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**Report Highlights:**

This report outlines regulatory requirements for agricultural imports into Brazil, including import procedures. Compared to the previous report released in 2007, significant modifications have been made on Section I, II, IV, V, VI and VII.

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## Table of Contents

|   |           |
|---|-----------|
| <b>SECTION I. FOOD LAWS.....</b>  | <b>3</b>  |
| I.I. Legal Framework.....   | 4         |
| I.II. Ministry of Agriculture, Livestock and Food Supply (MAPA) .....           | 4         |
| I.III. Ministry of Health (MS).....   | 6         |
| I.IV. Ministry of Environment (MMA).....  | 7         |
| I.V. Ministry of Development, Industry and Foreign Trade (MDIC) .....           | 7         |
| I.VI. Ministry of Justice (MJ) .....  | 8         |
| <b>SECTION II. LABELING REQUIREMENTS .....</b>                                  | <b>8</b>  |
| <b>SECTION III. PACKAGING AND CONTAINER REQUIREMENTS .....</b>                  | <b>9</b>  |
| <b>SECTION IV. FOOD ADDITIVE REGULATIONS .....</b>                              | <b>10</b> |
| <b>SECTION V. PESTICIDE AND OTHER CONTAMINANTS .....</b>                        | <b>10</b> |
| <b>SECTION VI. OTHER REGULATIONS AND REQUIREMENTS .....</b>                     | <b>11</b> |
| VI.I. MAPA's Inspection Requirements for Meat, Dairy, and Seafood Products..... | 11        |
| VI.II. MAPA's Inspection Requirements for Plant Products.....                   | 11        |
| VI.III. MAPA's Pest Risk Assessments .....                                      | 12        |
| VI.IV. MAPA's Inspection Requirements for Animal Feed .....                     | 12        |
| VI.V. MAPA's Requirements for Alcoholic and Other Beverages .....               | 12        |
| VI.VI. ANVISA's Requirements for Food and Beverage Products.....                | 12        |
| <b>SECTION VII. OTHER SPECIFIC STANDARDS .....</b>                              | <b>15</b> |
| VII.I. Organic Foods.....   | 15        |
| <b>SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS .....</b>                      | <b>16</b> |
| <b>SECTION IX. IMPORT PROCEDURES.....</b>                                       | <b>16</b> |
| IX.I. Imports Procedures Prior to Shipment .....                                | 16        |
| IX.II. Imports Procedures during Shipment .....                                 | 17        |
| IX.III. Imports Procedures upon Product Arrival .....                           | 17        |
| <b>APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS.....</b>                   | <b>19</b> |
| <b>APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS .....</b>                      | <b>20</b> |

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*This report was prepared by the US Agricultural Trade Office (ATO) of the USDA/Foreign Agricultural Service in Sao Paulo, Brazil for US exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.*

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## SECTION I. FOOD LAWS

Brazil is a member of the World Trade Organization (WTO) and therefore has made commitments to subscribe to the Sanitary and Phytosanitary (SPS) Agreement and to Codex Alimentarius (CODEX) principles. Food regulations issued at the federal level are contained in various types of legal documents and, in order to be implemented must be published in Brazil's Diario Oficial (similar to the U.S. Federal Register).

Brazil has three levels of government: federal, state and municipal. Legally, federal regulations must be followed when there are conflicts between federal, state and municipal legislation, or between regulations established by different Ministries at the federal level. State and municipal governments also have the authority to regulate and enforce state and municipal laws.

In the federal government, numerous agencies and several Ministries share jurisdiction for ensuring the safety of the Brazilian food supply and regulating imports of agricultural commodities and foods. However, the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and the Ministry of Health (MS) - through its National Agency of Sanitary Surveillance (ANVISA) - are the primary regulators of agricultural products. MAPA oversees and enforces a large number of regulations pertaining to production, marketing, import and export of animal origin products, fresh fruit and vegetables, alcoholic 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](http://www.agricultura.gov.br)) the search tool SISLEGIS makes available the current regulations on products that are under MAPA's supervision. A similar search tool called VISALEGIS can be found at ANVISA's website ([www.anvisa.gov.br](http://www.anvisa.gov.br)).

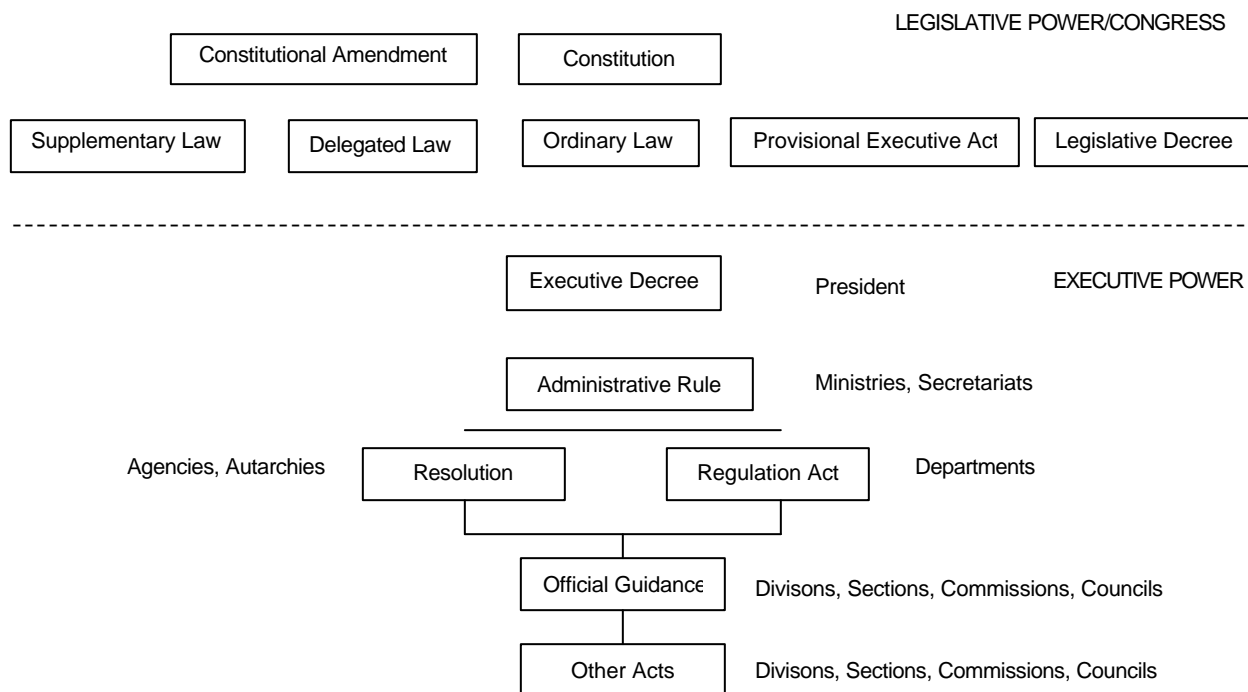
Other Ministries and/or agencies also involved in monitoring/control of food safety include the Environment Protection Institute (IBAMA), of the Ministry of the Environment; the National Institute of Metrology, Standardization and Industrial Quality (INMETRO) of the Ministry of Development, Industry 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.

The Brazilian Constitution defines the boundaries between federal, state and municipal law. It also defines the power each federal branch may hold through its legislative, judicial and executive power. As the executive power and its branches exercise authority to legislate activities related to foreign trade and food safety, importers/exporters may observe the set of rules each administrative agency releases as it directly impacts market access for foreign goods. Although Congress has responsibility for rule making, the power delegated to the

Ministries and its various branches are considerable as they implement those rules and define with more accuracy the procedures that must be followed.

### I.I. Legal Framework

Below is the scheme for the Brazilian legal system. The legislative process described illustrates the respective powers of bodies involved in enforcing food laws.



Brazilian legislation may be found on the internet, though they are only available in Portuguese. The legal terms translate as follow: Constitution (Constituicao), Constitution Amendment (Emenda Constitucional), Supplementary Law (Lei Complementar), Delegated Law (Lei Delegada), Ordinary Law (Lei Ordinaria), Provisional Executive Act (Medida Provisoria), Legislative Decree (Decreto Legislativo), Executive Decree (Decreto Executivo), Administrative Rule (Portaria), Resolution (Resolucao), Regulation Act (Instrucao Normativa), Official Guidance (Circular), Declaratory Act (Ato Declaratorio), and Normative Rule (Parecer Normativo).

### I.II. Ministry of Agriculture, Livestock and Food Supply (MAPA)

The Ministry of Agriculture, Livestock and Food Supply (MAPA), under the premise of safeguarding animal and plant health, is responsible for formulating and executing all policies related to Brazilian agribusiness development. MAPA integrates science, technology, and market aspects to respond to domestic and international demand. MAPA's functions include the regulation, classification and inspection of imported agricultural products entering Brazil. The Ministry is composed by five major offices called Secretariats: Secretariat of Agricultural Protection (SDA); Secretariat of Agricultural Policy (SPA); Secretariat of Agriculture and Livestock Development and Cooperativism (SDC); Secretariat of Production and Agro-Energy

(SPAÉ), and, Secretariat of International Agribusiness Relations (SRI). MAPA's regulatory activities of interest to this report are primarily enforced by SDA, SDC and SRI.

### **The Secretariat of Agricultural Protection (SDA)**

SDA through its six main departments is responsible for enforcing regulations related to domestic and imported plants and animals, including their respective products and by-products, and other inputs such as feed (including pet food), fertilizers, pesticides, and contaminants. Additionally, the General Coordination for Sanitary Inspection on Agriculture and Livestock (VIGIAGRO), also under SDA, responds for surveillance of all foreign products entering Brazilian borders.

#### **▪ Department of Animal Origin Products Inspection Service (DIPOA)**

DIPOA is responsible for ensuring that all animal origin products (meat derived from cattle, sheep, swine, goats, horses, game meat, poultry, dairy products, eggs, seafood, honey 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. Under DIPOA there are 3 divisions overseeing meat, dairy and seafood products:

- Division of Meat and by-products Inspection (DICAR)
- Division of Milk and by-products Inspection (DILEI)
- Division of Seafood and by-products Inspection (DIPES)

#### **▪ Department of Plant Origin Products Inspection Service (DIPOV)**

DIPOV has the regulatory authority to enforce federal laws regarding the registration, compliance and labeling of alcoholic and non-alcoholic beverages such as distilled spirits, wine, soft drinks and juices (except beverages for sport practices, water, energy drinks). Under DIPOV there is one branch for beverages:

- General Coordination for Wine and Beverages (CGVB), which is divided in two Divisions:
  - Division of Alcoholic and Non-alcoholic Beverages, excluding wine (DBEB)
  - Division of Wine and by-products (DVB)

#### **▪ Department of Animal Health (DSA)**

DSA is responsible for enforcing regulations on imports and exports of live animals, semen, embryos. In cooperation with state governments, DSA enforces federal laws and regulations to protect and improve animal health, and to control and eradicate animal diseases such as the Foot-and-Mouth Disease Eradication Program. It defends Brazilian borders against foreign and exotic animal diseases.

#### **▪ Department of Plant Health (DSV)**

DSV is responsible for protecting the health of plants, and preventing the introduction and spread of foreign pests within Brazil.

#### **▪ Department of Surveillance of Agricultural Inputs (DFIA)**

DFIA is responsible for the regulatory inspection and registration of all planting seeds and seeding (including biotech seeds), as well as for establishing standards for agricultural products such as grains, fruits and vegetables.

#### **▪ Department of Surveillance of Livestock Inputs (DFIP)**

DFIP is responsible for the regulatory inspection of feed for animal consumption (including pet food), the registration of establishments producing animal semen and embryos, and the genealogical registration of live animals. DFIP also regulates the use of veterinary products.

The legal framework providing SDA and its branches authority to regulate on products under MAPA's jurisdiction is:

- **General Coordination for Sanitary Inspection on Agriculture and Livestock (VIGIAGRO)**

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

**The Secretariat of Agriculture and Livestock Development and Cooperativism (SDC)**

One of SDC's functions is to regulate organic sector from the early stages of production until processing and trade. The Department overlooking organic issues is:

- Department of Production Systems and Sustainability (DEPROS)

The general regulatory framework that provides SDA, SDC and their branches with regulatory authority for domestic and imported products under their jurisdiction include: Decreto n° 30691 of March 29, 1952; Decreto n° 2314, September 4, 1997; Decreto n° 6323 of December 27, 2007; Instrucao Normativa n° 07 of May 17, 1999; Instrucao Normativa n° 19 of December 15, 2003; Instrucao Normativa n° 16 of June 11, 2004; Instrucao Normativa n° 36 of November 10, 2006; Lei n° 8918 of July 14, 1994; and, Lei n° 10831 of December 23, 2003.

**The Secretariat of International Agribusiness Relations (SRI)**

SRI is responsible for coordinating the Brazilian government positioning on agricultural matters during international forums such as the World Trade Organization (WTO), Office of International Epizootics (OIE), International Plant Protection Committee (IPPC), and Codex Alimentarius (CODEX). SRI also coordinates regional and bilateral agricultural agreements. The Secretariat is also the focal point for the United States and Brazil negotiations under the Consultative Committee on Agriculture (CCA). SRI is composed by three departments; two of each has a direct impact on US exports into Brazil.

- **Department of Commercial Affairs (DAC)**

DAC is responsible for bilateral, multilateral or regional negotiations involving agriculture and livestock.

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

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

### **I.III. Ministry of Health (MS)**

The Ministry of Health's (MS) regulatory activities are enforced by an agency called National Agency of Sanitary Surveillance (ANVISA). Within the structure of the federal public administration, ANVISA is considered an autonomous agency. ANVISA was created to function as the scientific regulatory agency responsible for the safety of all foods under its authority (mainly processed products). The agency is also responsible for overseeing the production and registration of drugs, food additives, medical devices, tobacco and tobacco products.

ANVISA's primary function is to protect the public (i.e., human health) by assessing food standards, safety, and contaminants. In addition, the agency is responsible for the compliance and registration of any food processing facility established in, or exporting to,

Brazil. Within ANVISA the regulation, inspection and clearance of food products is coordinated by the following branches:

**The General Management Office for Food Products (GGALI)**

GGALI is responsible for the implementation of regulation and inspections of all food products under ANVISA's competence. The Office is formed by three offices:

- **Office of Science and Food Technology (GACTA)**

GACTA is responsible for planning, organizing and promoting scientific and technological researches on food and contaminants in order to prevent health outbreaks.

- **Office of Special Products (GPESP)**

GPESP is responsible for rule making and analysis of products under mandatory registration.

- **Office of Capacity Building on Food Safety (GQTSA)**

GQTSA is responsible for the development and implementation of technical programs related to production systems and modernization of surveillance services provided on state and municipal level.

**The General Management Office for Ports, Airports and Borders (GGPAF)**

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

The general regulatory framework that provides ANVISA with regulatory authority for domestic and imported food products under their jurisdiction include: Decreto n° 986 of October 21, 1969; Lei n° 9841 of October 5, 1999; Resolucao n° 17 of April 30, 1999; Resolucao n° 22 of March 15, 2000; Resolucao n° 23 of March 15, 2000; Resolucao RDC n° 259 of September 20, 2002; Resolucao RDC n° 359 of December 23, 2003; Resolucao RDC n° 360 of December 23, 2003; and, Resolucao RDC n° 278 of September 22, 2005.

#### **I.IV. Ministry of Environment (MMA)**

Within the Ministry of Environment (MMA) the regulatory authority for activities that affect the environment is called Brazilian Institute for the Environment and Natural Resources (IBAMA). IBAMA is one of the key government agencies involved with approval of agricultural chemicals (pesticides and herbicides), but has joint authority for this function with the Ministry of Health (which is concerned with the toxicology aspects of agricultural chemicals) and the Ministry of Agriculture, Livestock, and Food Supply (which actually provides the registration for pesticides).

IBAMA is concerned with the possible environmental impact of pesticides. In general, it follows recommendations made by international standard setting organizations, such as the CODEX Alimentarius, and works closely with its U.S. counterpart, the U.S. Environmental Protection Agency (EPA). IBAMA is also the Brazilian regulatory agency that enforces the treaties established at the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). It is the agency responsible for monitoring and enforcing activities related to Brazilian fauna and flora.

The regulatory rules related to these subjects in Brazil can be found at [www.ibama.gov.br](http://www.ibama.gov.br) and [www.mma.gov.br](http://www.mma.gov.br).

#### **I.V. Ministry of Development, Industry and Foreign Trade (MDIC)**

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 is 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](http://www.inmetro.gov.br). Other MDIC legislation and procedures can be found at [www.mdic.gov.br](http://www.mdic.gov.br) or at Diario Oficial's website [www.in.gov.br](http://www.in.gov.br).

#### **I.VI. 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 as Lei nº 8078 of September 11, 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. 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.

For additional information on the Ministry of Justice's consumer department, please check the Ministry of Justice's home page [www.mj.gov.br](http://www.mj.gov.br). Other Brazilian federal regulations regarding the Ministry of Justice can be found at Diario Oficial's home page [www.in.gov.br](http://www.in.gov.br).

## **SECTION II. LABELING REQUIREMENTS**

The Brazilian Consumer Protection Lei nº 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. The information required on food products will follow the ruling of the respective regulating agency.

- Products under ANVISA follow Resolucao nº 259 of September 20, 2002
- Products under MAPA follow Instrucao Normativa nº 22 of November 24, 2005



MAPA requires that, in addition to the registration of the foreign processing plant, the Brazilian importer must also file a request for the pre-registration of the foreign labels of processed meat, dairy, and seafood products. Only those products that have their labels pre-approved by DIPOA are allowed to enter Brazil. For additional information, U.S. exporters should contact the Office of Agricultural Affairs (OAA) in Brasilia.

On December 23, 2003, the Brazilian Ministry of Health's ANVISA published Resolucao n° 359 and n° 360, establishing new nutritional labeling requirements for all packaged foods and beverages, including products under MAPA's responsibility. These nutritional labeling requirements are similar to those in force in the U.S. Brazilian companies have been required to comply with this regulation since July 31, 2006; these rules also apply to imported packaged foods and beverages.

The label must include the following information:

|                   |                                |
|-------------------|--------------------------------|
| Nutritional Facts | (g/100g of product)            |
| Carbohydrate      | (g/100g)                       |
| Protein           | (g /100g)                      |
| Total Fat         | (g/100g)                       |
| Saturated Fat     | (g/100g)                       |
| <i>Trans</i> Fat  | (g/100g)                       |
| Dietary Fiber     | (g/100g)                       |
| Sodium            | (g/100g)                       |
| Vitamins/Minerals | (mg or µg/100g) - when applied |

### SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

The Brazilian Association of Technical Norms (ABNT) is the only agency in Brazil responsible for elaboration of technical rules (standards and specifications) for the packaging and container industries. 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 conducts the certification for consumer packaging (paper and carton boxes, plastic bags, steel sheet, aluminum cans, tetrapak, PET bottles, etc). 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 Society of Plastics Industry and the Standard Recycling Symbol.

For detailed regulatory information about packaging and containers, as well as links to the main associations of packaging and containers, access the ABNT home page at: [www.abnt.org.br](http://www.abnt.org.br).

The government's regulatory agency involved with the quality and safety of packaging and containers for handling food is the National Institute of Metrology, Standardization, and Industrial Quality (INMETRO), linked to the Ministry of Development, Industry, and Foreign Trade (MDIC). For additional information, access INMETRO's home page at [www.inmetro.gov.br](http://www.inmetro.gov.br).

The government regulatory agency involved with the toxicological aspects of packaging and containers for handling food is the National Agency of Sanitary Surveillance (ANVISA), under the Ministry of Health (MS). For additional information access ANVISA's home page at

[www.anvisa.gov.br](http://www.anvisa.gov.br).

#### **SECTION IV. FOOD ADDITIVE 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 the sufficient to obtain the efficient result.

Before exporting food and beverage products to Brazil, U.S. 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:

- Portaria n° 540 of October 27, 1997
- Resolucao CNNPA 21/75
- Decreto n°55871 of March 26, 1965
- Decreto n°50040 of January 24, 1961

Specific regulation is founded 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.

#### **SECTION V. PESTICIDE AND OTHER CONTAMINANTS**

Brazil follows international standards on tolerances of pesticides, herbicides and fungicides used in fumigation of agricultural products, being Codex Alimentarius 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 chemical is held by a three party committee (MAPA, IBAMA, and ANVISA). ANVISA provides toxicological analysis and establishes maximum tolerance levels while IBAMA evaluates environmental impact. MAPA is the initial point of contact in the product registration process and also the party that deliberates final approval after receiving inputs from ANVISA and IBAMA.

A list of approved pesticides may be found at the Agrofit System at MAPA's home page [www.agricultura.com.br](http://www.agricultura.com.br). Maximum tolerance levels for pesticides can be obtained at ANVISA's webpage [www.anvisa.com.br](http://www.anvisa.com.br).

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; and, Resolucao nº 81 of September 5, 2000.

## **SECTION VI. OTHER REGULATIONS AND REQUIREMENTS**

### **VI.I. MAPA's Inspection Requirements for Meat, Dairy, and Seafood Products**

In order to export animal origin (beef, pork, powdered milk, whey, lactose, cheese, and seafood) products to Brazil, the local government requires that U.S. processed plants must be inspected by federal agencies. State level inspection is not accepted and products from these plants will not be registered in Brazil.

The only U.S. federal agencies approved by the Brazilian Government to certify U.S. processing plants are: the Food Safety and Inspection Service of the U.S. Department of Agriculture (FSIS/USDA) for meat and poultry, and the Agricultural Marketing Services (AMS/USDA) or the Food and Drug Administration (FDA) for dairy. The U.S. dairy product exporter must have the processing plant included in AMS's list of U.S. Dairy Plants Surveyed and Approved by the USDA Grading Service or have the Central File Number under FDA. The same procedure applies for exports of U.S. seafood. The U.S. plant must be inspected by either the National Oceanic and Atmospheric Administration/National Marine Fisheries Services (NOAA/NMFS) or FDA before exporting to Brazil, and must be included on DIPOA's list. The request for registration of the U.S. plant with DIPOA must be made through the USDA's Foreign Agricultural Service (FAS) office in the U.S. Embassy in Brasilia. The U.S. exporter must provide the FAS office in Brasilia, the following information:

- (1) Full name and address of the plant(s), including telephone, fax, and contact person;
- (2)
  - Plant registration number with the Food Safety Inspection Service (FSIS/USDA) for meat products (beef and pork only).
  - Plant registration number with the Agricultural Marketing Service (AMS/USDA) or the central file number from the FDA for dairy products.
  - The central file number from FDA or plant registration number with NOAA/NMFS for seafood products.
- (3) Description of the product to be exported to Brazil: fresh/frozen beef, beef products, beef, pork, pork products, prepared foods, milk and milk products (cheese, whey, butter, butter oil, lactose), and seafood products (in this case provide the scientific name of the fish in Latin and how the product will be shipped to Brazil).

Note: DIPOA officials do not register U.S. poultry plants for export of poultry products to Brazil.

### **VI.II. 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.

### **VI.III. MAPA's Pest Risk Assessments**

On March 27, 2002, the Brazilian Government published Instrucao Normativa nº 34, which requires Pest Risk Assessments (PRAs) for each species from every country of origin. Given this and other changes occurring in this area, U.S. exporters should check with the APHIS office in the U.S. Embassy in Brasilia for additional information on the status of phytosanitary import requirements. Instrucao Normativa nº 59 of November 21, 2002, establishes the procedures for submitting PRAs to the Brazilian Government. It clarifies the pest risk analysis methodology to be followed, and specifies the documentation to be submitted in Portuguese, and to be reviewed by USDA/APHIS/PPQ.

U.S. exporters need to be aware that PRAs will need to be done on third-country origin plant products that are re-exported from the U.S. to Brazil, with information provided by the country of origin. Instrucao Normativa nº 60 of November 21, 2002, allows for the importation of plant products traditionally imported by Brazil while the PRA is under review by MAPA/DSV.

### **VI.IV. MAPA's Inspection Requirements for Animal Feed**

U.S. exporters of animal feed and fodder, including pet food, must be registered with the Department of Surveillance of Livestock Inputs (DFIP). The U.S. exporter of animal feed should first establish a legal representative or importer in Brazil who will file the request for registration of the imported product with DFIP. The importer must also be registered with MAPA before submitting a request for registration. A comprehensive questionnaire must be filled out, including label information.

### **VI.V. MAPA's Requirements for Alcoholic and Other Beverages**

The General Coordination for Wine and Beverages (CGVB) has the regulatory authority to enforce federal laws regarding the registration and labeling of beer, distilled spirits, wine, soft drinks, and juices. In this respect, its regulatory responsibilities are similar to those ascribed in the United States to the Department of Treasury's Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), except that CGVB provides a broader spectrum of services, including laboratory tests. The major regulations for alcoholic and beverage products, both domestic and imported, are Decreto nº 2314 of September 4, 1997 and Decreto nº 4851 of October 2, 2003.

### **VI.VI. ANVISA's Requirements for Food and Beverage Products**

On March 16, 2000, ANVISA published Resolucao nº 22 and nº 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 nº 278 of September 22, 2005. 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 nº 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 a form (ANNEX III) requesting that the product be exempt from registration. 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 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:

| DESCRIPTION          | FEE BY COMPANY SIZE* |                     |                       |                      |                    |
|----------------------|----------------------|---------------------|-----------------------|----------------------|--------------------|
|                      | Group I**<br>Large   | Group II**<br>Large | Group III**<br>Medium | Group IV**<br>Medium | Group V**<br>Small |
| Product Registration | R\$6,000             | R\$5,100            | R\$4,200              | R\$2,400             | R\$600             |

Note:

\*Fees are charged in local currency: the "Real" (R\$). Average exchange rate in August 2008 US\$ 1.00=R\$1.572

\*\*For the purposes of this regulation, the size of the company is defined as follows: Group I (Annual Income above R\$50 million); Group II (Annual Income between R\$20 million and R\$50 million); Group III (Annual income between R\$6 million and R\$20 million); Group IV (Annual income between R\$2 million and R\$6 million), and Group V (Annual Income below R\$2 million). These criteria are based on Resolution nº 222 of December 28, 2006. Brazil also defines some companies as "micro" companies, with annual income below R\$434,000. In this case, companies are exempt from the above fees.

ANNEX I to RDC/ANVISA nº278/05: 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 nº278/05: 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.

#### FORM CIPDR to RDC/ANVISA nº 278/05

|         |  |
|---------|--|
| Field A | To be filled in by the sanitary authority  |
| Field B | <ul style="list-style-type: none"> <li>▪ corporate tax number</li> <li>▪ name of the importer or legal representative of the exporter or subsidiary</li> <li>▪ full address/phone/fax/e-mail</li> </ul>  |
| Field C | Information regarding the warehousing unit   |
| Field D | Term of responsibility to be signed by the importer <ul style="list-style-type: none"> <li>▪ importation date</li> <li>▪ sale date</li> </ul>  |
| Field E | To be filled in by the sanitary authority  |
| Field F | <ul style="list-style-type: none"> <li>▪ corporate tax number of the importer or legal representative of the exporter or subsidiary</li> <li>▪ corporate tax number of the warehousing unit</li> <li>▪ product category</li> <li>▪ category description</li> <li>▪ product name</li> <li>▪ expiration date</li> <li>▪ brand</li> <li>▪ type of packaging</li> <li>▪ manufacturer</li> <li>▪ country of origin</li> <li>▪ commercial perspective (if the product is to be sold in one specific city, state, or national territory)</li> </ul> |

Petition Form #1: Imported food products and packages with mandatory registration

|         |  |
|---------|--|
| Field A | <ul style="list-style-type: none"> <li>protocol number</li> <li>date</li> </ul>  |
| Field B | To be filled in by the sanitary authority  |
| Field C | Company information <ul style="list-style-type: none"> <li>name of the importer or legal representative of the exporter or subsidiary</li> <li>tax ID number</li> </ul>  |
| Field D | Product information <ul style="list-style-type: none"> <li>product category</li> <li>expiring date</li> <li>product name</li> </ul>                                      |
| Field E | Ingredients information <ul style="list-style-type: none"> <li>list of ingredients</li> <li>type</li> <li>concentration (quantity/volume)</li> <li>percentage</li> </ul> |

Petition Form #2: Imported food products and packages with mandatory registration

|         |   |
|---------|---|
| Field A | <ul style="list-style-type: none"> <li>protocol number</li> <li>date</li> </ul>   |
| Field B | To be filled in by the sanitary authority   |
| Field F | Petition description (codes and description)  |
| Field G | Manufacturer information <ul style="list-style-type: none"> <li>name</li> <li>tax ID number</li> <li>location</li> </ul>  |
| Field H | Product information <ul style="list-style-type: none"> <li>registration number</li> <li>type of use</li> <li>expiration date</li> <li>product name</li> <li>name/brand complement</li> <li>formula number</li> <li>product description</li> <li>packaging description</li> <li>care &amp; handling</li> </ul> |
| Field I | To be filled in by the sanitary authority   |
| Field J | Term of responsibility to be signed by the importer   |
| Field K | To be filled in by the sanitary authority   |

For products with mandatory registration, in addition to petition forms #1 and #2 the importer must present a Previous Laboratory Analysis; this analysis must be conducted by a laboratory recognized and approved by GoB.

The major laws and regulations that provide ANVISA's regulatory authority for domestic and imported processed food products, including authorization for sale and registration of food products and risk analysis include: Decreto n° 986 of October 21, 1969; Lei n° 9782 of January 26, 1999; Decreto nº 3029 of April 16, 1999; Resolucao nº 222 of December 28, 2006; Resolucao n° 22 of March 15, 2000; Resolucao n° 23 of March 15, 2000; Resolucao n° 278 of September 22, 2005, Resolucao nº 17 of April 30, 1999; and, Resolucao n° 16 of April 30, 1999.

**SECTION VII. OTHER SPECIFIC STANDARDS****VII.I. Organic Foods**



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 Cooperativism (SDC) has the authority regarding import approval of organic products.

The legal framework for organic foods in Brazil may be found under MAPA: Instrucao Normativa nº 7, May 17, 1999; Lei nº 10831, December 23, 2003; and, Decreto nº 6323 of December 27, 2007. They contain the standards for production, classification, processing, packaging, importation, distribution, identification, and certification of the quality of organic products, of both animal and plant origin.

## **SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS**

The National Institute of Industrial Property (INPI) is a federal agency created in 1970 and is linked to the Ministry of Development, Industry and Foreign Trade (MDIC). It is responsible for protecting patents, trademarks, and copyrights. INPI is currently regulated by Lei 9279 of May 14, 1996 (Industrial Property Law). Registration of a trademark in Brazil may be obtained by filing an application letter to INPI. Once registered, the validity of the registration is for 20 years.

According to trade specialists, despite recent improvements, Brazil continues to fall short in providing adequate and effective protection of Intellectual Property Rights (IPR). Although Brazil is one of the largest markets globally for legitimate copyrighted products, it is also one of the world's largest markets for pirated products. For general information on legislation, regulations, application for copyrights, patents, and trademarks, please access the INPI home page at [www.inpi.gov.br](http://www.inpi.gov.br).

## **SECTION IX. IMPORT PROCEDURES**

### **IX.I. Imports Procedures Prior to Shipment**

#### **STEP I: MAPA AND ANVISA**

The importer must ensure the Brazilian Government (GoB) allows import of the product. All ingredients contained in the U.S. product should meet GoB specifications and tolerance levels. It is common to make use of the services of a private regulatory affairs consultancy in this initial phase; however, contracting a private consultant is not mandatory. 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.

Products under MAPA follow stricter control such as approval of processing plants, registration, labeling, quota, FPS control, etc.

Before initiating any export process, U.S. companies may contact local FAS staff to make sure the information to be provided is acceptable to the Brazilian government.

#### **STEP II: MAPA AND ANVISA**

Labeling of food and beverage products must be in accordance to GoB regulations. Again, regulatory affairs consultants may be of great assistance. The exporter should forward a sample of the package to the importer.

#### STEP III: ANVISA

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/Annex I). 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.

#### STEP IV: MAPA AND ANVISA

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.

#### STEP V: MAPA AND ANVISA

The administrative process 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.

### IX.II. Imports Procedures during Shipment

#### STEP VI: MAPA AND ANVISA

Following embarkation, the exporter must send the documentation that will allow the importer to release goods from Brazilian customs. Documentation required includes:

- shipping information (bill of lading or AWB)
- commercial invoice (details of agreed payment methods must be included)
- certificate of origin (if required by Brazilian authorities)
- lab/phitosanitary certificate (if required by Brazilian authorities)

### IX.III. Imports Procedures upon Product Arrival

#### STEP VII: MAPA AND ANVISA

When goods arrive in Brazil, the importer (or a contracted customs broker officially representing the importer), must prepare the Import Declaration (DI). The necessary documentation to fill out the Import Declaration 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. Importers may present a single invoice for different NCMs, however, a separate LI is required for each NCM code.

#### STEP VIII: MAPA AND ANVISA

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.

MAPA and ANVISA also participate in the clearance process. The documents to be presented to the health authorities are:

- lab/ phytosanitary certificate
- certificate of origin
- control analysis (to be conducted *in loco* if requested by authorities)

**APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS**

Secretariat of Agricultural Protection (SDA)  
Ministry of Agriculture, Livestock, and Food  
Supply (MAPA)  
Esplanada dos Ministerios, Bloco D  
Anexo B, Sala 426  
70043-900 Brasilia, DF  
Phone: (55-61) 3218-2314/15  
Home page: [www.agricultura.gov.br](http://www.agricultura.gov.br)

Brazilian Environment Institute (IBAMA)  
Ministry of Environment (MMA)  
SCEN, Trecho 2, Ed. Sede  
70818-900 Brasilia, DF  
Phone: (55-61) 3216-1212  
Home page: [www.ibama.gov.br](http://www.ibama.gov.br)

Secretariat of International Agribusiness  
Relations (SRI)  
Ministry of Agriculture, Livestock and  
and Food Supply (MAPA)  
Esplanada dos Ministerios, Bloco D,  
Sala 304  
70043-900 Brasilia, DF  
Phone: (55-61) 3218-2510/2468  
Home page: [www.agricultura.gov.br](http://www.agricultura.gov.br)

Ministry of Science and Technology (MCT)  
Esplanada dos Ministerios, Bloco E  
70067-900 Brasilia, DF  
Phone: (55-61) 3317-7500  
Home page: [www.mct.gov.br](http://www.mct.gov.br)

Secretariat of Agriculture and Livestock  
Development and Cooperation (SDC)  
Esplanada dos Ministerios, Bloco D  
Anexo A, Sala 200  
70043-900 Brasilia, DF  
Phone: (55-61) 3218-2433  
Home page: [www.agricultura.gov.br](http://www.agricultura.gov.br)

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

Agency of Sanitary Surveillance (ANVISA)  
Ministry of Health  
Esplanada dos Ministerios, Bloco B, Ed.Omega  
70770-502 Brasilia, DF  
Phone: (55-61) 3448-6352  
Home page: [www.anvisa.gov.br](http://www.anvisa.gov.br)

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

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

**APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS**

## Brazilian Food Ingredients and Additives Association (ABIAM)

Rua Hungria, 664, cj.51  
01455-000 Sao Paulo, SP  
Phone: (55-11) 3034-3541  
Fax: (55-11) 3816-2928  
E-mail: [abiam@abiam.com.br](mailto:abiam@abiam.com.br)  
Home page: [www.abiam.com.br](http://www.abiam.com.br)

## Brazilian Food Processors' Association (ABIA)

Av. Brigadeiro Faria Lima, 11 andar  
01451-001 Sao Paulo, SP  
Phone: (55-11) 3030-1353  
Fax: (55-11) 3814-6688  
E-mail: [abia@abia.org.br](mailto:abia@abia.org.br)  
Home page: [www.abia.org.br](http://www.abia.org.br)

## Brazilian Food Exporters and Importers Association (ABBA)

Rua Machado Bitencourt, 190, cj. 609  
04044-000 Sao Paulo, SP  
Phone/Fax: (55-11) 5087-9546/5571-7290  
E-mail: [abba@aabba.org.br](mailto:abba@aabba.org.br)  
Home page: [www.aabba.org.br](http://www.aabba.org.br)

## Aduaneiras

Rua da Consolacao, 77  
01301-000 Sao Paulo, SP  
Phone: (55-11) 3120-3030  
Fax: (55-11) 3159-5044  
E-mail: [aduaneiras@aduaneiras.com.br](mailto:aduaneiras@aduaneiras.com.br)  
Home page: [www.aduaneiras.com.br](http://www.aduaneiras.com.br)

Please do not hesitate to contact the offices below with questions or comments regarding this report or to request assistance.

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

U.S. Consulate General  
Rua Henri Dunant, 700  
04709-110 Sao Paulo, SP  
Phone: (55-11) 5186-7400  
Fax: (55-11) 5186-7499  
E-mail: [atosapaulo@usda.gov](mailto:atosapaulo@usda.gov)  
Home page: [www.usdabrazil.org.br](http://www.usdabrazil.org.br)  
[www.fas.usda.gov](http://www.fas.usda.gov)

## Office of Agricultural Affairs (OAA)

U.S. Embassy  
Av. das Nacoes, quadra 801, lote 3  
70403-900 Brasilia, DF  
Phone: (55-61) 3312-7101  
Fax: (55-61) 3312-7659  
E-mail: [agbrasil@usda.gov](mailto:agbrasil@usda.gov)