



Market perspectives



Development and potential



Use and international regulations

Stevia from Paraguay

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Introduction

We are pleased to present the following study of the market opportunities for Stevia. The report is an analysis of existing information regarding the properties, uses and benefits of Stevia, the regulatory environment, the current market environment in Japan, a case study of a Brazilian production company, Steviafarma, and recommendations for marketing “Stevia from Paraguay” in the global market.

One of the main reasons for Paraguay Vende to complete this study was to help us better understand the wide ranging development of Stevia, and give shape to our current program of assistance to local companies, in addition to the many Paraguayan firms and associations that may benefit from the information in this study.

We look forward to expanding the original objective of this study, to propel “Stevia from Paraguay” into the global market, and increasing economic returns for Paraguayan families.

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September 2004

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Executive Summary

The most important market for Stevia is currently the food and beverage industry, where it is chiefly employed as a sweetener and flavoring agent. The health market takes second place in importance. In third place there are the byproducts made from the plant remains after removing the leaves destined for the tea industry or extractive industries. Seventy percent of the total worldwide production of Stevia is used to extract crystals known as "Steviosides" and "Rebaudioside-A," while the remaining 30 percent is destined for herbal uses.

Stevia was always subjected to a regulatory framework which determined its economic evolution. Its commercialization is somewhat more limited when it is regulated as a dietary supplement, and wider when it is defined as a food additive which includes, among other uses, food sweeteners. In most countries, the use of Stevia as a sweetener is not approved. It is noteworthy to add that the food and beverages industry is one of the most regulated industries worldwide. Therefore, it should not be a surprise to see barriers to the growth of Stevia, especially as a certified natural sweetener.

Scientific studies supporting the use of Stevia are available in Japan, Brazil, Denmark, and other countries. Around 1,500 scientific studies come from Japan alone. The Japanese use a holistic method, trying to use the whole plant and not only the leaves through several applications pertaining not only health and human well-being, but also those of the animals, soil, and ecology.

The biggest producer of Stevia is China. The Shandong Huaxian Stevia is the biggest and oldest Stevia factory of China. It accounts for almost 50 percent of that country's total production. More than half of this factory's production is sold in China's internal market, while 40 percent is sold to Japan, and the rest is sold to Korea, Indonesia, and the United States.

Paraguay, the world's second producer, is focused into supplying the Stevia industry of Brazil. It also exports to Europe, Mexico, and other Latin American countries. The ideal markets to be considered by Paraguay and Brazil would be those of the United States and the European Union member countries,

which have a limited regulatory framework for Stevia.

Production of Stevia leaves and extracts has flourished in China thanks to the accessible regulations of Japan. Near 95 percent of the raw material used in Japan comes from four producers of China.

The Codex Alimentarius serves as a reference for the international trade of foods. Its main goals are to protect the health of the consumers, to ensure fair practices in food trade, and to promote the coordination of all food regulation studies undertaken by international organizations, as well as both governmental and nongovernmental ones. Since June 2004, the Joint FAO/WHO Expert Committee on Food Additives) sees Stevia as a safe product, which opens the door to a more lenient future regulation.

There are elements which give more competitive advantages to Asian markets. Probably, these markets are better positioned than those of Paraguay and Brazil to take advantage of the benefits of a deregulation. However, conditions might change, especially if action is taken to improve Stevia growth in Paraguay, with investments in its production and sale, and its preferred use is promoted among the consumers of the world.

The Paraguayan Central Government, together with several Departmental Governments and Municipalities and the majority of the international

agencies operating in the country are aware that Stevia is an attractive crop for small farmers. Private companies have shown a growing interest in Stevia. In the 1980s, the James May company started operations, thus marking an important milestone in Paraguay's Stevia business. Later, in the 1990s, Paraguayan companies such as Telnet, KH Agrícola and the Ka'a He'e Poty Cooperative started to promote Stevia growth and to buy dried leaves in order to sell them to regional markets.

The efforts recommended by this study comprise the following points:

- Focus the efforts towards existing markets
- Improve Paraguay's Stevia competitiveness
- Inform consumers
- Work in partnership with government agencies and other agencies toward achieving a review of laws impacting on Stevia's sales

USAID's Paraguay Vende started to assist Stevia businesses, analyzing potential product demand, which in this case is ensured by regional companies willing to buy two times the current volume of grown leaves. Thus, Paraguay Vende focuses now into providing technical assistance to producers. In the short and medium term, this action will account for an increase in sales and jobs in the Northern corridor, where work currently is concentrated.

The existing markets require little effort in changing needed laws; rather, they ask for improved





competitiveness of Paraguay's Stevia in the world markets and to increase production in order to satisfy local demand.

In order to achieve Stevia's biggest potential, it is necessary that, in the long term, it be used as a food ingredient/sweetener. Stevia industry should continue to focus in that potential long-term market. However, it is imperative to keep using the current allowed market in order to change the regulations which in turn will open the doors to the potential market.

An industry review in the United States pointed out that China is, by far, the biggest Stevia provider in the market. Also, a review of the U.S. market shows that the American importer associates Stevia with China, and not with Paraguay. Therefore it is very important that Paraguay work to establish its reputation as a provider of a Stevia of superior quality. When American importers were asked about why they bought Stevia from China, they give a variety of answers such as quality, price, and lack of knowledge about Paraguayan providers.

If Paraguay is going to compete with China and with other Stevia producing countries, it will need to inform the consumers, seeking to internalize the notion that Stevia "is" from Paraguay, in the same way as the wine is from France, the cheese is from the Netherlands, the coffee is from Colombia, and the kiwi is from New Zealand.

China gives a steady offer of prices considerably lower for Stevia crystals, and it also has the image

of being "the" Stevia provider. This study suggests that Paraguay should not focus on obtaining the best price, but to offer a competitive price instead, which, when added to other strengths, will lead to the notion that buying Stevia from Paraguay is "the right choice." Other strengths are quality and image. A remark made by James May about Stevia quality states that "Good quality Stevia leaves, whether whole, cut and sifted or in tea bags, are about 30 times sweeter than sugar and have no calories. The best quality leaves are imported from South America and Mexico, and are about 12 percent to 13 percent Stevioside. The poorest quality, but most ample supply, is currently coming from China, where the leaves contain only 5 percent to 6 percent Stevioside. A simple taste test quickly demonstrates the difference."

The Paraguayan Stevia image in the world market is one of an unknown product and quality. This could be easily changed to Paraguay's favor. If Paraguay could make a difference in the image by which consumers perceive the "original" Stevia of Paraguay vis-à-vis those of different origin, this could be an advantage. Stevia culture and track record in Paraguay have centuries of production and use. This historical foundation could be used as an advantage by producers and marketers of Stevia of Paraguay. For example, "Terra Soda" is a Stevia-sweetened soda, natural and low-calorie, introduced in the U.S. market by the Web under the formula of "ecomarketing" as a product coming from Peru, focused towards social consciousness and an image that promotes saving the forest through the purchase of their products.

Section 1



1. Uses, Applications and Regulations of Stevia



1.1 Introduction

When exploring the possibilities of turning Paraguay into an important world producer of Stevia it is fundamental to first understand the nature of Stevia. Stevia has a number of properties, which makes it more attractive than sugar and much more attractive than most of the synthetic products available. Some of the reasons for increasing interest in Stevia may be the decreasing popularity of these artificial sweeteners and the increased consumer interest in natural organic products (Mitchell, 2003).

The sections of this report are organized to present the uses, properties and qualities of Stevia, the international regulatory framework, and how it affects the willingness to supply Stevia.

Stevia is a leafy green herb, native to the Rio Monday

Valley in the highlands of Paraguay, where it is well known by the name Ka'a-he'e and has been used as a sweetener by the Guaraní people long before the colonization of the Americas (Bertoni, 1905). In 1887, while studying the herbs used by natives in Paraguay, Moises Santiago Bertoni "discovered" Stevia. In 1905, in honor of the Paraguayan chemist Dr. Rebaudi, the plant was scientifically named *Stevia rebaudiana* (Bertoni).

Since its discovery, Stevia, as it is most commonly referred to, has been subjected to changing international regulations marking its economic evolution and use in the world market. Central to Stevia's international evolution, there is an important debate that could represent millions of dollars to the Stevia industry.

The Stevia Registration Debate

1921: US Trade Commissioner George Brady first presented Stevia to the US Department of Agriculture, calling it a "new sugar plant with great commercial possibilities." Brady took note of its non-toxicity and its ability to be used in its natural leaf state. He also claimed that it was "an ideal and safe sugar for diabetics."

1954: Japan, who is now today's largest user of Stevia in the world, began cultivating the plant.

1970: Food manufacturers began marketing Stevia in Japan.

1991: US Food and Drug Administration (FDA) banned the import of Stevia into the USA.

1995: US FDA modified its import guidelines to allow Stevia into the country as a dietary supplement, not a food additive.

2000: EU Commission refused to allow Stevia either as a novel food and/or a novel food ingredient, in the European market

2003: Paraguay sent documentation to the Codex Alimentarius Commission requesting a regulatory status of food additive.

2004: The 63rd JECFA meeting declared the ADI of Stevia extract to be 2mg/kg per day, a temporary decision that could influence the decisions in the next Codex Alimentarius Conference when re-evaluating the Stevia status, which will also be reviewed by the EU.

1.2 Many Types of Stevia Products

Seventy percent of all the world production is used for processing Stevioside crystals, while the remaining 30 percent of the world's production is designated for herbal uses. The leaf form includes all forms of the plant in its natural stage (fresh or dried), and the extracts from the leaves can be processed into either powders or liquids (see table next page). The best form of Stevia to use depends on the amount of sweetness required in a product and the degree to which the particular recipe or beverage will benefit from the licorice-like taste produced in less refined forms.



Stevia Leaves

Fresh leaves: have a mild licorice flavor. This is the simplest form of Stevia in its most natural and unrefined state. The leaves are used to prepare sauces but are best in herbal teas and for direct consumption. They do not dissolve. In various markets they may be purchased loose or in tea bags. They are 15 to 30 times sweeter than sugar.



Dried leaves: are 10 to 15 times sweeter than sugar. To dry them, one just removes all the water (the easiest way is to dry them with a dehydrator, but drying them in an oven on the lowest setting will also work), which allows them to have an extended storage period. They have the same uses as fresh leaves but are also for industrial purposes, to extract the Stevioside.



Powdered or ground leaves: can be found in bulk form and in tea bags. They have a greenish, leaf color and are used as a flavor enhancer or sweetener in teas, salads, fruit, and coffee, among others. Ground Stevia leaves do not dissolve.



Byproducts (plant remains): The remaining parts of the plant, including stems, seeds, flowers and even leaves that were not classified for industrialization, are collected and processed into animal feed or fertilizers.



The use of fresh or dried leaves (pieces or ground) is acceptable in domestic cooking but it leaves sediment and a greenish color in clear drinks (Midmore & Rank, 2002). Processed products were introduced as an alternative to avoid the side effects of the natural leaves. There are several forms of

processed Stevia (see table next page) and one of the challenges in using these various forms of Stevia in cooking and beverages lies in finding the right amount to suit the recipe and consumer taste (Bonvie et al., 1997).

Stevia Extracts

STEVIA LIQUID EXTRACTS

Dark liquid extracts: “a concentrated syrup made from the dried leaves in a base of water and alcohol” (Kirkland, 2000). Used for the sweetening of beverages.

Clear Liquid Extracts: a solution of powdered Steviosides dissolved in water, alcohol or glycerin. Used for the sweetening of beverages.

STEVIA POWDERS

Powdered Stevia extracts with 40–50 percent Sweet glycosides: the Stevia leaves are processed through one of several extraction methods, usually water or ethyl alcohol based. The resulting powder, usually off-white, contains 40 to 50 percent sweet glycosides and is more than 100 times sweeter than sugar (Richard, 1999). Used for the sweetening of food and beverages.

Powdered Stevia extracts with 85–97 percent Sweet glycosides: the same as above, except with greater concentration, it is usually between 200-300 times sweeter than sugar. Stevia is primarily used as a sweetener in this form. Not all Stevia powders are the same. The taste, sweetness and cost of the various white Stevia powders will likely depend on their degree of refinement and the quality of the Stevia plant used (Bonvie, L. et I, 1997).

STEVIA GLYCOSIDES AND ITS COMBINATIONS

Stevia blends: combine pure Stevioside extract with a filler to make an easy-to-measure great tasting powder. Stevioside is the purified or most highly processed form of Stevia. It is the most powerful form of Stevia glycoside and is available in either a white powder or a liquid extract. Because of the great strength of Stevioside, manufacturers combine Stevioside with filler. These blends are the most versatile and easy-to-use form of Stevia. The Stevia to sugar ratio most commonly used is 4:1.

- According to Kirkland (2002), the types of fillers used in Stevia Blends are:
- Lactose: Derived from milk, it has a slightly sweet taste and dissolves instantly.
- Malt dextrin: It is a non-sweet complex carbohydrate with virtually no taste. It can be derived from corn, rice, tapioca or other starches and has a very low glycemic index.
- F.O.S.: This is the common term for fructo-oligosaccharides. It is a sugar found in a variety of common foods like bananas, garlic and wheat.
- Dextrose: It is a common processing agent derived from corn sugar.

Stevia packets: these normally contain the same ingredients as Stevia blends, except in convenient and pre-measured servings.

Stevia quick dissolving tablets: They normally contain Stevioside along with other ingredients and are mainly used to sweeten beverages.



1.3 Many Qualities of Stevia Products

As the table above shows, not all Stevia products are the same. The taste, the sweetness and cost of the various white Stevia powders will likely depend on their degree of refinement and the quality of the Stevia plant used. Stevia quality is determined by the levels of Steviosides and Rebaudiosides-A, and is also often detected by the sweetness of the product.

Kirkland (2000) declares that the quality of any Stevia product depends on the amount of Steviosides it contains, but even more important is the percentage of Rebaudiosides, which is the result of the cultivation and the extraction methods. He also suggests that the presence of these additives at any time during growing, harvesting or processing, are an important issue in determining the final quality of the product.

Midmore further expand the argument when he references the conclusions from six scientific studies. “Stevioside (St) traditionally makes up the majority of the sweetener (60 to 70 percent of the total) and is assessed as being 110 to 270 times sweeter than sugar. It is also responsible for the aftertaste sometimes reported (licorice taste). Rebaudioside A (R-A) is usually present as 30–40 percent of total sweetener and has the sweetest measure of sweetness quality, the more R-A the better. If R-A is present in equal quantities to St (or more), it appears that the aftertaste is eliminated. The minor glycosides are considered to be less sweet, 30 to 80 times sweeter than sugar.”

The differences in quality, taste and prices are important when researching Stevia and comparing products from a Chinese and a Brazilian plant.

1.4 Research and development

Stevia has become a popular research topic in universities and laboratories the world over. Research objectives range from health studies, such as diabetes and cloning research to environmental impact assessments, and extraction patents. Some better known studies include “confirming the safety of Stevia for diabetic use, showing dental benefits in the form of plaque inhibition and cavity reduction, investigating carcinogenicity and mutagenicity (if any) in animal testing. The safety of animal consumption including, chickens and humans has also been confirmed by a wide range of studies.” (Midmore 2002) Some important studies in Paraguay are discussed in section 2.

There are hundreds of patents for the Stevia extraction processes around the world; Europe, the United States, and Canada all have valuable patents on Stevia. Japan alone has around 150 patents (Angelucci, 1982; Bonvie et al., 1997a). Brazil has conducted considerable R&D regarding Stevia and continues to do so (see section 3). These studies are important because they will help the industry to discover the best production methods. Although most basic research has been done, this does not mean that the results are accessible and open to all. In 2003, Norina et al published the following chart categorizing the extraction processes. (see table next page from Food New Zealand 2003).

Methods of Extracting Stevia Glycosides

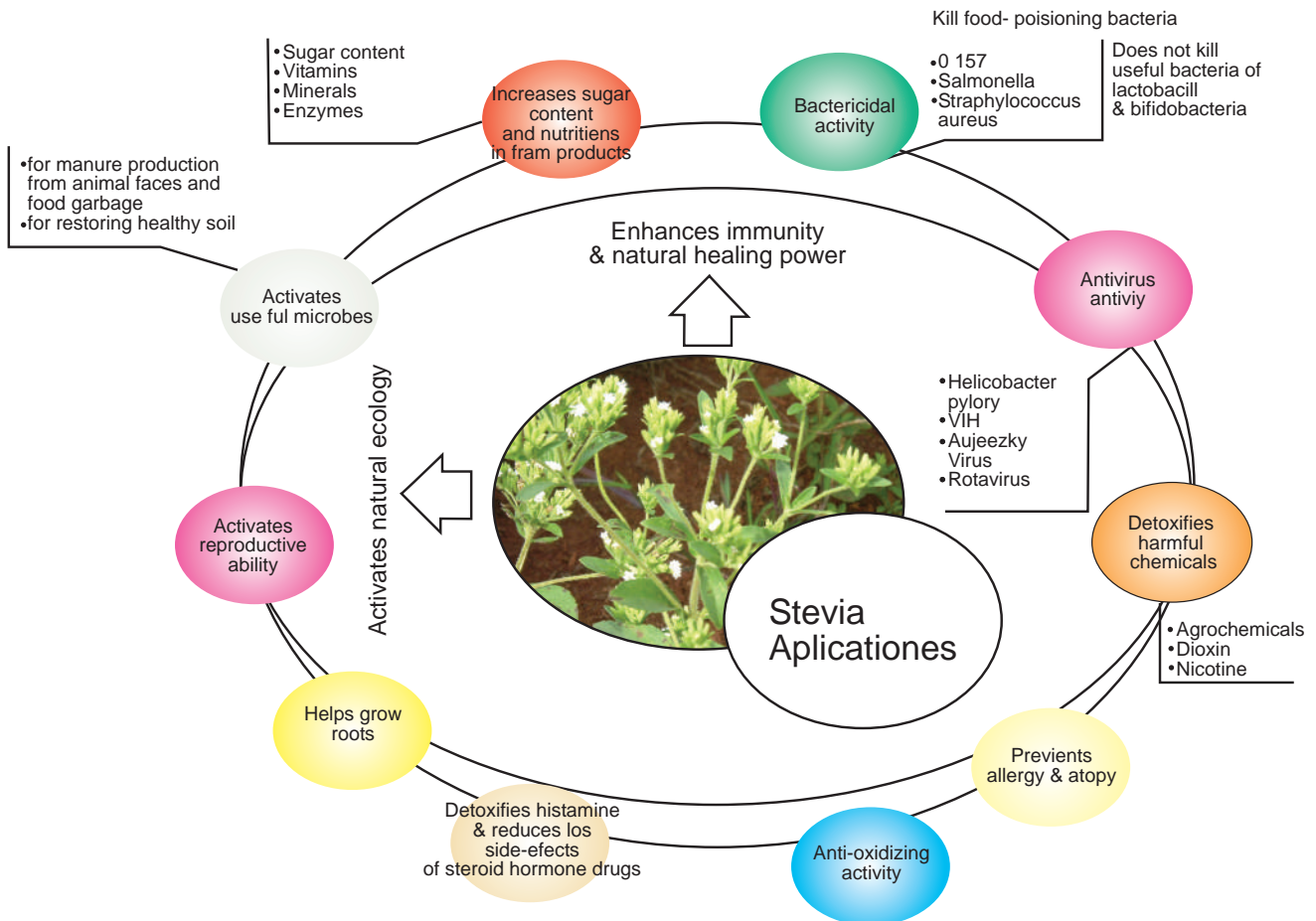
Method	Publication	Name
Based on solvent	Haga, T., R. Ise and T. Kobayashi (1976)	A method forpurifying Stevioside.
Ion exchange	Uneshi, H., R. Ise and T. Kobayashi (1977)	Purification of Stevia sweetening agent.
Absorption chromatography	Itagaki K., and Ito, T. (1979)	Purification of Stevioside
Solvent and decolorizing agents	T. Ogawa (1980)	Decolorization and purification of Stevia component.
Selective precipitation of individual glycosides	Matsushita, K. and T. Kitahara (1981)	Separation of Rebaudioside A by crystallization
Ultrafiltration	Tan, S. and H. Ueki (1994)	Method of extracting and separating sweet substances.

Scientific research studies on Stevia are available in Japan, Brazil and Denmark which are supporting the use of Stevia (Brandle, 1998). Around 1,500 scientific research works on Stevia have originated in Japan. The Japanese have an integrated approach, seeking to utilize the whole plant, not only the leaf,

through various applications that not only affect the people's health and well-being, but also animals, ecology and the soil. (JBB Stevia Laboratory, 1988). The table next page summarizes some of the important anti-oxidizing effects of Stevia, beneficial to the health and environmental communities.



The Antioxidizing Power of Stevia



1.5 Uses of Stevia

The single most important market for Stevia is the food and beverage industry, mainly as a sweetener and flavor enhancer. The health market is second in order of importance. The third most important market is byproducts, which consists of the remainder of the plant, after the best leaves have been harvested for tea or for extraction. Many producers have difficulty in finding buyers for these byproducts, which reduces their return per hectare considerably. The byproduct market can be developed by promoting use of these products for fertilizer and as an additive in animal food products. All three markets require considerable promotion to overcome the acceptance barriers.



Applications in Accordance with the Stevia Markets

(1) Food and Beverages Market

Stevia sweeteners are heat stable to 200° C, are acid stable, non-discoloring and do not ferment.

(Glycemic Research Institute, 2000; Midmore and Rank, 2002).

Enhances flavors and odors (Ikan, et al., 1993; Mowrey, 1992).

It has no calories and it is natural (Johnson, 1990)

It is a non-toxic and non-addictive sweetener (Alvarez, 1986; Kirkland, 2000)

It is potent, 250 to 300 times sweeter than sugar in its processed forms (Glycemic Research Institute, 2000)

It is a table top sweetener for tea, coffee, etc. (Midmore & Rank, 2002);

A source of antioxidants

Alcoholic beverage enhancer (aging agent and catalyst)

Potential products: Additive for soft drinks, cordials, fruit juices, ice creams, yoghurts, sherbets, cakes, biscuits, pastries, pies, baking, jams, sauces, pickles, jellies, desserts, chewing gum, candies, confectioneries, seafood, vegetables, weight loss diets, diabetic diets, flavor, color and odor enhancers

(2) Health Market

Hypoglycemic action

Diabetes treatment

Cardiovascular Action

Antimicrobial action

Digestive tonic action

Plaque retardant/ cavities prevention

Eczema and acne control, rapid healing agent for skin care

Zero calories

Treats hypertension and controls blood pressure

Calcium antagonist

Bactericidal agent

Potential products: mouthwash, weight loss programs, toothpaste, skin care agents, medical treatments

(3) Byproducts Market

Agriculture: green fertilizer, golf grasses, and garden grasses

Animal production: for balanced rations, farm animals, racing horses, fishes

Cosmetics: additives for creams, lotions, soaps and shampoos

Environment: to decontaminate dioxin and dangerous chemicals

Soil: disinfectant that kills bacteria, filamentous fungi and seaweed

1.6 Main Producers

The largest Stevia producing country is China. Stevia was introduced to China during the 1970s and has been produced commercially there since the 1980s. China is the main supplier to Japan, which is the major commercial producer and user of Steviosides. Within China, Stevia has been considered a major crop in the past (more than 2,000 tons per year), but there has been a reduction due to lower demand and price from Japan (Midmore & Rank, 2002).

According to Midmore, the Shandong Huaxian Stevia Company is the largest and oldest Stevia factory in China and produces about 50 percent of China's total production, with speculation that this figure might have changed with the new factories in the north. More than 50 percent of this company's production is sold within China, around 40 percent to Japan and the rest sold throughout Korea, Indonesia, and the United States. (op.cit).

In the late 1990s, Paraguay and Brazil started to produce and distribute Stevia products direct to consumers internationally via health food stores, herbal product outlets and by direct mail order sales. Paraguay – the world's second largest producer – currently has around 750 ha dedicated to Stevia (more than 500 tons per year; see Section 2). Other main Stevia producing countries are: Thailand, Korea, Russia, Indonesia, Australia, Spain, Brazil, Canada, Costa Rica, Colombia, Bolivia, and Peru.

The production of Stevia leaves and extracts in China has flourished because of Japanese regulations regarding these products, which allow greater access for Stevia producers than the regulations in the United States and Europe. Some 95 percent of the raw material used in Japan comes from four major producers in China (Midmore & Rank, 2002). The production of Paraguay and Brazil are focused on the Brazilian, Mexican and other Latin American markets. The ideal export markets for Brazil and Paraguay would be those of Europe and the United States. As latecomers, Brazil and Paraguay face competitive constraints when compared to China, for example, higher transport and transactional costs in the Japanese market.

1.7 Regulatory Constraints

The food and beverage industry is one the most regulated markets worldwide. Therefore it should be not surprising that Stevia is experiencing growth constraints, especially as a certified natural sweetener. Firms involved in the production of Stevia should take notice and keep track of regulatory developments.

1.7.1 Regulations in Japan

Today, Japan has the largest consumption of Stevia. In 1954, Japan, began cultivating the plant domestically. In 1970, food manufacturers began marketing Stevia in the country. Japan banned artificial

sweeteners in the 1960s, and has strict regulations regarding products that pose health concerns. In order to verify the safety of Stevia sweeteners, the Japanese authorities conducted several safety tests (carcinogenicity tests, teratogenicity and propagation tests, single administration test, repeated

administration tests, and mutagenicity tests), concluding that Stevia is safe (Chan et al. 1998; Chan et al. 2000). Why then do other countries restrict Stevia from entering their markets as a sweetener, when the Japanese have found it to be safe?

The Situation of Stevia in Japan and Other Countries

JAPAN	OTHER COUNTRIES
Stevia holds 41 percent of the sweeteners market (Bonvie et al., 1997a)	Stevia is almost unknown and accepted only as a dietary supplement
Artificial sweeteners such as saccharin and aspartame were banned or strictly regulated in the 1960s due to safety concerns (H. Fujita, T. Edahiro, 1979)	Artificial sweeteners such as aspartame and saccharin are consumed and used in food preparation
Japanese food processors use Stevia and its products in a wide variety of applications (Richard, 1999)	Stevia products can only be found in health shops as a dietary supplement
There are several Stevia manufacturers who have formed the Stevia Association of Japan (Richard, 1999)	There are some Stevia manufacturers but there are no strong associations of Stevia producers

1.7.2 Regulations in the United States

In 1921, the U.S. Trade Commissioner George Brady presented Stevia to the Department of Agriculture, declaring it a “new sugar plant with great commercial possibilities.” Brady took note of its non-toxicity and its ability to be used in its natural leaf state. He claimed that it was “an ideal and safe sugar for diabetics.” There was little movement in the Stevia market in the United States between 1921 and 1991. In 1991, the US FDA banned the import of Stevia into the U.S., and in 1995 it modified these restrictions to allow Stevia into the country as a dietary supplement, but not as a food additive.

According to the Federal Food, Drug and Cosmetic Act of 1994 (revised April 2000), Chapter 402 (a) (2) (c), Chapter 409, 21 CFR 170 and 21 CFR 189-1,

Stevia is a substance “Prohibited from use in human food.” Per 21 CFR 190, Stevia may be sold in the United States as a stand-alone “dietary supplement” or herb, but not as a sweetener. The US FDA authorities base their position on results of the study published in 1968 that claimed that certain tribes of Indians in Paraguay (the Matto Grosso) used Stevia tea as a contraceptive (Planas & Kuc, 1968). This position was unchanged even after other studies showed that Stevioside does not affect either growth or reproduction in animals (Yodyingyuad, & Bunyawong, (1991), Takanaka, Kawashima, Usami & Sakami, (1991), Bonvie et al., (1997)).

The impact of applying one or another of the terms “food additive” or “dietary supplement” in regard to Stevia regulations represents millions of dollars to the potential Stevia industry.

The statutory definition of “food additives” according to the FD&C Act Chapter 201(s) are any substances the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food...” (Ditto, 2002).

In reference to dietary supplements, the Dietary Supplement Health and Education Act of 1994 (DSHEA), states that “(dietary supplements) are the following: vitamins; minerals; herbals and other botanicals; amino acids; dietary substances used to supplement the diet by increasing its total daily intake; and concentrates, metabolites, constituents, extracts, and combinations of these ingredients. In addition, these products must be intended for ingestion in pill, capsule, tablet, or liquid form; must not be represented as a food or sole item of a meal or diet; and must be labeled as a “supplement.” (US FDA, 2001).

1.7.3 Regulations in the European Union

The European Union’s (EU) position, which is even more restrictive than the U.S. position on Stevia, is given in the Document 300DO196, 2000/196/EC, which says: “The Commission (Environment, Public Health and Food Safety Committee of the European Union) Decision of February 22, 2000 denied permission to place Stevia rebaudiana (Bertoni): plants and dried leaves as a novel food or novel food ingredient, in the market, under Regulation (EC) No. 258/97 of the European Parliament and the Council (notified under document number C) (2000) (77) Official Journal L 061, 08/03/2000 p. 0014.” It appears that the commission will change this position and allow Stevia in the food market, once they believe there is sufficient research done to better understand the side effects, dietary properties, etc., of Stevia (see the following section).

In apparent contradiction to this EU position, some European countries grow and use Stevia, including: Germany, Belgium, Italy and the United Kingdom (Glycemic Research Institute, 2001, Bonvie et al., 1997a, Kirkland, 2000). Individuals in Europe are also conducting research on Stevia to determine the

benefits, and safety of the products (op.cit.).

1.7.4 Codex Alimentarius Commission

The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and codes of practice under the Joint FAO/WHO Food Standards Program, as a reference for international food trade. The main objectives of this program is to protect the health of the consumers, ensure fair trade practices in the food trade, and promote coordination of food standards studies undertaken by international governmental and non-governmental organizations.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) recently held its 27th Session in the International Conference Centre in Geneva (Switzerland) June 28-July 3 2004. Paraguay presented its position paper, supported by a series of documents, from medical to quality studies, proving Stevia as a safe product. Other countries including Japan and China also presented similar documents requesting a change in Stevia's regulatory status.

This 63rd JECFA meeting updated the official opinion regarding Stevia. In a temporary decision, the committee declared that Stevia is innocuous and does not appear to be harmful in amounts of up to 2mg/kg of body weight per day. The Commission has requested additional studies to be completed and presented prior to 2007, to include experiments on humans. Although this does not open the commercialization in the European Union, this is an important step for the Commission and the European Union. The Stevia community anxiously awaits the outcome of the above mentioned studies.

1.7.5 Regulatory Environment in Mercosur

There are no regulations that prohibit the commercialization, processing or consumption of Stevia in Paraguay. The product can be found in its natural stage (whole leaves, powder, and teabags)

or in a processed form (crystals, liquid extracts, culinary uses). In 2000, the Paraguayan Congress declared Stevia of “national interest” and recommended to the executive branch, that the country strengthen its competitive development, train the growers, start market research, and promote investment. In 2001, a Presidential decree declared Stevia a “crop of interest” for the agricultural development of the country, and the Ministry of Agriculture, in a Resolution dated October 2003 declared Stevia of “institutional interest.”

Both at the MERCOSUR level, and within Paraguay, Stevia is not listed as a natural sweetener in the customs nomenclature code. The National Technical Committee of Customs Affairs and Nomenclature Codes (Sección Nacional del Comité Técnico de Asuntos Arancelarios y Nomenclatura) in Paraguay, states that Stevia is a relatively new export product and thus is not listed separately as a sweetener product. For this reason, Stevia products are listed in the miscellaneous category, as a product with general components, with no specific definition. However, this Commission is discussing the importance of listing Stevia as a separate item, apart from the miscellaneous category, to show consistency in the petitions Paraguay has presented to the Codex Alimentarius Commission.

In Brazil, the Ministry of Health, the National Secretary of Sanitary Monitoring, National Division of Sanitary Food Monitoring, Port N° 14, on September 10, 1986 decided to authorize the use of Stevioside as a natural sweetener (additive) in dietetic foods and drinks, with an acceptable ADI of 5.5 mg/kg of body weight per day.

In Argentina, the National Institution of Nutrition and the National Administration of Medicine, Nutrition and Medical Technology (Instituto Nacional de Alimentos y Administración Nacional de Medicamentos, Alimentos y Tecnología Médica INAL–ANMAT) informs that Article 1398.64.3 of the Argentine Food Code, classifies Stevioside as a “white crystalline powder, odorless, not fermentable, not hygroscopic, of a sweet taste even in water soluble and well diluted solutions.”

1.8 Changing the Regulations

To change these factors and laws in the consuming countries will require considerable resources. The benefits to a single country to change the regulatory norms in other countries are limited by a cost–benefit relationship just as they are for a single business. Paraguay could spend the time and money to help Stevia obtain approval as a sweetener and ingredient in the United States or Europe; however, due to a lack of monopoly controls on supply, Paraguay would not receive the complete reward for their efforts.

The competitive advantage can be measured in a number of areas, including:

- Lowest cost of production, processing and shipping
- Greatest ability to produce and meet the demands of the market for quality and supply.
- Product quality or product image advantage
- Logistical or location to market advantage – USAID is supporting or exploring Stevia production in Peru, Colombia and Eastern Europe.
- Available resources, and associated costs, to dedicate to the production and processing
- Processing technology
- Favorable or political advantage in country of consumption
- Cultural ties between exporter and consuming nation and businesses

This study evaluates the comparative advantage of the markets (see sections 2, 3 and 4). Considering these elements, some markets are most likely in a better position than Paraguay and Brazil, to benefit once the regulations are changed.

However, the conditions can change, and the Paraguayan market can benefit, especially if the recommended actions are followed, such as improving the cultivation, investing in the production and promoting the preference for Stevia from Paraguay with the international consumers.