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Report Highlights:

The FAIRS 2001 report includes an update on import regulations for animal origin products, nutritional labeling, and genetically modified organisms (GMOs).

Includes PSD changes: No
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TABLE OF CONTENTS

A. FOOD LAWS	Page 2 of 21
Ministry of Agriculture and Food Supply (MAA):	Page 2 of 21
Ministry of Health (MS)	Page 6 of 21
Ministry of the Environment (MMA)	Page 10 of 21
Ministry of Development, Industry and Commerce (MDIC)	Page 10 of 21
Ministry of Science and Technology (MCT)	Page 10 of 21
Ministry of Justice (MJ)	Page 11 of 21
B. LABELING REQUIREMENTS	Page 12 of 21
Labeling of Animal Origin Products (Meats, Dairy Products)	Page 12 of 21
Labeling of Seafood Products:	Page 13 of 21
Labeling of Other Food Products:	Page 13 of 21
C. FOOD ADDITIVE REGULATIONS	Page 13 of 21
D. PESTICIDE AND OTHER CONTAMINANTS	Page 14 of 21
E. OTHER REGULATIONS AND REQUIREMENTS	Page 14 of 21
Brazilian Inspection Requirements for Meat and Dairy Products	Page 14 of 21
Brazilian Inspection Requirements for Plant Products	Page 15 of 21
Brazilian Inspection Requirements for Animal Genetics	Page 15 of 21
Brazilian Inspection Requirements for Animal Feed	Page 16 of 21
Veterinary Biologics	Page 16 of 21
Alcoholic and Other Beverages	Page 16 of 21
F. OTHER SPECIFIC STANDARDS	Page 16 of 21
Endangered Species	Page 16 of 21
Supplemental/Dietary Foods	Page 17 of 21
Organic Foods	Page 17 of 21
Genetically Modified Organisms	Page 17 of 21
G. COPYRIGHT/TRADEMARK LAWS	Page 18 of 21
H. IMPORT PROCEDURE	Page 18 of 21
Establishing a Business Relationship	Page 18 of 21
Documentation and Merchandise Entry	Page 19 of 21
APPENDIX I - WORLD TRADE ORGANIZATION (WTO)	
INQUIRY POINT	Page 20 of 21
APPENDIX II - LIST OF MAJOR REGULATORY AGENCIES	Page 20 of 21

DISCLAIMER: This report has been prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Brasilia, Brazil for U.S. 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 were 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.

Please contact this office, if you have any comments, corrections or suggestions about the material contained in this report. Our telephone, fax, and e-mail address are provided at the end of this report.

A. FOOD LAWS

Brazil is a federated republic composed of 26 states plus the Federal District, with three levels of government: federal, state and municipal; similar to the United States' governmental structure. Food regulations issued at the federal level are contained in various types of legal documents (Laws, Decrees, Executive Orders, Directives, Circulars, Resolutions, Provisional Measures) and to become official, or in order to be implemented, must be published in Brazil's *Diario Oficial* (similar to the U.S. Federal Register). 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 the underlying Codex Alimentarius (CODEX) principles. State and municipal governments also have the authority to regulate and enforce state and municipal laws. Legally, federal regulations must be followed when there are conflicts between federal-state-municipal level legislation, as well as conflicts between Ministries within the federal level.

In the federal government numerous agencies within several Ministries share jurisdiction in ensuring the safety of the Brazilian food supply, and regulate imports of all agricultural commodities and foods. In general, the Ministry of Agriculture and Food Supply (MAA) is the primary Ministry which oversees and enforces most of the regulations regarding the production, marketing, import and export of *fresh and semi-processed* agricultural and food products.

The Ministry of Health (MS) is the primary Ministry which enforces most of the regulations regarding *processed* food products, regardless of its origin, and in this area has similar functions in regulating food as does the Food and Drug Administration (FDA) in the United States.

Other Ministries and/or agencies also involved in some aspects of food safety are the Environment Protection Institute (IBAMA), within the Ministry of the Environment; The National Institute of Metrology, Standardization and Industrial Quality (INMETRO), within the Ministry of Development, Industry and Commerce (MDIC); the National Technical Commission on Biosafety (CNTBio), which is an inter-Ministerial Commission but based in the Ministry of Science and Technology (MCT); and the Department of Consumer Protection and Defense (DPDC) within the Ministry of Justice.

Ministry of Agriculture and Food Supply (MAA):

The Brazilian Ministry of Agriculture and Food Supply (MAA) is composed of four major offices, called Secretariats: the Office of Agricultural Policy (SPA), the Office of Rural Development and Cooperativism (SARC), the Office of Agricultural Production and Marketing (SPC) and the Office of Agricultural Protection (SDA). MAA's regulatory activities of interest for this report are primarily enforced by SDA, and to a lesser extent by SARC.

1. Office of Agricultural Protection (SDA):

The Office of Agricultural Protection is responsible for enforcing regulations governing domestic and imported plants and animals, and their respective products and by-products, and certain other agriculturally related products. In cooperation with State governments, SDA administers Federal laws and regulations, and coordinates the Brazilian government positions in international forum, such as the World Trade Organization (WTO), Office of International Epizootic (OIE), and Codex Alimentarius (CODEX).

SDA is composed of three Departments:

- the Department of Animal Origin Products Inspection Service (DIPOA),
- the Department of Animal Health (DDA), and
- the Department of Plant Health and Inspection Service (DDIV).

1.1. Department of Animal Origin Products Inspection Service (DIPOA).

DIPOA is responsible for ensuring that all products of "animal origin" (meat derived from cattle, sheep, swine, goats, horses, game meat, poultry, dairy products, eggs, and seafood) moving in interstate and foreign commerce are safe, wholesome for consumption, and accurately labeled. DIPOA's regulatory responsibilities are similar to those ascribed in the United States to USDA's Food Safety Inspection Service (FSIS) for meat and meat products, and to USDA's Agricultural Marketing Service (AMS) for dairy products and eggs, as well as those of the U.S. Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) and the U.S. Department of Commerce's (USDOC) National Oceanic and Atmospheric Administration, National Marine Fisheries Services (NOAA/NMFS) for seafood products. DIPOA is also the federal agency responsible for enforcing federal regulations regarding the Hazard Analysis Critical Control Points (HACCP) for the meat, dairy and seafood industries.

Both domestic and foreign producers of meat and meat by-products sold in Brazil must be registered with SDA/DIPOA. In order to export meat and meat by-products to Brazil, the exporting country's inspection system must first be recognized by DIPOA as "equivalent" to the Brazilian system. In order for this to happen the appropriate regulatory authorities of the exporting country must fill out a questionnaire and include all the regulations concerning inspection of meat products in that country. On the basis of responses in the questionnaire, Brazilian authorities will judge if the inspection system of that country provides an equivalent level of protection to the Brazilian system. Random on-site visits to a sample group of processing plants will be conducted in order to verify the accuracy of the responses to the questionnaire. DIPOA will then issue a list of approved plants eligible to export meat and meat by-products to Brazil. Any future inclusion of meat plants in this list must be requested by the proper federal authority within the exporting country through their respective Embassies in Brasilia.

The major laws and regulations that provide DIPOA's regulatory authority for domestic and imported products of animal origin are:

- * Decree 30,691 of March 29, 1952
- * Ministerial Directive 574 of December 8, 1998
- * SDA Directive 183 of October 9, 1998
- * DIPOA Resolution Number 1 of January 21, 1999
- * Ministerial Directive 46 of February 10, 1998

Note: Brazilian federal regulations for 1998 and 1999 can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br>

1.2. Department of Animal Health - DDA

DDA is responsible for enforcing regulations governing the import and the export of live animals, semen and embryos, as well as the registration of veterinary products. In cooperation with State governments, DDA enforces federal laws and regulations to protect and improve animal health, control and eradicate animal diseases (such as the Foot-and-Mouth Disease Eradication Program). It defends Brazilian borders against foreign and exotic animal diseases. In this respect, DDA's regulatory responsibilities are similar to those ascribed in the United States to USDA Animal and Plant Health Inspection Service's (APHIS), Veterinary Services (VS). In addition, DDA is also responsible for the registration and regulation of veterinary products used in the animal industry. In this regard, its regulatory responsibilities are similar to those ascribed in the United States to HHS/FDA's Center for Veterinary Medicine as well as to APHIS Veterinary Biologics.

In order to export live animals, semen and embryos to Brazil, exporters of U.S. genetics must meet the animal health requirements issued by DDA, which can be seen on APHIS/VS's home page <http://www.aphis.usda.gov>. Several of these requirements were updated in the last few months before the publication of this report.

DAA also is responsible for enforcing the National Program for Controlling Biological Residue in Meats through their Animal Reference Laboratories.

The major laws and regulations that provide DDA's regulatory authority for domestic and imported animal genetics and veterinary products are:

- * Decree 24,548 of July 3, 1934
- * Decree 64,499 of May 14, 1969

Note: Brazilian federal regulations for 1998-2001 can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br>

Note: As of July 2000, DDA has a ban on imports of U.S. sheep (due to scrapie). As of July 2001, Brazil resumed imports of fertile ostrich eggs.

1.3. Department of Plant Health and Inspection Services - DDIV.

DDIV is responsible for protecting the health of plants, and to prevent the introduction into and spread of foreign pests within Brazil. In this respect, DDIV's regulatory responsibilities are similar to those ascribed in the United States to USDA/APHIS's Plant Protection and Quarantine (PPQ). In addition, DDIV also has the regulatory authority to enforce federal laws regarding the registration, compliance and labeling of beverages (including distilled spirits, wine, soft drinks, and juices). In this respect it's regulatory responsibilities are similar to those ascribed in the United States to the Department of Treasury's Bureau of Alcohol, Tobacco and Firearms (ATF), with the exception that DDIV provides a broader spectrum of services, including laboratory tests.

All U.S. unprocessed products of plant origin (bulk grains, fresh fruits and vegetables, nuts, and seeds) can only be exported to Brazil if accompanied by a APHIS/PPQ phytosanitary certificate. U.S. exporters should always check with the nearest PPQ office or the APHIS /PPQ home page at <http://www.aphis.usda.gov> to see the latest import requirements from Brazil for unprocessed plant products because Brazil's regulations in this area are changing frequently due to the gradual harmonization of plant health regulations within MERCOSUL.

DDIV also requires that imports of wine, beer, distilled spirits and juices be registered with DDIV. In addition, the importer must also be registered with DDIV. To clear customs, these products are subject to inspection by DDIV, who will hold samples for chemical analysis.

The major laws and regulations that provide DDIV's regulatory authority for domestic and imported plant products, distilled spirits, wine, beer, and juices are:

- * Decree Number 239 of December 30, 1998.
- * Decree 24, 144 of April 12, 1934
- * Directives 641, 642, and 643 of October 3, 1995
- * Directive 186 of March 21, 1996
- * Directive 130 of April 15, 1997
- * Directive 158 of April 16, 1997
- * Directive 182 of November 9 1998

Note: Brazilian federal regulations for 1998-2001 can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br>

2. Office of Rural Development and Cooperativism (SARC)

The Office of Rural Development is responsible for enforcing regulations regarding animal and plant production, such as animal genetics, quality standards for grains, seed, fruits and vegetables, and quality and production grades and standards for pet food. In addition to rural extension responsibilities, SDR has two departments that have responsibility for inspection related activities.

2.1. Department of Development and Surveillance of Animal Production (DFFPA).

DFPA is responsible for the regulatory inspection of feed for animal consumption (feeds and fodders as well as pet food), the registration of establishments producing animal semen and embryos, and the genealogical registration of live animals. In this respect it's regulatory responsibilities are similar to those ascribed in the United States to USDA/APHIS/VS, and the USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA).

U.S. companies exporting feed and fodder, pet food, live animals, semen and embryos must obtain an import permit from DFPA. Brazilian importers of live animals must obtain a permit for import that meets the Brazilian genetic requirements for a specific breed. Brazilian importers of pet food must register the imported products with DFPA before applying for an import permit. In all cases, the Brazilian importer must be registered with the Ministry of Agriculture and Food Supply (MAA).

2.2. Department of Development and Surveillance of Plant Production (DFFPV).

DFFPV is responsible for the regulatory inspection and registration of all planting seeds (including Genetically Modified Organisms (GMOs), as well as for establishing standards for agricultural products such as grains, fruits and vegetables. In this respect its regulatory responsibilities are similar to those described in the United States to USDA/APHIS/PPQ, USDA/AMS, and USDA/GIPSA. This Department is also responsible for registration and inspection of fertilizers.

Ministry of Health (MS)

The Ministry of Health's regulatory activities are now enforced by a newly created agency called the National Agency of Sanitary Surveillance (ANVISA). The structure of ANVISA was based on the United States' Food and Drug Administration (FDA) in that it is a semi-autonomous agency within the Ministry of Health. The ANVISA was officially created by Law 9,782 on January 27, 1999, and implemented by Decree 3,029 of April 19, 1999, and is now the scientific regulatory agency responsible for the safety of all foods (mostly processed products), except for those that fall under the regulatory authority of the Ministry of Agriculture and Food Supply (such as bulk commodities, meats, dairy, fisheries, alcoholic beverages and feed) as discussed above. The ANVISA is also responsible for overseeing the production and registration of drugs, food additives, medical devices, and tobacco and tobacco products.

The primary function of the ANVISA is to protect the public, i.e., human health in relation to food, assessing food standards, safety, and contaminants. In addition, it is responsible for the registration of any Brazilian company or multinationals established in Brazil producing food products, such as canned products, pasta, and snacks. Before a certain product can be placed on the Brazilian market, it must be registered with ANVISA and receive a registration number which must be placed on the label of the product. For food products the registration number is valid for 5 years, while the registration of foreign or domestic firms is done on a yearly basis.

Prior to Law 9,782/99 cited above, imported food products were exempt from the registration requirement of the MS under Article 58 of Decree-Law 986 of October 21, 1969. Law 9,782/99 revokes Article 58 of Decree-Law 986 and the exemption for imported food products and established a new rule under which all foreign food products must follow the same procedures for registration as those required for domestically manufactured food items.

On March 16, 2000 ANVISA published Resolutions 22 and 23 in the *Diario Oficial* (Brazil's Federal Register), regarding the new procedures for registration and exemption of registration of imported food products that fall under the regulatory authority of the Ministry of Health. The objective of Resolution 22 and 23 are to provide guidance to food importers and to improve ANVISA's efficiency in coordinating public health actions on imported food products.

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 mandatory registration requirement with ANVISA. The procedures and forms for registration and exemption of registration of imported food products are the same as those for domestic produced food products.

The request for registration or exemption of registration must be done by the food importer, the local subsidiary of the exporting company, or by a legal representative of the exporter. If there is more than one importer for the same imported product, each importer must make a separate request. In the case of the subsidiary or legal representative of the exporter, one request can be done for an imported product with different brands and importers.

All imported products, additives and packaging must be in accordance with Decree-Law Number 986, of October 21, 1969 and respective regulations.

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, according to the size of the company. The following fee structure is currently in force:

Description	Fee by Company Size*				
	Group I**	Group II**	Medium**	Small**	Micro**
Company Registration / Authorization to Sell	R\$6,000	R\$5,100	R\$4,200	R\$600	R\$300
Product Registration	R\$6,000	R\$5,100	R\$4,200	R\$600	Exempt

* Fee is charged in local currency; the "Real" (R\$).

** 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\$15 million and R\$50 million); Medium (Annual income between R\$1.2 million and R\$15 million); Small (Annual income between R\$0.12 million to R\$1.2 million), and Micro (Annual Income up to R\$0.12 million).

*** Current exchange rate is US\$1.00 = R\$2.45

The registration for these products is valid for 5 (five) years in the entire Brazilian territory. The codes used before each product in the Annexes below are control codes used by the Ministry of Health, and should not be confused with the codes of the Harmonized Tariff System (HS).

ANNEX I: Imported Food Products Exempt from Registration:

Code	Description of Product
4100115	Sugar
420038	Food and Beverages for Supplemental Nutrition
4100174	Frozen Products
4200082	Starches and Fecules
4100191	Flavoring Additives
4300167	Confectionery Products
4100085	Biscuits
4100018	Coffee
4300151	Cereals and Derivatives
4300025	Teas
4100107	Colors
4300084	Vegetable Creams
4300182	Erva-Mate Tea Compounds
4100093	Prepared Seasonings
4100077	Canned Vegetables (except for Heart of Palm)
4100034	Cakes

4200071	Packaging
4300051	Erva-Mate Tea
4100042	Seasonings
4100026	Flours
4300076	Wheat Flour and/or Corn Fortified with Iron
4300164	Fruits (dried or freeze dried)
4100050	Canned Fruits
4200012	Frozen Dairy Products
4300190	Mocoto Jam
4300131	Fruit Jams
4100131	Pasta
4200098	Powders or Mixes for Food and Beverage Preparations
4100158	Vegetable Oils and Fats
4100123	Breads
4300169	Pates
4300181	Fruit Pulp
4300191	Vegetable Pulp
4300092	Preparations and Products for Seasonings
4100166	Cocoa Products/Chocolates
4200063	Coconuts Products
4100141	Baking Products
4300068	Fruit Products, Cereals and Legumes for Use in Yogurt
4100182	Soybean Food Products
4100069	Tomato Products
4300101	Snack Foods
4300163	Oilseeds
4300160	Desserts and Powders for Dessert
4300168	Soups
4300165	Vegetables (Dissected and Freeze Dried)

ANNEX II: Imported Food Products With Mandatory Registration:

4200047	Additives (Formulated)
4100190	Additives (Sole Substance)
4100113	Artificial Sweeteners
4200020	Mineral Water
4200030	Potable Table Water
4300164	Purified Water
4200039	Foods with Added Essential Nutrients
4300032	Functional Foods
4300033	Infant Formulas
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 Participants
4300069	Foods of Animal Origin (only those under the Jurisdiction of the Ministry of Health)
4300017	Non-Alcoholic Beverages (only those under the Jurisdiction of the Ministry of Health)
4200055	Technology Coadjuvants
4300162	Liquid Compounds for Consumption
4300031	Recycled Packaging
4200123	Ice
4300030	New Foods and/or New Food Ingredients
4100204	Salt
4200101	Salt - Other
4300041	Vitamin and/or Mineral Supplements
4000009	Canned Vegetable (Heart of Palm)

ANNEX III: Information to be Provided on the Form for Imported Food Products Exempt from Registration:

Field A: To be filled in by the Sanitary Authority

Field B: Name of the Importer, Legal Representative of the Exporter or Subsidiary. Full address, Phone, Fax, E-mail, and Corporate Tax Number.

Field C: Information regarding the warehousing unit.

Field D: Terms of Responsibility to be signed by the importer.

Field E: Information about the product, including: validity (expiration) date of the product (Year/Month/Day); Code and Description of the Product (as per Annex I), Brand, Type of Packaging, Manufacturer (Exporter), Country of Origin, Commercial Perspective (if product is to be sold in one specific city, state or national territory)

Note: It is common practice in Brazil to retain the services of specialized firms in registration of products within the Ministry of Agriculture and Ministry of Health. For a list of these firms, U.S. exporters should contact the Office of Agricultural Affairs (OAA) in Brasilia (E-mail: Agbrasil@fas.usda.gov) or the Agricultural Trade Office (ATO) in Sao Paulo (E-mail: atosp@unisys.com.br.)

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 are:

- * Decree Law 986 of October 21, 1969
- * Law 9,782 of January 26, 1999
- * Decree 3,029 of April 19, 1999
- * Provisional Measure 1,912-5 of June 30, 1999
- * Resolution 237 of July 2, 1999
- * Resolution 22 of March 16, 2000
- * Resolution 23 of March 16, 2000

Note: Brazilian federal regulations for 1998-2001 can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br> or in ANVISA's home page at <http://www.anvisa.gov.br>

Ministry of the Environment (MMA)

The Brazilian Institute for the Environment and Natural Resources (IBAMA), within the Ministry of the Environment, has regulatory authority for activities that affect the environment. It is one of the key government agency that has regulatory authority for the approval of agricultural chemicals (pesticides, 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 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).

U.S. exporters can obtain a list of approved pesticides by writing to:

DDIV/SDA

Ministerio da Agricultura e do Abastecimento

Esplanada dos Ministerios, Bloco D, Anexo, 3 andar

70403-900 Brasilia, DF

Tel.: (55-61) 218-2172 or Fax (55-61) 224-3874

Ministry of Development, Industry and Commerce (MDIC)

The National Institute of Metrology, Standardization and Industrial Quality (INMETRO) is the Brazilian agency or Inquiry Point to handle comments regarding the notifications to the World Trade Organization (WTO). INMETRO also conducts tests of domestic and imported products (industrial or food products) to check that they meet the specifications of their labels.

Note: Brazilian federal regulations for 1998 and 1999 can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br> and MDIC's home page <http://www.mdic.gov.br>

Ministry of Science and Technology (MCT)

The National Technical Commission on Biosafety (CNTBio), an inter-governmental Commission which is based in the Ministry of Science and Technology, was formed as a result of the 1995 Brazilian Biosafety Law (Law 8,974/95 and its implementing regulation (Decree 1,752/95). CNTBio is composed primarily of scientists from government and academia, but also has representation from industry and consumer groups. As of July 2000, CNTBio has 36 members.

CNTBio is the national regulatory agency responsible for developing national and international biotechnology policy in Brazil. It provides recommendations to the Government of Brazil on specific applications for product release and experimental plantings, particularly genetically modified organisms (GMOs).

On December 28, 2000, the Brazilian President issued a new Provisional Measure (MP 2,137) which is intended to resolve the legal problems that have derived from the court battles involving the release of GMO varieties in Brazil, including court battles involving the importation of GMO corn from Argentina. MP 2,137 adds to and alters some clauses of Law 8,974/95 to more clearly define the role of CTNBio, providing CTNBio with the legal authority to issue final technical reports about the release of GMOs in Brazil, as well as redefining the functions of each Ministry within the federal government as it relates to GMOs.

Note: A Provisional Measure is an act issued by the President, under the powers and privileges granted to him by the 1998 Brazilian Constitution. It has the power of a law, until Congress gives final approval, and then, becomes a law.

The major laws and regulations that provide CNTBio's regulatory authority for domestic and imported Biosafety issues, such as GMO's are:

- * MP 2,137 of December 28, 2000
- *Law 8,974 of January 5, 1995
- *Decree 1,752 of December 20, 1995

Note: Brazilian federal regulations for 1998-2001 can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br> and CTNBio's home page is <http://www.ctnbio.gov.br>

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 Law 8,078 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 which assists consumers directly in pursuing their rights.

The major regulations that provides the Ministry of Justice regulatory authority over domestic and imported food products, mostly in the area of food labeling and consumer rights are:

- *Law 8,078 of September 11, 1990
- *Decree 3,871 of July 18, 2001

The President of Brazil signed Decree No. 3,871 on July 18, 2001 (published on July 19, 2001 in the Diario Oficial), which establishes a four (4) percent tolerance limit in packaged food products containing genetically modified organisms. This Decree applies to all genetically modified packaged food products that have received final technical approval from the National Technical Commission on Biosafety (CTNBio). This Decree also creates an Inter-ministerial Commission to analyze and review the provisions of the Decree and the methodology to detect the presence of genetically modified organisms. This Decree does not enter into force until December 31, 2001.

Note: Brazilian federal regulations for 1998-2001 can be found in the home page of the Diario Oficial (Brazil's Federal Register): <http://www.in.gov.br> and Ministry of Justice's home page <http://www.mj.gov.br>

B. LABELING REQUIREMENTS

In general, packaging for retail consumer food and beverage products is more elaborate in Brazil than in other Latin America countries. Brazilian food processors are very creative in packaging and have won several international prizes. Packaged retail food products from the United States and from the European Union have generally good acceptance among Brazilian consumers. U.S. exporters should be aware that Brazilian consumers prefer individual and small-size packages, due to the relatively high prices of imports.

As noted above, the Brazilian Consumer Protection Law number 8,078 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*.

It was a common practice in Brazil for local importers, agents or distributors to affix to the foreign label a small adhesive label in Portuguese with the following information from the U.S. exporter:

Name of the Food	Statement of Ingredients
Country of Origin	Special Storage Instructions (when necessary)
Net Weight (in metric units)	Date of Production
Food Additives and Colors	
Expiration Date (shelf life, established by the manufacturer)	

The adhesive label must also show the identification and full address of the Brazilian importer, including its Income Tax registration number (CGC number). 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 or validity or shelf life date is very important for Brazilian consumers, and should never be overlooked for marketing purposes.

On March 22, 2001, the Brazilian Ministry of Health published Resolution Number RDC40, establishing new nutritional labeling requirements for all packed foods and beverages. These nutritional labels follow the same standards of those in force in the United States. Brazilian companies have six months from March 22, 2001 to comply with this new regulation, which also applies to imported packed foods and beverages.

Labeling of Animal Origin Products (Processed Meats, Dairy Products):

The Department of Animal Origin Products Inspection (DIPOA), Ministry of Agriculture and Supply (MAA) 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 meats and dairy products. The registration process requires that the U.S. plant operators fill out a questionnaire concerning the product to be exported to Brazil. In addition to the signature of the plant operator, questionnaires must also be signed by the government inspector at the plant.

Directive 371/97 contains the technical regulations for labeling products of animal origin. Since January 4, 2000, only those products which have their labels pre-approved by DIPOA are allowed to enter Brazil. For additional information, U.S. exporters should contact the Food Safety and Inspection Service (FSIS) at:

International Programs
Food Safety and Inspection Service (FSIS)
U.S. Department of Agriculture (USDA)
1400 Independence Avenue SW
Washington, DC 20250
Tel.: (202) 720-6400
Fax: (202) 720-7990

Labeling of Seafood Products:

Brazilian regulations require that U.S. companies exporting fish and seafood products to Brazil, must have their products processed in plants under supervision of a federal agency of the U.S. Government, such as the Food and Drug Administration (FDA) or with the National Marine Fisheries Service (NMFS), USDOC/NOAA. In addition to the registration of the U.S. processing plant with DIPOA, the Brazilian Government requires pre-approval of labels for seafood products.

The Brazilian importer or agent of the U.S. plant/exporter must file a questionnaire with DIPOA officials in Brasilia requesting label approval before shipping the product.

Labeling of Other Food Products:

Food products other than animal origin products must be registered with the National Agency of Sanitary Surveillance (ANVISA), Ministry of Health.

ANVISA will require that the exporter presents the so-called "FDA's Good Manufacturing Practices (GMP) certification as part of the request for processing plant and label approval. The FAS office at the American Embassy in Brasilia can provide U.S. companies with names and addresses of Brazilian firms which specialize in assisting with the registration of labels with the Ministry of Health.

C. FOOD ADDITIVE REGULATIONS

The ANVISA within the Ministry of Health is the agency responsible for the regulatory approval of food or coloring additives in foods.

In general, ANIVSA requirements follow FDA regulations for food additives. For a complete list of approved food and coloring additives the U.S. exporter should contact ANVISA directly or a consulting firm in Brazil which specializes in this area.

D. PESTICIDE AND OTHER CONTAMINANTS

In general, Brazil adopts the international standards (Codex Alimentarius) for tolerances for pesticides, herbicides and fungicides used in fumigation of agricultural products. These tolerance level regulations apply to all chemically treated products produced in Brazil or imported which are intended for human and animal consumption.

Regulatory authority for the registration of agricultural chemicals in Brazil is divided among three agencies of the federal government; the Ministry of Agriculture and Food Supply (MAA) is the initial point for the petition for registration. The MAA will then forward the petition to the Ministry of the Environment which will assess the possible environmental impact of that specific chemical. The petition is then sent to the Ministry of Health which will assess the toxicology aspects of the product. Finally, the petition is returned to the MAA for final approval and registration.

E. OTHER REGULATIONS AND REQUIREMENTS

Brazilian Inspection Requirements for Meat and Dairy Products

Brazilian regulations, require U.S. companies exporting products of animal origin to Brazil to have their products (beef, pork, powder milk, cheese) processed in plants in the United States which are federally inspected. Brazilian inspection officials will not register U.S. plants on the basis of state inspection only or products from uninspected facilities.

The only federal agency eligible to approve U.S. processing meat plants is the Food and Safety Inspection Service (FSIS), U.S. Department of Agriculture. The U.S. exporter must request that the processing plant be included in the list of approved meat plants to export to Brazil. The request can be done through FSIS/USDA or through the FAS office in the American Embassy in Brasilia.

The only federal agency eligible to approve U.S. processing dairy plants to export to Brazil is the Agricultural Marketing Services (AMS), U.S. Department of Agriculture. The U.S. exporter must have the processing plant included in AMS's list of U.S. Dairy Plants Surveyed and Approved for USDA Grading Service. The exporter can request directly through the FAS office at the American Embassy in Brasilia that the plant be included in DIPOA's approved list of U.S. dairy plants eligible to export to Brazil.

IMPORTANT NOTES:

- (1) The same procedure applies for exports of U.S. seafood. The U.S. plant must be inspected by either NOAA/NMFS or FDA before exporting to Brazil, and be included on DIPOA's list.
- (2) Samples and mail orders of products of animal origin shipped to Brazil for trade shows or market testing must come from plants approved by DIPOA officials.
- (3) Registration of ice cream is done by the National Agency of Sanitary Surveillance (ANVS), Ministry of Health. It follows the same procedures as those for registration of processed foods, including the payment of a registration fee for the registration of the company as well as the specific product. (See Ministry of Health Section above.)
- (4) As of July 2001, DIPOA officials are only registering new U.S. seafood plants. DIPOA is not registering new U.S. meat and dairy plants for exports to Brazil until they complete the review of the U.S. inspection system. DIPOA has conducted an on-site visit of U.S. plants during the first half of 2001, but the final report has not been released. However, DIPOA is honoring the registration of U.S. meat and dairy plants registered with DIPOA previous to March 2, 1999.

(5) DIPOA officials do not register U.S. poultry plants for exports of poultry products to Brazil due the lack of reciprocity.

Brazilian Inspection Requirements for Plant Products

All U.S. unprocessed products of plant origin (bulk grains, fresh fruits and vegetables, nuts, and seeds) can only be exported to Brazil if accompanied by a 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 see latest import requirements and to see if there is a need to conduct a PRA (pest risk assessment) of the product before exporting to Brazil.

Questions about specific Brazilian import requirements can also be directed to APHIS/PPQ at the following address:

Export Certification Unit
Plant Protection and Quarantine (PPQ)
Animal and Plant Health Inspection Service (APHIS)
U.S. Department of Agriculture
4700 River Road Unit 139
Riverdale, MD 20737-1236
Tel: (301) 734-8537 Fax: (301) 734-5786

Brazilian Inspection Requirements for Animal Genetics

The Department of Animal Health (DDA), Ministry of Agriculture and Food Supply (MAA) is responsible for issuing the animal health requirements for imports of live animals, semen and embryos. In addition, the Office of Rural Development and Cooperativism (SARC) must also issues the genetic requirements/standards for each breed of animal. Before exporting live animals, semen or embryos to Brazil, the U.S. exporter should contact APHIS/VS at the following address:

National Center for Import and Export
Animals Program
Veterinary Services
Animal and Plant Health Inspection Service (APHIS)
U.S. Department of Agriculture
4700 River Road Unit 39
Riverdale, MD 20737-1231
Tel: (301) 734-7511
Fax: (301) 734-6402

Brazilian Inspection Requirements for Animal Feed

U.S. exporters of animal feed and fodder, including pet food, must be registered with the Department of Development and Surveillance of Plant Production (DFFPV), Office of Rural Development and Cooperativism (SARC), Ministry of Agriculture and Food Supply (MAA).

The first step is for the U.S. exporter of animal feed to find an importer (or a legal representative) in Brazil who must file the request for registration of the imported product with DFFPV/MAA. The importer must also be registered with the Ministry of Agriculture before submitting his request for registration. A comprehensive questionnaire must be filled out including label information.

Veterinary Biologics

The importation of veterinary biologics, such as vaccines, antiserums, and diagnostic test kits, are subject to prior registration with the Department of Animal Health (DDA), Ministry of Agriculture and Food Supply (MAA). DDA does not register growth promotants (hormone) for beef cattle, but does for dairy cattle. The first step for the U.S. exporter of veterinary biologics is to find an importer (or a legal representative) in Brazil to file the request for registration with DDA/MAA. The importer must also be registered with the Ministry of Agriculture before submitting his request for registration. A comprehensive questionnaire must be filled out including label information.

Alcoholic and Other Beverages

The Department of Plant Health and Inspection Service (DDIV), Ministry of Agriculture and Food Supply (MAA) 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 it's regulatory responsibilities are similar to those ascribed in the United States to the Department of Treasury's Bureau of Alcohol, Tobacco and Firearms (ATF), with the exception that DDIV provides a broader spectrum of services, including laboratory tests.

F. OTHER SPECIFIC STANDARDS

Endangered Species

The import and export of animals and plants into Brazil that are covered by the Convention on the International Trade in Endangered Species of Wild Flora and Fauna (CITES) fall under the regulatory responsibility of the Ministry of the Environment. A specific authorization is needed to enter or leave the country with animals and plants protected under the CITES.

Supplemental/Dietary Foods

The import of infant formula, dietary, and supplemental foods are under the responsibility of the National Agency of Sanitary Surveillance (ANVS), Ministry of Health. It follows the same procedures as those for registration of processed foods, including the payment of a registration fee for the registration of the company as well as the specific product. (See Ministry of Health Section above.)

Organic Foods

Organic farming is growing rapidly in Brazil. Growth is estimated at 20 percent per year, and commercial production is still limited mostly to grains and vegetables, although it is increasing in the meat and dairy sectors as well. The growth in organics in Brazil has been recently boosted by the large interest of the Brazilian supermarkets in buying organic products. The country has about 1,200 certified farmers and two private institutions with the authority to certify organic products. There are no official trade statistics about organic

products, either for imports or exports.

The rapid growth of organic farming in Brazil has prompted the Brazilian government to regulate the sector. On May 19, 1999, the Minister of Agriculture and Food Supply (MAA) published in the *Diario Oficial* (Brazil's Federal Register) Normative Instruction Number 7, which contains the standards for production, classification, processing packaging, imports, distribution, identification and certification of the quality of organic products, of both animal and plant origin.

Both domestic and imported organic products must be labeled with the term "organic product" and the name and registration number of the certifying organization. For bulk products, the shipment must be accompanied by a "certificate of organic quality". The Office of Agricultural Protection (SDA) of the Ministry of Agriculture and Food Supply (MAA) has the authority regarding import approval of organic products.

Genetically Modified Organisms

The current Brazilian regulatory framework for biotechnology, particularly as it pertains to food biotechnology, is as follows:

(1) The National Technical Commission of Biosafety (CTNBio) is an inter-governmental commission which is based in the Ministry of Science and Technology, and was formed as a result of the 1995 Brazilian Biosafety Law (Law 8,974/95 of January 6, 1995). CNTBio is the national regulatory agency responsible for developing national and international biotechnology policy in Brazil. It provides recommendations to the Government of Brazil on specific applications for product release and experimental plantings, particularly genetically modified organisms (GMOs).

Brazil's law 8,974/95 prohibits the entry of genetically modified organisms in Brazil without prior approval. The law does not distinguish between GMOs for planting and release into the environment and GMOs for processing into animal feed or human consumption.

CTNBio decision to release Round up Ready soybeans for commercial planting in Brazil has been suspended by an injunction of a federal judge. The request for the injunction was made by a Brazilian consumer protection group (IDEC) and Greenpeace. Monsanto has appealed the ruling, but as of July 2000 no further decision has been taken yet by a superior court.

The recent authorization of CTNBio for release of Bt corn imported from Argentina for animal feed has also resulted in a judicial battle among Brazilian government agencies and the judiciary. Although the shipment was unloaded in the Port of Recife, Brazilian importers of corn (mostly poultry and swine producers and processors) are reluctant to import corn without assurances that it is non-GMO corn. Consumer groups have appealed to Brazilian courts against CTNBio's decision on Bt corn.

(2) The Office of Consumer Protection and Defense (DPDC), Ministry of Justice (MJ), is the office in charge of applying the Brazilian consumer laws, including label regulations.

(3) The Ministry of the Environment is responsible for approving environmental impact assessments for GMOs.

(4) The Ministry of Agriculture and Food Supply (MAA) provides authorization, following input from CTNBio,

for planting, import/export, and consumption of all agricultural related GMOs.

(5) The Ministry of Health's agency, ANVISA, is responsible for recalling products from the retail outlets.

G. COPYRIGHT/TRADEMARK LAWS

Protecting intellectual property rights is basically the responsibility of each company. Obtaining registered protection for the company's intellectual property rights in Brazil is a matter for private legal counsel. A major concern of foreign companies trading with Brazil is that protection of intellectual property rights is often inadequate and uncertain. Brazil is a signatory to the Paris, Bern and Universal Copyright conventions on Intellectual Property Rights (IPR) protection. Most of the country's statutes on IPR are consistent with Western standards. The Industrial Property Law was enacted in 1996. Enforcement of IPR regulations is handled by the National Institute of Industrial Property (INPI), a federal agency within the Ministry of Development, Industry and Commerce (MDIC).

Some issues of concern to foreign patent holders are INPI's slow processing of patent applications, the federal judiciary's uncertain application of patent law, and the potential for arbitrary interpretation of compulsory licensing requirements.

H. IMPORT PROCEDURE

Establishing a Business Relationship

All the customary import channels exist in Brazil: agents, distributors, brokers, wholesalers, specialty import houses, trading companies, subsidiaries and branches of foreign firms, among others. The best way to do business in Brazil is to establish a business relationship with or through one of these established channels. As in other countries, the selection of the importer requires careful consideration. An unique aspect of the Brazilian market is that a single importer may not be able to cover the entire country adequately, and there is no need to grant exclusive rights.

Potential U.S. food exporters to Brazil should take into consideration the following factors while establishing a business relationship:

- a) Although Brazil is of vast geographic size, the majority of importers are located in Sao Paulo, and to a lesser extent in Rio de Janeiro, Belo Horizonte, Curitiba, Porto Alegre, Salvador, Recife, and Fortaleza.
- b) Participation in trade shows is encouraged. The major shows include: the National Supermarket Convention and Exhibition (ABRAS show), held annually in September in Rio de Janeiro; the Sao Paulo Supermarket Convention and Exhibition (APAS Show), held in May in Sao Paulo, and the International Food Show (FISPAL), held in June in Sao Paulo. FAS's Agricultural Trade Office (ATO) in Sao Paulo maintains a list of trade shows in Brazil which target specific products and sectors.
- c) A well-qualified Brazilian importer should have an office in one of the cities mentioned above and must be registered with the Brazilian Foreign Trade Office (DECEX) of the Ministry of Development, Industry and Commerce (MDIC).

d) Import duties and taxes. Since 1990, Brazil eliminated a number of non-tariff barriers to imports, and lowered most import duties on commodities and foods. Import duties vary from 10 to 15% for most bulk agricultural products and 15 to 25% on highly processed food products. Today, Brazil, together with its MERCOSUL partners (Argentina, Uruguay, and Paraguay), applies the MERCOSUL Common External Tariff (CET). In addition, Chile and Bolivia, as associate members of MERCOSUL, enjoy preferential import tariffs.

Documentation and Merchandise Entry

After you establish your business relationship, and negotiate your sale, the following basic steps are followed by your Brazilian importer, or agent:

- a) The U.S. exporter must supply the representative in Brazil with a *Pro forma* invoice for the product (s) to be exported to Brazil;
- b) The Brazilian representative files an application for an import permit for the specific transaction;
- c) In case of some agricultural products (plants, seeds); animal genetics (live animals, semen, embryos) and products of animal origin (meats, dairy) the importer must check with the Ministry of Agriculture and Food Supply (MAA) for the import requirements for that specific product. For instance, to import beef, the U.S. plant must be registered with the Department of Animal Origin Inspection Service (DIPOA), and have labels pre-approved by DIPOA. Most of these transactions are done on-line through the Automatic Import Licensing System called SISCOMEX;
- d) Once the application for the import of the shipment is approved by SECEX, the importer notifies the U.S. supplier to ship the product(s);
- e) The U.S. exporter should send all shipment documents (Bill of Lading, etc.) and the commercial invoice along with the product;

Note: For products of animal origin, the Ministry of Agriculture and Food Supply (MAA) requests that the export certificate be certified (stamped) by a Brazilian Consulate in the United States.

- f) The importer arranges for a licensed customs expediter to clear the goods and pay customs duties and other taxes (typically the ICMS (value-added) tax);
- g) A copy of the import license and the paid customs declaration are sent to the bank to complete the foreign exchange transaction.

Note: Before shipping an exporter should ask that the importer open an irrevocable and confirmed Letter of Credit.

APPENDIX I - WORLD TRADE ORGANIZATION (WTO) INQUIRY POINT

Each World Trade Organization (WTO) member government is responsible for the notification procedures associated with agreement. Examples relate to the Sanitary, Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements. WTO obligations include:

- notifying any trade significant proposals which are not substantially the same as international standards to the WTO; providing copies of the proposed regulation upon request;
- allowing time for comments;
- providing upon request copies of other relevant documents on existing regulations related to food and agriculture.

Information on the country's regulations, standards and certification procedures can also be obtained through the Enquiry Point(s) listed below:

Centro de Informacao e Difusao Tecnologica - CIDIT
Instituto Nacional de Metrologia, Normalizacao e Qualidade Industrial - INMETRO
Av. N.S. das Gracas 50
25250-020 Duque de Caxias, RJ
Brasil
Internet site: <http://www.inmetro.gov.br>
Tel: (55) (21) 779 1409
Fax: (55) (21) 779 1631 or (55) (21) 779 1405

APPENDIX II - LIST OF MAJOR REGULATORY AGENCIES

Office of Agricultural Protection (SDA)
Ministry of Agriculture and Food Supply (MAA)
Esplanada dos Ministerios, Bloco D
Anexo B, 4 Andar, Sala 406
Brasilia, DF 70043-900
Phone: (55-61)218-2314/15
FAX: (55-61) 224-3996 or 218-2316
Internet site: <http://www.agricultura.gov.br>

Office of Rural Development and Cooperativism (SARC)
Ministry of Agriculture and Food Supply (MAA)
Esplanada dos Ministerios, Bloco D, 3 Andar Sala 304
Brasilia, DF 70043-900
Phone: (55-61) 321-3594
Fax: (55-61) 321-4524
Internet site: <http://www.agricultura.gov.br>

Brazilian Environment Institute (IBAMA)
SAIN - Av. L 4 Norte
70800-200 Brasilia, DF
Phone: (55-61) 226-8221
Fax: 322-1058
Internet site: <http://www.ibama.gov.br>

Ministry of Science and Technology (MCT)
Esplanada dos Ministerios, Bloco E
70067-900 Brasilia, DF
Phone: (55-61) 321-8886
Fax: (55-61) 225-7496
Internet site: <http://www.mct.gov.br>

National Agency of Sanitary Surveillance (ANVS)
Ministry of Health
Esplanada dos Ministerios, Bloco G
70058-900 Brasilia, DF
Phone: (55-61) 315-2343
Fax: (55-61) 225-6056
Internet site: <http://www.saude.gov.br>

Ministry of Development, Industry and Commerce (MDIC)
Esplanada dos Ministerios, Bloco J
70056-900 Brasilia, DF
Phone: (55-61) 329-7000
Fax: (55-61) 329-7230
Internet site: <http://www.mdic.gov.br>

Brazilian Customs (Receita Federal)
Ministry of Finance
Esplanada dos Ministerios, Bloco P
70048-900 Brasilia, DF
Phone: (55-61) 412-3000
Fax: (55-61) 412-1721
Internet site: <http://www.fazenda.gov.br>

Brazilian Association of Supermarkets (ABRAS)
Av. Diogenes Ribeiro de Lima, 2872

Trade

05083-901 Sao Paulo, SP
Phone: (55-11) 838-4500
Fax: (55-11) 837-9933
Internet site: <http://www.abrasnet.com.br>

FoodNet (Coordinator FISPAL Food Show)
Rua Min. Nelson Hungria, 239 Con. 12
05690-050 Sao Paulo, SP
Phone: (55-11) 844-9111
Fax: (55-11) 844-8893
Internet site: <http://www.foodnet.com.br>

American Chamber of Commerce Sao Paulo
Rua Alexandre Dumas, 1976
04717-004 Sao Paulo, SP
Phone: (55-11) 246-9199
Fax: (55-11) 246-9080
Internet site: <http://www.amcham.com.br>

Ministry of Justice
Esplanada dos Ministerios, Bloco T
70064-900 Brasilia, DF
Phone: (55-11) 224-0954
Fax: (55-61) 322-6817
Internet site: <http://www.mj.gov.br>

Brazilian Assoc. of Food Industries (ABIA)
Av. Brigadeiro Faria Lima, 2003 11 Andar
01451-001 Sao Paulo, SP
Phone: (55-11) 814-6688
Fax: (55-11) 814-6688
Internet site: <http://www.abia.com.br>

Foodstaff (Consultant for food registration)
Alameda Guainumbis, 1089
04067-002 Sao Paulo, SP
Phone: (55-11) 5561-3276
Fax (55-11) 535-3976
Internet site: <http://www.foodstaff.com.br>

Agricultural Trade Office (ATO/FAS)
Alameda Santos, 2224 Ed. Suarez

Conj. 11
01418-200 Sao Paulo, SP
Phone: (55-11) 3082-3528
Fax: (55-11) 3083-7535
E-mail: atosp@unisys.com.br

Office of Agricultural Affairs (OAA/FAS)
American Embassy, Brasilia
Av. das Nacoes, lote 3
70403-900 Brasilia, DF
Phone: (55-61) 226-3159
Fax: (55-61) 226-6784
E-mail: Agbrasil@fas.usda.gov

