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Food and Agricultural Import Regulations and Standards Report

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Report Highlights:

In 2108 Brazil has not implemented significant changes to regulations that could affect imports of agricultural goods. However, with the election of President Jair Bolsonaro, a more liberal economic agenda is expected to be implemented. The new president plans to reduce the number of Brazilian ministries to 22, a move that will likely impact the way the federal government functions. Exporters interested in entering the Brazilian market should pay attention to regulatory changes that may occur in the near future.

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This report was prepared by the U.S. Agricultural Trade Office (ATO) of the USDA/Foreign Agricultural Service in Sao Paulo, Brazil, for exporters of U.S. 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. General 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, Venezuela (currently suspended), and Bolivia (in the process of accession). 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. Associated states to Mercosul such as Chile, Colombia, Ecuador, Guyana, Peru, and Surinam, also enjoy duty-free agreements.



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. From January 2019, President Jair Bolsonaro takes office. He is expected to implement significant changes in the federal government structure, extinguishing and merging ministries. The number of Brazilian ministries is projected to be reduced to twenty two. As per today, 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 found online. 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 the monitoring and 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 (MDIC); the National Technical Commission on Biosafety (CTNBio), 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 among federal, state, and municipal law. It also defines the power of each federal branch of government (legislative, judicial, and executive). Importers/exporters must always observe the set of rules each administrative agency releases as it directly impacts market access for foreign goods. Although the Brazilian congress has responsibility for rule-making, the power delegated to the ministries and their various branches are considerable as they implement the law 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 Agricultural Development and Cooperatives (SDC); Secretariat of Production and Agro-Energy (SPA-E); 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 derived products, byproducts, 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, is responsible for surveillance of all foreign agricultural 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 water, sports drinks, and energy drinks). Under DIPOV, there is one branch for beverages: 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, defend Brazilian borders against new foreign animal diseases, and control and eradicate existing animal diseases through programs such as the Foot-and-Mouth Disease Eradication Program.

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

DSV is responsible for protecting the health of plants, as well as 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 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), registration of establishments producing animal semen and embryos, and genealogical registration of live animals. DFIP also regulates the use of veterinary products.

- **General Coordination for Sanitary Inspection of Agriculture and Livestock (CGVIGIAGRO)**

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

The Secretariat of Agricultural Development and Cooperatives (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 Agro-ecology Coordination (COAGRE).

Secretariat of International Agribusiness Relations (SRI)

SRI is responsible for coordinating the Brazilian government's position on agricultural matters in international forums such as the World Trade Organization (WTO), World Organization for Animal Health (OIE), International Plant Protection Committee (IPPC), and Codex Alimentarius (CODEX). SRI also coordinates regional and bilateral agricultural agreements. Moreover, SRI is the focal point for the U.S.-Brazil negotiations under the Consultative Committee on Agriculture (CCA). SRI is composed of 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, and regional negotiations involving agriculture and livestock.

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

DASF supports all government commitments under 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 the National Agency of Sanitary Surveillance (ANVISA). ANVISA is considered an autonomous agency, designated as the scientific regulator 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, and 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:

- **Food Registration Management (GEREG)**

GEREG is responsible for managing the registration process for food products.

- **Risk Assessment and Effectiveness Management (GEARE)**

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

- **Post-Registration Management (GEPRA)**

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

- **Coordination for Examination of Appeals in Food Registration (COREA)**

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

Superintendent 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 for 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, called the 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's review is concerned with the possible environmental impact of pesticides. In general, it follows recommendations made by international standard-setting organizations like CODEX and works closely with its U.S. counterpart, the 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 (CITES). It is the agency responsible for monitoring and enforcing activities that affect Brazil's plants and animals. The regulatory rules related to these subjects in Brazil can be found at www.ibama.gov.br and www.mma.gov.br.

Section I.IV Ministry of Industry, Foreign Trade, and Services (MDIC)

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 (MDIC). This office monitors all import and export tariffs and issues import and export licenses. In addition, SECEX is the government agency responsible for adjudicating anti-dumping 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 MDIC is the National Institute of Metrology, Quality, and Technology (INMETRO). INMETRO also conducts tests of domestic and imported products (industrial and 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 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 at www.mj.gov.br. Other Brazilian federal regulations regarding the Ministry of Justice can be found at the "Diario Oficial" homepage www.in.gov.br. Section II. Food Additive Regulations ANVISA defines food additives as any ingredient without nutritional benefits deliberately added to food to modify its physical, chemical, biological, or sensorial characteristics during any stage (e.g., processing, storage, handling, transportation, etc.). Before being approved for consumption, any food additive is analyzed separately in order to assess its technological need and safety. This analysis includes: the relation of the additive to the product in which it will be incorporated; 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.

Section II. Food Additive Regulations

ANVISA defines food additives as any ingredient without nutritional benefits deliberately added to food to modify its physical, chemical, biological, or sensorial characteristics during any stage (e.g., processing, storage, handling, transportation, etc.). Before being approved for consumption, any food additive is analyzed separately in order to assess its technological need and safety. This analysis includes: the relation of the additive to the product in which it will be incorporated; 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.

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 the 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 the product's ingredients, which includes any additives. Brazilian legislation divides food products into categories, with allowable additives for each.

Section III. Pesticide and Other Contaminants

Brazil follows international standards for 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, registrations for agricultural chemicals are reviewed by a three-party committee composed of 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 fruits and vegetables in Brazil, in 2009 the National Program for Pesticides and Contaminants Detection was created. The program collects samples of domestic and imported fruits and vegetables, such as papayas, apples, pineapples, lettuce, rice, peanuts, bananas, lemons, limes, mangos, melons, corn, strawberries, peppers, tomatoes, and grapes. Imported products must comply with the same requirements established for local products.

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

Section IV. Packaging and Container Requirements

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 substances or cause modification to food content. Generally, food packages are exempt from registration, however 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). ABNT 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 Plastics Industry Association. For detailed regulatory information as well as links to the main associations of packaging and containers, access the ABNT homepage at www.abnt.org.br.

Section V. Labeling Requirements

Labeling of food and beverage products must be in accordance with the general legislation of labeling and warnings, as well as the specific laws applicable to the product category. The requirements are also found in 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.

When the product is meant to be further processed, the legislation does not require it to be labeled as a retail product would be. However, the exporter needs to supply the importer with all the necessary information. The information provided by the exporter does not necessary needs to be on the product

package (foodservice and industrial use packages), but at a minimum included on the documents that accompany the goods. The legislation does not impose a specific document, which means it can be the invoice, technical description sheet, etc.

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, per INMETRO Ordinance #157 of 2002)
 - Additional information required by technical regulations for 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 INMETRO, a sticker containing all the required information may be placed over the original label.

Other panels:

- List of ingredients
- Warnings
 - “Contains gluten” or “does not contain gluten”
 - Claim allergens: “contains...” (List the following ingredients as allergens: 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 nuts, macadamia nuts, pecans, pine nuts, chestnuts, and natural latex. The substance must be listed if it is detectable.)
 - “Avoid excessive consumption of alcohol”
 - Biotech content above 1 percent in its final composition must be indicated on the label.
- Country of origin
- Contact information for the manufacturer
- Contact information for the importer
- Cxpiration date (manufacture date only for animal-origin products)
- Lot number
- Care and handling information
- Instructions for use and preparation (if applicable)

- Percentage of alcohol content (for alcoholic beverages)
- Nutritional 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 Resolution #359 determines the serving size of each food and its corresponding household measures.

A serving is the average amount of food that should be consumed by healthy persons older than 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		% of Daily Requirement (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 (when applicable)	mg or µg	%

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

** daily requirement not established

Labeling Regulation Discussions

Currently, ANVISA is leading two discussions on food product labeling. The first is regarding an update of Brazil’s allergenic regulation. 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 a single ingredient would not have to provide a warning mentioning that same ingredient is contained in the product.

The second review is an initiative regarding labeling of nutritional information. According to ANVISA, an update is necessary to help consumers make healthier choices. Throughout 2017, ANVISA received proposals and technical inputs regarding designs for a new nutritional label. The proposal from “Rede Rotulagem” (an initiative that advocates for the “traffic light” scheme that uses a green, yellow, and red color-coding to indicate content of certain ingredients) seems to be preferred by the private sector. Rede Rotulagem is formed by the following 22 entities:

- Brazilian Food Processors (ABIA)
- National Confederation of Industries (CNI)
- Brazilian Association of Dairy Products (Viva Lacteos)
- Brazilian Association of Soda and Non-Alcoholic Beverages Producers (ABIR)
- Brazilian Association of Chocolate, Cocoa, Peanuts, Confectionery and By-Products (ABICAB)
- Sao Paulo State Union of Industries of Beef and By-Products (SINDICARNES - SP)
- Bahia State Union of Industries Dairy and By-Products (SINDILEITE)
- Brazilian Association of Vegetal Oil Processors (ABIOVE)
- Brazilian Association of Beverages (ABRABE)
- Brazilian Association of Food for Comercial Establishments (ABIAD)
- Brazilian Association of UHT Dairy Products (ABLV)
- Brazilian Association of Cheese Producers (ABIQ)
- Brazilian Association of Packaging (ABRE)
- Goias State Food Industries Union
- Brazilian Association of Processed Pastries, Mixes, Breads and Cakes (ABIMAPI)
- Brazilian Association of Animal Protein (ABPA)
- Brazilian Association of Food Ingredients and Additives (ABIAM)
- Brazilian Wheat Industry Association (ABITRIGO)
- Sugar Cane Industry Union (UNICA)
- Sao Paulo State Union of Pasta and Pastries Industry (SIMABESP)
- Brazilian Dairy Association of Small and Medium Cooperatives and Enterprises (G100)
- Brazilian Retail Association (ABRAS)

“TRAFFIC LIGHT” MODEL FOR NUTRITIONAL LABELING



Source: Rede Rotulagem

According to Rede Rotulagem, the model uses the words “HIGH,” “MEDIUM,” and “LOW” in capital letters on a red, yellow, and green background, respectively. They say this facilitates reading and comprehension by consumers. The model would highlight sugar, saturated fat, and sodium, and would be based on diet of 2,000 kcal/day. However, according to ATO contacts, it seems that ANVISA is more inclined towards the “alert” model. Brazilian regulators are expected to release new directives on this issue in the next year, which will be then subject to a public comment period.

“ALERT” MODEL FOR NUTRITIONAL LABELING



Source: ANVISA

More information can be found at:

www.portal.anvisa.gov.br/2017-2020/alimentos and www.portal.anvisa.gov.br/tomada-publica-de-subsidios.

Section VI. Other Specific Standards

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; or
- It has records of importation from a date before August 12, 1997.

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

The PRA process can be divided in three phases:

- Phase 1: START-UP. Involves identification of all disease pathways (hosts) and potential pests present in the exporting country, 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. 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 the 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 “Diario Oficial.”

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

Products classified as risk category zero (0) and one (1) are exempt from a 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 National Plant Protection Organization (NPPO) intervention and are not capable of transmitting pests in packaging material.
- Category 1: Plant products manufactured or devitalized due to the action of any technological process (cooking, blanching, pasteurization, sterilization, fermentation, or others) that changed them into products that will not directly be 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 – July 16, 2005, provided that it is from the same country of origin, serves the same use, has not presented a record of interception of quarantine pests to Brazil, and 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 the APHIS import and export database or with the APHIS office at 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 Instructions 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: <http://sistemasweb.agricultura.gov.br/siscole/consultaPublicaCadastro.action>.

The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) has the authority to certify labs and issue 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 qualified laboratories can be found at: www.ttb.gov/ssd/chemist_certification.shtml. For non-alcoholic beverages, ATO Sao Paulo should be the primary contact for U.S. companies to obtain specific information.

Organic Foods:

In order to export organic products to Brazil, foreign producers must comply with Brazilian regulations governing organic products. They must comply with Brazilian production standards and be certified by a MAPA-accredited compliance body. Foreign producers must be listed in the National Register of Organic Producers. In practical terms, this means that exporters must contract a local accrediting body to certify each organic product they intend to sell in Brazil.

The import process for organic products is similar to the standard import procedure. However, additional documents will be required by local authorities in order for the product to be sold as organic. Both domestic and foreign organic products must act in accordance with the organic legislation in force.

Labeling of organic products must follow the requirements below:

- Single-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 with a minimum of 95 percent of ingredients from certified-organic origin may be labeled “organic”
 - b. Products made with 70-95 percent of ingredients from certified-organic origin may 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

Any imported product subjected to quarantine treatment not compatible with Brazilian organic production regulation will lose its organic status. Since 2011, all organic products sold in Brazil must have the organic seal. The only exception is for products sold at street fairs or farmers markets, where the producer has been previously authorized by MAPA and products produced or imported before 2011.

Mandatory Seal for Organic Products



Source: MAPA

For additional information regarding Brazilian organic rules, please access:
[http://www.agricultura.gov.br/assuntos/sustentabilidade/organicos.](http://www.agricultura.gov.br/assuntos/sustentabilidade/organicos)

Section VII. Facility and Product Registration

MAPA’s Requirements for Meat, Dairy, and Seafood Products:

In order to export animal-origin products (beef, pork, powdered milk, whey, lactose, cheese, and seafood) to Brazil, MAPA mandates that U.S. processing plants 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 USDA Food Safety and Inspection Service (FSIS) for meat; the USDA Agricultural Marketing Service (AMS) for dairy; and the U.S. Department of Commerce’s National Oceanic and Atmospheric Administration/National Marine Fisheries Service (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 U.S. plants approved for export to Brazil. Registration of U.S. facilities can take

approximately 3 months. The request for registration of the U.S. plant with the Brazilian authority, DIPOA, must be done per the following procedures:

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

For more information: [Updated Plant and Label Registration Procedures for Beef Products](#)

- Dairy: registration under this category must be done directly through FAS/OAA, which requires a formal letter from the company to insert the producing plant in Brazil’s official list.

For more information: [Updated Plant and Label Registration Procedures for Dairy Products](#)

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

For more information: [Updated Plant and Label Registration Procedures for Fishery](#)

ANVISA’s Requirements for Processed 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 on 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 claims
Foods for weight control
Foods for nutrient-restricted 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 (including heart of palm), fruit products, and mushrooms
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 products
Packaging from new technologies (recycled, PET)
Novel foods and/or novel food ingredients
Bioactive substances and isolated probiotic and/or health claims

Meat, dairy, egg, honey, margarine, and fish products must be registered with MAPA in order to be exported to Brazil. The manufacturer must file a request for registration with the ministry.

Section VIII. Other Certification and Testing Requirements

All imported food products must be in accordance with the Brazilian legislation. It is recommended to perform a compliance study to determine whether products conform to all relevant Brazilian legislation, particularly the Technical Regulations (RT), limits on additives, and food-safety criteria. In the case of non-compliance, the product’s composition must be adjusted to meet regulatory requirements. Before shipping, exporters and importers must work together to guarantee documents are filled as required by Brazilian authorities. The following documents must be prepared before shipping:

- Pro-forma invoice
- Import license (LI), importer obtains from SISCOMEX (Foreign Trade Automated System) based on pro-forma invoice information
- Shipping instructions, must contain all documents to be submitted by the exporter to the importer:

- Certificate of Analysis and Certificate of Origin
- Bill of Lading
- Packing List

Before shipping goods to Brazil, exporters should be aware of wood pallets and wood packaging regulations. In general terms, pallets should be in compliance to International Standards for Phytosanitary Measures N° 15 (ISPM 15) standards and receive the International Plant Protection Convention (IPPC) stamp. For countries that have not adopted the ISPM 15 standards, the phytosanitary certificate may be substituted for the IPPC stamp, with an additional declaration on treatment records or the certificate of treatment stamped by the National Plant Protection Organization (NPPO). Wood pallets, both treated and untreated, are always inspected by MAPA. Inspectors will check for the presence of pests and may or may not release the cargo. Costs related to phytosanitary treatment or returning pallets/cargo to the country of origin will be under the exporter/importers' responsibility. Exporters should always confirm the full set of regulations with importers. More information can be found at:

<http://idg.receita.fazenda.gov.br/orientacao/aduaneira/manuais/despacho-de-importacao/legislacao/outras-normas/instrucao-normativa-mapa-no-32-2015>

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. A breakdown of MAPA and ANVISA's respective regulatory responsibilities is presented below:

MAPA	ANVISA
<u>Consumer-oriented products</u> Animal products: red meat and by-products, poultry meat and by-products, fish, seafood products, dairy products, eggs, honey, and margarine; Beverages: alcoholic and nonalcoholic (except energy drinks, hydroelectrolitic beverages, and soy beverages); Fruits and vegetables: dried, fresh, and processed	<u>Consumer-oriented products</u> Food: all consumer-ready or processed products, (except those under MAPA's authority) Beverages: energy drinks, hydroelectrolitic beverages, and soy beverages
<u>Intermediate products</u> Wheat flour, planting seeds, etc.	<u>Intermediate products</u> Sugar, sweeteners, mineral water, flavored waters, additives, and other ingredients (excluding those under MAPA's authority)
<u>Bulk commodities</u> Wheat, grains, rice, soybean, cotton, tobacco, pulses, peanuts, flour, etc.	

Pet food, feeds, and fodders	
Plants and seeds	
Animals, semen, and embryos	

There are a few steps to follow during the import process. The list presented below are the common actions needed to import food and beverage products. To fulfill local requirements, the exporter must work together with importer, particularly in the initial phase, when shipping documents are prepared. Upon product arrival, most import companies contract a customs agent who will be responsible for clearance formalities. Rules from each administrative agency must be observed prior to shipment, as it directly impacts market access for foreign goods. For additional information on import process please refer to the Exporter Guide BR18032.

GENERAL STEPS TO IMPORT FOOD AND BEVERAGE PRODUCTS

Prior Shipment

- Confirm whether registration or any specific action is needed prior to shipment.
- Confirm labeling requirements for the specific product.
- Confirm information to be included in the pro-forma invoice
- Obtain Import License (LI)
- Prepare shipping instruction

Once Cargo Arrives at the Port

- Cargo manifest
- Registration of Import Declaration (DI) with SISCOMEX. The DI is a document containing all information about the importation:
 - Importer data
 - Cargo data
 - Bonded warehouse data
 - Merchandise data
 - Negotiated payment terms
 - Federal taxes (Import Tax (II), Industrialized Products Tax (IPI), PIS, COFINS, and anti-dumping rights, as applicable); federal taxes are automatically debited from importer or customs agent account
 - State taxes – State Value Added Tax (ICMS); the ICMS is collected using the Form of State Collection (GAE), which is payable at any bank branch in Brazil. The Federal Revenue Service should receive the original payment evidence.
 - Additional information, as the case may be (for example, authorized customs agent)
 - The exchange rate of the negotiation currency, as determined by the Brazilian Central Bank
 - A detailed description of merchandise, according to the LI and the commercial invoice

Checking and release of cargo by MAPA/ANVISA inspector: The importer (or customs broker) must file a process with the MAPA/ANVISA Unit located at the point of entry of merchandise in Brazil, requesting the release of imported beverages.

Cargo Release

After the registration of DI, the Federal Revenue Service performs the parameterization in the SISCOMEX. The system performs the parameterization, and selects one of following channels:

- Green channel: exempts examination of documents and review of merchandise, and the release usually occurs in about a day.
- Yellow channel: only the review of records is required, and the release of merchandise takes place in about 2 days.
- Red channel: in addition to a review of documents, merchandise must be physically examined, and the release of the product takes place in about 4 days.
- Gray channel: this is a special customs control channel, and it may take more than 60 days after parameterization.

After the inspection, a Proof of Import (CI) is issued with the date of DI, importer, load, and customs clearance details. After the issuance of CI, the customs clearance process closes, and the merchandise can be picked up at the bonded warehouse.

- Clearance by MAPA/ANVISA for commercialization

Section X. Copyright and Trademark Laws

The National Institute of Industrial Property (INPI) is a federal agency linked to the Ministry of Industry, Foreign Trade, and Services (MDIC). INPI is responsible for registering patents, industrial designs, trademarks, and geographical indications, 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:

- by a waiver from the patentee;
- upon forfeiture or non-payment of annual fees;
- upon failure to observe of Law 9279 of May 14, 1996, article 217, which states “a person domiciled abroad must maintain permanently a duly-qualified attorney resident in the country, with powers to represent him administratively and judicially, including 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, 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 geographical indications. General information can be found on the INPI website: www.inpi.gov.br.

Discussion on Geographic Indications

Under the free trade agreement (FTA) being negotiated between Mercosul and the European Union (EU), the two blocs exchanged lists of geographical indications (GIs) intended to be recognized and protected under the trade deal. The EU presented a list of approximately 350 GIs, while Mercosul presented around 200 GIs. In 2017, Brazil submitted the EU list for public comment, but to date there is no conclusive decisions on the subject. According to contacts, the parties have already negotiated many of the GIs, but they have reportedly not reached agreement on the full list of GIs proposed by EU,

causing delays to finalizing the FTA. Part of the negotiated solution to many of the GIs has been a “grandfather clause,” allowing existing producers to continue using otherwise-protected GIs but banning new producers from using the terms. The final provisions for GI protection under an EU-Mercosul FTA remain unclear, as does its potential impact on sales of U.S. products to Brazil.

Brazil also recently proposed a Normative Instruction to establish the requirements for registering domestic GIs. The proposed regulation was open for public comment for 30 days, which ended on December 6, 2018. After analyzing the proposals, the National Institute of Industrial Property (INPI), the agency responsible for regulating this matter, will present the definitive text for the Normative Instruction.

More information can be found at: www.portalintelectual.com.br/revista-da-propriedade-industrial-rpi-2444-comunicados3-inpi/

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
Website: www.agricultura.gov.br

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

Ministry of Environment (MMA) Brazilian Institute
for the Environment and Natural Resources
(IBAMA)
SCEN, Trecho 2, Ed. Sede 70818-900
Brasilia, DF
Phone: (55-61) 3216-1212
Website: 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
Website: www.anvisa.gov.br

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

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

Appendix II. Other Import Specialist Contacts

ABIA
Brazilian Food Processors' Association
Av. Brigadeiro Faria Lima, 11 andar
01451-001 São Paulo, SP

ABIAM
Brazilian Food Ing. and Additives Assoc.
Rua Hungria, 664, cj. 51
01455-000 São Paulo, SP

Phone: (55-11) 3030-1353
E-mail: abia@abia.org.br
Website: www.abia.org.br

Phone: (55-11) 3034-3541
E-mail: abiam@abiam.com.br
Website: www.abiam.com.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, Sao Paulo
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