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Brazil

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:

This report outlines regulatory requirements for agricultural imports into Brazil, including import procedures. Compared to the previous report released in 2011, no significant modifications have been made. Some editing was made on Section I, VI, VII and IX.

This report was prepared by the US Agricultural Trade Office (ATO) of the USDA/Foreign Agricultural Service in Sao Paulo, Brazil for US exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and

consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Section I. Food Laws

Brazil is a member of the World Trade Organization (WTO) and therefore has made commitments to subscribe to the Sanitary and Phytosanitary (SPS) Agreement and to Codex Alimentarius (CODEX) principles. Food regulations issued at the federal level are contained in various types of legal documents and, in order to be implemented must be published in Brazil's Diario Oficial (similar to the U.S. Federal Register).

Brazil has three levels of government: federal, state and municipal. Legally, federal regulations must be followed when there are conflicts between federal, state and municipal legislation, or between regulations established by different Ministries at the federal level. State and municipal governments also have the authority to regulate and enforce state and municipal laws.

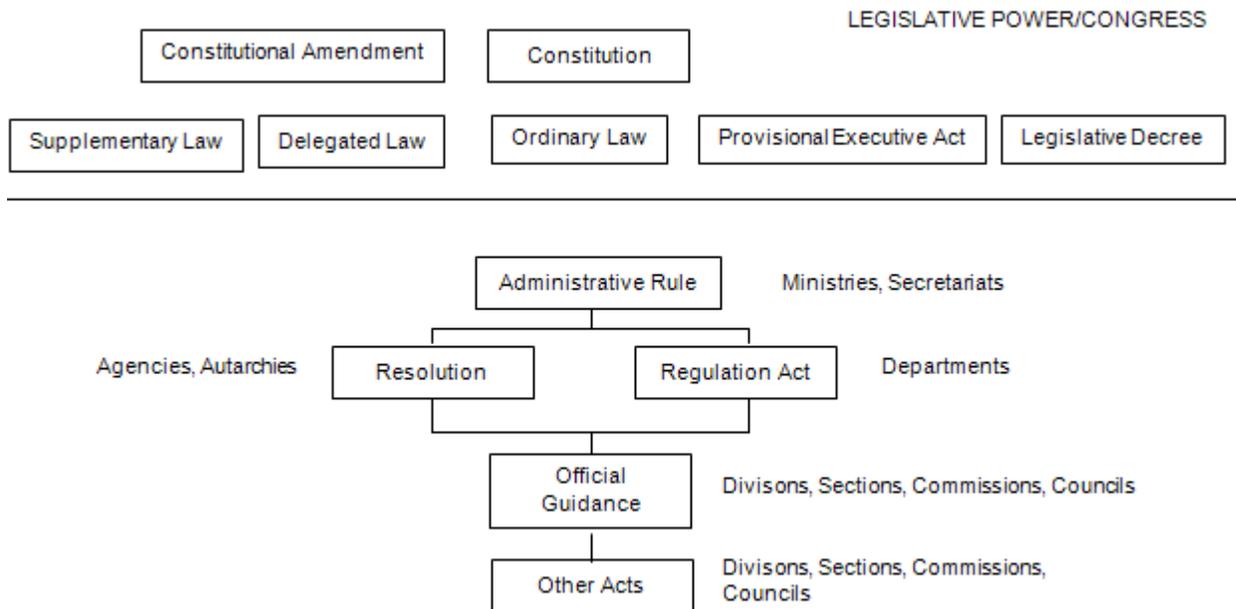
In the federal government, numerous agencies and several Ministries share jurisdiction for ensuring the safety of the Brazilian food supply and regulating imports of agricultural commodities and foods. However, the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and the Ministry of Health (MS) - through its National Agency of Sanitary Surveillance (ANVISA) - are the primary regulators of agricultural products. MAPA oversees and enforces a large number of regulations pertaining to production, marketing, import and export of animal origin products, fresh fruit and vegetables, alcoholic beverages, juices, grains, seeds, and animal feed (including pet food). ANVISA enforces most of the regulations regarding processed food products. MAPA and ANVISA's regulations may be consulted on-line. On MAPA's website (www.agricultura.gov.br) the search tool SISLEGIS makes available the current regulations on products that are under MAPA's supervision. A similar search tool called VISALEGIS can be found at ANVISA's website (www.anvisa.gov.br).

Other Ministries and/or agencies also involved in monitoring/control of food safety include the Environment Protection Institute (IBAMA), of the Ministry of the Environment; the National Institute of Metrology, Standardization and Industrial Quality (INMETRO) of the Ministry of Development, Industry and Commerce (MDIC); the National Technical Commission on Biosafety (CNTBio), which is an Inter-Ministerial Commission based in the Ministry of Science and Technology (MCT); and the Department of Consumer Protection and Defense (DPDC) within the Ministry of Justice.

The Brazilian Constitution defines the boundaries between federal, state and municipal law. It also defines the power each federal branch may hold through its legislative, judicial and executive power. As the executive power and its branches exercise authority to legislate activities related to foreign trade and food safety, importers/exporters may observe the set of rules each administrative agency releases as it directly impacts market access for foreign goods. Although Congress has responsibility for rule making, the power delegated to the Ministries and its various branches are considerable as they implement those rules and define with more accuracy the procedures that must be followed.

Section I.I. Legal Framework

In terms of the enforcement of sanitary legislation overall, the principle of “positive legislation” is in place. That is, only that which is expressly established can be practiced. That which is not expressly addressed is prohibited. Below is the scheme for the Brazilian legal system. The legislative process described illustrates the respective powers of bodies involved in enforcing food laws.



Brazilian legislation may be found on the internet, though mainly available in Portuguese. The legal terms translate as follow: Constitution (Constituicao), Constitution Amendment (Emenda Constitucional), Supplementary Law (Lei Complementar), Delegated Law (Lei Delegada), Ordinary Law (Lei Ordinaria), Provisional Executive Act (Medida Provisoria), Legislative Decree (Decreto Legislativo), Executive Decree (Decreto Executivo), Administrative Rule (Portaria), Resolution (Resolucao), Regulation Act (Instrucao Normativa), Official Guidance (Circular), Declaratory Act (Ato Declaratorio), and Normative Rule (Parecer Normativo).

Section I.II. Ministry of Agriculture, Livestock and Food Supply (MAPA)

The Ministry of Agriculture, Livestock and Food Supply (MAPA), under the premise of safeguarding animal and plant health, is responsible for formulating and executing all policies related to Brazilian agribusiness development. MAPA integrates science, technology, and market aspects to respond to domestic and international demand. MAPA’s functions include the regulation, classification and inspection of imported agricultural products entering Brazil. The major offices, called Secretariats, are: Secretariat of Agricultural Protection (SDA); Secretariat of Agricultural Policy (SPA); Secretariat of Agriculture and Livestock Development and Cooperativism (SDC); Secretariat of Production and Agro-Energy (SPA), and, Secretariat of International Agribusiness Relations (SRI). MAPA’s regulatory activities of interest to this report are primarily enforced by SDA, SDC and SRI.

The Secretariat of Agricultural Protection (SDA)

SDA through its six main departments is responsible for enforcing regulations related to domestic and imported plants and animals, including their respective products and by-products, and other inputs such as feed (including pet food), fertilizers, pesticides, and contaminants. Additionally, the General Coordination for Sanitary Inspection on Agriculture and Livestock (VIGIAGRO), also under SDA, responds for surveillance of all foreign products entering Brazilian borders.

- **Department of Animal Origin Products Inspection Service (DIPOA)**

DIPOA is responsible for ensuring that all animal origin products (meat derived from cattle, sheep, swine, goats, horses, game meat, poultry, dairy products, eggs, seafood, honey and other products with more than 50 percent of animal origin composition) moving in interstate and foreign commerce are safe, wholesome for consumption, and accurately labeled. Under DIPOA there are 3 divisions overseeing meat, dairy and seafood products:

- Division of Meat and by-products Inspection (DICAR)
- Division of Milk and by-products Inspection (DILEI)
- Division of Seafood and by-products Inspection (DIPES)

- **Department of Plant Origin Products Inspection Service (DIPOV)**

DIPOV has the regulatory authority to enforce federal laws regarding the registration, compliance and labeling of alcoholic and non-alcoholic beverages such as distilled spirits, wine, soft drinks and juices (except beverages for sport practices, water, energy drinks). Under DIPOV there is one branch for beverages:

- General Coordination for Wine and Beverages (CGVB), which is divided in two Divisions:
 - Division of Alcoholic and Non-alcoholic Beverages, excluding wine (DBEB)
 - Division of Wine and by-products (DVB)

- **Department of Animal Health (DSA)**

DSA is responsible for enforcing regulations on imports and exports of live animals, semen, embryos. In cooperation with state governments, DSA enforces federal laws and regulations to protect and improve animal health, and to control and eradicate animal diseases such as the Foot-and-Mouth Disease Eradication Program. It defends Brazilian borders against foreign and exotic animal diseases.

- **Department of Plant Health (DSV)**

DSV is responsible for protecting the health of plants, and preventing the introduction and spread of foreign pests within Brazil.

- **Department of Surveillance of Agricultural Inputs (DFIA)**

DFIA is responsible for the regulatory inspection and registration of all planting seeds and seeding (including biotech seeds), as well as for establishing standards for agricultural products such as grains, fruits and vegetables.

- **Department of Surveillance of Livestock Inputs (DFIP)**

DFIP is responsible for the regulatory inspection of feed for animal consumption (including pet food), the registration of establishments producing animal semen and embryos, and the genealogical registration of live animals. DFIP also regulates the use of veterinary products.

- **General Coordination for Sanitary Inspection on Agriculture and Livestock (VIGIAGRO)**

VIGIAGRO is responsible for inspection and clearance of foreign products under MAPA's jurisdiction at Brazilian ports and airports. VIGIAGRO also establishes the documents and procedures international companies must follow to have products cleared to enter the country.

The Secretariat of Agriculture and Livestock Development and Cooperativism (SDC)

One of SDC's functions is to regulate organic sector from the early stages of production until processing and trade. The Department overlooking organic issues is

- Department of Production Systems and Sustainability (DEPROS), which has recently created a new division:

- Agroecology Coordination (COAGRE)

The Secretariat of International Agribusiness Relations (SRI)

SRI is responsible for coordinating the Brazilian government positioning on agricultural matters during international forums such as the World Trade Organization (WTO), Office of International Epizootics (OIE), International Plant Protection Committee (IPPC), and Codex Alimentarius (CODEX). SRI also coordinates regional and bilateral agricultural agreements. The Secretariat is also the focal point for the United States and Brazil negotiations under the Consultative Committee on Agriculture (CCA). SRI is composed by three departments; two of each has a direct impact on US exports into Brazil.

- **Department of Commercial Affairs (DAC)**

DAC is responsible for bilateral, multilateral or regional negotiations involving agriculture and livestock.

- **Department of Sanitary and Phitosanitary Affairs (DASF)**

DASF supports all government commitments on international negotiations regarding sanitary and phitosanitary issues.

I.III. Ministry of Health (MS)

The Ministry of Health's (MS) regulatory activities are enforced by an agency called National Agency of Sanitary Surveillance (ANVISA). Within the structure of the federal public administration, ANVISA is considered an autonomous agency. ANVISA was created to function as the scientific regulatory agency responsible for the safety of all foods under its authority (mainly processed products). The agency is also responsible for overseeing the production and registration of drugs, food additives, medical devices, tobacco and tobacco products.

ANVISA's primary function is to protect the public (i.e., human health) by assessing food standards, safety, and contaminants. In addition, the agency is responsible for the compliance and registration of any food processing facility established in, or exporting to, Brazil. Within ANVISA the regulation, inspection and clearance of food products is coordinated by the following branches:

The General Management Office for Food Products (GGALI)

GGALI is responsible for the implementation of regulation and inspections of all food products under ANVISA's competence. The Office is formed by three offices:

- **Office of Special Products (GPESP)**

GPESP is responsible for rule making and analysis of products under mandatory registration.

- **Office of Food Inspection and Risk Control (GICRA)**

GICRA is responsible for coordination, control, supervision and inspection of issues related to food inspection and risk management at the state and municipal level.

The General Management Office for Ports, Airports and Borders (GGPAF)

GGPAF is responsible for the clearance and inspection procedures of any food product under ANVISA's competence at entry ports.

The International Affairs Advisory Board (NAINT)

NAINT coordinates the Brazilian government's commitments and proposals on food health and food safety issues during international discussions. The board is also the primary contact for foreign governments on legislative and market access matters.

I.IV. Ministry of Environment (MMA)

Within the Ministry of Environment (MMA) the regulatory authority for activities that affect the environment is called Brazilian Institute for the Environment and Natural Resources (IBAMA). IBAMA is one of the key government agencies involved with approval of agricultural chemicals (pesticides and herbicides), but has joint authority for this function with the Ministry of Health (which is concerned with the toxicology aspects of agricultural chemicals) and the Ministry of Agriculture, Livestock, and Food Supply (which actually provides the registration for pesticides).

IBAMA is concerned with the possible environmental impact of pesticides. In general, it follows recommendations made by international standard setting organizations, such as the CODEX Alimentarius, and works closely with its U.S. counterpart, the U.S. Environmental Protection Agency (EPA). IBAMA is also the Brazilian regulatory agency that enforces the treaties established at the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITIES). It is the agency responsible for monitoring and enforcing activities related to Brazilian fauna and flora.

The regulatory rules related to these subjects in Brazil can be found at www.ibama.gov.br and www.mma.gov.br.

I.V. Ministry of Development, Industry and Foreign Trade (MDIC)

All food products imported or exported by Brazil must be registered at the Secretariat of Foreign Trade (SECEX) of the Ministry of Development, Industry, and Foreign Trade (MDIC). This office monitors all import and export tariffs and issues import and export licenses. In addition, SECEX is the government agency responsible for judging antidumping cases against foreign products.

Since January 1997, SECEX, the Secretariat of Federal Revenue (SRF) of the Ministry of Finance (MF), and the Brazilian Central Bank (BCB) have been responsible for import related activities such as licensing, customs clearance and exchange monitoring through the Integrated Foreign Trade System (SISCOMEX), an administrative software program for completing import documentation requirements. Since this system has been implemented, import and export procedures have become more transparent. In addition, the system enables the government to better control tax payments. Only Brazilian or multinational companies registered with the Importers and Exporters Registry Office of SECEX are allowed to import products for commercial use. It is necessary to be registered at the SRF in order to obtain access to the SISCOMEX.

Also under the MDIC are the National Institute of Metrology, Standardization, and Industrial Quality (INMETRO). INMETRO also conducts tests of domestic and imported products (industrial or food products) to make sure they meet the specifications of their labels and the safety of packaging materials. Information on INMETRO can be found on their home page www.inmetro.gov.br. Other MDIC legislation and procedures can be found at www.mdic.gov.br or at Diario Oficial's website www.in.gov.br.

I.VI. Ministry of Justice (MJ)

The Department of Consumer Protection and Defense (DPDC) within the Ministry of Justice is the federal agency responsible for enforcing the Brazilian Consumer Code (CDC), published in 1990. The code regulates consumer claims against adulterated food products, incorrect or misleading labels, and fraud. Each state in Brazil has an office of the Department of Consumer Protection and Defense that assists consumers directly in pursuing their rights.

For additional information on the Ministry of Justice's consumer department, please check the Ministry of Justice's home page www.mj.gov.br. Other Brazilian federal regulations regarding the Ministry of Justice can be found at Diario Oficial's home page www.in.gov.br.

Section II. Labeling Requirements

MAPA and ANVISA define labeling requirements for all food products that have Product Identity and Quality (PIQ) standards defined. If the product is permitted but not under PIQ specifications, which is the case for few products, the importer still needs to follow the rules established by the Consumer Protection Agency. The Brazilian Consumer Protection Law requires that all domestic and imported foods and beverages must provide the consumer with correct, precise, clear and easily readable information about the product in Portuguese. According to the law, the Brazilian importer is held liable in case of health risk to the consumer of an imported product. The expiration date, validity, or shelf life date, is very important for Brazilian consumers and should never be overlooked. Regulatory framework for labeling domestic and imported food products may be found under the PIQ of the specific food category. The Legislation requires the following information on labels:

Front panel

- technical name (according to MAPA/ANVISA classification)
- brand
- quantity indication
- % alcohol content (for alcoholic beverages)

For all products:

Liquid content (grams or milliliters)	Minimum font height (mm)
below or equal 50	2.0
above 50 and below or equal 200	3.0
above 200 and below or equal 1000	4.0
above 1000	6.0

Side panel

- list of ingredients
- country of origin
- contact information for the processing company
- contact information for the importer
- expiration date
- lot number
- care and handling information
- instructions for product use (if necessary)
- claim "contains gluten" "does not contain gluten"
- notice "evite o consumo excessivo de alcool", which translates to "avoid excessive consumption of alcohol" (for alcoholic beverages)

- nutritional information

Nutritional labeling requirements are similar to those in force in the United States. The Nutritional Information must be set by portion of food, and the portion listing must be accompanied by its respective "household measurement", for example, cup, tablespoon, and teaspoon. The label must include the following information:

NUTRITIONAL INFORMATION		
Portion of ... grams (household measurement)		
Quantity per portion		% Daily Required (VD*)
Energy Value	kcal = kJ	%
Carbohydrates	g	%
Protein	g	%
Total Fat	g	%
Saturated Fat	g	%
Trans Fat	g	**
Dietary Fiber	g	%
Sodium	mg	%
Vitamins/Minerals (when applied)	mg or µg	%

* % daily requirements with reference to the basis in a 2,000Kcal, or 8,400kJ diet.

** daily requirement not established

The letters used for writing unit-of-measure symbols must have a minimum height of 2/3 of the height of the algorithms.

For products whose label is not in the Portuguese language, an adhesive sticker can be used on the original label, for the information referred to the "side panel" and "nutritional information".

Most consumer-oriented products are exempt of labeling registration. Products with mandatory labeling registration follow more strict control. Depending on product nature, MAPA or ANVISA may require additional notes, such as plant number, product registration number, etc. For animal origin products, such as meat, dairy, and seafood products, the Brazilian importer must file a request for the pre-registration of the foreign labels. It is recommended that the exporter contact FAS/OAA Brasilia to initiate this process. Only those products that have their labels pre-approved by DIPOA are allowed to enter Brazil. The National Institute of Metrology, Standardization and Industrial Quality (INMETRO) also regulates labeling. INMETRO defines bar coding and other technical issues related to label format, layout and measurement.

Section III. Packaging and Container Regulations

Regulations on food packaging and containers fall under ANVISA's jurisdiction. Dairy products, are the only exception; an additional license must be granted by MAPA. To obtain the Product Use Authorization (AUP), the company must provide evidence that ANVISA's requirements have been fulfilled. ANVISA establishes quality and identity standards for different types of materials, such as plastic, glass, metal, ceramic, and cellulosic. The agency's objective is to guarantee that recipients do not contain any toxic substance or cause any modification to food compositions. Although in 2000 food packages became exempt of registration, recycled packages still have a mandatory registration. As Brazil follows the principle of positive legislation, companies that make use of new technologies have the right to send a petition to ANVISA and request an inclusion on the list, which is subject to ANVISA's approval. The legislation on food packaging and

containers may be consulted on line at www.anvisa.gov.br/alimentos/legis/especifica/embalagens.htm.

The Brazilian Association of Technical Norms (ABNT) is responsible for elaboration of technical rules (standards and specifications) for packaging and containers. ABNT is also a founding member of the International Organization for Standardization (ISO), the Mercosul Standardization Association (AMN), and the Pan American Commission for Technical Ruling (COPANT). ABNT conducts the certification for consumer packaging (paper and carton boxes, plastic bags, steel sheet, aluminum cans, tetrapak, PET bottles, etc). The Association also regulates the recycling of packaging and containers for food products. All manufacturers or importers shall be responsible for the recycling, disposal and removal of packages or containers that are likely to cause serious pollution to the environment after consumption or use. ABNT follows the international Resin Identification Code (numbering from 1 to 7) of the Society of Plastics Industry and the Standard Recycling Symbol. For detailed regulatory information as well as links to the main associations of packaging and containers, access the ABNT home page at: www.abnt.org.br.

The government's regulatory agency involved with the quality and safety of packaging and containers for handling food is the National Institute of Metrology, Standardization, and Industrial Quality (INMETRO), linked to the Ministry of Development, Industry, and Foreign Trade (MDIC). For additional information, access INMETRO's home page at www.inmetro.gov.br.

Section IV. Food Additives Regulations

ANVISA defines food additives as any ingredient without nutritional benefits deliberately added to food to modify its physical, chemical, biological and sensorial characteristics during any stage - processing, storage, handling, transportation, etc. Before approved for consumption, any food additive is analyzed separately in order to prove its technological need and safety. This analysis includes: the relation of the additive to the product it will be incorporated to; its functionality; studies and toxicological data which allows an adequate risk assessment; studies on estimates of potential ingestion; regulatory framework from other countries; and, international benchmark.

Depending on its nature, the approval or incorporation of the additive to the food regulatory framework may occur with restrictions of use. In this case ANVISA will establish maximum limits for the active substance for the specific food product in which the additive will be incorporated to. If the additive is approved but the safety tolerance has not been set up, the amount to be used by the industry is the sufficient to obtain the efficient result.

Before exporting food and beverage products to Brazil, U.S. exporters must make sure that not only the final product complies with the local legislation but also its ingredients, which includes the additives used. Brazilian legislation divides food products into categories. For each category, allowed additives are listed.

Section V. Pesticides and Other Contaminants

Brazil follows international standards on tolerances of pesticides, herbicides and fungicides used in fumigation of agricultural products, being Codex Alimentarius the general reference. Codex has a committee in Brazil (CCAB) in order to implement the adoption of its standards. This committee is composed by 14 segments of the Brazilian government.

Based on Codex norms, registration of agricultural chemical is held by a three party committee (MAPA, IBAMA, and ANVISA). ANVISA provides toxicological analysis and establishes maximum tolerance levels while IBAMA evaluates environmental impact. MAPA is the initial point of contact in the product registration process and also the party that deliberates final approval after receiving inputs from ANVISA and IBAMA.

In order to improve the inspection of pesticides and contaminants on vegetables in Brazil, in 2009 the National Program for Pesticides and Contaminants Detection was created. The program consists in collecting samples of domestic and imported vegetables, such as papaya, apple, pineapple, lettuce, rice, peanut, banana, lemon, acid lime, mango, melon, corn, strawberry, pepper, tomato and grape. Imported products must comply with the same requirements established for local products.

A list of approved pesticides may be found at the Agrofit System at MAPA's home page www.agricultura.com.br. Maximum tolerance levels for pesticides can be obtained at ANVISA's webpage www.anvisa.com.br.

Section VI. Other Regulations and Requirements

VI.I. MAPA's Inspection Requirements for Meat, Dairy, and Seafood Products

In order to export animal origin (beef, pork, powdered milk, whey, lactose, cheese, and seafood) products to Brazil, the local government requires that U.S. processed plants must be inspected by federal agencies. State level inspection is not accepted and products from these plants will not be registered in Brazil.

The only U.S. federal agencies approved by the Brazilian Government to certify U.S. processing plants are: the Food Safety and Inspection Service of the U.S. Department of Agriculture (FSIS/USDA) for meat, and the Agricultural Marketing Services (AMS/USDA) or the Food and Drug Administration (FDA) for dairy. The U.S. dairy product exporter must have the processing plant included in AMS's list of U.S. Dairy Plants Surveyed and Approved by the USDA Grading Service. The same procedure applies for exports of U.S. seafood. The U.S. plant must be inspected by either the National Oceanic and Atmospheric Administration/National Marine Fisheries Services (NOAA/NMFS) or FDA before exporting to Brazil, and must be included on DIPOA's list. The request for registration of the U.S. plant with DIPOA must be made through the USDA's Foreign Agricultural Service (FAS)/Office of Agricultural Affairs (OAA) in Brasilia.

VI.II. MAPA's Inspection Requirements for Plant Products

All unprocessed U.S. products of plant origin (bulk grains, fresh fruits and vegetables, nuts, and seeds) can only be exported to Brazil if accompanied by an Animal and Plant Health Inspection Service/Plant Protection and Quarantine (APHIS/PPQ) phytosanitary certificate. Frozen fruits and vegetables do not need a phytosanitary certificate. U.S. exporters should always check the nearest PPQ office or the APHIS home page to view the latest import requirements and to see if there is a need to conduct a Pest Risk Assessment (PRA) of the product before exporting to Brazil.

VI.III. MAPA's Pest Risk Assessment (PRA)

The importation of plant species, their parts, products, and by-products are regulated by MAPA, due to the risk of introduction of exotic pests in Brazil. MAPA may define import requirements based on product risk category, historical interception data, and risk assessment.

A pest risk analysis is mandatory to define specific import requirements for plant species, their parts, products, and by-products when:

- It has never been imported into Brazil;
- It is intended for a new use;
- It is from a new country of origin;
- It has records of importation from a date before August 12, 1997.

PRA will be carried out by Department of Plant Health (DSV) and it shall be conducted according to the standards approved by MAPA. Should the PRA be necessary, the interested party must contact the DSV or its superintendents at the state level to initiate the process.

The PRA process can be divided in 3 phases:

PHASE I: START-UP. It involves identification of all disease pathways (hosts) and potential pests present in the exporting country. This phase is completed via bibliographic survey.

PHASE II: EVALUATION OF PEST RISKS. Pests are evaluated on a case-by-case basis to determine whether or not they meet the criteria to be considered quarantine pests. Pest characteristics such as morphology, biology, ecology, means of dispersion, methods of detection, inspections and control mechanisms and prior presence in the importing country will all be evaluated. Based on this information, the potential for introduction and potential economic impact will be reviewed and the determination made as to whether the pest is to be considered a "quarantine pest."

PHASE III: PEST RISK MANAGEMENT. The phytosanitary measures that could reduce this risk to an acceptable level will be identified. According to the information about the pest, the Brazilian National Organization of Phytosanitary Protection (ONPF) will establish measures to mitigate the risk of introducing a pest. After the establishment of an appropriate phytosanitary measure, a Regulatory Act specifying import parameters will be sent by the ONPF to their counterpart in the country of origin-APHIS. Negotiations between the interested parties may follow, and a final phytosanitary protocol will be published in Brazil's Official Gazette.

Interested parties may use the services provided by collaborative centers accredited by MAPA to develop the phase I of the analyses and pay for their costs.

Products that are exempt from mandatory risk assessment:

A. Products classified as risk category zero (0) and one (1) are exempt from PRA.

Category 0: Products that do not require any type of phytosanitary control due to their degree of processing, even if they are of plant origin, and therefore do not require NPPO intervention and are not capable of transmitting pests in packaging material.

Category 1: Plant products, manufactured, devitalized due to the action of any technological process (cooking, blanching, pasteurization, sterilization, fermentation or others) that changed them into products that will not be directly affected by pests, but may transmit pests to packaging materials, transportation means or storage.

B. Plant species and their parts, products, and by-products that have had at least one shipment imported in the period between August 12, 1997 and July 16, 2005, provided that it is from the same country of origin, it serves the same use, it has not presented a record of interception of quarantine pests to Brazil and provided that it has no specific regulated phytosanitary

requirements. Products considered enterable under this condition are listed as Vegetal Products with Authorized Importation (PVIA) on MAPA's webpage.

Given continuous changes occurring in this area, U.S. exporters should check APHIS EXCEPT database or at the APHIS-IS office in the U.S. Embassy in Brasilia for additional information on the status of phytosanitary import requirements.

VI.IV. MAPA's Inspection Requirements for Animal Feed

U.S. exporters of animal feed and fodder, including pet food, must be registered with the Department of Surveillance of Livestock Inputs (DFIP). The U.S. exporter of animal feed should first establish a legal representative or importer in Brazil who will file the request for registration of the imported product with DFIP. The importer must also be registered with MAPA before submitting a request for registration.

VI.V. MAPA's Requirements for Alcoholic and Non-alcoholic Beverages

MAPA Normative Instruction no. 54 and no. 55 of November 18th, 2009 changed import procedures for alcoholic and non-alcoholic beverages. This regulation establishes formats (presented in ANNEX VIII) for the certificate of analysis and certificate of origin for beer, distilled spirits, wine and by products, soft drinks, and juices. MAPA also requires from exporting countries a list of entities eligible to issue these documents. The list of labs/entities can be found at (<http://sistemasweb.agricultura.gov.br/siscole/consultaPublicaCadastro!consultarCadastro.action>).

The Alcohol and Tobacco Tax and Trade Bureau (TTB) has the authority to certify labs and to issue the certificates of origin for alcoholic beverages. If a lab approved by TTB is not included on MAPA's list, TTB can request an update. TTB's list of Certified Chemists can be found at (http://www.ttb.gov/ssd/chemist_certification.shtml). As per non-alcoholic beverages, the OAA/Brasilia or ATO/Sao Paulo office should be the primary contact for U.S. companies to get specific information.

VI.VI. ANVISA's Requirements for Food and Beverage Products

In 2000, ANVISA established the procedures for registration and exemption of registration for imported food products that fall under the regulatory authority of the Ministry of Health. The objectives of these rules are to provide guidance to importers and to improve ANVISA's efficiency in coordinating public health actions on imported food products.

The request for registration, or exemption from registration, must be made by the legal representative of the exporting company, a local subsidiary, or by the food importer. If there is more than one importer for the same product, each importer must make a separate request. The registration is valid for 5 years, after which a new petition must be filed.

Importers of food products that are exempt from registration are still required to request that the product be exempt from registration by presenting the appropriate documents to ANVISA. Importers of food products under mandatory registration must register their products and pay fees, which vary according to the size of the company. The following fee structure is currently in force:

DESCRIPTION	FEE BY COMPANY SIZE*				
	Group I**	Group II**	Group III**	Group IV**	Group V**

	Large	Large	Medium	Medium	Small
Product Registration	R\$6,000	R\$5,100	R\$4,200	R\$2,400	R\$600

Note: *Fees are charged in local currency: the "Real" (R\$). Exchange rate in December 14th, 2011: US\$ 1.00=R\$1.840
 **For the purposes of this regulation, the size of the company is defined as follows: Group I (Annual Income above R\$50 million); Group II (Annual Income between R\$20 million and R\$50 million); Group III (Annual income between R\$6 million and R\$20 million); Group IV (Annual income between R\$2 million and R\$6 million), and Group V (Annual Income below R\$2 million). These criteria are based on Resolution #222 of December 28, 2006. Brazil also defines some companies as "micro" companies, with annual income below R\$434,000. In this case, companies are exempt from the above fees.

IMPORTED FOOD PRODUCTS AND PACKAGES EXEMPT FROM REGISTRATION
Sugar and sweeteners
Food additives
Diet sugars
Salt enriched water
Natural mineral water and natural water
Foods and beverages with complementary nutritional information (light, zero calories, free, low)
Foods for weight control
Foods with dietary restrictions of nutrients
Foods for diets with controlled sweeteners
Foods for pregnant and nursing woman
Foods for the elderly
Foods for athletes
Confectionary products (candies and gums)
Coffee, barley, tea, mate and instant products
Chocolates and cocoa products
Technological coadjuvants
Packaging
Enzyme and enzyme preparations
Seasonings, condiments and sauces
Frozen products and preparations for frozen products
Ice
Mixes for food preparation and ready for consumption products
Vegetable oils, fats and vegetable cream
Cereal products, starch, flour and meal
Products containing protein of vegetable origin
Vegetable products (exc. Heart of palm), fruit products and edible mushroom (5)
Preserved/canned vegetables
Salt
Hiposodic salt/salt substitutes
Vitamin and/or mineral supplements

IMPORTED FOOD PRODUCTS AND PACKAGES WITH MANDATORY REGISTRATION
Functional foods or health claims
Infant foods
Foods for enteral nutrition
Packaging from new technologies (recycled)
Novel foods and/or novel food ingredients
Bioactive substances and probiotic isolates claiming functional and/or healthy attributes

Under MAPA, animal origin (meat, fish, dairy and egg products), margarine and honey must be registered in order to be exported to Brazil. The importer or a legal representative may file a request with MAPA.

Section VII. Other Specific Standards

VII. I. Organic Foods

According to NOTA TECNICA COAGRE N° 006/2011 of February 8, 2011 in order to export organic products to Brazil, foreign producers must comply with the Brazilian regulation for organics, which means that they must be in accordance with the Brazilian production standards and must also be certified by a compliance body, accredited by MAPA. Foreign producers must also be listed under the National Register of Organic Producers. In practical terms, it means that exporters must contract a local accredited body to certify each product they intend to sell in Brazil.

The import process follows the standard import procedure. However, additional documents will be required by the local authorities as organic products, domestic or foreign, must act in accordance with the organic legislation in force.

Labeling of organic products must follow the requirements below:

- one-ingredient products may be labeled as "organic product" once certified;
- products made of more than one ingredient, including additives, in which not all the ingredients are of certified-organic origin, must be labeled in the following manner:
 - a. mixed products which are a minimum of 95 percent from ingredients of certified organic origin will be labeled "organic products";
 - b. mixed products which are made from 70 to 95 percent from ingredients of certified organic origin will be labeled as "products with organic ingredients", and must include the proportions of the organic and non-organic ingredients on their labels, excluding water and salt from the calculation;
 - c. mixed products not meeting the demands of previously-mentioned sections "a" and "b" will not be labeled as organic.

Any imported product subjected to quarantine treatment not compatible with Brazilian organic production regulation will lose its organic status. For additional information on organic set of rules, please access DEPROS's home page at www.prefiraorganicos.com.br.

Section VIII. Copyright and/or Trademark Laws

The National Institute of Industrial Property (INPI) is a federal agency created in 1970, and it is linked to the Ministry of Development, Industry and Foreign Trade (MDIC). It is responsible for registering patents, industrial designs, trademarks, geographic indications and computer software, among other industrial property and related rights. Under INPI regulations, registration of patents is valid for 15 (patent of utility model) to 20 years (patent of invention) from the term of application date. According to the law, a patent will become extinct on the expiration of the term of protection; on waiver by the patentee (considering not incur losses for third parties); on forfeiture; on non-payment of annual fee, or on non observance of Law 9279 of May 14, 1996, article 217 "a person domiciled abroad must maintain permanently a duly qualified attorney resident in the country, with powers to represent him administratively and judicially, including for receiving summons".

The trademark registration certificate is valid for 10 years from the date it was granted, with the possibility of being renewed for equal and successive periods. As for geographic indication, its use is restricted to the producers and providers of services established in the locality. Quality requirements will also have to be met referring to appellations of origin. INPI will establish the conditions of registration for geographic indications. For general information on intellectual property rights, please access the INPI home page at www.inpi.gov.br.

Section IX. Import Procedures

Oversight of imported food and beverage products is primarily under the responsibility of MAPA and ANVISA. These two government bodies ensure the safety of the food supply, and enforce regulations related to food and beverage products throughout the supply chain.

MAPA and ANVISA's JURISDICTION

MAPA	ANVISA
Consumer-oriented products <i>animal products</i> : red meat and by-products, poultry meat and by-products, fish, seafood products, dairy products, and eggs; <i>beverages</i> : alcoholic and non alcoholic (except energy drinks, hydroelectrolitic beverages, soy beverages); <i>fruits and vegetables</i> : dried, fresh and processed	Consumer-oriented products <i>food</i> : all consumer-ready or processed products, (except those under MAPA's authority) <i>beverages</i> : energy drinks, hydroelectrolitic beverages and soy beverages
Intermediate products (wheat flour, planting seeds, etc)	Intermediate products (sugar, sweeteners, mineral water, flavored waters, additives, and other ingredients (excluding those under MAPA's authority)).
Bulk commodities (wheat, grains, rice, soybean, cotton, tobacco, pulses, peanuts, flour, etc)	
Pet food, feeds and fodders	
Plants and seeds	
Animals, semen and embryos	

In Brazil import procedures may be divided into 3 major phases: Import Procedures Prior Shipment, Import Procedures during Shipment and Import Procedures upon Product Arrival. To go from one phase to the other, the importer must complete a series of actions. Although the process may vary according to the product nature, in general terms, the actions under each phase may be presented as shown on the table below:

IMPORT PROCEDURES

Prior shipment	During Shipment	Upon Product Arrival
1. Plant Registration	7. Shipping Instructions	9. Notification of Cargo Arrival
2. Formula Evaluation	8. Bill of Lading (B/L) or Airway Bill (AWB)	10. Import Declaration (DI)
3. Labeling		11. Inspection
4. Product Registration		12. Customs' Evaluation
5. Pro Forma Invoice		13. Re-Inspection/Product Release
6. Import License (LI)		

IX.I. Import Procedures Prior Shipment

1. Plant Registration

Products regulated by MAPA follow stricter control such as approval of processing plants, registration, labeling, quota, FPS control, etc. Before initiating exports of animal origin products, U.S. companies may contact local OAA staff to initiate the registration process and make sure the information to be provided is acceptable to the Brazilian government.

Prior to exporting alcoholic and non-alcoholic beverages that fall under MAPA's responsibility, the exporter must check with ATO Sao Paulo or the Alcohol and Tobacco Tax and Trade Bureau (TTB) to determine if the laboratory or producer issuing the lab certificate is eligible to do so. MAPA demands from foreign countries exporting beverages to Brazil to provide a list of entities eligible to issue laboratory certificates and certificates of origin.

1. Plant Registration

Stricter control is set for animal origin goods, which means that all manufacturing plants must be approved and registered by MAPA prior to exporting their products to Brazil. To comply with the Brazilian regulation, U.S. companies may contact the local USDA/FAS/Office of Agricultural Affairs (OAA) who is responsible for initiating the registration process with MAPA.

Other product categories also require pre-shipment procedures:

- MAPA establishes phytosanitary measures to allow imports of vegetable origin products. Products of vegetable origin are classified according to risk level. In order to approve imports, MAPA must evaluate the risk of the product in question. According to the risk presented, a Pest and Risk Assessment (PRA) may be requested. Once completed, the product must be included in the List of Products Authorized to Import (PVIA), indicating no risk or the risks are controlled under phytosanitary measures.
- To allow foreign alcoholic and non-alcoholic beverages into the country, MAPA requires the exporting country to provide a list of entities eligible to issue Certificate of Analysis and Certificate of Origin. Once the list is sent to MAPA by an official source, the name of the institution will be placed at: <http://sistemasweb.agricultura.gov.br/siscole/consultaPublicaCadastro!consultarCadastro.action>. At clearance, MAPA will only accept documents from entities included in this list. The Alcohol and Tobacco Tax and Trade Bureau (TTB) has the authority to certify labs and institutions to issue the certificates for alcoholic beverages. Should a lab approved by TTB not be included on MAPA's list, TTB can request an update. The current TTB list of wine, distilled and beer chemists is found at http://www.ttb.gov/ssd/chemist_certification.shtml. For obtaining guidance for non-alcoholic beverages, the exporter may contact ATO Sao Paulo.
- To export organic products to Brazil, foreign producers must comply with the Brazilian regulation for organics, which means that they must be in accordance with the Brazilian production standards and must also be certified by a compliance body accredited by MAPA. Foreign producers must also be listed under the National Register of Organic Producers. In practical terms, it means that exporters must contract a local accredited body to certify each product they intend to sell in Brazil.

2. Ingredients Evaluation

Brazilian legislation is "positive", which means that only products (including additives, colorings, preservatives, etc) that are authorized by Brazilian regulations are allowed to enter the market. Therefore, the importer must ensure the Brazilian Government (GoB) permits the entry of the foreign product. All ingredients contained in food or beverage items should meet GoB specifications and tolerance levels. For that, the Identity and Quality Standard (PIQ) established

by MAPA and ANVISA must be followed.

Under ANVISA, food products containing new ingredients and foods containing ingredients that are already consumed but with tolerance levels above the Brazilian diet patterns are considered "new foods". Such products must be analyzed and approved by ANVISA prior to importation.

3. Labeling

Labeling of food and beverage products must be in accordance to GoB regulations.

4. Product Registration

If the product is allowed to be marketed, the legal representative of the exporting company, (usually a local subsidiary, or the importer) must request product registration, or an official exemption from registration. If there is more than one importer for the same product, each importer must make an independent request.

5. Pro Forma Invoice

The *pro forma* invoice must be filled out properly otherwise the importer will not be able to file an import application (delays are very common as a result of inadequate information being reported on the *pro forma* invoice).

6. Import License (LI)

With the request for an import authorization the administrative process formally starts. The importer requests an import permit, also called Import License (LI), which must be obtained before shipment.

IX.II. Import Procedures during Shipment

7. Shipping Instructions

Shipping Instructions consist of a document containing all the information related to the sale and merchandise's condition upon shipment, such as the quantity of product, form of payment, transport temperature, packaging, pallet used, etc. The Shipping Instructions should further contain all the documents to be sent to the importer.

8. Bill of Lading (B/L) or Airway Bill (AWB)

With the Shipping Instruction provided by the exporter, the shipping company will be able to issue the B/L or the AWB. This is the proof of loading, issued by the shipping company, containing the entire description of shipping.

IX.III. Import Procedures upon Product Arrival

9. Notification of Cargo Arrival

Upon arrival, the cargo must be sent to the Customs Terminal (storage). Once the goods are duly placed, the "presence of Cargo" must be created. This must be done through the SISCOMEX system and prior the Import Declaration".

10. Import Declaration (DI)

Once goods arrive in Brazil, the importer (or a contracted customs broker officially representing the importer), must prepare the Import Declaration (DI) through the SISCOMEX. Mercosul countries (including Brazil, Argentina, Paraguay and Uruguay), have adopted the Mercosul Common Nomenclature (NCM) system for product classification. The NCM is based on the international methodology of the Harmonized Commodity Description and Coding System or simple Harmonized System (HS). The NCM is formed by 8 digits, the first 6 digits follow the HS codes while the seventh and eighth digits correspond to Mercosul specifications. Through the NCM the amount of taxes to be paid are defined.

11. Inspection

Before going through Customs, the importer must present the LI to MAPA or ANVISA officials. Officials will verify whether or not the cargo was duly authorized and if the documents are accurate.

12. Customs' Evaluation

The clearance process starts when the product arrives in Brazil. Clearance from customs consists of a series of acts carried out by a customs official who will authorize the release of the goods to the importer after the verification of product classification and tax payments. After the reception of documents, the system will automatically select inspection/verification method to be applied. They are:

- GREEN: customs clearance authorization is automatically issued.
- YELLOW: mandatory inspection of documentation is required and, if no evidence of irregularities is found, customs clearance is issued.
- RED: mandatory inspection of documentation and of goods is required before customs clearance authorization is issued.
- GRAY: mandatory inspection of documents, merchandise, and recalculation of import taxes applied.

Except for the green option, all documents including the Import Declaration, the receipt generated by the SISCOMEX and the Value Added Tax (ICMS) payment receipt (or waiver), must be presented to the Secretariat of Federal revenue (SRF). For goods assigned the gray option, a Declaration of Customs Value (DVA) must be made and transmitted via SISCOMEX to justify the product price and commercial aspects of the transaction. Any correction to the information presented must be carried out in accordance with SISCOMEX procedures. After registering customs clearance the fiscal authority - the Secretariat of Federal Revenue - will release an Import Confirmation (CI), approving customs clearance and the entry of goods.

13. Re-inspection/Product Release

MAPA and ANVISA inspectors must perform a re-inspection before admissibility. The admissibility will depend on:

- Documents review
- Physical examination
- Lab analysis/sample collection (to be conducted *in loco* if requested by authorities)

To obtain more detailed information on step-by-step import procedures please contact ATO Sao Paulo. The ATO has developed a market access study to catalogue administrative procedures and

legal requirements mandated by the GoB for 26 categories of food products. This study analyses actual procedures followed by importers to comply with government requirements. Always note that the most updated set of rules each administrative agency releases must be observed prior to shipment as it directly impacts the entry of foreign goods into Brazil.

Appendix I. Government Regulatory Agency Contacts

Secretariat of Agricultural Protection (SDA)
Ministry of Agriculture, Livestock, and Food
Supply (MAPA)
Esplanada dos Ministerios, Bloco D
Anexo B, Sala 426
70043-900 Brasilia, DF
Phone: (55-61) 3218-2314/15
Home page: www.agricultura.gov.br

Brazilian Environment Institute (IBAMA)
Ministry of Environment (MMA)
SCEN, Trecho 2, Ed. Sede
70818-900 Brasilia, DF
Phone: (55-61) 3216-1212
Home page: www.ibama.gov.br

Ministry of Agriculture, Livestock and
(MAPA)
Esplanada dos Ministerios, Bloco D,
Sala 304
70043-900 Brasilia, DF
Phone: (55-61) 3218-2510/2468
Home page: www.agricultura.gov.br

(MCT) Ministry of Science and Technology Food Supply
Esplanada dos Ministerios, Bloco E
70067-900 Brasilia, DF
Phone: (55-61) 3317-7500
Home page: www.mct.gov.br

Secretariat of Agriculture and Livestock
Development and Cooperation (SDC)
Esplanada dos Ministerios, Bloco D
Anexo A, Sala 200
70043-900 Brasilia, DF
Phone: (55-61) 3218-2433
Home page: www.agricultura.gov.br

Brazilian Customs (Receita Federal)
Ministry of Finance
Esplanada dos Ministerios, Bloco P
70048-900 Brasilia, DF
Phone: (55-61) 3412-3000/2000
Home page: www.fazenda.gov.br

Agency of Sanitary Surveillance (ANVISA)
Ministry of Health
Esplanada dos Ministerios, Bloco B, Ed.Omega
70770-502 Brasilia, DF
Phone: (55-61) 3462-6000
Home page: www.anvisa.gov.br

Ministry of Justice (MJ)
Esplanada dos Ministerios, Bloco T
70064-900 Brasilia, DF
Phone: (55-61) 3429-3000
Home page: www.mj.gov.br

Ministry of Development, Industry and
Foreign Trade (MDIC)
Esplanada dos Ministerios, Bloco J
70053-900 Brasilia, DF
Phone: (55-61) 3425-7000
Home page: www.mdic.gov.br

Appendix II. Other Import Specialist Contacts

Brazilian Food Ingredients and Additives Association (ABIAM)

Rua Hungria, 664, cj. 51
01455-000 Sao Paulo, SP
Phone: (55-11) 3034-3541
Fax: (55-11) 3816-2928
E-mail: abiam@abiam.com.br
Home page: www.abiam.com.br

Brazilian Food Processors' Association (ABIA)

Av. Brigadeiro Faria Lima, 11 andar
01451-001 Sao Paulo, SP
Phone: (55-11) 3030-1353
Fax: (55-11) 3814-6688
E-mail: abia@abia.org.br
Home page: www.abia.org.br

Please do not hesitate to contact the Foreign Agricultural Service (FAS) offices below with questions or comments regarding this report or to request assistance.

U.S. Agricultural Trade Office (ATO)

U.S. Consulate General
Rua Henri Dunant, 700
04709-110 Sao Paulo, SP
Phone: (55-11) 5186-7400
Fax: (55-11) 5186-7499
E-mail: atosaopaulo@usda.gov
Home page: www.usdabrazil.org.br
www.fas.usda.gov

Office of Agricultural Affairs (OAA)

U.S. Embassy
Av. das Nacoes, quadra 801, lote 3
70403-900 Brasilia, DF
Phone: (55-61) 3312-7101
Fax: (55-61) 3312-7659
E-mail: agbrasil@usda.gov