



USDA Foreign Agricultural Service

# GAIN Report

Global Agriculture Information Network

Template Version 2.09

Scheduled Report - Public distribution

**Date:** 7/31/2008

**GAIN Report Number:** EC8011

## Ecuador

### FAIRS Country Report

### Annual

### 2008

**Approved by:**

Eugene Philhower  
U.S. Embassy

**Prepared by:**

Andres Barahona

---

**Report Highlights:**

Report has been updated to reflect the most recent changes in Ecuador Health Law and changes in the list of responsible agencies and organizations. It is important to note that Ecuador is going through a very critical time and many laws and regulations can change if a new constitution is approved by public referendum on September 28th, 2008.

---

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

<b>SECTION I. FOOD LAWS</b> .....	<b>4</b>
A. The Official Register .....	4
B. The Ministry of Agriculture, Livestock, Aquaculture and Fisheries (MAGAP) .....	5
Laws and Regulation related to the agriculture and food industry ruled by the MAGAP....	5
1. Agricultural Development Law .....	5
2. Plant Health Law .....	5
3. Animal Health Law .....	5
4. Law of Seeds.....	5
5. Law for the Formulation, Manufacture, Import, Trade and Use of Pesticides and Similar Products of Agricultural Use .....	5
Agencies within the MAGAP .....	6
1. Ecuadorian Animal and Plant Health Service (SESA) .....	6
2. Domestic and International Trade Office.....	6
3. Undersecretary for Agricultural Promotion and Development .....	6
C. The Ministry of Public Health (MSP) .....	6
1. The Health Law .....	7
2. The Sanitary Registration Law.....	7
3. Food Regulation .....	7
4. The Law of Consumer Defense .....	7
D. Other Institutions Involved in Foreign Trade.....	7
The Ministry of Foreign Affairs .....	8
Ministry of Industries and Competitiveness (MIC) .....	8
Foreign Trade and Investment Council (COMEXI) .....	8
1. Law of Foreign Trade .....	8
Ecuadorian Normalization Institute (INEN) .....	8
The Ecuadorian Customs Corporation (CAE) .....	9
<b>SECTION II. LABELING REQUIREMENTS</b> .....	<b>9</b>
A. General Requirements .....	9
B. Requirements Specific to Nutritional Labeling .....	10
Exceptions and Special Dispositions Regarding Mandatory Nutritional Labeling .....	10
<b>SECTION III. PACKAGING AND CONTAINER REQUIREMENTS</b> .....	<b>10</b>
<b>SECTION IV. FOOD ADDITIVE REGULATIONS</b> .....	<b>11</b>
<b>SECTION V. PESTICIDE AND OTHER CONTAMINANTS</b> .....	<b>11</b>
<b>SECTION VI. OTHER REGULATIONS AND STANDARDS</b> .....	<b>11</b>
A. The Sanitary Registration .....	11
B. Phytosanitary and Health Certification.....	14
Other Requirements.....	14
C. Registration of Agricultural and Livestock Inputs.....	15
D. Control of Products at Retail/Wholesale Distribution .....	15
<b>SECTION VII. OTHER SPECIFIC STANDARDS</b> .....	<b>15</b>
A. Wine, Beer and Other Alcoholic Beverages.....	15
B. Products Samples and Mail Order Shipments:.....	16
<b>SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS</b> .....	<b>17</b>
A. Trademarks .....	17
B. Brand Names .....	18
<b>SECTION IX. IMPORT PROCEDURES</b> .....	<b>18</b>
Specific Rules for Agricultural Imports.....	19
<b>APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS</b> .....	<b>20</b>
<b>APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS</b> .....	<b>24</b>

**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."

Also, it is important to remark that Ecuador is living a very critical political time and many laws and regulations can change if a new constitution is approved in a public referendum in September 28<sup>th</sup>, 2008.

## SECTION I. FOOD LAWS

Ecuador has been a member of the World Trade Organization 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 in the media, 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.

In 2004, most of the current laws were reviewed and codified. All the codifications can be found at:

[http://www.derechoecuador.com/index.php?option=com\\_content&task=category&sectionid=6&id=59&Itemid=418](http://www.derechoecuador.com/index.php?option=com_content&task=category&sectionid=6&id=59&Itemid=418)

### 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, 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 US\$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 US\$200.00. For more information on how to obtain the Official Register please visit the following web page: <http://www.tribunalconstitucional.gov.ec>, and click on the link "Registro Oficial".

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

The Ministry of Agriculture, Livestock, Aquaculture and Fisheries is responsible for promoting 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:

### **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 in 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.

## Agencies within the MAGAP

### 1. Ecuadorian Animal and Plant Health Service (SESA)

SESA's basic purpose is to ensure good phytosanitary conditions of agricultural crops and good health of livestock population. It is also responsible for impeding 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 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).

### 2. 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 instance in the MAGAP in charge of receiving prior import authorization requests and passing them onto SESA for sanitary certification, and to the Undersecretary of 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.*

### 3. Undersecretary for Agricultural Promotion and 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 vegetal material.

## C. The Ministry of Public Health (MSP)

The Ministry of Public Health, through the National Control and Surveillance System, and its dependencies, regulates the entry and consumption of processed food products, beverages, additives and pesticides. On 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 #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 with out 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.

## **2. 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.

## **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, regularity 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, including the obligation of providing clear, complete and enough information about their products. It also determines the minimum necessary information in 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: 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 requirement in Ecuador's labeling requirements.

## **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**

The Ministry of Foreign Affairs is in charged of 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 celebration of agreements and other international conventions. It is responsible for supporting commercial negotiations and offering assistance in the solution of controversies.

## **Ministry of Industries and Competitiveness (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 on negotiating multilateral and bilateral trade agreements.

## **Foreign Trade and Investment Council (COMEXI)**

COMEXI is an institution that coordinates actions regarding Foreign Trade and Investments. Its role is to maintain a constant link between the private and public sector and is responsible for the Law of Foreign Trade.

### **1. Law of Foreign Trade**

This law was published in the Official Register #82 on June 9, 1997, and regulates all activities of COMEXI. 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 an adequate 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 the compliance of 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 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 Law, 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 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 case of 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 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 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. 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 of 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, tealeaves, soluble tea, and 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" in this case.
- 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 a processed food product should meet the conditions of the Ecuadorian Technical Standards (NTE) for 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 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) with contact information 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 Administrative Unit of Plant Health of SESA, 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 STANDARDS**

##### **A. The 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 re-designed, and new laws have been written on this matter. The June-2001 released 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 and will be issued to the name of the manufacturer, unless specifically requested otherwise.
- The sanitary registration usually is issued for ten (10) years. The registration fee is approximately US\$480.00 per item. Before the registration takes place the product has to pass an analysis on a certified lab which can cost around US\$160.00. 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 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 had not justified its denial in the term of 30 days after the last observation had 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 of consumption in the label. For example, if the product is good for 6 months, then 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.

- 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 a natural person), 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 US\$560.00 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 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. 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 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.

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.
- Given the case, SESA 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 infect-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 SESA 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 SESA 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 the Plant Health Directorate of SESA or other designed 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 the products must have been priory registered 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 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 in the principal or secondary label, meeting disposition 1828 of the Decree dated June 10<sup>th</sup>, 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:**

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 from US\$500.00 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 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.

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.

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<sup>th</sup> of 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 obtainment. 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 renovated. The average cost for registering a trademark is around US\$800.00. A trademark's renovation has to be requested at the same agency, six months prior to its expiration.

- 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.

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.

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

## 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:

- If the FOB value of the imported goods exceeds US\$4,000.00, 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 limit time, 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 in the 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 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\$4,000.00. 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\$4,000.00. 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 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 upon the real quantity, but if the difference exceeds 10%, it is considered illegal.
- The physical examination generally takes more time than predicted, 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.
- 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 in the 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 here 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 Bolivar.

**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**

### MINISTERIO DE RELACIONES EXTERIORES

Address: Carrión 10-40 y Av. 10 de Agosto  
Quito - Ecuador

Web-site: <http://www.mmrree.gov.ec>

#### Ministerial Office

Contact: Vice-Minister: Eduardo Egas

Phone: 593-2-2993281

Fax: 593-2-2993245

#### Economic Affairs Office

Contact: Under-secretary of Economic Affairs: Emb. Mentor Villagómez

Phone: 593-2-2993281

Fax: 593-2-2993245

#### Departamento de Comercio Exterior

Contact: Director: Rolando Suárez

Phone: 593-2-2993281

Fax: 593-2-2993245

### MINISTRY OF PUBLIC HEALTH

Address: Republica del Salvador 950 y Naciones Unidas  
Quito, Ecuador

Web-site: [www.msp.gov.ec](http://www.msp.gov.ec)

#### Ministerial Office

Contact: Minister: Dra. Caroline Chang.

Phone: 593-2 248954/2920637

Fax: 593-2-263706

#### National Health Director

Contact: Dra. Carmen Laspina

Phone: 593-2-268887

Fax: 593-2- 254 3588

#### Food Control Directorate

Contact: Dra. Magda Saltos

Fax/ Phone: 593-2-297-2900 ext. 2955

Contact: Ing. Yolanda Lara

Fax/Phone: 593-2-297-2900 ext. 2770

MINISTRY OF AGRICULTURE AND LIVESTOCK

Address: Av. Amazonas y Eloy Alfaro, MAG Building  
Quito, Ecuador  
Web-site: www.mag.gov.ec

Ministerial Office

Minister: Economista Walter Poveda  
Phone: 593-2-250-4433 / 593-2-256-5450  
Fax: 593-2-250-0873

Ecuadorian Animal and Plant Health Service (SESA)

Contact: Director: Dr Luis Nevada  
Phone: 593-2-254-4476  
Fax: 593-2-222-8448 ext. 102

*Plant Quarantine Directorate*

Contact: Ing. Gerardo Robalino  
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. Dennys Vásquez  
Phone: 593-2- 254-3319  
Fax: 593-2-222-8448

*Pesticides Control and Register Division*

Contact: Ing. Carlos Navas  
Phone: 593-2-396100

Domestic and International Trade Directorate

Contact: Dr. Carlos Romero  
Phone: 593-2- 396 0203  
Fax: 593-2- 222 8011

Under Secretariat for Strategic Agriculture Development

Contact: Under Secretary: Manuel Andrade  
Fax Phone: 593-2-396-0201

MINISTRY OF INDUSTRIES AND COMPETITIVENESS

Address: Av. Amazonas y Eloy Alfaro  
Quito, Ecuador  
Website: www.micip.gov.ec

Ministerial Office

Contact: Minister- Doctor Xavier Abad  
Phone: 593-2-290-6127/ 593-2-254-3893  
Fax: 593-2-250-7549

International Trade Under-Secretariat

Contact: Under-Secretary- Economista Alexis Valencia  
Phone: 593-2-256-6784  
Fax: 593-2-250-4922

International Trade Directorate

Contact: Director- David Sotomayor  
Phone: 593-2-254-1854

CODEX COMMITTEE IN ECUADOR

President: Dra. Hipatia Nogales  
Phone: 593-2-256-7232 ext. 134

ECUADORIAN INSTITUTE OF NORMALIZATION (INEN)

Address: Baquerizo Moreno E8-29 y Almagro  
Quito, Ecuador  
Web-site: <http://www.inen.gov.ec>  
E-mail: [inen1@inen.gov.ec](mailto:inen1@inen.gov.ec)

Director's Office

Contact: Director: Felipe Urresta  
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.: 227

NATIONAL HEALTH AND TROPICAL MEDICINE INSTITUTE "LEOPOLDO IZQUIETA PEREZ"

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

Director's Office – Quito Branch

Contact: Director- Ingeniero Santiago Escalante  
Address: Iquique N14285 y Yaguachi  
Quito, Ecuador  
Phone: 593-2-568041/565527  
Fax: 593-2-256-8041

Director's Office – Quito Branch

Contact: Director-Telmo Fernandez Ronquillo  
Address: Julian Coronel 905 y Esmeraldas  
Guayaquil, Ecuador  
Phone: 593-4-228-1542/ 228-0414/ 228-2281  
Fax: 593-4-229-3189

ECUADORIAN CUSTOMS CORPORATION (CAE)

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

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  
Guayaquil, Ecuador  
Phone: 593-4-248-1166 / 248-1879

Aero Cargo Deputy Manager Office:

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

Regional Deputy Manager Office for Customs Quito:

Contact: Regional Manager- Econ. Ricardo Troya  
Address: Pasaje Amazonas y Río Arajuno  
Quito, Ecuador  
Phone: 593-2-244-4033

District Manager Office:

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

NATIONAL INSTITUTE OF INTELLECTUAL PROPERTY

Address: Av. Republica 396 y Diego de Almagro  
Quito, Ecuador  
Web-site: [www.inen.gov.ec](http://www.inen.gov.ec)

President's Office

Contact: National President - Dr. Alfredo Corral  
Phone: 593-2-250-8000, ext. 302  
Fax: 593-2-250-8027

Department of Trademarks

Contact: *Director*- Dra. Susana Vasquez.  
Phone: 593-2-250-8000, ext. 235

Department of Patents

Contact: *Director*- Ing. Martha Carvajal  
Phone: 593-2-250-8000 ext. 230  
Fax: 593-2-254-3894

CAMARA DE AGRICULTURAPrimera Zona

Contact: President: Patricio Donoso  
Address: Avs. Amazonas y Naciones Unidas Ed. Banco La Previsora,  
Torre B, Piso 8  
Quito, Ecuador  
Phone: 593-2-227 4187  
Fax: 593-2-225 7618

Segunda Zona

Contact: President: Carlos Cevallos  
Address: Escobedo 1210 entre Velez y 9 de Octubre  
Guayaquil, Ecuador  
Phone: 593-4-232 1754  
Fax: 593-4-232 1754

Tercera Zona

Contact: President: Felipe Andrade Ugarte  
Address: Galapagos 237 entre Guayas y Remigio Tamariz  
Cuenca, Ecuador  
Phone: 593-7-288 5930  
Fax: 593-7-288 3870

**APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS****U.S. EMBASSY QUITO**

*USDA/ Foreign Agricultural Service*

Address: Av. Colombia #1573 y Queseras del Medio, 3<sup>rd</sup> floor  
Quito, Ecuador.

Contact : Agricultural Admin & Marketing Assistant: Andres Barahona.  
Phone: 593-2-256-4147 / 252-9088  
Fax: 593-2-250- 6283/ 250-4888  
E-mail: Agquito@fas.usda.gov