2009. Eurotrends: The world of natural ingredients. *Nutraceuticals World*. www.nutraceuticalsworld.com.
- 2 Nutrition Business Journal (NBJ). 2012. *NBJ's Global Supplement & Nutrition Industry Report: An analysis of markets, trends, competition and strategy in the Global Nutrition Industry*. Penton Media, Inc. www.nutritionbusinessjournal.com. Gruenwald, J. 2012. Health Claims Regulation Impacts European Market: Uncertainty results in reduction of claims and overall decrease in innovation. *Nutraceuticals World*. www.nutraceuticalsworld.com.
- 3 See, for example, the case of Maca. ETC Group. 2002. Peruvian Farmers and Indigenous People Denounce Maca Patents. *Genotype*, 2 July 2002. www.etcgroup.org.
- 4 Robinson, MM and Zhang, X. 2011. *The World Medicines Situation 2011: Traditional Medicines: Global situation, issues and challenges*. World Health Organization, Geneva.
- 5 This discussion draws upon the definitions and distinctions made in the 2004 US Department of Health and Human Services, FDA, and CDER *Guide for Industry: Botanical Drug Products*, www.fda.gov/cder/guidance.
- 6 Health Canada defines functional foods as "similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions." Conventional foods with health properties are not included in this brief as botanicals. Jegtvig, S. 2013. *Defining Functional Foods*. About.com, May 15, 2013.
- 7 US Department of Health and Human Services, FDA, and CDER. 2004. *Guide for Industry: Botanical Drug Products*, www.fda.gov/cder/guidance.
- 8 The diversity of ways in which botanicals are used, and the different definitions for segments and categories, means that botanicals markets are difficult to characterize, and a range of figures have been produced for the sector. NBJ, 2012; Gruenwald, 2008. Freedonia Group. 2013. *World Nutraceutical Ingredients to 2015 - Demand and Sales Forecasts, Market Share, Market Size, Market Leaders*. Cleveland, Ohio; Cavaliere, C., Rea, P. Lynch, M.E. and Blumenthal, M. 2010. Herbal supplement sales rise in all channels in 2009. *Herbalgram* 86: 62-65.
- 9 Global Industry Analysts, Inc. 2012. *Herbal Supplements and Remedies: A Global Strategic Business Report*. GIA, San Jose, California. www.StrategyR.com. Herbs and botanicals make up 17% (\$5.1 billion) of the \$30 billion 2011 US supplement market. Other components of the US dietary supplement market include vitamins (34%), sports nutrition (12% and growing rapidly), meal replacements (10%, also with rapid growth), minerals (8%) and specialty (19% - eg probiotics and omega-3s).
- 10 NBJ, 2012. *NBJ's Supplement Business Report: An analysis of markets, trends, competition and strategy in the US dietary supplement industry*. www.nutritionbusinessjournal.com; Smith, T. 2012. Nutrition Industry and Market Research Organizations Fill Data Gaps on Supplement Use. *Herbalgram*, issue 93, pp 64-66.
- 11 Increased purchases of botanical medicines by consumers appear in part to reflect efforts to save on health care costs by purchasing more affordable medicines and self-medicating during difficult economic times. In some countries, consumers increasingly purchase botanicals through cheaper, mass market outlets and the internet. The dietary supplements industry in the US in 2011 surpassed \$30 billion in sales, growing 7% that year, which represented a \$2 billion increase in sales from 2010 (NBJ, 2012); GIA, 2012; Dennis, J. 2012 International Herb & Botanical Trends. *Nutraceuticals World*, July 2012; Smith, 2012.
- 12 Freedonia Group, 2013; NBJ, 2012; Dennis, 2012; GIA, 2012
- 13 Freedonia Group, 2013. Even in countries with long and formal traditional medical systems (eg Traditional Chinese Medicine in China, Ayurveda in India, and Jamu in Indonesia), and large domestic industries based on these practices, significant demand still exists for imported products from Europe and the United States. Imports account for over 80% of the Indonesian supplement market, for example, with around 60% of these coming from the US (Gruenwald, 2008). Brazil also imports a range of botanical products from other countries including ginkgo, ginseng, horse chestnut, white willow and artichoke (Dennis, 2012).
- 14 Nutrition Business Journal (NBJ). 2012. *NBJ's Global Supplement & Nutrition Industry Report: An analysis of markets, trends, competition and strategy in the Global Nutrition Industry*. Penton Media, Inc. www.nutritionbusinessjournal.com.
- 15 *NBJ*, 2012.
- 16 Gruenwald, 2008; GIA, 2012; Dennis 2012.
- 17 The top 10 products in the US address inflammation, prostate health, immunity, adrenal support, detox, stress relief, sleep and libido (Dennis, 2012). Heart health played a dominant role in the last decade of the industry, and many think that brain health - eg cognition, mood, and insomnia - might play a similarly dominant role in the coming ten years. Gut health is also a growth category, particularly as understanding of the role of microorganisms in human digestion and health increases (NBJ, 2012; Gruenwald, 2012).
- 18 The American Herbal Products Association estimates that there were about 3000 species of plants in as many as 50,000 different products sold as herbal supplements in the United States in 2004.
- 19 This is the definition of food provided in the 2004 US Department of Health and Human Services, FDA, and CDER *Guide for Industry: Botanical Drug Products*, www.fda.gov/cder/guidance.
- 20 Source: Symphony IRI Group, 2011; Blumenthal, M, Lindstrom, A, Ooyen, C and Lynch, ME. 2012. Herb Supplement Sales Increase 4.5% in 2011. *Herbalgram*, issue 95, pp 60-64.
- 21 Starling, 2010; Robinson and Zhang, 2011. "*Allium sativa* (garlic) is a useful example when trying to understand the complicated regulatory environment for traditional medicines. Garlic is eaten as a food or spice all over the world, but it is also frequently used for health benefits, including to lower blood cholesterol

- and to inhibit some cancer processes... In Europe alone, garlic is marketed as a foodstuff, a herbal supplement, a herbal medicinal product, a food supplement, a health food or as a pharmaceutical preparation... in the USA garlic is classed as a food or as a dietary supplement only. In Bangladesh garlic is sold as a "phytoprotectant", as a "functional food" in Nepal, and as a "phytotherapeutic agent" in Brazil..." (Robinson and Zhang, 2011).
- 22 NBJ, 2012. Considering a Post-DSHEA World. *Nutrition Business Journal*, 17, 576, June/July 2012. Globally, there is also increasing regulatory scrutiny of energy beverages following deaths and hospitalizations linked to over-caffeination. Substances like ephedrine, synephrine and yohimbine have also been of concern for a number of years. As one industry researcher put it: "Some companies put everything but the kitchen sink in the bottle, and not only extracts of coffee, tea, kola, and so on, along with yohimbe and others... Health concerns mainly focus on caffeine, but in some cases that could be the least of your problems. The interaction between all of the plant alkaloids could be very dangerous." In 2012, the British Medical Journal investigated 431 performance-enhancing products that contain 'dangerous steroids, stimulants and hormones' and soon thereafter the UK medicines regulator MHRA flagged 84 sports supplements for containing dangerous ingredients. (NBJ, 2012; Gruenwald, 2012. Eurotrends: Sports Nutrition 'Slaughterfest'. *Nutraceuticals World*. www.nutraceuticalsworld.com.)
- 23 Confusion with traditional medicine regulation led to the creation in 2006 of the International Regulatory Cooperation for Herbal Medicine (IRCH), coordinated by WHO, to protect and promote public health and safety through improved regulation of herbal medicine (Robinson and Zhang, 2011).
- 24 The industry regional association Latin American Responsible Nutrition Alliance (ALANUR) was formed in part to help guide policies and regulations, and create harmonization in legislation across the region (Dennis, 2012).
- 25 Gruenwald, 2008; Dennis, 2010. Further arguing for global harmonization of regulations is the fact that the internet has become a major part of the business.
- Around the world, consumers are purchasing more botanicals on the internet, which makes it difficult for countries to control the sale of products that do not comply with their regulations. As Ivan Wasserman, a US lawyer specializing in this field put it: "...the internet has become part of our life... so you now have the ability for companies to easily market and advertise dietary supplements and other products to a national, nay international, market. Without, and even with, adequate funding, it's become a difficult task to police that enormous market." (NBJ, 2012).
- 26 NBJ, 2012. Considering a Post-DSHEA World. *Nutrition Business Journal*, vol 17, no 576, June/July 2012; Fu et al, 2009.
- 27 Dennis, 2012; Dennis, 2010.
- 28 Plants produced within their original natural, historical, and cultural context have been shown to surpass those produced from other regions in quality and clinical effects. Geographic indications for herbs have been proposed that would not only impact the quality and efficacy of herbal drug preparations, but could also encourage sustainable supply and protection of TK. Brinckmann, JA. 2012. Emerging Importance of Geographical indications and Designations of Origin – Authenticating Geo-Authentic Botanicals and Implications for Phytotherapy. *Phytotherapy Review*, 2012).
- 29 Gruenwald, J. 2010. Eurotrends: Ethnic Botanicals, a growing trend. *Nutraceuticals World*. www.nutraceuticalsworld.com.
- 30 With the exception that in Europe labels for phytomedicines are tightly controlled, and logos for certification programs making claims about sustainability or fair trade are not allowed.
- 31 Brinckmann, J and B. Morgan. 2012. Linking a wild medicinal plant cooperative to socially responsible companies. *ETFRN News* 54, December 2012.



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