



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Scheduled Report - Public distribution

Date: 7/30/2007

GAIN Report Number: EC7007

Ecuador

FAIRS Country Report

Annual

2007

Approved by:

Eugene Philhower
U.S. Embassy

Prepared by:

Rene A. Alarcon

Report Highlights:

Sections Updated: Section I, Food Laws, has been updated to reflect recent changes to Ecuador's Health Code, which prohibits imports, use and trade of foodstuffs containing genetically modified organisms. Although Ecuador's food import regulations are generally based on international standards, the country faces challenges in enforcing its food regulations. New laws are generally passed without a profound technical analysis and without a public and international comment period.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Quito [EC1]
[EC]

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FOOD AND AGRICULTURAL IMPORT REGULATIONS AND STANDARDS (FAIRS)

"This report was prepared by the Office of Agricultural Affairs of the USDA/ Foreign Agricultural Service in Quito, Ecuador for U.S. exporters of domestic food and agricultural products. While every possible care was 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 costumers, 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."

SECTION I. FOOD LAWS

Ecuador has been a member of the World Trade Organization since 1996. Its Foreign Trade Law prohibits any economic, administrative or technical practice that may limit or discourage foreign and internal trade, free competition and local production of goods and services. This legislation also allows the application of corrective measures only in the instances included in the World Trade Organization normative.

In practice, Ecuador maintains tariff and non-tariff barriers that may interfere with agricultural and food imports. Although imports are not subject to excessive tariffs, technical and Sanitary/Phytosanitary (SPS) restrictions may not always be established with the sole purpose of protecting human, animal and plant health. Weak institutions often create inefficiency and there can be sudden changes in the application or interpretation of rules and requirements. Some administrative procedures are cumbersome and require excessive documentation.

Food safety is a shared responsibility in Ecuador. The Ministries of Agriculture and Health are in charge of controlling the food supply. Several agencies within these ministries handle the technical and administrative processes of prior authorization, inspection and control of local and imported foods and agricultural products.

Lately, with the increasing importance of biotechnology, the Ministry of Environment and the Ministry of Health have played a major role in proposing regulations regarding the safe use and consumption of transgenic products. Politically-biased decisions, however, are an important part of Ecuador's rulemaking, especially with regards to biotechnology and Genetically Modified Organisms (GMOs): In April 2006, without a scientific basis, Ecuador's Congress passed a food security law that prohibits the development, use, trade and imports of products derived from GMOs for human consumption. The legislation was not enforced because Ecuador's Attorney General qualified this law as inapplicable. Later, in December of the same year, Ecuador passed a new Health Code. This legislation included the same prohibitions mentioned in the prior law plus an article prohibiting Ecuador from accepting food donations of GMO products for human consumption. To date, this part of the legislation has not been enforced, mainly because Ecuador does not have a control and certification system in place.

The Official Register

The Official Register (RO) is Ecuador's counterpart to the United States Federal Register. New laws, application rules, executive decrees, ministerial agreements or standards issued in Ecuador come into legal effect on the day after their publication in the Official Register, unless a specific date had been established for this purpose.

The Official Register is the official legal publication of Ecuador, and its purpose is to inform stakeholders and the population about any new laws, decrees, agreements or other legal dispositions. It is a paper-printed publication sold mainly in Quito, at a price of US\$0.25. A few private companies also commercialize this publication in electronic format for a yearly charge of approximately \$200.

The Ministry of Agriculture, Livestock, Aquaculture and Fisheries (MAGAP)

The Ministry of Agriculture, Livestock, Aquaculture and Fisheries is responsible for promoting harmonic and sustained development of the agricultural and livestock sectors of Ecuador, through direction and evaluation of agricultural and livestock activities. The laws by which this agency is ruled are mainly the following:

Agricultural Development Law

This law, published in OR #55 of April 30, 1997, guarantees free imports and internal trade of agricultural inputs, improved seeds, improved plants and animals, machineries, equipment and technology, except for those qualified by the country of origin as harmful to the environment.

Plant Health Law

This law, published in OR #475 of January 18, 1974, is aimed at preventing and controlling plagues, illnesses and pests that could affect agricultural crops. This norm establishes regulations, conditions and prohibitions for imports, exports and local trade and production of certain plant products.

Animal Health Law

The Animal Health Law, published in OR #409 of March 31, 1981, was enacted to prevent, control and eradicate illnesses in Ecuador's livestock population. This Law points out that the Ministry of Public Health, along with the MAGAP, must control the quality of animal origin products destined for human consumption. Also, these two institutions must prohibit trade and call back harmful products from the market. This law also states the obligation to obtain prior authorization and a sanitary certificate from MAGAP for importing and exporting animals and their products and by-products.

Seeds Law

This law is related to all requirements for imports and exports of seeds. It also mentions the obligation of seed importers and exporters to register as such with the MAGAP. Furthermore, this law regulates commercialization of seeds and seeds products.

Law for the Formulation, Manufacture, Import, Trade and Use of Pesticides and Similar Products for Agricultural Use

This law establishes the obligation of every person or company importing, manufacturing or distributing pesticides and similar products for agricultural use, to register at the MAGAP for such purposes. It also regulates the transportation, storage, labeling and advertisement of these products. This legal body also determines tolerance residue levels for pesticides.

Agencies within the MAGAP

Ecuadorian Animal and Plant Health Service (SESA)

SESA's basic purpose is to ensure good phytosanitary conditions for agricultural crops and good health for livestock populations. It is also responsible for preventing the entry and spread of exotic pests and diseases, and for eradicating existing animal diseases and plant pests. SESA is the Ecuadorian counterpart of APHIS.

Among its duties, SESA must demand the fulfillment of legal norms and international regional standards (such as Andean Standards) that regulate imports, exports manufacturing, formulation, distribution, local trade and end-use of agricultural products, pesticides, and veterinary products. This agency issues Health or Phytosanitary certificates

that allow imports of products and by-products from animals and plants (including plant breeding material).

Domestic and International Trade Office

This office, under the supervision of the Undersecretary for Strategic Management of the MAGAP, is responsible for gathering and analyzing agricultural trade and production data in order to suggest policies and legislation changes. In practice, this office is the administrative entity in the MAGAP in charge of receiving prior import authorization requests and passing them onto SESA for sanitary certification, and to the Undersecretary for Strategic Management for final approval.

Note: *The Prior Authorization requirement for food and agricultural products is embodied in COMEXI (Foreign Trade Council) Resolution 383 of June 11, 2007. This document provides a positive list of 100 agricultural products subject to prior import authorization by the MAGAP. This ruling applies only for products originating outside the Andean Community of Nations. This may constitute a violation of WTO non-discrimination principles.*

Undersecretary for Agricultural Development

Main responsibilities of this office are:

- a. Establish requirements for manufacture, formulation, import and trade of fertilizers, animal feed and seeds.
- b. Control the quality of locally traded fertilizers, animal feed, seeds and vegetable material.

The Ministry of Public Health (MSP)

The Ministry of Public Health, through the National Control and Surveillance System, and its branches, regulates the entry and consumption of processed food products, beverages, additives and pesticides. With regard to food imports, the National Control and Surveillance System is ruled by the following laws and regulations:

The Health Code

The health code establishes the obligation of obtaining the Sanitary Registration prior to import, trade, production, storage or transportation of processed food, beverages, additives, and pesticides for domestic, agricultural or industrial use. According to this law, the Ministry of Public Health (MSP) and its agencies are responsible for the inspection and control of all processed foods, beverages and food additives. The Health Code of 2006 also prohibits the development, use, trade and imports of foodstuffs derived from Genetically Modified Organisms (GMOs), and provides for the labeling of such products. It also prohibits Ecuador from receiving food donations containing GMOs, and establishes an interagency system for GMO control. To date, the GMO-related provisions of this law have not been enforced.

The Sanitary Registration Law

This law regulates the process to obtain sanitary registrations for imported and locally produced food products and beverages. It affirms the obligation to obtain the Sanitary Registration prior to importation and local distribution of food products. It also provides different requirements for imported products and locally produced products.

Food Regulation

This set of rules describes all requirements for food products to be authorized for free sale. It contains information on manufacturing processes, container, packaging and labeling requirements. Moreover, the food regulation governs the activities of transportation, distribution and trade of food products.

The Consumer Defense Law

Its objective is to guarantee consumer rights to obtain quality, consistency and fair prices in goods and services. The dispositions of this law are applicable to all government entities and private companies (or professionals and business owners) that produce, import, export or distribute goods and services.

The consumer defense law establishes the obligations and responsibilities that all goods or services providers have towards consumers. Among them is the obligation to provide clear, complete and sufficient information about their products. It also determines the minimum information necessary for a label, including price (in local currency) and indications about the content and weight of the product, expressed in Standard International Units of Measurement. It states that products from GMOs must contain all necessary information about their transgenic origin in order to alert consumers.

Note: Although this law and all its dispositions are in effect, the particular requirement for GMO labeling has not been enforced through application rules or inclusion of such requirements in Ecuador's labeling requirements.

Other Institutions Involved in Foreign Trade

Besides the Ministries of Health and Agriculture, which have the lead in agricultural and food trade, there are other Ecuadorian institutions involved that need to be mentioned, as follows:

Ministry of Industries and Trade (MIC)

MIC is the government agency responsible for planning, directing, controlling and executing policies for trade, industrialization and investments. Its mission is to improve the business environment in Ecuador, and to facilitate domestic and international competitiveness of the productive sectors. This institution is the main player in negotiating multilateral and bilateral trade agreements.

Law of Foreign Trade

This law was published in the Official Register #82 on June 9, 1997, and regulates all activities of MIC. It also prohibits any practice or administrative disposition that may limit free competition or obstruct development of domestic and international trade and production. Nevertheless, the law allows corrective actions to be applied in the cases contemplated under the regulations of the World Trade Organization (WTO). In spite of that, the inefficiency of certain public agencies and other institutions block the appropriate development of import activities. Examples of this are the actions of the National Health and Tropical Medicine Institute "Leopoldo Izquieta Pérez", co-responsible for the issuance of the sanitary registration, and those of the Ecuadorian Customs Corporation (CAE), which administers customs services.

Ecuadorian Normalization Institute (INEN)

INEN is an agency of the MIC and is responsible for:

- Preparing Ecuadorian Technical Standards (NTE), which define the characteristics of raw materials, intermediate products and finished products marketed in Ecuador. Also, INEN must formulate the methods for inspection, analysis, measurement, classification and denomination of such materials or products.
- Administering the Quality Certification System.
- Implementing and enforcing the use of the International Measurement System (SI).
- Inspecting compliance with the requirements set for in the Ecuadorian Technical Standards NTE for imported and local products, including labeling requirements.
- INEN also serves as Ecuador's Point of Contact for CODEX related issues.

The Ministry of Foreign Affairs

The Ministry of Foreign Affairs collaborates with the Office of the President and coordinates with the Ministry of Foreign Trade and the Ministry of Agriculture in the formulation of international policies, direction of international affairs and approval of agreements and other international conventions. It is responsible for supporting commercial negotiations and offering assistance in the solution of controversies.

The Ecuadorian Customs Corporation (CAE)

The Ecuadorian Customs Corporation (CAE) administers customs operations. This agency is responsible for the surveillance and control of the entrance or departure of people, commodities, and means of transportation through the borders and ports of Ecuador. It is also responsible for the collection of import duties and taxes. The Organic Law of Customs and its Application Rule govern CAE's activities.

SECTION II. LABELING REQUIREMENTS

A. General Requirements

The Health Code, the Sanitary Registration Law, the Food Regulation, and the Technical Standard NTE INEN 1334-1, provide labeling requirements for processed food products.

Food containers must have a visible printed or tagged label with certain minimum information, as detailed below. Imported products with tags in English and containing the aforementioned minimum information may be allowed to clear customs, subject to the addition of a tag or sticker in Spanish before the product is offered in the market. This additional tag must at least contain the expiration date (good through), lot number, the sanitary registration code, the list of ingredients, and name of the importer reading "Importado por...".

In addition to the aforementioned requirements, Ecuadorian labeling standards set the following guidelines:

- Labels containing words, pictures or other graphic representations introducing the product as having medicinal, therapeutic, preventive, curative, nutritional, or special

features; which may misrepresent the real nature, origin, composition or quality of the product are not allowed.

- When a product is very small in size and it is not possible to show all the information required in a food label, such information must be presented in a larger package that contains several units of the product. This is the case for candy, chocolate, and most confectionery products.
- Imported products may have labels in a foreign language, preferably with the respective translation in Spanish, in the same form and characters, and containing all previously listed requirements. It is advisable to apply labels prior to export, because the product has to enter the country in its final presentation.
- The Solid Waste Management regulation determines that every label must promote recycling, recuperation or re-use of the package or container.
- Ecuadorian standards do not differ significantly from those established by the United States; they are based on Codex Alimentarius and FDA (Food and Drug Administration) stipulations. In fact, Ecuador's common practice provides for FDA's standards to be used in case of inexistence of national (INEN) standards for a given product.

B. Requirements Specific to Nutritional Labeling

The technical standard NTE INEN 1334-2 refers to minimum requirements for nutritional labeling of processed food products offered as such for sale. This standard gathers the declaration of nutrients and explains that the complementary nutritional information is optional.

The bases of this standard are the Codex Alimentarius and the FDA guidelines, for which U.S. standards are acceptable. Recommended Daily Intake (RDIs) is based on the Recommended Daily Intake of nutrients provided by the FAO/ IHO.

Exceptions and Special Dispositions Regarding Mandatory Nutritional Labeling

Foods Containing Insignificant Quantities of Nutrients

An insignificant quantity is defined as one that allows the declaration of "Zero", except for total carbohydrates values, dietetic fiber and protein, for which an insignificant quantity is less than one gram. Examples of exempted products are grain coffee, tea leaves, soluble tea, unsweetened coffee, dehydrated vegetables for seasoning, extracts of flavors and colorings for food.

Dietetic Supplements

This exception does not apply for dietetic supplements in the form of conventional foods, such as breakfast cereals. These products are subject to all requirements specified in NTE INEN 1334-2

Packaged Food

These products are exempt only if they are shipped in bulk and are not meant for direct sale to the consumer, but are imported for use in processing industries. Example: Bulk-packaged sweet corn to be re-packaged and sold as a vegetable mix.

Fresh Food Products

Fresh products (fresh fruits and vegetables) and seafood (fresh or frozen fish and seafood) are also exempt.

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

The food regulation establishes that food containers must meet the following conditions:

- The container must have adequate shape, capacity and closing seal for its contents. No further explanation of what is deemed “adequate” is included.
- The container should be made of the right materials, in relation with the physical-chemical nature of its content.
- Containers must guarantee proper protection, conservation and identification of the product during its shelf life.

The materials used in the containers and packages for processed food products should meet the conditions of the Ecuadorian Technical Standards (NTE) established for each product or group of products. Moreover, the Solid Waste Management Regulation asserts that all packaging material and containers must allow recycling.

SECTION IV. FOOD ADDITIVE REGULATIONS

Standards and regulations for food additives are those set for in the Health Code, the Food Regulation and the technical standard NTE INEN 2074-96. The Food Regulation establishes that food additives are allowed for importation and in-country sale when:

- They are innocuous for human health; and,
- They have obtained the Sanitary Registration.

The technical standard NTE INEN 2074-96 is based in the Codex Alimentarius standards and the Regulation Code of the Food Drug Administration (FDA). It establishes a positive list of allowed additives, regulations for tolerance levels, and a list of prohibited substances for human consumption. This positive list is periodically checked and/or modified according to new scientific, technological and toxicological studies.

The NTE INEN 2074-96 standard, as well as other technical norms, are available for public sale. U.S. exporters can obtain a copy by sending a request to the Ecuadorian Institute of Normalization (INEN), whose contact information is included in Appendix I below. However, these norms are written in Spanish and there are no English copies available.

SECTION V. PESTICIDE AND OTHER CONTAMINANTS

The Law of Formulation, Manufacture, Import, Trade and Use of Pesticides was issued to guarantee the integrity of pesticides, and that manufacturers, importers and distributors declare their chemical composition. The Ministry of Agriculture, through the Plant Health Administrative Unit of SESA, is the agency in charge of the application of this law.

Ecuador does not set its own maximum tolerance levels. In fact, it applies Codex maximum residue limits. Other maximum tolerance levels established by widely recognized international institutions, such as the Environmental Protection Agency (EPA), are also accepted.

The Ministry of Agriculture and Livestock (MAGAP) will temporarily retain agricultural products suspected of being contaminated with pesticides or similar products. If analysis and testing carried out by the Ministry of Agriculture prove excessive residues, products will be destroyed and no compensation will be granted.

SECTION VI. OTHER REGULATIONS AND STANDARDS

A. The Sanitary Registration

In order to protect consumers' health, the current Health Code establishes that all national or foreign processed food products and additives must obtain a Sanitary Registration prior to their importation and sale in Ecuador. The process for sanitary registrations has been re-designed, and new laws have been written on this matter. The June 2001 Sanitary Registration Law provides the following guidance:

- The sanitary registration petition can either be filed by the manufacturer or by its Ecuadorian legal representative. In both cases, the registration belongs to and will be issued in the name of the manufacturer, unless specifically requested otherwise.
- The sanitary registration is valid for ten (10) years. The registration fee is approximately \$560 per item, and there is an annual maintenance fee of \$170.

The sanitary registration for imported products is granted by homologation (or equivalence) after 30 calendar days of having filed a correct application at any office of the National Hygiene Institute "Izquieta Perez" (NHI). Observations will be directed to the applicant five (5) days after the NHI receives the application. An additional provision on this topic provides that sanitary registrations for imported products be automatically issued if the NHI has not justified its denial within the 30 day term after the last observation has been resolved.

Currently, the application must include the following documents:

1. Request form (obtained at the NHI) including the following information:

- 1.1. Product name in full, including brand name
- 1.2. Name, and full address of the manufacturer
- 1.3. Name and address (in full) of the applicant (usually the importer)
- 1.4. Product Description:
 - 1.4.1. Ingredients list or composition formula (in percentages) used in the product (including additives), declared by the manufacturer in descending order.
 - 1.4.2. Elaboration date
 - 1.4.3. Expiration date or maximum consumption time

Note: Since exporters usually do not know when the first shipment would take place, or what lot of products will be exported, these two requirements are only intended for declaring a maximum time for consumption on the label. For example, if the product is good for six

months, then the production date may be declared as January 1, 2005 and Expiration date as June 1, 2005. The dates are not relevant, but the period of time in which the product is good for consumption is.

- 1.4.4. Packaging Information: must declare type of container, and content expressed in units of the International Measurements System (SI).
 - 1.4.5. Conservation conditions
 - 1.5. Applicant's signature accompanied by the signature of the product's technical representative in Ecuador (a food chemist or food engineer registered at the Ecuadorian Ministry of Health)
2. The applicant must include a copy of his/her identification document (in the case of an individual), or a certificate of company registration accompanied by the legal representative's appointment (in the case of a company).
3. The Certificate of Free Sale issued by a competent health authority in the exporting country. This document must list the products to be registered and must state that the products are authorized for free sale and consumption in the country of origin. In the United States, this document can be obtained at the Health Services Department of your state.
4. Product analysis certificate, which may be issued by the manufacturer or the competent health authority in the country of origin. A certificate of quality from a quality control laboratory would be ideal.
5. A legalized letter signed by the manufacturer regarding the following:
 - 5.1. The representation of the product in Ecuador. This document must appoint an exclusive representative in Ecuador, who would be authorized to register, import and distribute the product.
 - 5.2. The ownership of the sanitary permit. The manufacturer must state its decision regarding who will own the sanitary registration; the manufacturer or the importer. In case this statement is not included, it will be understood that the manufacturer owns the sanitary registration of its products.
6. Product's label or tag draft (original and copy).
7. Invoice for payment of registration fees (approximately \$560 per item).

Notes:

- All documents and certificates written in languages other than Spanish must be translated.
- All official certificates and documents must be either notarized or legalized by the Consul of Ecuador in the exporting country.
- It is recommended that Sanitary Registrations are filed in the INH offices in Quito rather than in Guayaquil, due to administrative and compliance problems with the INH-Guayaquil.
- A new Sanitary Permit will be necessary in the following events:

- If there is a change in the product composition.
- The product needs a different conservation process.
- There is a substantial modification of the following additives: colorings, flavorings, sweeteners, conservation agents, and nutritional additives.
- Changes in the nature of the container
- Change of manufacturer.

IMPORTANT: The Sanitary Registration Law provides an exemption of the Sanitary Registration for food products and ingredients to be used by restaurants and food industries. However, health authorities are not enforcing this particular provision. The U.S. Embassy is currently requesting clarification on the issue.

B. Phytosanitary and Health Certification

Under the law, importers of plant and animal products and by-products are required to obtain a Phytosanitary Certification or a Health Certification (depending on the case), prior to importation. Out of the law, prior administrative authorization must also be requested for importation of most commodities, seeds, animals, and plants. To be valid, such authorization requires two signatures or approvals, one from SESA (which represents the Phytosanitary or Health Certificate) and one from the Under Secretary of Strategic Management of the Ministry of Agriculture, a political appointee.

The request must be filed at the Domestic and International Trade Directorate of the Ministry of Agriculture in Quito, accompanied by the following documentation:

- The Unique Import Document (DUI) (See Section IX. Import Procedures)
- Note of Requisition (original and three copies)
- Pro-forma Invoice (original and three copies)
- "Prior Import Authorization" form (original and three copies)
- For importation of animals and other products of animal origin, the importer must include a payment receipt for the import fee at the National Agricultural Development Bank (BNF)

An individual or collective PEDIGREE certificate must be included for importation of pets and breed animals. The Pedigree Certificate will be analyzed and checked by the Under Secretariat for Agricultural Development in Quito, or by the Undersecretary of the Coastal Region in Guayaquil, depending on the case.

The Ecuadorian Animal and Plant Health Service (SESA) will check the documentation and will issue the phytosanitary or health permit, depending on the product. If the documents were not correct, SESA will return the application to the Domestic and International Trade Directorate indicating that such import is not authorized.

In the phytosanitary and health permits, SESA will indicate the treatment and conditions to be met by the product in order to enter the country, depending on pre-established phytosanitary and health norms.

If the product is granted a phytosanitary or health certificate, the documents will be pending the signature and final approval by the Under Secretary of Agriculture for Policy, Trade and Investment. In the last instance, this authority will decide if the product can be imported or not, even after having passed the technical examination of SESA.

Other Requirements

There are additional requirements specific for imports of plants and plant breeding material:

- The product must be free of soil and products in animal or vegetal decomposition.
- Use of poor quality, re-used, infected or infested packaging material is prohibited.
- The plant breeding material must come from a country or area known to be free of pathogens or diseases exotic to Ecuador.
- In such a situation, SESA may request the product to be accompanied by a Fumigation Certificate or Quarantine Treatment, signed by the competent authority of the country of origin.

In the case of animal imports, the following requirements must be met:

- Animals must come from zones in which no infectious or contagious illnesses affecting the species were detected, during a specific period of time previous to the shipment. Ecuador follows OIE standards on this issue.
- Animals must have been appropriately immunized with all the vaccines required by Ecuador through SESA authorities.
- Results of laboratory tests and exams carried out to investigate the presence of infectious and contagious illnesses should be negative.
- Animals should have received treatment against parasites and they should be in good physical condition, without clinical symptoms of infectious or contagious illnesses.

C. Registration of Agricultural and Livestock Inputs

Natural Persons or Companies importing and/or producing agricultural and livestock inputs (seeds, plants and plant breeding material, improved animals, semen, fertile eggs and embryos) must be registered with SESA or with the Under Secretariat for Agricultural Development at MAGAP. The validity of the registration is indefinite, but it can be canceled because of non-compliance with the dispositions stated in the Law of Seeds and in its respective regulation.

D. Control of Products at Retail/Wholesale Distribution

The Ministry of Health has the obligation of controlling processed food products and additives offered for sale in the Ecuadorian market. If a product does not meet the minimum quality standards, or does not have a Sanitary Registration, it could be immediately confiscated and/or destroyed.

The Ministry of Public Health, in coordination with MAGAP, controls the products of animal origin destined for human consumption and will prohibit or remove those that are harmful to human health.

MAGAP, through employees of the Plant Health Directorate of SESA or other designated persons, may inspect commercial or industrial facilities storing and selling seeds to verify the health status of the plant breeding material. If plant pests or infectious diseases are found, the staff can declare the facilities as "Observation Zones" or "Quarantined" depending on the seriousness of the case and, if necessary, can order the incineration of the infected material.

SECTION VII. OTHER SPECIFIC STANDARDS**A. Wine, Beer and Other Alcoholic Beverages**

Imports of alcoholic products, including beer, require prior authorization from the Ministry of Health and the products must have been previously registered with the sanitary authority. Imports of these products must meet INEN regulations PyM 1992-20, PyM 1992-17, and PyM 1992-21 for containers. Alcoholic products and beer must necessarily show the following information on their front label:

"Importado por (Name of the representative or importing company)", alcohol content per volume, and the capacity of the bottle in cubic centimeters.

Also the following health advisory note has to be included:

"Advertencia: El consumo excesivo de alcohol causa graves daños en su salud y perjudica a su familia. Ministerio de Salud Pública", that must be written on the principal or secondary label, meeting disposition 1828 of the Decree dated June 10, 1994.

Alcoholic products and imported beers sold in the national market which do not fulfill these requirements will be considered as smuggled into the country.

B. Products Samples and Mail Order Shipments:

Import and Export regulations governing samples establish that these are exempt from the payment of import duties, Value-Added Tax (IVA) and Special Consumption Tax (ICE), when the CIF value does not exceed US\$ 500 or its equivalent in other currencies. Merchandise exceeding this value will pay (for the excess) the established tariff for imports.

Samples without commercial value must meet the following requirements in order to obtain this exemption:

- They must be sent by the manufacturer itself, its representative or the authorized exporter;
- The addressee shall be a company or an importer habitually dedicated to this commercial activity.
- The documentation (commercial invoices, transportation invoices or others concerning the shipment), shall contain annotations demonstrating the products are samples without commercial value; and,
- Samples must show legends, signs or impressions identifying themselves as samples without commercial value and forbidding sale. In case of doubt, the Customs Administration may mark the samples with perforations, seals and others in order to impede their sale.

Correspondence and small packages (up to 2 Kilograms) are also exempt of taxes. Other types of packages and international postal cargo leaving or entering the country, with or without commercial purposes and made by any type of mail agency, are subject to the payment of the corresponding taxes, in relation to the CIF value.

Similarly, small packages, other packages and postal cargo, and samples without commercial value, exempt or not of taxes and whose CIF values do not exceed \$160, will be dispatched by customs through a simplified declaration.

Imports or exports by mail of products such as: narcotics, explosives, tobaccos, liquors, inflammable products and other dangerous or contaminant substances are forbidden.

SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS

The Law of Intellectual Property, published in the Official Register on May 19, 1998, regulates and guarantees the intellectual property acquired according to the law. Basically, this law refers to inventions, trademarks, commercial logos and models, commercial and industrial secrets, brand names, distinctive appearances of businesses and commercial establishments and any other intellectual creation for agricultural, industrial or commercial use. It also includes vegetal material. Dispositions of this law apply to both Ecuadorians and foreigners, residing in the country or not.

A. Trademarks

The trademark registration application should be filed at the National Institute of Intellectual Property (IEPI). The first request to register a trademark presented in a member country of the World Trade Organization, the Andean Community, or the Paris Agreement for the Protection of Industrial Property, will grant the applicant the priority right for a period of six months until the same trademark application is filed in Ecuador. This request should not refer to different or additional products than those contained in the first request.

A trademark's register will have a ten-year validity from the date of its concession and it can be renovated. A trademark's renovation has to be requested at the same agency, six months prior to its expiration.

B. Brand Names

Brand names can be registered at the National Institute of Intellectual Property, for which the same procedure used for registration of trademarks must be applied. However, the right to exclusive use is created by the public and continuous use in trade (for at least six months) of the brand name. Brand names will be protected without the obligation of registration. The registration of a brand name does not have a maximum validity time.

SECTION IX. IMPORT PROCEDURES

In order to clear customs, the following procedure must be carried out:

- If the FOB value of the imported goods exceeds US\$ 4000, the owner, consignee or consigner, personally or through a customs agent, must present the declaration in the Unique Import Document (DUI).
- The Unique Import Document (DUI) should be filed and revised by any bank or financial society acting on behalf of the Central Bank of Ecuador. After establishing the importer's identity, the bank or financial society will accept the document within the following two working days.

- The approved DUI form does not have a validity time limit; it is indefinite, except in goods with restrictions. In this case, the validity time is determined by the authorizations or import licenses.
- The declaration must be presented at customs, anytime between seven days before to fifteen days after the arrival of the goods. This customs declaration must be accompanied by the following documents:
 1. Note of Requisition (mandatory)
 2. Authorizations or licenses (if needed): If the type of good demands it, it is necessary to obtain authorizations from a Ministry or other public entity depending on the case (See Section VI. Other Regulations and Requirements above).
 3. Insurance Certificate (if needed).
 4. Import Verification Request (if needed): Only for goods whose FOB value exceeds US\$ 4000. The request has to be filled and then delivered to the verification company (SGS, Bureau Veritas, Cotecna o ITS) along with the requisition note.
 5. Certificate of Inspection (Certificado de Inspeccion): This certificate is issued by the verification company after having previously issued the SVI, and only for goods exceeding FOB value of US\$ 4000. According to the Law, if a good enters Ecuador without the CI, it cannot be nationalized.
 6. Certificate of Origin (if needed)
 7. Shipment Manifest (mandatory)
 8. Bill of Lading (mandatory)
 9. Commercial Invoice (Factura Comercial) (mandatory)
 10. Customs Declaration of Value (DAV) (mandatory): Is an oath that the consigned value is the real one.

Note: Import documents do not need to be translated into Spanish.

- The import declaration has to be presented in the respective customs district, which will verify the data and confirm compliance with all requirements. If there are no observations, the declaration will be accepted and the district will assign a validation number so the procedure may continue. Once the declaration is accepted, it is final and cannot be amended.
- The next step is documental revision or visual examination of the goods, to establish its nature, quantity, value and its tariff classification.
- In the visual examination, the verification company checks the merchandise, verifies that the security seal has not been violated and compares the declaration with the actual load. If everything is correct, the documental revision takes place. If the declaration does not match the load, the verification company will make sure that the difference is within the tolerance margin (maximum 10% of the taxes) and the importer will pay the appropriate taxes based on the actual quantity shipped. However, if the difference exceeds 10%, the shipment will be considered illegal.
- The physical examination generally takes more time than predicted, hence it is recommended to increase, by 30%, the budget established for customs clearance. It is calculated that 70% of the containers arriving at the port of Guayaquil stay there more than 15 working days.

- The verification company also carries out the document revision. This consists in verifying that what was declared is equal to what the accompanying documents of the DUI stated. If there are no observations, the customs district will authorize the payment of tariffs, which will be done through one of the authorized banks for this matter. Subsequently, customs will proceed to confirm this payment and will authorize the delivery of the merchandise.
- Where there is an obstacle for tax payment, the Ecuadorian Customs Corporation (CAE) demands a guarantee of 20% of the total amount to be paid with a time limit of 60 days.
- If in the declaration and document delivery only the commercial invoice is missing, for example, the merchandise can be taken out with a guarantee, but the term is only 30 days to present a new invoice to the CAE. However, if the Certificate of Origin is missing, it is better to leave the merchandise in Customs until the certificate arrives.
- Claims upon any customs administrative act can be presented to the manager within 20 days after it was carried out or notified.

Specific Rules for Agricultural Imports

The Inspection in the Country of Origin of agricultural product shipments is a requirement established by law. Verification companies hired for this purpose will carry out this inspection.

Imports of agricultural and livestock products (except industrialized products) can only arrive at seaports and airports where SESA has displayed animal and plant quarantine officers, according to the Law of Animal Health and the Law of Plant Health.

Airports: Quito and Guayaquil

Sea Ports: Guayaquil, Manta, Esmeraldas and Puerto Bolívar

Land Ports: Tulcan, Macara and Huaquillas

When the merchandise arrives, a SESA inspector will check and examine the documents and will inspect the product itself to confirm the phytosanitary condition. Products in good condition will be granted a merchandise entry license.

APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS

MINISTRY OF INDUSTRIES AND COMPETITIVENESS

Address: Av. Amazonas y Eloy Alfaro

Ministerial Office

Phone: 593-2-290-6127/ 593-2-254-3893

Fax: 593-2-250-7549

Contact: *Minister*- Econ. Raul Sagasti

International Trade Under-Secretariat

Phone: 593-2-256-6784

Fax: 593-2-250-4922

Contact: Under-Secretary- Genaro Baldeon

International Trade Directorate

Phone: 593-2-254-1854

Contact: *Director*- Jeanneth Mariño / David Sotomayo

Website: www.micip.gov.ec

CODEX Committee in Ecuador

President: Dra. Hipatia Nogales

Phone: 593-2-256-7232 ext. 134

MINISTRY OF PUBLIC HEALTH

Address: Juan Larrea 445, A Building, 3rd Floor.

Quito, Ecuador

Ministerial Office

Phone: 593-2-223-2713 / 593-2-255-6984

Fax: 593-2-256-9786

Contact: Minister-Dr. Caroline Chang.

National Health Director

Contact: Dra. Nancy Vasconez

Phone: 593-2-297 2900 ext. 2954

Fax: 593-2- 254 3588

Web-site: www.msp.gov.ec

Food Control Directorate

Fax/ Phone: 593-2-297-2900 ext. 2773

Contact: Dra. Magda Saltos Fax/Phone: 593-2-297-2900 ext. 2770

MINISTRY OF AGRICULTURE AND LIVESTOCK

Address: Av. Amazonas y Eloy Alfaro, MAG Building, Quito

Minister: Ing. Carlos Vallejo

Phone: 593-2-250-4433 / 593-2-256-5450

Fax: 593-2-250-0873

Ecuadorian Animal and Plant Health Service (SESA)

Contact: *Director*- Dr. Carlos Nieto

Phone: 593-2-254-4476

Fax: 593-2-222-8448 ext. 102

Plant Quarantine Directorate

Contact: Ing. Edwin Caseres

Phone: 593-2-254 8823 ext. 131

Fax: 593-2-222-8448 ext. 130

Animal Health

Contact: Dr. Alex Andrade

Phone: 593-2-254 8823 ext. 136

Fax : 593-2-222-8448 ext. 133

Agricultural Products Control and Register Division

Contact: Ing. Liliana Guaman

(5932) 254-3319

Fax: 593-2-222-8448

E-mail: directsesa@mag.gov.ec

Domestic and International Trade Directorate

Contact: Dr. Carlos Romero

Phone: (5932) 396 0203

Fax: (5932) 222 8011

Under Secretariat for Strategic Agriculture Development

Contact: *Under Secretary: Ing. Guillermo Ortega*

Fax Phone: (5932) 396-0201

Website: www.mag.gov.ec

Quito, Ecuador

ECUADORIAN INSTITUTE OF NORMALIZATION (INEN)

Director: Felipe Urresta

Address: Baquerizo Moreno E8-29 y Almagro

Phone: 593-2-250-1885

Fax: 593-2-256-7815

International Normalization Directorate

Contact: Ing. Gustavo Jimenez Phone ext.: 232

Consumer Control Directorate

Contact: Ing. Enrique Troya Phone ext.: 210

e-Mail: inen1@inen.gov.ec

Web-site: www.ecua.net.ec/inen

Quito, Ecuador

NATIONAL HEALTH AND TROPICAL MEDICINE INSTITUTE "LEOPOLDO IZQUIETA PEREZ"

Address: Iquique N14285 y Yaguachi / Quito, Ecuador

Contact: *Director-* Marcelo Chiriboga

Phone: 593-2-255-2715

Fax: 593-2-256-8041

E-mail: mhchiriboga@hotmail.com

Office in Guayaquil:

Address: Julian Coronel 905 y Esmeraldas / Guayaquil, Ecuador

Contact: *Director-* Francisco Hernandez

Phone: 593-4-228-1542/ 228-0414/ 228-2281

Fax: 593-4-229-3189

E-Mail: dirnainh@telconet.net

ECUADORIAN CUSTOMS CORPORATION (CAE)

General Manager Office:

Contact: *General Manager-* Econ. Santiago León

Address: Av. 25 de Julio Km 4, vía a Puerto Marítimo.

Phone: 593-4-250-0100

Fax: 593-4-248-4251

District Manager Office:

Contact: *District Manager*- Ec. Fabian Ronquillo
Address: Sea Port
Phone: 593-4-248-1166 / 248-1879
Guayaquil, Ecuador

Aero Cargo Deputy Manager Office:
Contact: *District Manager*- Manuel Jacho
Address: Airport "Simón Bolívar".
Phone: 593-4-228-7834 / 228-7827
Guayaquil, Ecuador

Regional Deputy Manager Office for Customs Quito:
Contact: *Regional Manager*- Econ. Patricio Troya
Address: Pasaje Amazonas y Río Arajuno.
Phone: 593-2-244-4033
Quito, Ecuador

District Manager Office:
Contact: *Regional Manager*- Jorge Ernesto de la Torre Cisneros
Address: Av. 10 de Agosto 1665, 4th floor
Phone: 593-2-321-5024 / 321-5025
Quito, Ecuador

Website: www.corpae.com

NATIONAL INSTITUTE OF INTELLECTUAL PROPERTY
Contact: National President - Dr. Alfredo Corral
Address: Av. Republica 396 y Diego de Almagro
Phone: 593-2-250-8000, ext. 302
Fax: 593-2-250-8027
www.iepi@interactive.net.ec

Department of Trademarks
Contact: *Director*- Dr. Marco Armas.
Phone: 593-2-250-8000, ext. 235

Department of Patents
Contact: *Director*- Ing. Martha Carvajal
Phone: 593-2-250-8000 ext. 230
Fax: (5932) 254-3894
Quito- Ecuador

APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS

U.S. EMBASSY QUITO

USDA/ Foreign Agricultural Service
Address: Av. Colombia #1573 y Queseras del Medio, 3rd floor
René A. Alarcón, Agricultural Specialist
Phone: (5932) 256-4147 / 252-9088
Fax: (5932) 250- 6283/ 250-4888
e-mail: Agquito@fas.usda.gov
Quito, Ecuador.

