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## **Report Highlights:**

On October 2022, Brazil adopted the Front of Panel Nutritional Label, which has been under discussion since 2014. The two major government regulators for agricultural goods, the National Agency of Sanitary Surveillance (ANVISA) and the Ministry of Agriculture Livestock and Food Supply (MAPA), have also concluded the great majority of the task of reviewing and consolidating the comprehensive set of regulations related to technical and administrative procedures; however, there are still ongoing public consultations, and those are expected to be concluded in 2023. In 2023, a new government will be in place; therefore, changes in the structure of MAPA and ANVISA are expected to occur, which may affect business as currently established.

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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 elected Luiz Inacio Lula da Silva as its next President. From January 2023, President Lula makes the return of a left-leaning government after four years of far right-administration. This will be President Lula third mandate after governing the country between 2003 and 2010. This victory is a stunning personal comeback for Lula after the Supreme Court annulled a series of corruption allegations and imprisonment, restoring his right to run for the Presidency.

President Lula will find an economy that is still recovering from the effects of the COVID-19 pandemic. Brazil's economic forecast is challenging. The new Administration will face modest Gross Domestic Product (GDP) growth, the urgency to implement fiscal reforms, and address social programs to support the poor. Another major challenge is the political environment in Brazil. Polarization was a prominent component in this election. For good or bad, Lula will be watched closely by his opponents, which will leave the new President with little room for mistakes.

President Bolsonaro's administration predicts a 2.5 percent GDP growth for 2023. However, the uncertain climate surrounding the fiscal policy for next year is dominating discussions. The Proposed Amendment to the Constitution (PEC) currently being discussed by the Transition Team is the most uncertain element as it authorizes expenditures above the ceiling for the next year. This unknown climate is already making analysts discuss a scenario with higher inflation and an increase of the interest rate. The delays in naming the Minister of Finance put extra pressure on the scenario. The market expects the Ministry of Finance to be the first cabinet to be defined as it sends a clear message of what will be the economic policy under President Lula.

In 2022, exports of overall U.S. agricultural goods to Brazil increased 54.3 percent from January-September, reaching US\$792.3 million, pushed by grains and ethanol, while consumer-oriented products registered a 34.4 percent growth, amounting US\$203.6 million. Importers expect the same levels of trade in 2023. In terms of bureaucracy, some measures implemented by President Bolsonaro, such as Decree #10,139 of November 28, 2019, mandating the review and consolidation of all normative acts, will continue to set the tone in terms of transparency. In 2021, the Ministry of Agriculture, Livestock and Food Supply (MAPA) and National Agency of Sanitary Surveillance (ANVISA) reviewed and updated the great majority of their respective legal framework related to food products, nevertheless, the two government bodies continued this process throughout 2022.

#### **Section I. Food Laws**



Brazil is a member of the Common Market of the South (Mercosul as referred to 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 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. As a founding member of the WTO, Brazil has incorporated WTO agreements into the Brazilian legal framework. From the agricultural perspective, Brazil follows the Sanitary and Phytosanitary (SPS) Agreement and the 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" (like 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 different Ministries' regulations at the federal level. State and municipal governments also have the authority to regulate and enforce state and municipal laws.

In the federal government, different agencies and ministries share jurisdiction to ensure the safety of the Brazilian food supply and regulate imports of agricultural commodities and foods. 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 many regulations about 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 regarding processed food products. MAPA and ANVISA's regulations can be found online.

On MAPA's website (please note all links related to Brazilian food laws provided in this report are in Portuguese), <a href="https://www.gov.br/agricultura/pt-br">https://www.gov.br/agricultura/pt-br</a>, the search tool SISLEGIS makes available the current regulations on products under MAPA's supervision. There are two search tools that can be found at ANVISA'S website <a href="http://www.gov.br/anvisa/pt-br">http://www.gov.br/anvisa/pt-br</a>, VISALEGIS or through the search ASSUNTOS>ALIMENTOS>LEGISLACAO VIGENTE, that leads to a PDF named "BIBLIOTECA DE ALIMENTOS", <a href="https://www.gov.br/anvisa/pt-br/assuntos/alimentos/paineis-de-consulta-de-alimentos">https://www.gov.br/anvisa/pt-br/assuntos/alimentos/paineis-de-consulta-de-alimentos</a>. It brings the current regulations organized by subject and product category.

Other ministries and agencies also 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; the National Institute of Metrology, Quality, and Technology (INMETRO), which functions under the Ministry of Economy; 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 each federal branch of government (legislative, judicial, and executive). Importers and 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 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. 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 regulating, classifying, and inspecting imported agricultural products entering Brazil. The Secretariat of Agricultural Protection (SDA), the Secretariat of Aquaculture and Fishing (SAP), and the Secretariat of Trade and International Relations (SRI) primarily enforce MAPA's regulatory activities of interest to this report.

## 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) and organic goods. Additionally, the General Coordination for Sanitary Inspection on Agriculture and Livestock (VIGIAGRO) 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, 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 two groups of products. Group one is composed by alcoholic and nonalcoholic beverages such as distilled spirits, wine, juices, soft drinks, carbonated drinks, ready-todrink teas, and vinegars (except water, sports drinks, and energy drinks). Group two is composed by
  fresh fruit and vegetables, grains, seeds, and by-products, which includes wheat flour, some

vegetable oils and margarine). Under DIPOV, the General Coordination for Wine and Beverages (CGVB) is responsible for group one while the General Coordination for vegetable Quality (CGQV) 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, 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. 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 the health of plants' 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 and seeding (including biotech seeds) and establishing standards for agricultural products such as grains, fruits, and vegetables.

## Organic Production Coordination (CPOR)

CPOR function is to regulate the organic sector from the early stages of production until 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. 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 the approval of agricultural chemicals (pesticides and herbicides) but has joint authority for this function with ANVISA (which is concerned with the toxicology aspects of agricultural chemicals) and the Ministry of Agriculture, Livestock, and Food Supply (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 (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 <a href="http://www.gov.br/ibama/pt-br">http://www.gov.br/ibama/pt-br</a> and <a href="https://www.gov.br/mma/pt-br">https://www.gov.br/mma/pt-br</a>.

# **Section I.III. Ministry of Economy**

All food products imported or exported by Brazil require registration through the Secretariat of Foreign Trade (SECEX). This entity is part of the Ministry of Economy, formerly known as 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 former Ministry of Finance (now Ministry of Economy) and the Brazilian Central Bank (BC) 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. 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.

The National Institute of Metrology, Quality, and Technology (INMETRO) is another entity under the Ministry of Economy. It conducts tests of domestic and imported products (industrial and food products) to ensure they meet their labels' specifications and the packaging materials' safety. INMETRO executes national metrology policies, which include indicating the content of packages, standardizing the weight of products, and defining units of measurement of products. It is also under INMETRO responsibility to guarantee the quality and safety of products included as gadgets or toys in food products.

Information on INMETRO can be found on their home page <a href="https://www.gov.br/inmetro/pt-br">https://www.gov.br/inmetro/pt-br</a>. Other related legislation and procedures can be found at on the "Diario Oficial" website <a href="https://www.gov.br/imprensanacional/pt-br">https://www.gov.br/imprensanacional/pt-br</a>.

## **Section I.IV. 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 <a href="http://www.gov.br/mj/pt-br">http://www.gov.br/mj/pt-br</a>. Other Brazilian federal regulations regarding the Ministry of Justice can be found on the "Diario Oficial" homepage <a href="http://www.in.gov.br/servicos/diario-oficial-da-uniao">http://www.in.gov.br/servicos/diario-oficial-da-uniao</a>

## **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, it must keep in

mind that before the application of the label it is important to make sure the product composition is in accordance with the 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
- Front of panel labeling
- Weight/volume indication (note the minimum height of figures and letters indicated in the table below, per INMETRO Ordinance #249 of 2021)
- Additional information required by technical regulations for each product

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

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.
  - ."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
- 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)
- And 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 on this matter before shipping products into Brazil.

## **Other Specific Labeling Requirements**

Brazil has yet to establish a legal ground for plant-based products marketed as meat/dairy alternatives. This category will likely represent a significant challenge to local legislators. Concerns are related to labeling and claims that may mislead or confuse consumers.

## **Nutritional Labeling**

After a process initiated in 2014, the National Agency of Sanitary Surveillance (ANVISA) approved the new nutritional label regulation. On October 9, 2020, the Brazilian Official Gazette published the Resolution of the Collegiate Board 429 and Normative Instruction 75, which refer to the new regulations on nutritional labeling of packaged food and can be found at <a href="http://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/legislacao/bibliotecas-tematicas">http://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/legislacao/bibliotecas-tematicas</a>.

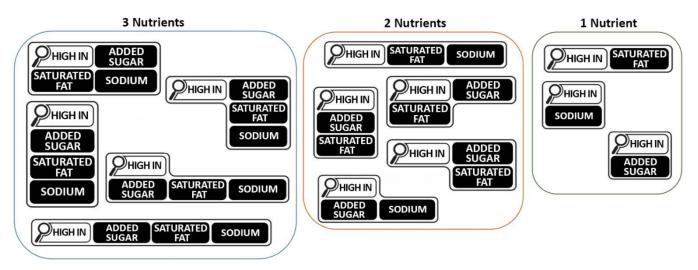
The new rules aim to facilitate nutritional information and lead consumers to make more conscious food intake decisions. The new legal framework establishes significant changes in the legibility of information, content, and how information must be displayed on the nutritional tables. It also covers nutritional claims; however, the most accentuated modification 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. According to ANVISA, these three nutrients were chosen because they represent the most critical ones to consumers' health, as there is robust evidence pointing in this direction. In addition, ANVISA took into consideration the concerns of Brazilian consumers towards these nutrients.

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 great 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.

## 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.

### **Model Labels on Mandatory Warning for Nutrients**



#### **Table of Nutritional Information**

For the Table of Nutritional Information, from now on, it will be mandatory to use a black font and white background. The information presented must meet legibility criteria, including type of font (Arial or Helvetica), font size, line spacing, compression criteria. In addition to pre-defined formats that must necessarily 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 also be required to place the nutritional information table close to the ingredients list. 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.

NUTRITIONAL INFORMATION			
Servings per package: 000 servings			
Serving: 000 g or ml (	household	d 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.			

Note: The regulation permits the table of nutritional information to be presented in different models, vertical, horizontal, aggregating up to 3 products, using two columns, and linear, in the case there is not enough space for the table.

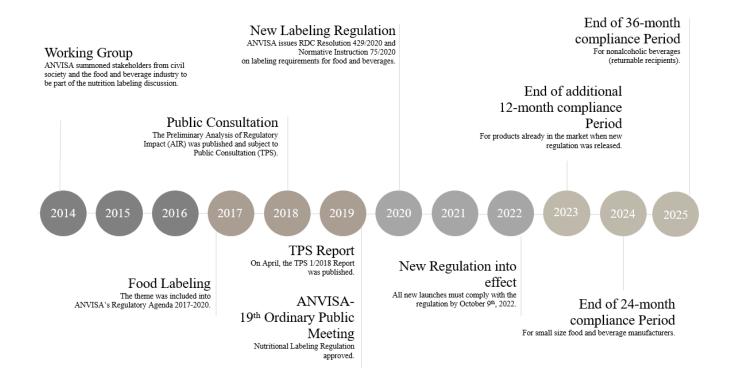
#### **Claims**

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

- Foods that display the frontal label for added sugar cannot have claims for sugars or added sugars.
- Foods that display the frontal label for saturated fat cannot have claims for total fat, saturated fat, trans fat, or cholesterol.
- Foods that display the 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.

## **Timeframe for Implementation and Compliance**

- On October 9, 2022, the new labeling regulation went into effect (products manufactured before the regulation may be marketed until its expiration date).
- 12 months after the regulation goes into effect (Oct. 9, 2023), all products manufactured from this date onwards must comply with the new regulation.
- 24 months after the regulation goes into effect (Oct.9, 2024), 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.
- Up to 36 months after the regulation goes into effect (Oct.9, 2025) for compliance of non-alcoholic beverages in reusable packages.
- 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 than other Mercosul countries, and for this reason, the topic must be taken into Mercosul consideration. The discussions are already in course.



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

Regulations on food packaging and containers fall under ANVISA's jurisdiction. ANVISA establishes quality and identity standards for materials and equipment in contact with foods, 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 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 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 Standards (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 <a href="https://www.abnt.org.br">www.abnt.org.br</a>.

All materials in contact with food must comply with Mercosul technical resolutions, considering Brazil is a member of the trade bloc. 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 at: <a href="http://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/alimentos/embalagens">http://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/alimentos/embalagens</a>.

## **Packaging Sustainability Measures**

Brazil does not have a set of rules addressing packaging sustainability measures, however since 2011, the Brazilian Packaging Association (ABRE) has a memorandum with the Ministry of the Environment within the Plan for Sustainable Production and Consumption (PPCS), 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 the Technical Rule NBR 16,182/2013 of the Brazilian Association of Technical Standards (ABNT).

## **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, transportation, etc.). 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 such as Codex, the European Union, and the Food and Drug Administration (FDA).

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 complies with the local legislation and the product's ingredients, which includes any additives and processing aids. Brazilian legislation divides food products into categories, with allowable additives for each. More information on the regulatory framework for additives is available at: https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/alimentos/aditivos-alimentares

#### Section V. 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 the party that deliberates 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 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, <a href="http://www.agricultura.gov.br/assuntos/insumos-agropecuarios/insumos-agricolas/agrotoxicos/agrofit">http://www.agricultura.gov.br/assuntos/insumos-agropecuarios/insumos-agricolas/agrotoxicos/agrofit</a>.

Maximum tolerance levels for pesticides can be obtained on ANVISA's webpage: <a href="https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/agrotoxicos/monografias">https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/agrotoxicos/monografias</a>.

General information about pesticides regulations may be found at: <a href="https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/agrotoxicos">https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/agrotoxicos</a>

## Section VI. Other Requirements, Regulations and Registration Measures 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 the 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 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 and Agricultural Inputs (DSVIA) and shall be conducted according to the standards approved by MAPA. 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 can be divided into three phases:

*Phase I:* START-UP. Involves identification of all disease pathways (hosts) and potential pest 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, 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, 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 Vegetal Products with Authorized Importation (PVIA) on MAPA's webpage: <a href="https://www.gov.br/agricultura/pt-br/assuntos/importacao-e-exportacao/importacao/consulta-de-produtos-de-importacao-autorizada">https://www.gov.br/agricultura/pt-br/assuntos/importacao-e-exportacao/importacao/consulta-de-produtos-de-importacao-autorizada</a>

U.S. exporters should always 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: <a href="https://www.aphis.usda.gov/aphis/ourfocus/importexport">https://www.aphis.usda.gov/aphis/ourfocus/importexport</a>

#### **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 Animal Health and Livestock Inputs (DSAIP). 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 DS. 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. This regulation establishes formats for the certificate of analysis, certificate of origin and certificate of typicity. On December 30, 2019, MAPA published the Consolidated Regulations for Beverages, Vinegar, Wines and By-products of Grape and Wine. The document brings updated analytical parameters for beverages, which can be found at: <a href="https://www.gov.br/agricultura/pt-br/assuntos/inspecao/produtos-vegetal/legislacao-1/biblioteca-de-normas-vinhos-e-bebidas/AnexoNormaInternaDIPOVverso301219001.pdf/view">https://www.gov.br/agricultura/pt-br/assuntos/inspecao/produtos-vegetal/legislacao-1/biblioteca-de-normas-vinhos-e-bebidas/AnexoNormaInternaDIPOVverso301219001.pdf/view</a>

Moreover, MAPA 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 at: <a href="http://sistemasweb.agricultura.gov.br/siscole/consultaPublicaCadastro.action">http://sistemasweb.agricultura.gov.br/siscole/consultaPublicaCadastro.action</a>

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 list of qualified laboratories can be found at:

https://www.ttb.gov/scientific-services-division/certified-wine-chemists,

https://www.ttb.gov/scientific-services-division/certified-beer-chemists,

https://www.ttb.gov/scientific-services-division/certified-distilled-spirits-chemists

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

## 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 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 up to a 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 USDA AMS, submitting a "Letter of Request for Approval." USDA AMS will then contact OAA and request the registration to be included in Brazil's official list. Detailed information on this process is found on BR2022-0023.
- 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. It is recommended that Health Certificates are filled in English and Portuguese. For more information, please refer to <u>BR2022-0025</u>.

## **MAPA's Requirements for Organic Foods**

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, 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 like 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 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". Water and salt should not be considered when calculating the percentage of organic ingredients. from the calculation.

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**



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





For additional information regarding Brazilian organic rules, please access <a href="https://www.gov.br/agricultura/pt-br/assuntos/sustentabilidade/organicos">https://www.gov.br/agricultura/pt-br/assuntos/sustentabilidade/organicos</a>

## **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 on imported food products. Products under ANVISA jurisdiction are classified into two categories: products with mandatory registration and products exempt of registration.

Foods with Mandatory Registration						
Enteral	Foods for	Supplements	Foods with	Novel	Desalinated,	Packaging from
feeding	infants	with probiotic	functional	Foods/Novel	potable and	New
products		and/or	and/or	Ingredients	bottled water	Technologies
		enzymes	health			(recycled, PET)
			claims			
Products und	ler these	These are categ	gories of	Safety approval i	is required for	Specific
categories ad	ldresses	products in whi	ich safety and	these categories.		composition is
vulnerable co	onsumer	efficacy must b	e approved			required
groups – den	nanding	by Anvisa.		Products under these categories		
control of nu	ıtritional			may require mar	ket data, studies	
aspects and s	stability.			for risk level and scientific		
When novel	ingredient is			evidence.		
added safety	and efficacy					
must be appr	roved.					

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 (state or municipality) through a simplified system. The local sanitary authority (state or municipality) also performs sanitary inspections and control of all products at point of sales.

Considering that Brazilian legislation is positive, the use of novel ingredients requires it to be predicated in specific food regulations. 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 (RT) and request changes or inclusions of ingredients, composition, and quality parameters, always observing instructions set in Anvisas's guides. The set of regulations is dynamic, and the demands of the regulated sector industry and market players drive updates.

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

## **Vitamin Enrichment Requirements**

In 2018 ANVISA created the Food Supplements category. Products previously classified in other food groups migrated to food supplements from that date. "Foods for athletes", foods for pregnant woman, vitamin and mineral enriched foods were gathered 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 established a period of five years for companies to comply with the RDC 243. Within this period, products that were previously under other food categories, regulated by ANVISA can be marketed in accordance with previous regulations, if there were new alterations after the publication of RDC 23. The compliance process must be taken as one single act. The possibility of gradual adjustment was not predicted. As per products with mandatory registration, all alterations to comply with the new regulation must be approved by ANVISA. Furthermore, all new products, those developed after July 27, 2018, must comply with all requirements established by RDC 243, 2018. For more information, please access <a href="https://www.gov.br/anvisa/pt-br/assuntos/alimentos/suplementos-alimentares">https://www.gov.br/anvisa/pt-br/assuntos/alimentos/suplementos-alimentares</a>

## **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 acts in the inspection of the rules established by the Agency and in the regularization of foods for special purposes that are exempt from registration (e.g., dietary sweeteners, foods for nutrient-restricted diets). The Ministry of Agriculture, Livestock and Food Supply (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. The process of updating and reviewing the regulation pertaining to this topic will take place during 2021-2023.

#### 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 list of associated entities eligible to issue a halal certificate at <a href="https://www.ccab.org.br/en/meet">https://www.ccab.org.br/en/meet</a> in Brazil. At the same time, for kosher certification, the process starts with a Jewish entity eligible to conduct, to obtain information on the Jewish Confederation of Brazil (Conib) <a href="https://www.conib.org.br/">http://www.conib.org.br/</a>.

#### **Food Sanitation Laws/Guidelines**

In Brazil, the Ministry of Agriculture, Livestock and Food Supply (MAPA) and the National Agency of Sanitary Surveillance (ANVISA) are the two government institutions that play a role in food sanitation to safeguard public health and provide food that is safe, unadulterated, and fairly displayed. Food sanitary control is done at federal, state and municipality levels. The competencies of MAPA and ANVISA are defined in a complex regulatory framework that includes the entire food production chain. Regulations include definitions, quality and standards, food protection, MAPA and ANVISA has jurisdiction over specific agricultural goods, however the control of the processing phases and food distribution may be done by both government bodies, in some cases. ANVISA, the states and the municipal sanitary authorities are responsible for approving licensing and inspecting establishments that sell food, such as supermarkets, food service operators and other establishment that sell meals. Other entities involved with food regulation includes INMETRO and the Department of Consumer Protection and Defense (DPDC). For additional information, please refer to <a href="https://www.gov.br/anvisa/pt-br/assuntos/alimentos/controle-sanitario">https://www.gov.br/anvisa/pt-br/assuntos/alimentos/controle-sanitario</a>

This rule establishes definitions, sets standards for management and personnel, food protection, and equipment and facilities, water supply, sewage disposal, provides for food establishment plan review, and employee restriction to safeguard public health and provide consumers food that is safe, unadulterated, and fairly presented.

### **Plant-Based Meat and/or Dairy Alternatives**

Brazil has not established a legal framework for plant-based such as meat/dairy alternatives. With an expanding popularity and speedy growth of these new foods globally, the Ministry of Agriculture, Livestock and Food Supply (MAPA) opened a Public Consultation in June 2021 (for 90 days) to allow industry, other government agencies, academia, and the public to contribute to the discussion.

## 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, 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 ten 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.gov.br/inpi/pt-br.

## Geographic Indications Under the Mercosul – European Union Free Trade Agreement

Under the free trade agreement (FTA) negotiated between Mercosul and the European Union (EU) on July 4, 2019, the two parties recognized geographical indications (GIs) intended to be protected under the trade deal. Mercosul recognized 355 EU GIs while Brazil will have 38 GIs protected in the EU. The "grandfather clause" allows existing producers to continue using specific GIs but banning new producers from using the terms.

Under the trade deal, imported products must comply with the terms of the agreement and member countries must provide legal means for interested parties to seek enforcement of the protection. The agreement is still on hold, as EU countries are still seeking legal commitments on the Amazon deforestation as a trade-off to ratifying the EU-Mercosul agreement. More information can be found at: Texto do Acordo Mercosul – União Europeia — Português (Brasil) (www.gov.br)

## **Section IX. Import Procedures**

Oversight of imported food and beverage products is primarily the responsibility of MAPA and ANVISA. These two government bodies ensure the safety of the food supply and enforce regulations related to food and beverage products throughout the supply chain. A breakdown of MAPA and ANVISA's respective regulatory responsibilities is presented below:

MAPA	ANVISA
Consumer-Oriented Products  Animal products: red meat and by-products, poultry meat and by-products, fish, seafood products, dairy products, eggs, and honey.  Beverages: alcoholic and nonalcoholic (except energy drinks, non-dairy beverages such as soy, almond, etc.).  Fruits and vegetables: dried and fresh.	Consumer-Oriented Products . Food: all consumer-ready or processed products, (except those under MAPA's authority) . Beverages: energy drinks, non-dairy beverages such as soy, almond, etc.
. Margarine	
Intermediate Products  . Wheat flour, planting seeds, etc.  . Vegetable oils (soy, cotton, canola, corn, sunflowers)	Intermediate Products . Sugar, sweeteners, mineral water, flavored waters, additives, and other ingredients (excluding those under MAPA's authority)

Bulk Commodities	. Oils (excluding those under MAPA's
. Wheat, grains, rice, soybean, cotton, tobacco, pulses,	authority)
peanuts, flour, etc.	
<u>Others</u>	
. 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 below presents 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 affects market access for foreign goods. For additional information on the import process, please refer to the <a href="Exporter Guide 2021">Exporter Guide 2021</a>.

## **Shipping Procedures**

Before shipping, exporters and importers must work together to guarantee documents are filled as required by Brazilian law. The following documents must be prepared before shipping:

- Pro-forma invoice
- Import license (LI), 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

#### **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 adopts 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 at: <a href="https://www.aphis.usda.gov/aphis/ourfocus/planthealth/sa\_export/sa\_wood\_packaging/ct\_wood\_packaging\_material">www.aphis.usda.gov/aphis/ourfocus/planthealth/sa\_export/sa\_wood\_packaging/ct\_wood\_packaging\_material</a>

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.

#### GENERAL STEPS TO IMPORT FOOD AND BEVERAGE PRODUCTS

## **Prior Shipment**

- Confirm if product complies with Brazilian regulations (composition, additives, processing aids, contaminants, and microbiological standards)
- 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  $\mbox{\sc Bank}$
  - . 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 goods.

#### 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 go through physical examination, and then 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. Trade Facilitation**

## **Geographic Indication (GI)**

The Mercosul – European Union Agreement is considered the most complex agreement ever negotiated by Mercosul. Ninety percent of goods and services will be impacted by the agreement and expected to have its import tariff zeroed after the transition period of fifteen years. The cheeses Fontina, Gorgonzola, Grana, Gruyere/Gruyere Parmesan, and beverages Geneva and Steinhaeger/Steinhager, even when produced in Brazil, use the name of the European regions, constituting the use of Geographic Indications.

To continue using these names, producers had to submit supporting documentation to MAPA early in the year. The list of previous users eligible to use protected names under the GI Mercosul - European Union Agreement has already been released by MAPA. After the agreement enters into force, Brazilian producers who are not on the list will not be able to use GI terms. The list of companies is available at <a href="https://www.in.gov.br/web/dou/-/portaria-n-2-de-24-de-maio-de-2022-403324836">https://www.in.gov.br/web/dou/-/portaria-n-2-de-24-de-maio-de-2022-403324836</a>. The treaty still is on hold. It must have unanimous approval by the European Council and approval from the European Parliament, however EU members have raised serious concerns over the deal as it is, claiming for the inclusion of a climate and deforestation commitments.

## **Temporary Tariff Reduction**

Under Resolution 269 of November 5, 2021, the Brazilian government announced a decrease of approximately 10 percent on approximately 87 percent of all goods under import tariff treatment. The tariff reduction was expected to be into effect until through December 31, 2022, to alleviate the negative economic effects of the COVID-19 crisis.

Resolução Gecex Nº 269, de 4 de novembro de 2021 - Resolução Gecex Nº 269, de 4 de novembro de 2021 - DOU - Imprensa Nacional (in.gov.br)

On July 21, 2022, the Brazilian Government announced the tax cut to be permanent. This was a first time full out reduction since the Common External Tariff (TEC) was created in 1995. The measure does not apply to products listed under Mercosul exception list.

https://www.gov.br/mre/pt-br/canais\_atendimento/imprensa/notas-imprensa/nota-conjunta-do-ministerio-das-relacoes-exteriores-e-do-ministerio-da-economia-revisao-da-tarifa-externa-comum-tec

#### **Review of Normative Acts**

#### **ANVISA**

Continuing with the process of reviewing and consolidating normative acts established by Decree #10,139 of November 28, 2019, ANVISA published 22 legislations in place of 51 regulations that were revoked. All changes are 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, which facilitates consultation. This review also grouped the provisions of different food categories into a single legislation. No changes have been made to the requirements currently applied to products covered by the regulations.

For 2023, a new legislation is expected to regulate products under ANVISA. This proposed legislation is under public consultation, with December 13, 2022, as the deadline for comments, which will bring major changes in the process of food regularization. In addition to the "Registration" and the "Communication of Exemption from Registration", a new regularization procedure is foreseen, which is the "Product Notification", which does not require ANVISA's prior approval. Thus, depending on the category of food, a "Registration", a "Communication of Exemption from Registration" or "Product Notification" will be required.

To launch a new product in the Brazilian market, the submission of several documents is necessary, including a stability study for all food categories with mandatory notification, which includes, among others, all food supplements. See the table below for the food categories and the regularization procedures that are being proposed:

RE	GISTRATION
1	Dietary formulas for inborn errors of metabolism – currently exempt from registration
2	Follow up formula
3	Formulas for special medical purposes intended for infants
4	Infant formulas
5	Modified formulas for enteral nutrition
6	Pediatric formulas for enteral nutrition
NO	TIFICATION
1	Desalinated, potable and bottled sea water
2	Foods with functional and/or health claims
3	Canned bay foods diets
4	Foods for weight control
5	Processed cereal-based foods for infants and young children
6	Standard formula for enteral nutrition
7	Enteral nutrition module
8	Resin, parent article and final packaging recycled from food grade PET-PCR
9	Food supplements
NO	TICE OF START OF PRODUCT MANUFACTURING OR IMPORTATION
1	Sugar, invert liquid sugar, confectionery sugar, table sweetener, candy, bonbon, cocoa
1	powder, soluble cocoa, chocolate, white chocolate, chewing gum, cocoa butter, cocoa mass,

	molasses, and brown sugar
2	Food additives
3	Low sodium salt, foods for nutrient-restricted diets and foods for sugar-controlled diet foods
4	Natural mineral water, natural water, waters with added salts and ice
5	Coffee, barley, teas, yerba mate, spices, seasonings, and sauces
6	Processing aids, including enzymes and enzyme preparations
7	Food packaging, except recycled food grade PET-PCR packaging
8	Edible ices and preparations for edible ices (ice-cream)
9	Mixture for preparing food and ready-to-eat foods
10	Vegetable oils and fats
11	Starches, cookies, whole grains, processed cereals, bran, flour, whole meal flour, pasta and
11	bread
12	Edible mushrooms, fruit products and vegetable products
13	Salt enriched with iodine
PRO	ODUCTS EXEMPTED FROM REGULARIZATION
1	Food raw materials
2	In natura foods
3	Food equipment, including those for domestic use
	Food products made according to standards that establish their composition, quality, safety
4	and labeling requirements and that are used as ingredients in the preparation of industrialized
	foods
	Products handled and prepared in food services when intended for direct sale to the
5	consumer, such as bakery, pastry, confectionery, sweets, rotisserie, ice cream, bars,
	restaurants, canteens, food and nutrition units of health services, schools, day care centers,
	among others

In all food regularization procedures under Anvisa, it will be necessary to present, for imported products, 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 the procedures. The new legislation aims to benefit from the *reliance* tool, such as access to documents, the exchange of information, cooperative monitoring data, and reciprocity.

## **MAPA**

#### **Beverages**

To consolidate the legislation on beverages, including alcoholic, non-alcoholic and beverages obtained from grapes and wine, MAPA provided access via website to the DIPOV Internal Standard n° 1/2019, which brings together in a single document all beverage legislation published by MAPA. This regulation, updated periodically, also brings ANVISA provisions related to beverages, such as

maximum tolerance levels for contaminants. Although in Portuguese, the document may be found at https://www.gov.br/agricultura/pt-br/assuntos/inspecao/produtos-vegetal/legislacao-1/bebidas

#### Wines

The review of the Identity and Quality Standards for the different types of wines, which had been under public consultation since 2021, has not yet been approved.

## Other Alcoholic and Non-Alcoholic Beverages

Decree No. 6,871/2009, which regulates alcoholic and non-alcoholic beverages, except wine and grape and wine by-products, is under public consultation. Major changes are expected for the new version that will be published in 2023.

The deadline for complying with the labeling of beverages, covered by MAPA Ordinance 123/2021, was extended to September 10, 2023, to match the deadline given for adapting to the new nutrition labeling legislation. New drinks launched after June 1, 2021, should already be in line with the new legislation.

## **Plants and Vegetables**

MAPA website brings the DIPOV Internal Standard 2/2019, which consolidates the Plant Quality legislation and the Technical Regulations for plant products, by-products, and residues (of economic value). This regulation is also updated periodically. To regulation may be accessed through the link <a href="https://www.gov.br/agricultura/pt-br/assuntos/inspecao/produtos-vegetal/qualidade-vegetal">https://www.gov.br/agricultura/pt-br/assuntos/inspecao/produtos-vegetal/qualidade-vegetal</a>.

Under the tab "Compêndio da Qualidade Vegetal."

Below are the topics that were under public consultation and for which the publication of a new regulation is awaited:

- General legislation on plant classification
- Soy and its by-products

Several plant quality control programs were instituted, namely:

- Programa Nacional de Monitoramento das Cadeias Produtivas dos Produtos de Origem Vegetal (National Program for Monitoring Production Chains for Products of Plant Origin, PNMONITOR) The objective of this program is to contribute to the improvement of production chains for products of plant origin, with a view to the safety and quality of products destined for the domestic and foreign markets. ⇒ Portaria SDA/Mapa n° 571/2022 (DOU May, 2022).
- Programa Nacional de Qualidade de Produtos de Origem Vegetal (National Program for the Quality of Products of Plant Origin, PNQUALIPOV)
   The main objective of this program is to promote the conformity of products offered in the Brazilian market and exported by Brazil. ⇒ Portaria SDA/Mapa n° 572/2022 (DOU May 10, 2022).

- Programa Nacional de Prevenção e Combate à Fraude e Clandestinidade em Produtos de Origem Vegetal (National Program for the Prevention and Combat of Fraud and Clandestinity in Products of Plant Origin, PNFRAUDE)
  - The main objective of this program is to mitigate the occurrence of fraud and clandestinity in products of plant origin. ⇒ Portaria SDA/Mapa n° 573/2022 (DOU May 10, 2022).
- Programa Nacional de Controle de Resíduos e Contaminantes em Produtos de Origem Vegetal (National Program for Control of Residues and Contaminants in Products of Plant Origin, PNRCC/Vegetal)
  - Defines the scope, objectives, criteria, and procedures for carrying out official controls.  $\Rightarrow$  Portaria SDA/Mapa n° 574/2022 (DOU May 10, 2022).

# **Approved/Changed Legislation**

- Roasted and Ground Coffee: grading standard (new)
- Almonds, cashews, walnuts, and dried fruits: classification standard (new)
- Wheat flour (modified)

#### **Animal Products**

The procedures for registering products of animal origin were changed to be in line with the provisions of Decree No. 9.013/2017 - RIISPOA. Major changes are:

- Expiration of registration: the expiration of the registration has been terminated; that is, the registration of a product of animal origin will no longer need to be revalidated. The registration renewal petition no longer exists.
- Products exempt from registration: a list of products exempt from registration was defined, facilitating access to this information. This list may be updated by DIPOA. The products of animal origin exempt from registration are:
  - . Bee products (Apitoxin, Beeswax, Bee pollen and Propolis);
  - . Dairy flour;
  - . Gelatin and collagen products not intended for human consumption;
  - . Pururuca (crispy fried pork skin) and Crackling;
  - . Inedible animal products, including;
  - . Waste from industrial production of edible products; and
  - . Other products not fit for human consumption, including those obtained from condemning products of animal origin and products not fit for consumption obtained inseparably from the slaughter process; and
  - . Products of animal origin manufactured by national establishments that do not meet quality specifications or sanitary requirements for use for human consumption and which are intended for animal feed or other purposes outside the human food chain.
- Single registration: situations in which single registration may be requested for different product categories are described.

- Eligibility: an establishment can only request the registration of a product for which it is authorized to export to Brazil.
- Change in the computerized registration system: registrations must be requested through a new computerized system (SIGSIF)
- Registry changes: new procedures/deadlines were approved for situations in which a registry change occurs:
  - . When the change in the registration implies the alteration of the sketch of the label, the national establishment may use the previously printed packages until the new packages are received, for a period of up to 120 days, counting from the date of the change in the registration in the computerized system, provided that the conditions set out in the new legislation are met.
  - . When the change in the registration implies a change in the CNPJ, corporate name, address or contact details of the establishment registered with DIPOA, or in cases of change in the layout of an already registered label without modifying other information, the use of these for up to 180 days, counted from the date of alteration of the registration in the computerized system, observing the conditions foreseen in the new legislation, is permitted.
  - . When DIPOA makes a change in the category or the standardized product, the establishments will have 180 days from the change in the system to provide a new registration in the new category or in the classification of the standardized product. At the end of this period, the previous registration will be canceled, regardless of whether or not the establishment has requested a new registration.

## **Under Public Consultation/Awaiting Publication**

- Bee products, honey, beeswax, and by-products
- Cephalopod mollusk products
- Cattle (slaughter procedures and ante and post-mortem inspection)

#### Standards Published in 2022

- Ground Beef (technical regulation)
- Cream cheese (approval of optional ingredients)

## **APPENDIX I. Government Regulatory Key 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.gov.br/agricultura/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

## Ministry of Economy (ME) Brazilian Customs (Receita Federal)

Esplanada dos Ministerios, Bloco P

70048-900, Brasilia, DF

Phone: (55-61) 3412-3000/2000 Website: <a href="www.gov.br/economia/pt-br">www.gov.br/economia/pt-br</a> www.gov.br/receitafederal/pt-br

## **APPENDIX II. Other Import Specialist Technical Contacts**

# **Brazilian Food Processors' Association** (ABIA)

Rua Butanta, 336, 3<sup>rd</sup> floor 05424-000, Sao Paulo, SP Phone: (55-11) 3030-1353 E-mail: abia@abia.org.br Website: www.abia.org.br

# **Brazilian Food Ingredients and Additives Association (ABIAM)**

Rua Hungria, 664, cj 51 01455-000 Sao Paulo, SP Phone: (55-11) 3034-3541 Email: 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 Phone: (55-11) 3250-5400

E-mail: <a href="mailto:atosaopaulo@usda.gov">atosaopaulo@usda.gov</a>
Home Page: <a href="mailto:www.usdabrazil.org">www.usdabrazil.org</a>

## 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: agbrasilia@usda.gov

#### **Attachments:**

No Attachments