



Required Report: Required - Public Distribution

Date: December 11, 2023 **Report Number:** BR2023-0034

Report Name: FAIRS Annual Country Report Annual

Country: Brazil

Post: Sao Paulo ATO

Report Category: FAIRS Country Report

Prepared By: Alexandre Vendemiatti

Approved By: Megan Francic

Report Highlights:

The Food and Agricultural Imports Regulations and Standards (FAIRS) report provides an overview of the food laws and regulatory environment in Brazil as it relates to food and agricultural exports. This report is intended to be used in conjunction with the 2023 FAIRS Export Certificate Report for Brazil.

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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 PRODUCTS IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETADE BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY."

Executive Summary

Brazil's vast geography, large population, and abundant natural resources make it one of the world's most important agricultural producers and exporters. In calendar year (CY) 2022, Brazil imported \$13.3 billion of agricultural products and exported \$139.7 billion. The United States is the 4th leading supplier of agricultural products to Brazil. In CY22, the United States exported \$1.01 billion of agricultural and related products to Brazil, led by ethanol and wheat. U.S. exports are down to-date in CY23, as imports of U.S. ethanol and wheat have dropped significantly. Consumer-oriented products have registered growth, however.

In 2021, the National Agency of Sanitary Surveillance (ANVISA) began to modernize the food sector regulatory framework, aiming to update and simplify existing regulations to make the food registration process more efficient without compromising food safety. In April 2023, the analysis for public consultation 1.158/23 concluded, with the goal to create a new framework by the end of 2023 that will define regulations, facilitate innovation, and maintain competitiveness in the sector.

In addition, ANVISA finished reviewing and consolidating normative acts in compliance with Decree 10,139, dated November 28, 2019. This resulted in a reduction in obsolete normative acts and improvements to older normative acts. The objective of this government-wide project was to make the overall regulatory environment more business-friendly.

SECTION I. FOOD LAWS



Brazil is a member of the Common Market of the South ("Mercosul," in Portuguese) and the World Trade Organization (WTO). Mercosul, formed by Argentina, Brazil, Paraguay, Uruguay, Venezuela (currently suspended), and Bolivia (in the process of accession), is a customs union that allows duty-free access 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 (Chile, Colombia, Ecuador, Guyana, Peru, and Suriname), also enjoy duty-free agreements. As a founding member of the WTO, Brazil has incorporated WTO agreements into its legal framework. Brazil also follows Codex Alimentarius (CODEX) principles.

Food regulations issued at the federal level are

contained in various types of legal documents. To be implemented, they 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. The Brazilian constitution defines the relationship among federal, state, and municipal law. It also defines each federal branch of government (legislative, judicial, and executive). Legally, federal regulations must be followed when there are conflicts between federal, state, and municipal legislation. State and municipal governments have the authority to regulate and enforce state and municipal laws.

In the federal government, different agencies and ministries share jurisdiction to ensure food safety and regulate imports of agricultural commodities and foods. The Ministry of Agriculture and Livestock (MAPA) and the Ministry of Health (MS), through ANVISA, are the primary regulators of agricultural products. MAPA oversees and enforces many regulations related to production, marketing, import, and export of animal-origin products, fresh fruit and vegetables, organic products, alcoholic and nonalcoholic beverages, juices, grains, seeds, and animal feed (including pet food). ANVISA enforces most regulations for processed food products. MAPA and ANVISA's regulations are all online.

On <u>MAPA's website</u> (please note all links related to Brazilian food laws provided in this report are in Portuguese), the search tool SISLEGIS contains the current regulations for products under MAPA's supervision. There are two search tools on <u>ANVISA'S website</u>, VISALEGIS, and the "<u>Biblioteca de</u> <u>Alimentos</u>."

Other ministries and agencies involved in the monitoring and control of food safety include: the Ministry of Economy; the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) of the Ministry of the Environment (MMA); the National Institute of Metrology, Quality, and Technology (INMETRO), which functions under the MMA; the National Technical Commission on Biosafety, which is an inter-ministerial commission based in the Ministry of Science, Technology,

Innovation, and Communication (MCTIC); the Department of Consumer Protection and Defense (DPDC) within the Ministry of Justice; and the Ministry of Fisheries and Aquaculture.

Importers and exporters must always observe the set of rules each administrative agency releases. Although the Brazilian Congress is responsible for rulemaking, the power delegated to the ministries and their various branches is considerable. They implement the law and define the procedures that must be followed in greater detail. In terms of sanitary legislation enforcement, the principle of "positive legislation" is in place. That is, only that which is expressly established can be practiced and that which is not expressly addressed is prohibited.

SECTION I.I. MAPA

MAPA is responsible for formulating and executing all policies related to Brazilian agribusiness development, as it safeguards animal and plant health. MAPA's functions include regulating, classifying, and inspecting imported agricultural products. The Secretariat of Agricultural Protection (SDA), and the Secretariat of Trade and International Relations (SRI) primarily enforce MAPA's regulatory activities of interest to this report.

SDA

SDA 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) and organic goods. Its main departments include:

Department of Animal Origin Products Inspection Service (DIPOA)

DIPOA is responsible for ensuring that all animal-origin products (meat derived from cattle, sheep, swine, goats, horses, game meat, poultry, dairy products, eggs, seafood, honey, and other products with more than 50 percent 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 two groups of products. Group one is alcoholic and non-alcoholic beverages, such as distilled spirits, wine, juices, soft drinks, carbonated drinks, ready-to-drink teas, and vinegars (except water, sports drinks, and energy drinks). Group two is fresh fruits and vegetables, grains, seeds, and by-products, which includes wheat flour, some vegetable oils, and margarine). The General Coordination for Wine and Beverages is responsible for group one while the General Coordination for Vegetable Quality is responsible for group two.

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 also enforces federal laws and regulations to protect and improve animal health, defends Brazilian borders against new foreign animal diseases, and controls and eradicates existing animal diseases through programs such as the Foot and Mouth Disease Eradication Program. DSA 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. DSA also regulates the use of veterinary products.

Department of Plant Health and Agricultural Inputs (DSV)

DSV is responsible for protecting plant health and preventing the introduction and spread of foreign pests within Brazil. DSV is also responsible for the regulatory inspection and registration of all planting seeds (including seeds derived from biotechnology) and establishing standards for agricultural products such as grains, fruits, and vegetables.

- Organic Production Coordination (CPOR)
 CPOR regulates the organic sector from production through processing and trade.
- General Coordination of the International Agricultural Surveillance System (CGVIGIAGRO)

CGVIGIAGRO is responsible for the 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.

SECTION I.II. MMA

Within MMA, IBAMA is the regulatory authority for activities that affect the environment. IBAMA is one of the key government agencies involved in the approval of agricultural chemicals (pesticides and herbicides). It exercises joint authority with ANVISA, which is concerned with the toxicology aspects of agricultural chemicals, and MAPA, which provides the registration for pesticides.

IBAMA's review is concerned with the possible environmental impact of pesticides. Generally, it follows recommendations by international standard-setting organizations like CODEX and works closely with its U.S. counterpart, the Environmental Protection Agency. It is the agency responsible for monitoring and enforcing activities that affect Brazil's plants and animals and also enforces the treaties established at the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Regulatory rules are located <u>here</u> and <u>here</u>.

SECTION I.III. MINISTRY OF ECONOMY

All food products imported or exported by Brazil require registration through the Secretariat of Foreign Trade (SECEX). SECEX is part of the Ministry of Economy, formerly known as the Ministry of Industry, Foreign Trade, and Services and 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 now Ministry of Economy (former Ministry of Finance) and the Brazilian Central Bank has 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. 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 to obtain access to the SISCOMEX.

INMETRO, another entity under the Ministry of Economy, tests domestic and imported products (industrial and food products) to ensure they meet label specifications and packaging material safety regulations. INMETRO executes national metrology policies, including indicating the content of packages, standardizing the weight of products, and defining units of measurement of products. INMETRO also oversees the quality and safety of products included as gadgets or toys in food products.

Information on INMETRO can be found on their <u>homepage</u>. Other related legislation and procedures can be found on their <u>"Diario Oficial."</u>

SECTION I.IV. MINISTRY OF JUSTICE

The DPDC within the Ministry of Justice is the federal agency responsible for enforcing the Brazilian Consumer Code, published in 1990. The code regulates consumer claims against adulterated food products, incorrect or misleading labels, and fraud. Each state in Brazil has a DPDC office that directly assists consumers. For additional information on the Ministry of Justice's consumer department, please see the Ministry of Justice's homepage. Other Brazilian federal regulations regarding the Ministry of Justice can be found on their **Error! Hyperlink reference not valid.**

SECTION I.V. REGULATORY FRAMEWORK UPDATES

ANVISA Review of Normative Acts

ANVISA finished reviewing and consolidating normative acts in compliance with Decree 10,139, dated November 28, 2019. This initiative resulted in a 52 percent reduction in obsolete normative acts, as well as improvements to older normative acts. Out of 1,932 acts reviewed, 742 remained unchanged and 187 consolidated acts were published. All changes were aimed at improving the wording and form of normative acts to provide more clarity without altering the merits of the contents. Different legislations that dealt with the same topic, such as food labeling, were grouped into a single legislation. This review also grouped the provisions of different food categories into a single legislation.

Modernization of the Regulatory Framework

The modernization of the food sector regulatory framework aims to update and simplify existing regulations to make the food registration process more efficient without compromising food safety. In April 2023, the analysis for <u>Public Consultation 1.158/23 concluded</u>, with the goal to create a new framework that will define regulations, facilitate innovation, and maintain competitiveness in the sector by the end of 2023. The analysis demonstrated the regulation of new foods and ingredients is outdated and has gaps, resulting in unnecessary barriers to the commercialization of new products in the market, and legal uncertainty.

To launch a new product in Brazil, companies must submit several documents, including a stability study for all food categories with mandatory notification, which includes, among others, all food supplements. See this <u>link</u> for the proposed food categories and regularization procedures.

In all food regularization procedures under ANVISA, for imported products it will be necessary to present a document that proves the manufacturer's regularity with the health authority of the country of origin. This document is currently not required.

To speed up the approval process of new ingredients and foods with claims of functional and/or health properties, ANVISA approved the general criteria for Admissibility of Analysis carried out by a Foreign Regulatory Authority (Resolution RDC No. 741/2022). ANVISA will take advantage of the analyses carried out by foreign regulatory authorities in the product registration approval processes, which will help accelerate procedures.

SECTION II: 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; however, before the application of the label, it is important to ensure the product composition is in accordance with Brazilian legislation.

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 can be on something other than the product package (food service and industrial use packages), but at a minimum, included on the documents that accompany the goods. The legislation does not impose a specific document, such as 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 flavor and coloring
- Weight/volume indication (note the minimum height of figures and letters indicated in the table below, per INMETRO Ordinance #249 of 2021) (Table 1)
- Additional information required by technical regulations for each product

The label must be in Portuguese. Stickering is allowed. It should contain all the required information and be affixed to the back of the product.

Table 1: Minimum Font Height for Food and 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		

Source: ATO Sao Paulo based on INMETRO information

The letters used for writing unit-of-measure symbols must have a minimum height of 2/3 of the size of the numbers. 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 and other alerts are defined by specific technical regulations:
 - o "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.)
 - o "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
- Expiration date
- 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 #429 and Normative Instruction ANVISA #75 of 2020)
- Other information required by specific technical regulations

It is important to be aware that other requirements must be followed for specific food product categories. Importers should always be consulted before shipping products into Brazil.

Nutritional Labeling

On October 9, 2020, the Brazilian Official Gazette published the Resolution of the <u>Collegiate Board 429</u> and <u>Normative Instruction 75</u>, which refer to the new regulations for nutritional labeling of packaged food. The new rules aim to facilitate nutritional information and lead consumers to make more conscious food intake decisions. The new legal framework established significant changes in the legibility of information, content, and how information must be displayed on the nutritional tables. It also covers nutritional claims; however, the largest change was the adoption of the front of panel labeling. Under the new regulation, warnings must be placed on the front panel of packaged foods using simple and clear icons to emphasize high contents of saturated fat, added sugar, and sodium (Table 2 and Figure 1). According to ANVISA, these three nutrients were chosen because they are the most critical to consumer health.

The new model does not include warnings for non-caloric sweeteners. Alcoholic beverages have been exempted from displaying nutritional labels in the past. In the new set of regulations, ANVISA states that nutritional labels are mandatory for the majority of beverages, including non-alcoholic beverages,

and adds that nutritional labeling is voluntary for alcoholic beverages. In this case, the producer may include the nutritional table in its totality or just the energy value.

Table 2: Minimum/Maximum Levels to be Considered High in Added Sugar, Saturated Fat, or Sodium

Nutrient	Limits for Solids and Semi-Solids Foods	Limits for Liquid Foods	
Added Sugar	Equal or above 15g of added sugar per 100g of	Equal or above 7.5g of added	
	food.	sugar per 100ml of food.	
Saturated Fat	Equal or above 6g of saturated fat per 100g of	Equal or above 3g of saturated	
	food.	fat per 100ml of food.	
Sodium	Equal or above 600mg of sodium per 100g of	Equal or above 300mg of sodium	
	food.	per 100ml of food.	

Source: ATO table based on ANVISA information

Figure 1: Model Labels on Mandatory Warning for Nutrients



Source: ATO Sao Paulo based on ANVISA information

Timeframe for Implementation and Compliance

There is a phased-in timeline for labeling compliance (Figure 2):

- On October 9, 2022, the new labeling regulation went into effect (products manufactured before the regulation may be marketed until their expiration date).
- From October 9, 2023, 12 months after the regulation went into effect, all products manufactured from this date must comply with the new regulation.
- On October 9, 2024, 24 months after the regulation goes into effect, small companies must comply with the new regulation. (One additional year is given to small companies such as small family farmers, rural entrepreneurs, micro-entrepreneurs, individuals, small-sized agro-industries, artisanal industries, or artisanal productions.)
- On October 9, 2025, 36 months after the regulation goes into effect, non-alcoholic beverages in reusable packages must comply.
- For imported products, it will be taken into consideration the date when the product was produced. This legislation is subject to Mercosul harmonization, even though Brazil has approved a different version from other Mercosul countries. Discussions are ongoing.

Figure 2: Timeline for Labeling Compliance



Source: ANVISA

Table of Nutritional Information

For the table of nutritional information, it will be mandatory to use a black font and white background (Figure 3). The information presented must meet legibility criteria, including type of font (Arial or Helvetica), font size, line spacing, and compression criteria, in addition to pre-defined formats that must be followed. Total sugars and added sugars, as well as information on 100g or 100ml of the product and per serving, and the indication of the number of servings per package, will be mandatory. It will also be mandatory to place the table of nutritional information close to the list of ingredients. It will not be permitted to cover, break, or display the table in areas of difficult reading or areas where the package's nature may deform. The only accepted exception will be for products with a small display area (below 100cm2). It will be permitted for such products to display nutritional information in covered areas; however, it must be accessible to consumers.

Figure 3: Model Nutritional Information

NUTRITIONAL INFORMATION			
Servings per package: 000 servings			
Serving: 000 g or ml (household measure)			
	100 g	Serving	%VD*
Energy Value			
(kcal)			
Carbohydrates (g)			
Total Sugars (g)			
Added Sugars (g)			
Proteins (g)			
Total fat (g)			
Saturated fat (g)			
Trans fat (g)			
Dietary Fibre (g)			
Sodium (mg)			
*Percentage of daily value provided by the			
serving.			

Source: ATO Sao Paulo based on ANVISA information

Note: The regulation permits the table of nutritional information to be presented in different models, vertical, horizontal, aggregating up to three products, using two columns, and linear, in the case there is not enough space for the table.

Claims

Under the new regulations, the major requirements for claims are:

- Foods that display a frontal label for added sugar cannot have claims for sugars or added sugars.
- Foods that display a frontal label for saturated fat cannot have claims for total fat, saturated fat, trans fat, or cholesterol.
- Foods that display a frontal label for sodium cannot have claims for sodium or salt.
- It will not be allowed to place claims on the superior part of the main panel if the product has frontal nutritional information.

SECTION III: PACKAGING AND CONTAINER REGULATIONS

Regulations on food packaging and containers fall under ANVISA. ANVISA establishes quality and identity standards for materials and equipment in contact with foods, such as plastic, glass, metal, ceramic, and cellulosic products. The agency's objective is to guarantee that packaging materials do not contain toxic substances or cause modification to food content. Generally, food packages and equipment 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 must send a petition to ANVISA and request inclusion on the list, which is subject to ANVISA's approval.

The Brazilian Association of Technical Standards (ABNT) is also a founding member of the International Organization for Standardization, the Mercosul Standardization Association, and the Pan American Commission for Technical Ruling. 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 <u>ABNT homepage</u>.

All materials in contact with food must comply with Mercosul technical resolutions. Similarly, reviews and new resolutions must be approved under the bloc's regulatory scheme. The rules that regulate the packaging of food and beverage products are located <u>here</u>.

Packaging Sustainability Measures

Brazil does not have a set of rules addressing packaging sustainability measures; however since 2011, the Brazilian Packaging Association has a memorandum with the MMA within the Plan for Sustainable Production and Consumption, which provides for the inclusion of selective disposal symbols on the packaging of 1,000 products per year. The main goal is to educate consumers about the proper disposal of packaging waste. This voluntary initiative is associated with the National Solid Waste Policy, involving private and public players. The recycling symbols are found in ABNT Technical Rule NBR 16,182/2013.

SECTION IV: FOOD ADDITIVE REGULATIONS

ANVISA defines food additives as any ingredient, without nutritional benefits, which was deliberately added to food to modify its physical, chemical, biological, or sensorial characteristics during any stage (e.g., processing, storage, handling, or transportation). Before approval for consumption, any food additive is analyzed separately 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 allow 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 into the food regulatory framework may include restrictions on 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 ensure that the final product and the product's ingredients, which includes any additives and processing aids, comply with local legislation. Brazilian legislation divides food products into categories, with allowable additives for each. More information on the regulatory framework for additives is available <u>here</u>.

ANVISA has a <u>new tool</u> with information on approved ingredients and foods, including enzymes and probiotics. This platform, designed in a panel format, enables users to search by ingredient name or purpose of use. Users can explore various categories, including sugars, amino acids, carbohydrates, copolymers, enzymes, spices, dietary fibers, lipids, minerals, oligosaccharides, other nutrients, probiotics, proteins, bioactive substances, and vitamins.

SECTION V: PESTICIDES AND OTHER CONTAMINANTS

Brazil follows international standards for tolerances of pesticides, herbicides, and fungicides on agricultural products and uses CODEX as a general reference. The Codex Alimentarius Committee of Brazil represents the country in international CODEX Committees and advocates for the use of CODEX standards in the country.

Based on CODEX norms, a three-party committee composed of MAPA, IBAMA, and ANVISA reviews registrations for agricultural chemicals. ANVISA provides toxicological analysis and establishes maximum tolerance levels, IBAMA evaluates environmental impact, and MAPA is the initial point of contact in the product registration process and grants final approval after receiving inputs from ANVISA and IBAMA.

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 from domestic and imported fruits and vegetables. Imported products must comply with the same requirements established for local products.

A list of approved pesticides may be found in the <u>Agrofit System</u> on MAPA's home page.

Maximum tolerance levels for pesticides can be obtained on ANVISA's webpage.

General information about pesticide regulations may be found here.

SECTION VI: OTHER REQUIREMENTS, REGULATIONS AND REGISTRATION MEASURES

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 (APHIS)/Plant Protection and Quarantine phytosanitary certificate. Frozen fruits and vegetables do not need a phytosanitary certificate. U.S. exporters should always confirm if there is a need to conduct a pest risk analysis (PRA) of the product before exporting to Brazil.

PRAs

The importation of plant species, their parts, products, and by-products are regulated by MAPA, due to the risk of the introduction of exotic pests into Brazil. MAPA may define import requirements based on product risk category, historical interception data, and risk assessment. A PRA 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 new use.
- It is from a new country of origin; or
- It has records of importation from a date before August 12, 1997.

The MAPA Department of Plant Health and Agricultural Inputs (DSVIA) will carry out the PRA according to MAPA-approved standards. Should a PRA be necessary, the interested party must contact DSVIA or its superintendents at the state level to initiate the process.

The PRA process occurs in three phases:

- Phase I: START-UP
 - 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 they meet the criteria to be considered quarantine pests or not. 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 will be 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, ONPF will send a Regulatory Act specifying import parameters to their counterpart in the country of origin. 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 its costs.

Products classified as risk categories "0" and "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 other) 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, if 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 are considered allowed into Brazil. Products considered enterable under this condition are listed as <u>Vegetal Products with Authorized Importation on MAPA's webpage</u>.

U.S. exporters should always check the <u>APHIS import and export database</u> 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 DSA. 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 DSA. 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 67 of November 5, 2018, updated import procedures for beverages, fermented beverages, wines, grape, and wine by-products establishes formats for the certificate of analysis, certificate of origin, and certificate of typicity. On December 30, 2019, MAPA published the <u>Consolidated Regulations for Beverages</u>, <u>Vinegar</u>, <u>Wines</u>, and <u>By-products of Grape and Wine</u> which updated analytical parameters for beverages.

MAPA also requires a list of entities eligible to issue these documents from exporting countries. The list of laboratories and entities that are currently issuing certificates of analysis, typicity, and origin for beverages intended to be exported from the United States to Brazil can be found <u>here</u>.

The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) has the authority to certify labs and issue certificates of origin and typicity for alcoholic beverages. If a lab approved by TTB is not included on MAPA's list, TTB can request an update. TTB's has lists of qualified laboratories for <u>wine</u>, <u>beer</u>, and <u>distilled spirits</u>.

For non-alcoholic beverages, ATO Sao Paulo should be the primary contact for U.S. companies to obtain specific information. Contact information can be found at the end of this report.

Through Ordinance 586, dated May 16, 2023, MAPA updated Normative Instruction 15, dated March 31, 2011 and Normative Instruction 29, dated September 19, 2012. The regulations now require that imported distilled spirits provide official proof of typicity and regionality, if applicable, in accordance with the stipulations outlined in Article 82 of Decree 6,871, issued on June 4, 2009. Ordinance 586 came into effect on July 3, 2023, and all distilled spirit products imported after this date must adhere.

MAPA's Facility Requirements for Meat, Dairy, and Seafood Products

To export animal-origin products (beef, beef products, beef offal, pork casings, powdered milk, whey, lactose, cheese, and seafood) to Brazil, MAPA mandates that U.S. processing plants be inspected by federal agencies. The Brazilian government has approved 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 up to one month. The request for registration of the U.S. plant with the Brazilian authority, DIPOA, must be done per the following procedures:

- Meat: all beef 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. Please refer to GAIN report <u>BR2022-0024</u> for additional information.
- Dairy: the producer (dairy plant) must make a formal request to AMS, submitting a "Letter of Request for Approval." AMS will then contact the OAA and request the registration be included in Brazil's official list. Please refer to GAIN report <u>BR2022-0023</u> for more information.
- Seafood: all fishery plants must prepare a formal request to NOAA, which will contact the OAA and
 request the registration be included in Brazil's official list. It is recommended that Health
 Certificates are filled out in English and Portuguese. Please refer to GAIN report <u>BR2022-0025</u> for
 additional information.

ANVISA's Requirements for Processed Food and Beverage Products

ANVISA establishes the procedures for registration and exemption of registration for imported food products. The objectives of these rules are to provide guidance to importers and to improve ANVISA's efficiency in coordinating public health actions for imported food products. Products under ANVISA jurisdiction are classified into two categories: products with mandatory registration; and products exempt from registration (Table 3).

Product	Enteral	Foods	Supplements	Foods	Novel	Desalinated,	Packaging
	feeding	for	with	with	Foods/Novel	potable and	from New
	products	infants	probiotic	functional	Ingredients	bottled	Technologies
			and/or	and/or		water	(recycled,
			enzymes	health			PET)
				claims			
Notes	Products under ANVISA n		ANVISA mus	t approve	Safety approval is required		Specific
	these cate	gories	safety and effi	cacy.	for these categories.		composition
	addresses						is required
	vulnerable	e			Products unde	r these	
	consumer	groups.			categories may	y require	
					market data, s	tudies for risk	
	When a novel				level and scien	ntific	
	ingredient	t is			evidence.		
	added, sat	fety and					
	efficacy n	nust be					
	approved.						
Sources A7	TO Sao Daulo		•		•		

Table 3: Products with Mandatory Registration

Source: ATO Sao Paulo

If the product is allowed to be marketed, the legal representative of the exporting company established in Brazil, 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 sanitary authority (state or municipality) 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 in terms of revenue. 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 the local sanitary authority through a simplified system. The local sanitary authority also performs sanitary inspections and controls all products at point of sale.

It is possible to request the inclusion of new additives and processing aids, as well as request the use of additives already approved in other food categories, if the requirements defined in ANVISA's guides are observed. For food categories that have additives legislation harmonized by Mercosul, any update must be carried out in the Mercosul forum. Likewise, it is possible to update technical regulations and request changes or inclusions of ingredients, composition, and quality parameters, observing instructions set by ANVISA. The set of regulations is dynamic, with the regulated sector industry and market demands driving updates.

SECTION VII: OTHER SPECIFIC STANDARDS

Organic Foods

To export organic products to Brazil, foreign producers must comply with Brazilian regulations governing organic products, including 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, 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 for the product to be sold as organic. Both domestic and foreign organic products must act in accordance with the organic legislation in force. Any imported product subjected to quarantine treatment not compatible with Brazilian organic production regulation will lose its organic status.

Labeling of organic products must meet the following requirements:

- 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:
 - Mixed products with a minimum of 95 percent of ingredients from certified-organic origin may be labeled "organic."
 - Products made with 70-95 percent of ingredients from certified-organic origin may be labeled as "products with organic ingredients." Water and salt should not be considered when calculating the percentage of organic ingredients.

Since 2011, all organic products sold in Brazil must have the organic seal (Figure 4). 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.

Figure 4: Mandatory Seal for Organic Products



Source: MAPA

The "organic seal" may be obtained through an Organism of Conformity Evaluation. In Brazil, the Associação de Certificação Instituto Biodinamico and Ecocert are the major institutions accredited by MAPA (Figure 5).

Figure 5:



Source: IBD and Ecocert Brasil

Visit MAPA's organics page for additional information regarding Brazilian organic rules.

Vitamin Enrichment Requirements

In 2018, through the <u>RDC 243</u>, ANVISA created a "food supplements" category, and products previously classified in other food groups migrated to food supplements. Foods for athletes, foods for pregnant woman, and vitamin and mineral enriched foods fell into in this category. ANVISA defined more specific requirements, including minimum and maximum limits, indicated individuals to consume these products, authorized ingredients, and claims with scientific evidence. ANVISA provided a five-year grace period for companies to adhere to the new regulation, which concluded in July 2023. For products with mandatory registration, ANVISA must approve all alterations to comply with the new regulation. Find more information here.

Dietetic or Special Use Foods

In general, ANVISA is responsible for regulating and registering some categories of dietetics or foods for special dietary uses (e.g. enteral formulas and infant foods). The National Health Surveillance System regulates these products based on rules established by ANVISA and in the regularization of foods for special purposes that are exempt from registration (e.g., dietary sweeteners, foods for nutrient-restricted diets). MAPA is responsible for regulating dairy products formulated for lactose-restricted diets. The main reason for regulatory intervention by ANVISA is to ensure the safety, quality, and the efficacy of foods for special dietary uses available in the market.

Halal/Kosher

The Brazilian government does not have a role in the certification process of halal and kosher foods. These processes fall under the responsibility of certification companies accredited by the respective religious authorities or government bodies from countries that follow halal/kosher rules. The Arab Brazilian Chamber maintains a <u>list of associated entities eligible to issue a halal certificate</u> in Brazil. For kosher certification, the process starts with a Jewish entity eligible to conduct this type of service.

Plant-Based Meat and/or Dairy Alternatives

MAPA recently closed <u>public consultations</u> (SDA/Mapa No. 831/2023) regarding establishing minimum identity and quality requirements, labeling rules, and the obligation to register with MAPA for plant-based analogous products. Despite existing regulations for processed and industrialized foods, which also apply to plant-based products, there are no specific regulations in Brazil for plant-based products, especially concerning identification standards and nomenclature.

SECTION VIII: TRADEMARKS, BRAND NAMES, AND INTELLECTUAL PROPERTY RIGHTS

The National Institute of Industrial Property (INPI) is a federal agency responsible for registering patents, industrial designs, trademarks, and geographical indications, among other industrial property and related rights. Under INPI regulations, the registration of patents is valid for 15 (patent of utility model) to 20 years (patent of invention) from the application date. A patent could become extinct if some of the following situations occur:

- waiver from the patentee
- forfeiture or non-payment of annual fees
- failure to observe 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.

Geographic Indications (GIs)

Use of GIs is restricted to the producers and providers of services established in the locality. There are also quality requirements, referring to appellations of origin. INPI will establish the conditions of registration for GIs. General information can be found on the <u>INPI website</u>.

Under the free trade agreement negotiated between Mercosul and the European Union (EU), Mercosul will recognize 355 EU GIs, while Brazil will have 38 GIs protected in the EU. The agreement has not been ratified and is currently on hold. More information can be found <u>here</u>.

SECTION IX: IMPORT PROCEDURES

MAPA	ANVISA
Consumer-Oriented ProductsAnimal products: red meat and by-products, poultrymeat and by-products, fish, seafood products, dairyproducts, eggs, and honey.Beverages: alcoholic and nonalcoholic (except energydrinks, non-dairy beverages such as soy, almond, etc.)Fruits and vegetables: dried and freshMargarineIntermediate ProductsWheat flour, planting seedsVegetable oils (soy, cotton, canola, corn, sunflower)	Consumer-Oriented ProductsFood: all consumer-ready or processedproducts (excluding those under MAPA'sauthority)Beverages: energy drinks, non-dairybeverages such as soy, almond, etc.Intermediate ProductsSugar, sweeteners, mineral water, flavoredwaters, additives, and other ingredients(excluding those under MAPA's authority)Oils (excluding those under MAPA'sauthority)
Bulk Commodities Wheat, grains, rice, soybean, cotton, tobacco, pulses, peanuts, flour	
Others Pet food, feeds, and fodders Plants and seeds Animals, semen, and embryos	

Source: ATO Sao Paulo

The list below presents the common actions needed to import food and beverage products into Brazil. To fulfill local requirements, the exporter must work together with importer, particularly in the initial phase, when preparing shipping documents. 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. For additional information on the import process, please refer to the Exporter Guide 2022.

GENERAL STEPS TO IMPORT FOOD AND BEVERAGE PRODUCTS

Prior to Shipment

- Confirm if product complies with Brazilian regulations
- 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
- Prepare shipping instructions

Once Cargo Arrives at the Port

- Cargo manifest
- Registration of import declaration (DI) with SISCOMEX. The DI contains:
 - Importer data
 - Cargo data
 - Bonded warehouse data
 - Merchandise data
 - Negotiated payment terms
 - Federal taxes (import tax, industrialized products tax, 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, which is payable at any bank branch in Brazil. The Federal Revenue Service should receive the original payment evidence.
 - Additional information, as required (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 import license and the commercial invoice
- Inspection and release of cargo by MAPA/ANVISA
 - The importer or customs broker must file with the MAPA/ANVISA Unit located at the point of entry in Brazil, requesting the release of imported goods.
 - After inspection, SISCOMEX issues a proof of import (CI) with the date of the 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.

Cargo Release

After the registration of DI, the Federal Revenue Service performs the parameterization in the SISCOMEX:

- Green channel: exempt from examination of documents and review of merchandise. Release usually occurs in a day.
- Yellow channel: only the review of records is required. Release occurs in approximately two days.
- Red channel: in addition to a review of documents, merchandise must go through physical examination. Release occurs in approximately four days.
- Gray channel: this is a special customs control channel, and it may take more than 60 days to release the cargo after parameterization.

Wood Pallets

Before shipping goods to Brazil, exporters should be aware of wood pallets and wood packaging regulations. In general terms, pallets should comply with International Standards for Phytosanitary Measures N° 15 (ISPM 15) standards and receive the International Plant Protection Convention (IPPC) stamp. As the United States has adopted ISPM 15, USDA, in coordination with the wood packaging material industry, has developed an export program to guarantee U.S. companies comply with the importation requirements of foreign countries. More information is located <u>here</u>.

For countries that have not adopted the ISPM 15 standards, a phytosanitary certificate may be substituted for the IPPC stamp, with an additional declaration containing treatment records or the certificate of treatment stamped by the 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 the exporter/importers' responsibility. Exporters should always confirm the full set of regulations with importers.

SECTION X: TRADE FACILITATION

Conducting business in Brazil can pose challenges due to the complex regulatory landscape. U.S. companies frequently encounter regulations that are perceived as duplicative, and sometimes arbitrary, and serve as trade barriers for U.S. products in Brazil. To succeed, U.S. companies should collaborate with Brazilian partners and showcase their commitment to the Brazilian market.

On February 2, 2022, the <u>U.S.-Brazil Protocol Relating to Trade Rules and Transparency</u> entered into force, updating the existing Agreement of Trade and Economic Cooperations. It encompasses commitments in three areas: trade facilitation, good regulatory practices, and anti-corruption.

According to the <u>WTO Trade Policy Review</u>, Brazil continued to streamline foreign trade formalities and enhance SISCOMEX during the review period under its single window program (Programa Portal Único de Comércio Exterior). Initiated in 2014 and jointly overseen by SECEX and the Special Secretariat of the Federal Revenue of Brazil, the program aims to reduce the time and costs associated with importing, exporting, and transiting goods. The development of SISCOMEX has focused on further aligning customs and other border agencies' procedures, expediting information flows, and expanding the utilization of information technology and risk management solutions.

According to the WTO, the average customs clearance time for imports at all Brazilian entry points has consistently decreased. It went from 34.16 hours in 2016 to 23.44 hours in 2017, slightly increased to 23.89 hours in 2018, and then decreased to 19.52 hours in 2019, 18.50 hours in 2020, and 15.32 hours in 2021.

APPENDIX I: GOVERNMENT REGULATORY AGENCY CONTACTS

Ministry of Agriculture and Livestock (MAPA)

Esplanada dos Ministerios, Bloco D 70043-900, Brasilia, DF Phone: +55 61 3218-2510/2468 Website: www.gov.br/agricultura/pt-br

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

APPENDIX II: OTHER IMPORT SPECIALIST CONTACTS

Brazilian Food Processors' Association (ABIA)

Rua Butanta, 336, 3rd floor 05424-000, Sao Paulo, SP Phone: +55 11 3030-1353 E-mail: <u>abia@abia.org.br</u> Website: <u>www.abia.org.br</u> Brazilian Food Ingredients and Additives Association (ABIAM) Rua Hungria, 664, cj 51 01455-000 Sao Paulo, SP Phone: +55 11 3034-3541 Email: <u>abiam@abiam.com.br</u> Website: <u>www.abiam.com.br</u>

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 Phone: +55 11 3250-5400 E-mail: <u>atosaopaulo@usda.gov</u> Home Page: <u>www.usdabrazil.org.br</u>

Attachments:

No Attachments

Office of Agricultural Affairs (OAA)

U.S. Embassy Av. das Nações, Quadra 801, Lote 3 70403-900 Brasília, DF Phone: +55 61 3312-7000 E-mail: <u>agbrasilia@usda.gov</u> Home Page: <u>www.usdabrazil.org.br</u>