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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 food and agricultural product imports into Brazil, including import procedures. In 2017, there were no significant changes to general regulations that could impact sales of U.S. agricultural products to Brazil. However, labeling of nutritional information is expected to change in the near future. In addition, Brazil, as a Common Market of the South (Mercosul) member is currently negotiating a trade agreement with the European Union. The proposed list of Geographic Indications being negotiated may impact imports of food and beverage products into Brazil.

This report was prepared by the U.S. Agricultural Trade Office (ATO) of the USDA/Foreign Agricultural Service in Sao Paulo, Brazil for U.S. 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. The country is also a member of the Common Market of the South (Mercosul) formed by Argentina, Brazil, Paraguay, Uruguay and Venezuela. The Customs Union allows duty-free tariffs among member states and imposes a common external tariff on non-member countries. It also establishes a common commercial policy toward third countries.

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 and nonalcoholic beverages, juices, grains, seeds, and animal feed (including pet food). ANVISA enforces most 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 Brazilian Institute of Environment and Renewable Natural Resources (IBAMA), of the Ministry of the Environment; the National Institute of Metrology, Quality and Technology (INMETRO) of the Ministry of Industry, Foreign Trade and Services (MICES); the National Technical Commission on Biosafety (CNTBio), which is an Inter-Ministerial Commission based in the Ministry of Science, Technology, Innovation and Communication (MCTIC); and the Department of Consumer Protection and Defense (DPDC) within the Ministry of Justice.

The Brazilian constitution defines the relationship between federal, state and municipal law. It also defines the power of each federal branch of government (legislative, judicial and executive). 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 their various branches are considerable as they implement those rules and define in greater details the procedures that must be followed. 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.

#### Section I.I 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 (SPAE), 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, margarine 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.

#### • 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 athletes, water, and energy drinks). Under DIPOV there is one branch for beverages for General Coordination for Wine and Beverages (CGVB).

#### • Department of Animal Health (DSA)

DSA is responsible for enforcing regulations on imports and exports of live animals, semen, and 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 Brazil's Footand-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 (CGVIGIAGRO)

CGVIGIAGRO 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 the organic sector from the early stages of production until processing and trade. The Department overlooking organic issues is the Department of Production Systems and Sustainability (DEPROS), through the Agroecology Coordination (COAGRE).

#### **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 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 which have a direct impact on U.S. 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 Phytosanitary Affairs (DASF)

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

#### **Section I.II 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, foods, food additives, proceeding aids, packaging, 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 Brazil. Within ANVISA the regulation, inspection and clearance of food products is coordinated by the following branches:

#### **General Management 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 four offices:

#### • Coordination for Examination of Appeals in Food Registration (COREA)

COREA is responsible for examining appeals of petitions of food products that had registration denied by ANVISA.

#### • Risk Assessment and Effectiveness Management (GEARE)

GEARE is responsible for product registration, analysis, control, supervision, inspection and risk management of food products.

#### • Management for Food Registration (GEREG)

GEREG is responsible for managing the registration process for food products. It also regulates food standards, quality and identity and labeling.

#### • Post Registration Management (GEPRA)

GEPRA is responsible for approving product revalidation, formula alteration. It also regulates food standards, quality and identity and labeling.

#### Superintendency of Ports, Airports, Borders and Customs Enclosure (SUPAF)

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

#### **International Affairs Assistance (AINTE)**

AINTE 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.

#### **Section I.III Ministry of Environment (MMA)**

Within the Ministry of Environment (MMA) is 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 <a href="www.ibama.gov.br">www.ibama.gov.br</a> and <a href="www.ibama.gov.br">www.ibama.gov.br</a>.

#### Section LIV Ministry of Industry, Foreign Trade and Services (MICES)

All food products imported or exported by Brazil must be registered at the Secretariat of Foreign Trade (SECEX) of the Ministry of Industry, Foreign Trade and Services (MICES). This office monitors all import and export tariffs and issues import and export licenses. In addition, SECEX is the government agency responsible for adjudicating 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 though 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 MICES, is the National Institute of Metrology, Quality and Technology (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 <a href="www.inmetro.gov.br">www.inmetro.gov.br</a>. Other MICES

legislation and procedures can be found at www.mices.gov.br or on the *Diario Oficial* website www.in.gov.br.

#### **Section I.V 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 <a href="www.mj.gov.br">www.mj.gov.br</a>. Other Brazilian federal regulations regarding the Ministry of Justice can be found at the *Diario Oficial* homepage <a href="www.in.gov.br">www.in.gov.br</a>.

#### **Section II. Labeling Requirements**

Labeling of food and beverage products must be in accordance with the general legislation of labeling, warnings, as well as the specific laws applicable to the product category. The requirements are also found on the specific Technical Regulation and the Consumer Protection Code. The exporter should forward a sample of the package to the importer to facilitate label development. In general, labels must contain the following information":

#### Front panel

- technical name (as defined in the specific Technical Regulation)
- brand
- information about aroma and coloring
- weight/volume indication (note the minimum height of figures and letters indicated in the table below as per INMETRO Ordinance #157 of 2002)
- Additional information required by Technical Regulation of each product

#### For food/beverage products:

Net 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 1,000	4.0
above 1,000	6.0

The letters used for writing unit-of-measure symbols must have a minimum height of 2/3 of the height of the algorithms. For imported products, if the original packaging gives no indication of quantity on the main panel, or if such indication is in dimensions or units which do not agree with those established by National Institute of Metrology, Quality and Technology (INMETRO), a sticker can be used on the original label, containing all the required information.

#### Other panels

- list of ingredients
- warnings
  - . "contains gluten" or "does not contain gluten,"
  - claim allergens: contains... (the following products listed as allergens are: wheat, rye, barley, oats and their hybridized strains; crustaceans, fish, eggs, peanuts, soy, milk of all species of mammalian animals, almonds, hazelnuts, cashew nuts, brazil-nut or brown-nuts, macadamia nuts, pecans, pinoli, chestnuts and natural latex. If the substance is detectable it must be labeled.
  - "evite o consumo excessivo de alcool," which translates to "avoid excessive consumption of alcohol" (for alcoholic beverages)
  - . biotech content above one percent in its final composition must be indicated on the label.
- country of origin
- contact information for the manufacturer
- contact information for the importer
- expiration date (manufacture date only for animal origin products)
- lot number
- care and handling information
- instructions for use and preparation (if applicable)
- % alcohol content (for alcoholic beverages)
- nutritional information (information required to comply with RDC Resolutions # 359 of 2003 and #163 of 2006)

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 RDC #359 determines the serving of each food and their corresponding household measures.

A serving is the average amount of food that should be consumed by healthy persons, with age above 36 months, at each consumption occasion, to allow a healthy diet. The label must include specific content. Below is one example:

NUTRITIONAL INFORMATION Serving of grams/ml (household measurement)			
Quantity per serving		% Daily Required (VD*)	
Energy Value	kcal =kJ	%	
Carbohydrates	g	%	
Protein	g	%	
Total Fat	g	%	
Saturated Fat	g	%	
Trans Fat	g	**	
Dietary Fiber, and	g	%	
Sodium	mg	%	

Vitamins/Minerals	mg or μg	%
(when applied)		

<sup>\* %</sup> daily values based on a 2,000kcal, or 8,400kJ diet. Your daily values can be higher or lower, depending on your energy needs.

Note: on November 1, 2017, local media reported that the Brazilian Food Processing Association (ABIA) proposed a new labeling scheme that would use a green, yellow, and red color-coding method to indicate content for certain nutritional criteria per 100 grams. This "traffic light" labeling is similar to a system used by some European countries. The National Agency of Sanitary Surveillance (ANVISA) is currently reviewing ABIA's proposal along with three others. Since the topic is somewhat controversial, the labeling debate is expected to continue into 2018. All proposals, as well as status updates should be posted to the ANVISA website: <a href="https://www.anvisa.gov.br">www.anvisa.gov.br</a>.

#### **Section III. Packaging and Container Regulations**

Regulations on food packaging and containers fall under ANVISA's jurisdiction. ANVISA establishes quality and identity standards for materials, such as plastic, glass, metal, ceramic, and cellulosic. The agency's objective is to guarantee that packaging materials do not contain toxic substance or cause modification to food content. Although food packages are exempt from registration, mandatory registration is required for recycled packaging material. 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 Brazilian Association of Technical Norms (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). 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 homepage at: <a href="https://www.abnt.org.br">www.abnt.org.br</a>.

#### **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 benchmarks.

<sup>\*\*</sup> daily requirement not established

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. If the additive is approved but a safety tolerance is not set, the additive may be used at the level required to obtain desired 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. 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 on agricultural products, and uses Codex Alimentarius as a general reference. The Codex Alimentarius Committee of Brazil (CCAB) represents the country in international Codex Committees and advocates for the use of Codex standards in the country

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 collects samples of domestic and imported fruit and 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 <a href="https://www.agricultura.com.br">www.agricultura.com.br</a>. Maximum tolerance levels for pesticides can be obtained at ANVISA's webpage <a href="https://www.anvisa.com.br">www.anvisa.com.br</a>.

#### **Section VI. Other Regulations and Requirements**

#### 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, MAPA mandates the U.S. processing plants must be inspected by federal agencies in the country of origin. 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; the Agricultural Marketing Services (AMS/USDA) or the Food and Drug Administration (FDA) for dairy; and the National Oceanic and Atmospheric Administration/National Marine Fisheries Services (NOAA/NMFS) for fishery products.

The U.S. exporter must contact these federal agencies and request the inclusion of the processing plant in the list of approved U.S. plants to export to Brazil. The request for registration of the U.S. plant with the Brazilian authority, DIPOA, must be done as per the following procedures:

Meat: all beef or pork plants must make a formal request to FSIS. FSIS will then contact the Foreign Agricultural Service/Office of Agricultural Affairs (FAS/OAA) in Brasilia and request the registration to be included in the Brazil's official list.

Dairy: registration under this category must be done directly through FAS/OAA. FAS will need a formal letter from the company to insert the producing plant in the Brazil's official list.

Seafood: all fishery plants must prepare a formal request to NOAA. NOAA will then contact FAS/OAA and request the registration to be included in the Brazil's official list.

Registration of U.S. facilities can take approximately six months.

#### **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.

#### **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 three 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: EVALUATON 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:

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.

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 import and export database or with the APHIS office in the U.S. Embassy in Brasilia for additional information on the status of phytosanitary import requirements.

#### **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.

#### MAPA's Requirements for Alcoholic and Non-alcoholic Beverages:

MAPA Normative Instruction # 54 and 55 of November 18, 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: <a href="http://sistemasweb.agricultura.gov.br/siscole/consultaPublicaCadastro!consultarCadastro.action">http://sistemasweb.agricultura.gov.br/siscole/consultaPublicaCadastro!consultarCadastro.action</a>).

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: (<a href="http://www.ttb.gov/ssd/chemist\_certification.shtml">http://www.ttb.gov/ssd/chemist\_certification.shtml</a>). As per non-alcoholic beverages, the ATO office should be the primary contact for U.S. companies to obtain specific information.

#### **ANVISA's Requirements for Food and Beverage Products:**

ANVISA establishes 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.

Products under ANVISA jurisdiction are classified into two categories: products exempt from registration and products with mandatory registration. If the product is allowed to be marketed, the legal representative of the exporting company, a local subsidiary or the importer, must request product registration or an exemption from registration. If there is more than one importer for the same product, each importer must make an independent request. These forms must be delivered to the local office of the Ministry of Health in the state where the importer is legally based. Importers of food products under the mandatory list must register their products and pay fees, which vary according to the size of the company. 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.

IMPORTED FOOD PRODUCTS AND PACKAGES EXEMPT FROM REGISTRATION
Sugar and table top sweeteners
Additives
Dietetic sweeteners
Table waters
Mineral water and natural water
Foods and beverages with nutritional claim
Food for weight control

Food for nutrient restriction diets	
Foods for controlled sugar intake diets	
Foods for pregnant and lactating woman	
Foods for elderly people	
Foods for athletes	
Confectionary products	
Coffee, barley, tea, mate and instant products	
Chocolates and cocoa products	
Processing aids	
Packaging	
Enzyme and enzyme preparations	
Seasonings, condiments and sauces	
Edible ices and preparation for edible ices	
Ice	
Mixes for food preparation and ready for consumption products	
Vegetable oils, fats and fat spreads	
Cereal products	
Products containing protein of vegetable origin	
Vegetable products (excl. heart of palm), fruit products and mushrooms	
Vegetable products (heart of palm)	
Salt substitutes (hipossodic salt/succedaneous salt	
Vitamin and/or mineral supplements	

IMPORTED FOOD PRODUCTS AND PACKAGES WITH MANDATORY REGISTRATION	
Foods with functional and/or health claims	
Foods for Infants	
Enteral feeding	
Packaging from new technologies (recycled, PET)	
Novel foods and/or novel food ingredients	
Bioactive substances and isolated probiotic and/or health claims	

Under MAPA meat, dairy, egg, honey, margarine, and fish products must be registered in order to be exported to Brazil. The manufacturer must file a request with MAPA.

#### **Organic Foods:**

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 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 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 the set of organic rules, please access www.agricultura.gov.br/desenvolvimento-sustentavel/organicos.

#### **Section VII. Other Specific Standards**

#### **Discussion on Labeling Regulation**

Currently ANVISA is leading two discussions related to labeling of food products. One refers to the update of allergenic regulation and the other refers to nutritional information. ANVISA plans to review the warning regulation related to allergenic ingredients, which was published few years ago. The goal is to make the rule more effective, for example, products that contain one single ingredient would not have to provide a warning mentioning that same ingredient is contained in the product. The other initiative refers to the labeling of nutritional information. According to ANVISA, the update is necessary to help consumers make healthier choices. ANVISA is currently reviewing four different proposals on nutritional labeling and is expected to present a proposal in 2018 or later, which takes into consideration a series of studies conducted by consumer protection entities, universities, and the food industry itself.

More information is provided at:

http://portal.anvisa.gov.br/rss/-/asset\_publisher/Zk4q6UOCj9Pn/content/id/3647942

#### **Discussion on Geographic Indications**

Brazil, along with its Mercosul partners, is currently considering a list of 350+ proposed geographic indications presented by the EU as part of the EU-Mercosul free trade agreement (FTA) negotiations. Brazil published the list and invited public comments until December 22, 2017. While there was strong political pressure to announce agreement on FTA terms before the end of 2017, negotiations are ongoing

## and it remains unclear how this potential trade agreement will unfold or impact sales of U.S. products to Brazil.

More information is provided at:

http://www.inpi.gov.br/noticias/prorrogado-prazo-para-subsidios-sobre-reconhecimento-de-igs-da-uniao-europeia

#### Section VIII. Copyright and/or Trademark Laws

The National Institute of Industrial Property (INPI) is a federal agency linked to the Ministry of Industry, Foreign Trade and Services (MICES) and 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 duty 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 indications, its use is restricted to the producers and providers of servicers 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 please access the INPI home page at www.inpi.gov.br.

#### **Section IX. Import Procedures**

Oversight of imported food and beverage products is primarily 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	ANVISA
Consumer-oriented products	Consumer-oriented products
animal products: red meat and by- products,	food: all consumer-ready or processed products,
poultry meat and by-products, fish, seafood	(except those under MAPA's authority) beverages:
products, dairy products, eggs, honey, and	energy drinks, hydroelectrolitic beverages and soy
margarine;	beverages
beverages: alcoholic and nonalcoholic (except	
energy drinks, hydroelectrolitic beverages,	
soy beverages);	
fruits and vegetables: dried, fresh and processed	
Intermediate products	Intermediate products
(wheat flour, planting seeds, etc.)	(sugar, sweeteners, mineral water, flavored waters,
	additives, and other ingredients (excluding those

Bulk commodities	under MAPA's authority).
(wheat, grains, rice, soybean, cotton, tobacco,	
pulses, peanuts, flour, etc.)	
Pet food, feeds and fodders	
Plants and seeds	
Animals, semen and embryos	

To fulfill local requirements the importer must work together with the exporter, particularly in the initial phase, when the documents for shipment are prepared. On the clearance phase, upon product arrival, most import companies contract a customs agent who will be responsible for clearance formalities. The most updated set of rules each administrative agency releases must be observed prior to shipment as it directly impacts the access for foreign goods into Brazil.

#### **Appendix I. Government Regulatory Agency Contacts**

Ministry of Agriculture, Livestock and Food Supply (MAPA)

Esplanada dos Ministerios, Bloco D 70043-900

Brasilia, DF

Phone: (55-61) 3218-2510/2468 Home page: www.agricultura.gov.br

Ministry of Finance Brazilian Customs (Receita Federal) Esplanada dos Ministerios, Bloco P

70048-900 Brasilia, DF Phone: (55-61) 3412-3000/200

Phone: (55-61) 3412-3000/2000 Home page: www.fazenda.gov.br

Ministry of Environment (MMA) Brazilian Institute for the Environment and Natural Resources (IBAMA) SCEN, Trecho 2, Ed. Sede 70818-900

SCEN, Trecno 2, Ed. Sede 70818-900 Progilio DE

Brasilia, DF

Phone: (55-61) 3216-1212 Home page: www.ibama.gov.br Ministry of Health Agency of Sanitary Surveillance (ANVISA) SIA Trecho 5, Área Especial 57 71205-050 Brasilia, DF Phone: (55-61) 3462-6000

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

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

#### **Appendix II. Other Import Specialist Contacts**

Brazilian Food Processors' Association (ABIA) Brazilian Food Ingredients and Additives

Association (ABIAM)

Av. Brigadeiro Faria Lima, 11 andar Rua Hungria, 664, cj. 51

01451-001 São Paulo, SP
Phone: (55-11) 3030-1353
Phone: (55-11) 3034-3541
E-mail: abia@abia.org.br
Home page: www.abia.org.br
Home page: www.abia.org.br

Please do not hesitate to contact the offices below for questions or comments regarding this report or to request assistance to export processed food products into Brazil:

#### **U.S.** Agricultural Trade Office (ATO)

U.S. Consulate General Rua Thomas Deloney, 381 04709-110 São Paulo, SP Tel: (55-11) 3250-5400 Fax: (55-11) 3250-5499

E-mail: atosaopaulo@fas.usda.gov

#### Office of Agricultural Affairs (OAA)

U.S. Embassy

Av. das Nações, quadra 801, lote 3

70403-900 Brasília, DF Tel: (55-61) 3312-7000 Fax: (55-61) 3312-7659

E-mail: agbrasilia@fas.usda.gov