

General technical import requirements Brazil

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Introduction

In the Brazilian federal government, numerous agencies and several Ministries share jurisdiction for ensuring the safety of the Brazilian food supply and regulating imports of agricultural commodities and foods. However, the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and the Ministry of Health (MS)—through its National Agency of Sanitary Surveillance (ANVISA)—are the primary regulators of agricultural products.

MAPA oversees and enforces a large number of regulations pertaining to production, marketing, import and export of animal origin products, fresh fruit and vegetables, alcoholic beverages, juices, grains, seeds, and animal feed (including pet food).

ANVISA enforces most of the regulations regarding processed food products. MAPA and ANVISA's regulations may be consulted on-line. On MAPA's website (www.agricultura.gov.br), the search tool SISLEGIS makes available the current regulations on products that are under MAPA's supervision. A similar search tool called VISALEGIS can be found at ANVISA's website (http://www.anvisa.gov.br/eng/legis/resol/40_01_e.htm).

Other Ministries and/or agencies involved in monitoring/control of food safety include the Environment Protection Institute (IBAMA), of the Ministry of the Environment; the National Institute of Metrology, Standardization and Industrial Quality (INMETRO) (<http://www.inmetro.gov.br/english/institucional/index.asp>), of the Ministry of Development Industry and Commerce (MDIC); the National Technical Commission on Biosafety (CNTBio), which is an inter-Ministerial Commission based in the Ministry of Science and Technology (MCT); and the Department of Consumer Protection and Defense (DPDC) within the Ministry of Justice.

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

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

Also under the MDIC are the National Institute of Metrology, Standardization, and Industrial Quality (INMETRO). INMETRO also conducts tests of domestic and imported products (industrial or food

products) to make sure they meet the specifications of their labels and the safety of packaging materials. Information on INMETRO can be found on their home page www.inmetro.gov.br. Other MDIC legislation and procedures can be found at www.mdic.gov.br or at Diário's Official website www.in.gov.br.

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 as Lei nº 8078 of September 11, 1990 (Brazil std no.16). 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. The major regulations that provide the Ministry of Justice regulatory authority over domestic and imported food products, mostly in the area of food labeling and consumer rights, are Lei nº 8078 of September 11, 1990 and Decreto nº 4680 of April 24, 2003.(Brazil std no.17)

Pre-Embarkation

1. Plant Registration

Products under MAPA follow stricter control such as approval of processing plants, registration, labeling, quota, FPS control, etc. Before initiating exports of animal origin products, companies should initiate the registration process and make sure the information to be provided is acceptable to the Brazilian government.

2. Formula Evaluation

Brazilian legislation is "positive," which means that only products (especially additives, colorings, preservatives, etc) that are specifically authorized by Brazilian regulations are allowed to enter the market. Therefore, the importer must ensure the Brazilian Government (GoB) permits the entry of their product. All ingredients contained in food or beverage items should meet GoB specifications and tolerance levels. For that, the **Identity and Quality Standard (PIQ)** established by MAPA and ANVISA must be followed. The importer will generally request that the exporter provide a list of ingredients (quantitative/qualitative characteristics) and additives, colorants, etc., by chemical names and a description of the ingredient's functions.

3. Labeling

Labeling of food and beverage products must be in accordance to GoB regulations. Exporters are expected to provide a sample of the package to the importer.

4. Food Product Registration

If the product is allowed to be marketed, the legal representative of the exporting company, (usually a local subsidiary, or the importer) must request product registration, or an official exemption from registration (ANVISA). **It is common practice in Brazil to retain the services of a private consultant for registration of products.** If there is more than one importer for the same product, each importer

must make an independent request. These forms must be delivered to the local office of the Ministry of Health in the state where the importer is legally based. Importers of food products under the mandatory list (ANVISA/Annex II) must register their products and pay fees, which vary according to the size of the company.

ANVISA’s Requirements for Food and Beverage Products

On March 16, 2000, ANVISA published *Resolucao n° 22 and n° 23* in the Diario Oficial (Brazil’s Federal Register), establishing the procedures for registration and exemption of registration for imported food products that fall under the regulatory authority of the Ministry of Health. These regulations were updated by *Resolucao n° 278 of September 22, 2005 (Brazil std no.18)*. The objectives of these three rules are to provide guidance to importers and to improve ANVISA’s efficiency in coordinating public health actions on imported food products. Under the Resolucao n° 278 of September 22, 2005, the products listed under ANNEX I (see below) are those food products which are exempt from product registration, while ANNEX II lists those products which have a mandatory registration requirement with ANVISA.

The request for registration, or exemption from registration, must be made by the legal representative of the exporting company, a local subsidiary, or by the food importer. If there is more than one importer for the same product, each importer must make a separate request. All imported products, additives and packaging must be in accordance with *Decreto Lei 986, of October 21, 1969 and respective regulations*. The registration is valid for 5 years, after which a new petition must be filed. Importers of food products that are exempt from registration are still required to complete documents requesting that the product be exempt from registration. These documents must be delivered to the local office of the Ministry of Health in the state where the importer is legally based. Importers of food products under ANNEX II must register their products and pay fees, which vary according to the size of the company. The following fee structure is currently in force:

ANNEX I to RDC/ANVISA n°278/05: Imported food products and packages exempt from registration

CODE	PRODUCT DESCRIPTION
4100115	Sugar and table top sweeteners
4100191	Flavoring additives
4200039	Foods enriched with essential nutrients (minerals and vitamins)
4200038	Foods and beverages with complementary nutritional information (light, zero calories, free, low)
4300167	Confectionery products
4100018	Coffee, barley, tea, erva-mate and instant products
4100166	Chocolates and cocoa products
4200071	Packaging

4300194	Enzyme and enzyme preparations
4100042	Seasonings, condiments and sauces
4200012	Frozen products and preparations for frozen products
4200123	Ice
4200098	Mixes for food preparation and ready for consumption products
4100158	Vegetable oils, fats and vegetable cream
4300151	Cereals and derivatives
4300196	Products containing protein of vegetable origin
4100077	Canned vegetable products (excl. palmito), fruit products and mushrooms

ANNEX II to RDC/ANVISA n°278/05: Imported food products and packages with mandatory registration

CODE	PRODUCT DESCRIPTION
4200047	Additives
4100114	Dietetic sweeteners
4300164	Waters containing salt
4200020	Mineral water and natural water
4300032	Functional foods or health claims
4300033	Infant food
4300083	Food for weight control
4300078	Food with dietary restrictions of nutrients
4300086	Foods for diets with controlled sweeteners
4200081	Foods for special diets
4300088	Foods for pregnant and lactating women
4300087	Foods for elderly people
4300085	Foods for sport activities
4200055	Processing aids
4300031	Packaging from new technologies (recycled, PET)
4300030	Novel foods and/or novel food ingredients
4100204	Salt

4200101	Other salts
4300090	Bioactive substances and probiotic isolates claiming functional and/or healthy attributes
4300041	Vitamin and/or mineral supplements
4000009	Canned vegetable (palmito)

Note: The codes used before each product in the ANNEXES above are control codes used by the Ministry of Health and should not be confused with the codes of the Harmonized Tariff System (HS).

Importers of food products that are exempt from registration are generally still required to complete the Import Notice for Products Exempt of Registration (CIPDR). Food additives permitted in Brazil and recognized by Good Manufacturing Practice (GMP) of Codex Alimentarius (unless otherwise specified) also fall under this regulation.

5. Pro Forma Invoice

Before shipment, a *pro forma* invoice must be sent to the Brazilian importer, as this document starts the import clearance process. The *pro forma* invoice must be filled out properly; otherwise the importer will not be able to file an import application. Delays are very common as a result of inadequate information being reported on the *pro forma* invoice.

6. Import License (LI)

With the request for an import authorization the administrative process formally starts. Since 1997, all import and export approval operations occur through the SISCOMEX. The importer requests an import permit, also called Import License (LI), which must be obtained before shipment. All food and beverage products fall under the “non-automatic clearance” category. In the case of agricultural products under ANVISA, approval must be released by the Ministry of Health prior to shipment. In general the authorization is granted within a week. It is not uncommon for importers to contact ANVISA and MAPA for follow-up or to speed up the process.

7. Shipping Instructions

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

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

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

Post-Embarkation

1. Notification of Cargo Arrival

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

2. Import Declaration (DI)

Once goods arrive in Brazil, the importer (or a contracted customs broker officially representing the importer), must prepare the Import Declaration (DI) through the SISCOMEX. The necessary documentation to fill out the DI includes:

- Commercial invoice
- Shipping information
- Import License
- Receipt for payment of Import Tax (II)
- Receipt for payment of Tax on Industrial Products (IPI)
- Other documents may be required depending on the specific product and/or transaction type

Mercosul countries (including Brazil, Argentina, Paraguay and Uruguay), have adopted the Mercosul Common Nomenclature (NCM) system for product classification. The NCM is based on the international methodology of the Harmonized Commodity Description and Coding System or simple Harmonized System (HS). The NCM is formed by 8 digits, the first 6 digits follows the HS codes while the seventh and eight digits correspond to Mercosul specifications. Through the NCM the amount of taxes to be paid are defined.

3. Inspection

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

4. Customs' Evaluation

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

- GREEN: customs clearance authorization is automatically issued.

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

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

5. Re-inspection/Product Release

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

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

Although, the scheme above presents a general structure for imports of food and beverages in Brazil, importers/exporters must note other Ministries, besides MAPA and ANVISA, share jurisdiction for ensuring the safety of the Brazilian food supply and for regulating imports of agricultural commodities and foods. The most updated set of rules each administrative agency releases must be observed prior to shipments as it directly impacts the access for foreign goods into Brazil.

Food Safety

Labeling Requirements

The Brazilian Consumer Protection Lei n° 8078 of September 11, 1990, requires that all domestic and imported foods and beverages must provide the consumer with correct, precise, clear and easily readable information about the product in Portuguese. According to the Consumer Protection Law, the Brazilian importer is held liable in case of health risk to the consumer of an imported product. The expiration date, validity, or shelf life date is very important for Brazilian consumers and should never be overlooked. ANVISA provides the general regulatory framework for labeling domestic and imported food products, comprising: *Resolucao RDC n° 259 of September 20, 2002* *Lei n° 10674 of May 16, 2003*;

Resolucao RDC n° 359 of December 23, 2003(Brazil std no.11); ; and, Resolucao RDC n° 360 of December 23, 2003(Brazil std no.12). INMETRO also regulates labeling. Portaria INMETRO n° 157 of August 19, 2002 defines bar coding and other technical issues related to label format, layout and measurement.

Food Additives Regulations

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

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

Before exporting food and beverage products to Brazil, exporters must make sure not only the final products complies with the local legislation but also its ingredients, which includes the additives used. Brazilian legislation divides food products into categories. For each category, allowed additives are listed. The major regulatory framework for domestic and imported additives is:

Decreto n°55871 of March 26, 1965 (Brazil std no.13) modifying the Decreto n°50040 of January 24, 1961

Specific regulations are found for: sugars, sweeteners, food for special needs, aromas, confectionery, chocolates, alcoholic and non-alcoholic beverages, soup and broths, meat and meat products, cereals, fruits and vegetable products, frozen products, jams, dairy products, sauces and condiments, oils, fat, eggs and egg products, seafood and seafood products, cookies, breads, desserts, supplements, colorants, flavorings, yeast and additives in accordance with GMP.

Pesticides and Other Contaminants

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

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

In order to improve the inspection of pesticides and contaminants on vegetables in Brazil, in July 2nd, 2009 the National Program for Pesticides and Contaminants Detection was created. The program consists in collecting samples of domestic and imported vegetables, such as papaya, apple, pineapple, lettuce, rice, peanut, banana, lemon, acid lime, mango, melon, corn, strawberry, pepper, tomato and grape. Imported products must comply with the same requirements established for local products.

Major laws and regulations providing the regulatory framework for domestic and imported pesticides and contaminants includes: *Decreto nº 55871 of March 26, 1965; Portaria nº 685 of August 27, 1998; Resolucao nº 274 of October 15, 2002; Resolucao nº 34 of 1976; Resolucao nº 281 of October 6, 2003; Instrucao Normativa nº 42 of December 31, 2008 (Braz std no.14); Instrucao Normativa nº 21 of June 30, 2009 (Brazil std no. 15);*

A list of approved pesticides may be found at the Agrofit System at MAPA's home page www.agricultura.com.br. Maximum tolerance levels for pesticides can be obtained at ANVISA's webpage: <http://portal.anvisa.gov.br/wps/portal/anvisa/home>

See also:

<http://portal.anvisa.gov.br/wps/portal/anvisa-ingles>

http://portal.anvisa.gov.br/wps/portal/anvisa-ingles/anvisaingles/Home!/ut/p/c5/04_SB8K8xLLM9MSSzPy8xBz9CP0os3hfRw8jDoNnA3cLSw83Ao8jS18nMwNnAxMDA6B8pFm8AQ7gaEBAzjIPmQVlf4uQBWOoc5m5n6GFsbmEHk85vt55Oem6hfkRhhkmTgqAgCkxZ1/dl3/d3/LolDUolKSWdrbUEhIS9JRFJBOUlpQ2dBek15cXchLzRCRWo4bzBGBEdpdC1iWHBBRUEhLzdfTUFIMkgxQzBHODIIRjBJMjINQjYwQzAoTzlvOkNnNzA1Nzc1MDAwMQ!!/?WCM_PORTLET=PC_7_MAH2H1CoG89HFol29MB6oCo4O2020591_WCM&WCM_GLOBAL_CONTEXT=/wps/wcm/connect/Anvisa+Ingles/Anvisa/Health+Protection/Food/

Specific Standards

Organic Food

To import organic products into Brazil, the local company must comply with the normal import procedure for a conventional product. However, complementary documents will be required by the local authorities. To use the term "organic product," both domestic and imported organic products must be labeled with the name and registration number of the certifying organization. For bulk products, a "certificate of organic quality" must accompany the shipment. The Department of Production Systems and Sustainability (DEPROS) under the Secretariat of Agriculture and Livestock Development and Cooperatives (SDC) has the authority regarding import approval of organic products.

Labeling of organic products must follow the requirements below: one-ingredient products may be labeled as "organic product" once certified; products made of more than one ingredient, including additives, in which not all the ingredients are of certified-organic origin, must be labeled in the following manner:

A. mixed products which are a minimum of 95 percent from ingredients of certified organic origin will be labeled "organic products"

B. mixed products which are 70 percent from ingredients of certified organic origin will be labeled as "products"

Useful Links

On MAPA "Sislegis" portal

<http://extranet.agricultura.gov.br/sislegis-consulta/consultarLegislacao.do>

ON ANVISA (Ministry of Health) HS

http://portal2.saude.gov.br/saudelegis/leg_norma_pesq_consulta.cfm?limpar=pesquisa

Punto focal:

<http://www.puntofocal.gob.ar/legislacion.htm#3>

http://www.puntofocal.gov.ar/formularios/registro_otc.php?lista=BRA

Sysportal inmetro:

<http://www.inmetro.gov.br/sysportal/cgi/sysportal.exe/index#2>