

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Required Report - public distribution

Date: 11/21/2012

GAIN Report Number:

Ecuador

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

Approved By:

Prepared By:

Andres Barahona

Report Highlights:

This report has been updated to reflect the most recent changes in Ecuadorian laws and in the list of responsible agencies and organizations. It is important to note that Ecuador is enforcing a new constitution approved by public referendum on September 28, 2008, resulting in the creation and modification of several laws.

"This report was prepared by the Office of Agricultural Affairs of the USDA/ Foreign Agricultural Service in Quito, Ecuador for U.S. exporters of 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 (WTO) since 1996. The Foreign Trade Law prohibits any economic, administrative or technical practice that may limit or discourage foreign and internal trade, free competition or local production of goods and services. This legislation allows the application of corrective measures only as specified by the WTO.

In practice, Ecuador's tariff and non-tariff barriers interfere with agricultural and food imports. While import tariffs are not excessive, technical barriers and sanitary/phytosanitary (SPS) restrictions are not always established with the purpose of protecting human, animal and plant health but to restrict or limit imports. Weak government institutions create inefficiency and there are 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 protecting 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.

Recently, as concerns over biotechnology have been raised, 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 in regards to biotechnology and Genetically Modified Organisms (GMOs). In April 2006, without a scientific base, 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 General Attorney qualified this law as inapplicable. Later, in December of the same year, Ecuador passed a new Health Law. This legislation includes the same prohibitions mentioned in the prior law plus an article prohibiting Ecuador from accepting food donations of GMO products for human consumption without the previous harmlessness analysis accepted by the national sanitary authority. To date, this part of the legislation has not been enforced, mainly because Ecuador does not have a control and certification system in place. However, under the 2008 constitution, a Food Sovereignty Law was created. In this law, it is stated that genetically modified crops and seeds are prohibit in the country, and its importation is banned, unless it is previously approved by the President and the National Assembly.

Most laws and codifications can be found at:
<http://www.derechoecuador.com/>

A. The Official Register

The Official Register (RO, because of its name in Spanish) is Ecuador's counterpart of the United States Federal Register. New laws, application rules, executive decrees, and ministerial agreements or standards issued in Ecuador come into legal effect on the day after its 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 run by the Constitutional Court, 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 \$0.25. A few private companies, as well as the Constitutional Court, also commercialize this publication in electronic format for a yearly charge of approximately \$500.00. For more information on how to obtain the Official Register please visit the following web page: <http://www.derechoecuador.com/>

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

MAGAP is responsible for promoting sustained development of the agricultural, livestock and aquaculture sectors of Ecuador, through direction and evaluation of agricultural and livestock activities. The laws by which this agency is ruled are mainly the following:

Laws and Regulation related to the agriculture and food industry ruled by the MAGAP

1. Agricultural Development Law

This law, published in RO #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.

2. Plant Health Law

This law, published on RO #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.

3. Animal Health Law

The Law of Animal Health, published on RO #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 the MAGAP for importing and exporting animals and their products and by-products.

4. Law of Seeds

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. This law was published on RO#594, of May 26, 1978.

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

This law establishes the obligation of every natural person or company importing, manufacturing or distributing pesticides and similar products for agricultural use, to register at the MAGAP for such purposes. It also rules transportation, storage, labeling and advertisement of these products. This legal body also determines tolerance residue levels for pesticides. This law is ruled by the Andean Nations Community (CAN) regimen, decision 436, with some changes made on May 21st, 2008 by the CAN decision #684.

6. Food Sovereignty Law

The Organic Law for the Food Sovereignty Regime, LORSA (due to its name in Spanish), published in RO supplement #583 of May 5th, 2009, declares Ecuador as a country free of transgenic crops and seeds, these could only be introduced after being approved by the President and the National Assembly. The state has to regulate the use and development of modern biotechnology and any activity related to it, the use of experimental or hazardous biotechnologies is prohibited. This law tends to promote the development of small producers by giving certain benefits such as special credits, preference for public purchases, and agricultural insurance. Under this law a new commission was created in charge of proposing new laws including the water law and land tenure law.

http://www.economiasolidaria.org/files/Ley_Soberania_Alimentaria_Ecuador.pdf

Agencies within the MAGAP

1. Ecuadorian Agri-Quality Guarantee Agency (Agrocalidad)

AGROCALIDAD formerly known as SESA has not only changed names, but it has adopted new roles, in addition to ensuring good phytosanitary conditions of agricultural crops and good health of livestock population. AGROCALIDAD is also responsible for impeding the entry and spread of exotic pests and diseases, and for eradicating existing animal diseases and plant pests.

Among its duties, AGROCALIDAD must demand the fulfillment of legal norms, and international and regional standards (such as Andean Standards) that regulate imports, exports manufacturing, formulation, distribution, local trade and end-use of agricultural products, pesticides, and veterinarian products. This agency issues Health or Phytosanitary certificates that will allow imports of products and by-products from animals and plants (including plant breeding material).

AGROCALIDAD also has been added with tasks such as food harmlessness, good agricultural practices, product quality and productive chain.

2. Domestic and International Trade Office

This office, under the supervision of the Undersecretary for Agricultural Commerce 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 instance in the MAGAP in charge of receiving prior import authorization and import licenses requests, and passing them onto AGROCALIDAD for sanitary certification, and to the Undersecretary of Agricultural Commerce for final approval.

Note: *The Prior Authorization and import license requirement for food and agricultural products are embodied in COMEXI (Foreign Trade Council) Resolutions 585 and 590. These documents provide a positive list of agricultural products subject to prior import authorization or license 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.*

<http://www.comexi.gob.ec>

C. The Ministry of Public Health (MSP)

MSP through the National Control and Surveillance System, and its dependencies, regulates the entry and consumption of processed food products, beverages, additives and pesticides. In regards to food imports, the National Control and Surveillance System is ruled by the following laws and regulations:

1. The Health Law

The Health Law, published on RO Supplement #423 of December 22, 2006, replaces the Health Code and 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 Law of 2006 also prohibits the development, use, trade and imports of foodstuffs derived from Genetically Modified Organisms (GMOs) without previous authorization of the designated agency within the MSP. This authorization has to be based on technical and scientific analyses which also have to be accepted by the national sanitary authority. Furthermore, this law provides instructions for the labeling of such products. It also prohibits Ecuador to receive food donations containing GMOs without following the same procedures described above, and establishes an interagency system for GMO control. To date, the GMO-related provisions of this law have not been enforced.

http://www.elportaldelasalud.com/index.php?option=com_content&task=view&id=41&Itemid=134

2. The Sanitary Registration Regulation

Ministerial Decree (RO#510) was issued on January 20, 2009 as the Regulation for Sanitary Control and Registration. This set of rules regulates the process to obtain sanitary registrations for imported and locally produced food products and beverages. It affirms the obligation to obtain Sanitary Registration prior to importation and local distribution of food products. It also provides different requirements for imported products and locally produced products.
http://www.derechoecuador.com/index.php?option=com_content&view=article&id=4808:registro-oficial-no-510-martes-20-de-enero-de-2009&catid=292:enero&Itemid=512

3. Food Regulation

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

4. The Law of Consumer Defense

Its objective is to guarantee consumer rights to obtain quality goods and services and fair prices. 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, including the obligation of providing clear, complete and enough information about their products. It also determines the minimum necessary information on 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 indications about their transgenic origin in order to alert consumers.

Note: This law and all its dispositions, in particular the requirement for GMO labeling have not been enforced.

5. Regulation for Authorization and Control of Food Publicity and Promotions

On February 18, 2011 this new regulation was published to control the publicity and promotion of food products in general. It is important to take this regulation into consideration if promotional events are planned to either introduce an imported product as well as to try to increase sales.

http://www.derechoecuador.com/index2.php?option=com_content&do_pdf=1&id=6096

D. 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:

The Ministry of Foreign Affairs, Commerce and Integration

The Ministry of Foreign Affairs, Commerce and Integration is responsible for foreign trade. It collaborates with the Office of the President and coordinates with the Ministry of Agriculture in the formulation of international policies, direction of international affairs, and enforcement of agreements and other international conventions. It is responsible for supporting commercial negotiations and offering assistance in the resolution of controversies.

Ministry of Industries and Productivity (MIPRO)

MIPRO 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 on negotiating multilateral and bilateral trade agreements.

Ministry of Production, Employment and Competitiveness

The Ministry of Production, Competitiveness and Trade is an umbrella entity for the Ministry of Agriculture, Ministry of Foreign Affairs, Commerce and Integration, and the Ministry of Industries and Competitiveness. The main role of this ministry is to coordinate the policies and actions taken by each ministry previous mentioned, so they are aligned with the government goals. This ministry works to prevent duplications of efforts.

Foreign Trade Council (COMEX)

The Foreign Trade Council was created under the Production, Commerce and Investment Organic Code published on the RO#351 in December 29, 2010. This new council has the responsibility to approve commercial policies, and replaces the previously Foreign Trade and Investment Council (COMEXI). Also this council is in charge of coordinating actions regarding foreign trade.

1. Foreign Trade Law

This law was published in the Official Register #82 on June 9, 1997. It 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 an adequate development of import policies. Examples of this are the actions of the National Health and Tropical Medicine Institute "Leopoldo Izquieta Pérez", co-responsible for the issuance of sanitary registrations, and those of the Ecuadorian Customs Corporation (CAE), which administers customs services.

http://www.comexi.goB.ec/docs/ley_sin_reformas.doc

Ecuadorian Normalization Institute (INEN)

INEN is an agency of the MIPRO 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 the compliance of the requirements set 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 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.

<http://www.aduana.gob.ec/archivos/LEY-ORGANICA-DE-ADUANA-2007.pdf>

Section II. Labeling Requirements:

A. General Requirements

The Health Law, the Sanitary Registration Regulation, the Food Regulation, and the technical standard norms NTE INEN 1334-1:2011, NTE INEN 1334-2:2011, and NTE INEN 1334-3:2011, 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 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 acknowledge the following guidelines:

- Labels containing words, pictures or other graphic representations introducing the product as having medicinal, therapeutic, preventive, curative, nutritional, or especial 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 foreign language, preferably with the respective translation in Spanish, in the same form, 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 the 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. Nutritional Labeling Specific Requirements

The technical standard norm NTE INEN 1334-2:2011 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 of the FAO/WHO.

The technical standard norm NTE INEN 1334-3:2011 establishes minimum requirements for labels, containers or packages

containing food products for human consumption, which include voluntary nutritional and health claims

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, tealeaves, soluble tea, and unsweetened coffee; dehydrated vegetables for seasoning, extracts of flavors and food colorings.

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 Regulations:

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" in this case.
- The container should be made of the right materials, in relation to 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 a processed food product 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 Additives Regulations:

Standards and regulations for food additives are those set for in the Health Law, 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 sending a request to the Ecuadorian Institute of Normalization (INEN), the contact information can be found on Appendix I. However, these norms are written in Spanish and there are no English copies available.

Section V. Pesticides 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 Administrative Unit of Plant Health of AGROCALIDAD, is the agency in charge of the application of this law.

Ecuador has 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 such affirmation, products will be destructed and no compensation will be granted.

Section VI. Other Regulations and Requirements:

A. Sanitary Registration

In order to protect consumers' health, the current Health Law 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 redesigned, and new laws have been written on this matter. The January-2009 released Sanitary Registration Law Review provides the following guidance:

- The sanitary registration petition can be filed by the manufacturer or by its Ecuadorian legal representative. In both cases, the registration belongs and will be issued to the name of the manufacturer, unless specifically requested otherwise.
- The sanitary registration usually is issued for five (5) years. The registration fee is approximately US\$620.00 per item (Items coming from outside of Ecuador). Before the registration takes place the product has to pass an analysis in a certified lab which can cost around US\$400.00. However, if stability analysis is required due to the product type, three lab analyses can be requested. Once all the lab analyses have taken place and the registration documents have been filled, the process takes around 60 days.

The sanitary registration for imported products is granted by confirmation (or equivalence) after 30 calendar days of having filed a "correct" application at any office of the National Hygiene Institute "Izquieta Perez" (NHI). A new revision procedure was establish this year prior to accepting the documents requested to file an application as a way to help accelerate the process. Observations will be directed to the applicant Three (3) days after the NHI receives the application though the electronic system.

Currently, the application must include the following documents:

- Request form (filled in electronic system) including the following information:
 - Name and address of the natural or legal person under whose name the sanitary registration is requested;
 - Name, phone, and full address of the manufacturer;
 - Product name in full, including brand name;
 - Product Description;
 - Ingredient list or composition formula (in percentages) used in the product (including additives), declared by the manufacturer in descending order; and,
 - Production code interpretation;
 - Expiration time
 - Packaging information, declaring type of container, and content expressed in units of the International Measurement System (SI)
 - Conservation conditions
 - Signatures of the legal representative of the company requesting the sanitary registration, as well as a technician responsible of the request

- The applicant must include a copy of his/her identification document (in the case of a natural person), or a certificate of company registration accompanied by the legal representative's appointment (in the case of a company).

- 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.

- Technical report explaining the processing procedure signed by a the responsible technician

- Stability Study which justifies the product's shelf life or maximum consumption time accompanied by the signature of the responsible technician (Stability Card)

- Chemical specifications of the container/packaging.

- Product's original label and draft of the tag that complies with the requests of the corresponding INEN Technical Regulation.

- Certificate that the product comes from an authorized manufacturer or distributor, except when the manufacturer is requesting the registration.

- Copy of the Sanitary Certificate issue by the Ministry of Health to the storage company where the product will be received.

- In case of organic products, include a copy of certification, issued by the authority at country of origin, that the product has this condition.

- Invoice of registration fees payment (approximately US\$620.00 per item).

Notes:

- All documents and certificates written in languages other than Spanish must be translated into Spanish.
- 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 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.
- The Sanitary Registration regulation provides an exemption of the Sanitary Registration for food products and ingredients to be used by food industries. However, to import under this particular provision the product needs authorization from the General Health Directors Office and is not easy to obtain since the importer has to prove that the product will not be commercialized prior to undergoing a transformation. The new product will need a sanitary registration.

IMPORTANT: Changes in sanitary registration procedures are expected as a new institution is being created that will take responsibility over the whole process. This new agency also will be in charge of creating new regulations regarding sanitary registration. The new agency should be fully operative the second semester of 2013.

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. 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 AGROCALIDAD (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 of 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.

Ecuadorian Agri – Quality Guarantee Agency (AGROCALIDAD) will check the documentation and will issue the phytosanitary or health permit, depending on the product. If the documents were not correct, AGROCALIDAD will return the application to the Domestic and International Trade Directorate indicating that such import is not authorized.

In the phytosanitary and health permits, AGROCALIDAD 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 AGROCALIDAD.

Other Requirements

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

- The product must be free of soil and animal or vegetal products in 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.
- Given the case, AGROCALIDAD shall 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-contagious illnesses affecting the specie were detected, during a specific period of time previous to the shipment. Ecuador follows OIE standards on this issue.
- Animals must have been opportunely immunized with all the vaccines required by Ecuador through AGROCALIDAD authorities.
- Results of laboratory tests and exams carried out to investigate the presence of infectious and contagious illnesses should be negative, and;
- Animals should have received treatment against parasites, and they should be in good physical conditions without clinic 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 AGROCALIDAD or in 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 the MAGAP, will control the products of animal origin destined to human consumption, and will prohibit or retire from trade those resulting harmful to human health.

MAGAP, through employees of AGROCALIDAD 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 outbreak infectious diseases are in place, the staff can declare "Observation Zone" or "Quarantine" depending on the seriousness of the

case, and if it is necessary they 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 prior registration with the sanitary authority. Imports of these products must meet INEN regulations PyM 1992-20, PyM 1992-17, PyM 1992-21 for containers. Alcoholic products and beer must 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 in the principal or secondary label, meeting disposition 1828 of the Decree dated June 10th, 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.

http://www.inen.gov.ec/Web_sp/Normalizacion/Reglamentacion/PRTE%20tramite%20regular/PRTE-032.pdf

B. Products Samples and Mail Order Shipments:

Samples Import and Export regulations 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\$400.00 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 4 Kilograms) are also exempt from 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.

In the same way, small packages, other packages and postal cargo and samples without commercial value, exempt or not of taxes, whose CIF values do not exceed US\$160.00 will be dispatched by customs through a simplified declaration.

Eventhough, samples are allowed to be imported, in general there are complications to nationalize sample products since

there is always some discrepancy that custom authorities will find.

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. Dispositions of this law apply to both Ecuadorians and foreigners residing or not in the country.

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 renewed. The applicant has to pay IEPI an input fee of \$116 plus a \$260 fee for tests, \$28 for annual maintenance and \$54 to obtain the trademark title. Besides these fees, the applicant must consider lawyer fees which could go over \$1000. A renewal of a trademark 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 for registration of trademarks is necessary. This registration represents a presumption for the holder's benefit. However, the right for exclusive use is created by the public and continuous use in trade, at least for 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:

- The owner, consignee or consigner, need to hire a register customs agent in order to present the declaration in the Unique Import Document (DUI) physically and electronically.
- The 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 to customs 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 in 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 which FOB value exceeds US\$2,000.00. 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 in goods exceeding FOB value of US\$2,000.00. According to the Law, if a good enters Ecuador without the CI, it cannot be distributed.
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): DAV 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 that 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 it is not equal, 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 same upon the totality. Taxes are paid on the real quantity, but if the difference exceeds 10%, it is considered illegal.
- The physical examination generally takes more time than expected, for which it is recommended to calculate a 30% more of 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.
- If 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.
- For example, if only the commercial invoice is missing in the declaration and document delivery, 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 in the law. Verification companies hired for this purpose will carry out this inspection.

According to the Law of Animal Health and the Law of Plant Health, imports of agricultural and livestock products (except industrialized products) can only arrive at seaports and airports where animal and plant quarantine officers of AGROCALIDAD are present.

Airports: Quito and Guayaquil

Sea Ports: Guayaquil, Manta, Esmeraldas and Puerto Bolívar.

Land Ports: Tulcan, Macara and Huaquillas.

When the merchandise arrives, an AGROCALIDAD 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 PUBLIC HEALTH

Address: Av. República del Salvador 36-64 y Suecia

Quito-Ecuador

Phone: (593 2) 3814400

Web-site: <http://www.salud.gob.ec/>

Ministerial Office

Contact: Minister Carina Vance

Phone: (593 2) 3814400 Ext.: 6113

General Health Director

Contact: Xavier Toledo

Phone: (593 2) 3814400 Ext.: 7150

Health Surveillance

Contact: Director Liliana Sacoto

Phone: (593 2) 3814400 Ext.:1200

MINISTRY OF AGRICULTURE, LIVESTOCK, AQUACULTURE AND FISHERIES

Address: Eloy Alfaro 30-350 y Amazonas

Quito-Ecuador

Phone: (593 2)-3960100 / 3960200

Web-site: <http://www.agricultura.gob.ec/>

Ministerial Office

Contact: Minister Javier Ponce Cevallos

Mail: ministro@magap.gob.ec

Phone: (593 2) 3960100 / 3960200

Fax: (593 2) 2228448 Ext.: 102

Viceminister of Agriculture and Livestock

Contact: Viceminister Luis Valverde

Phone: (593-2) 3960100 / 3960200 Ext: 1069

Viceminister for Rural Development

Contact: Viceminister Silvana Vallejo

Phone: (593-2) 3960100 / 3960200 /Ext: 1071

Viceminister for Aquaculture and Fisheries

Contact: Viceminister Guillermo Morán

Address: Cdla Kennedy Norte, Mz 106. Av. Francisco de Orellana y Justino Cornejo, Guayaquil

Phone: (593-4) 268-1005

Agricultural Commerce Under-Secretariat

Contact: Undersecretary Diego Vizcaino Cabezas

Phone: (593-2) 3960100 / 3960200 Ext: 1100

Ecuadorian Agri – Quality Guarantee Agency (AGROCALIDAD)

Contact: Director María Gracia Abad

Phone: (593 2) 254-3319

Fax: (593 2) 256-7232

Plant Health Director

Contact: Patricio Almeida

Phone: (593 2) 2548823 Ext.:131

Fax: (593 2) 2228448 Ext.:130

Animal Health Director

Contact: Xavier Vargas

Phone: (593 2) 2548823 Ext.:136

Fax: (593 2) 2228448 Ext.:133

Agricultural Products Control and Register Division

Contact: Ing. Denise Vásquez

Phone: (593 2) 2543319

Fax: (593 2) 2228448

Food Safety Director

Contact: Rommel Betancourt

Phone: (593 2) 396100

MINISTRY OF INDUSTRIES AND PRODUCTIVITY

Address: Av. Eloy Alfaro y Av. Amazonas

Quito - Ecuador

Web-site: <http://www.mipro.gob.ec/>

Ministerial Office

Contact: Minister Verónica Sión

Mail: vsion@mipro.gob.ec
Phone: (593 2) 2546690 Ext: 116 - 118
Fax: (593 2) 2503818

Trade and Investment Under-Secretariat

Contact: Undersecretary Dennis Zurita
Mail: dzurita@mipro.gob.ec
Phone: (593 2) 2546690 Ext.: 129, 130, 107, 150
Fax: (593 2) 2503818

MINISTRY OF PRODUCTION, EMPLOYMENT AND COMPETITIVENESS

Address: Av La Coruña N2558 y San Ignacio. Edificio Altana Plaza Piso 4.
Quito-Ecuador
Web-site: <http://www.mcpec.gob.ec/>

Ministerial Office

Contact: Minister Santiago Leon Abad
Mail: sleon@mcpec.gob.ec
Phone: (593 2) 3815600

CODEX COMMITTEE IN ECUADOR

Contact: María Davalos
Phone: (593 2) 2565626
Fax: (593 2) 2567815
Web-site: <http://www.codexalimentarius.net/>

ECUADORIAN INSTITUTE OF NORMALIZATION (INEN)

Address: Baquerizo Moreno E8-29 y Diego de Almagro
Quito-Ecuador
Web-site: <http://www.inen.gob.ec/>

Director's Office

Contact: Director Patricia Leon
Phone: (593 2) 2528556 - 2565626
Fax: (593 2) 2567815

International Normalization Directorate

Contact: Ing. Gustavo Jiménez
Phone: (593 2) 2501885 Ext.: 232

Consumer Control Director

Contact: Ing. Enrique Troya
Phone: (593 2) 2501885 Ext.:227

NATIONAL HEALTH AND TROPICAL MEDICINE INSTITUTE "IZQUIETA PEREZ"

Web-site: <http://www.inh.gob.ec/>

Director's Office – Guayaquil Branch

Contact: National Juan Carlos Pérez Ycaza
Address: Julián Coronel 905 y Esmeraldas
Phone: (593 4) 2282281
Fax: (593 4) 2293189

Director's Office – Quito Branch

Contact: Regional Director Juan Mateo Borrero Brauer
Address: Iquique 2045 y Yaguachi - El Dorado
Phone: (593 2) 2552715
Fax: (593 2) 2568041

ECUADORIAN CUSTOMS CORPORATION (CAE)

Web-site: <http://www.aduana.gob.ec/>

General Manager Office-GUAYAQUIL

Contact: General Director Xavier Cárdenas
Address: Av. 25 de Julio Km 4, Vía a Puerto Marítimo
Phone: (593-4) 2480-640 Ext. 1009-1005

District Manager Office

Contact: District Director Jorge Luis Rosales
Address: Seaport
Phone: (593 4) 2481166 - 2481879

Aero Cargo Deputy Manager Office

Contact: Sub Director Alex Rodriguez
Address: Simón Bolívar Airport
Phone: (593 4) 2287834 – 2287827

District Manager Office – QUITO

Contact: District Director Ricardo Troya
Address: Pasaje Amazonas y Río Arajuno
Phone: (593 2) 2444010 – 2444015
Fax: (593 2) 2444049 - 2448581

Regional Deputy Manager Office

Contact: Deputy Director Angel Paez
Address: Av. 10 de Agosto 1731 y San Gregorio - Edificio Epsilon
Phone: (503 2) 2287834 - 2287827

NATIONAL INSTITUTE OF INTELLECTUAL PROPERTY

Address: Av. Republica 396 y Diego de Almagro - Edificio Forum 300
Quito-Ecuador
Web-site: <http://www.iepi.gob.ec/>

President's Office

Contact: President Andrés Ycaza Mantilla
Phone: (593 2) 2508000 Ext.: 301
Fax: (593 2) 2508027

Department of Trademarks

Contact: Director Lilian Carrera Gonzalez
Phone: (593 2) 2508000 Ext.: 235

Department of Patents

Contact: Director Martha Carvajal Aguirre
Phone: (593 2) 2554887 Ext.: 220
Fax: (593 2) 2543894
Mail: mcavajal@iepi.gob.ec

CAMARA DE AGRICULTURA

Primera Zona

Contact: President Mauricio Bustamante
Address: Av. NN UU 1084 y Amazonas, Torre B-Edificio La Previsora, 8vo. Piso-Oficina 805
Quito-Ecuador
Phone: (593 2) 2257618 / 2274187
Fax: (593 2) 2257618
Web-site: <http://www.agroecuador.com/>

Segunda Zona

Contact: President Luis Salvador Andrade
Address: Carchi 809 y 9 de Octubre
Guayaquil-Ecuador
Phone: (593 4) 2394449
Fax: (593 4) 2394449

Tercera Zona

Contact: President Paúl Sánchez Moscoso
Address: Galápagos 237 entre Guayas y Remigio Tamariz
Cuenca-Ecuador
Phone: (593 7) 2885930
Fax: (593 7) 2883870

Appendix II. Other Import Specialist Contacts:

US EMBASSY QUITO

USDA/Foreing Agricultural Service

Address: Avigiras E12-170 y Av. Eloy Alfaro
Quito-Ecuador
Phone: (593 2) 3985000 -3985247
Fax: (593 2) 3985031
Mail: Agquito@fas.usda.gov

