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GAIN Report

Global Agricultural Information Network

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Ecuador

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:

Ecuador's 2008 constitution has led to the creation of new laws; some of which are adversely affecting food and agricultural product imports. "This report was prepared by the USDA/ Foreign Agricultural Service – Office of Agricultural Affairs in Quito 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's World Trade Organization (WTO) accession dates to January 21, 1996. The country's Foreign Trade Law prohibits any economic, administrative, or technical practice that limits or discourages foreign and or internal trade, free competition, or the local production of goods and services. This legislation only sanctions WTO specified corrective measures.

FAS Quito nonetheless finds that Ecuador's tariff and non-tariff barriers interfere with food and agricultural product imports. While its import tariffs are not excessive, technical barriers and sanitary/phyto-sanitary (SPS) restrictions are problematic. We believe that these are not always established with the purpose of protecting human, animal or plant health. Rather Ecuador's SPS measures aim to restrict imports. Ecuador's weak government institutions are inefficient; prone to sporadically reinterpret the application of rules and their requirements without warning. Most administrative procedures remain cumbersome, often requiring excessive documentation.

Food safety responsibilities are shared by the Ministries of Agriculture, Livestock, Aquaculture and Fisheries (MAGAP) and Public Health (MoPH). Several agencies within these ministries handle the technical and administrative processes of prior authorization, inspection, and control of local and imported food and agricultural products.

The Ministries of Health and Environment (MoE) are increasingly active in proposing new regulations for the safe use and consumption of transgenic products. FAS Quito finds these non-science based regulations to represent another in a line of unwarranted attempts to restrict biotechnology and Genetically Modified Organisms (GMO).

Current rulemaking aims to build upon the food security law of April 2006, which prohibits the development, use, and trade (including imports) of GMO derived products for human consumption. Despite the law being deemed unenforceable by the country's Attorney General, Congress in December 2006 passed a new health law expanding upon the earlier legislation's provisions; incorporating a prohibition against the acceptance of GMO content food donations in the absence of harmless analysis certificate. Ecuador has failed to enforce this legislation given its lack of an adequate control and certification system.

More troubling is the food sovereignty provision enshrined in the 2008 constitution. The [Organic Law on Food Sovereignty](#) (May 2009) expands upon the constitutional provision by banning genetically modified crops and their seeds from Ecuador. Imports are only permissible with prior presidential authorization and approval of the National Assembly (replaced the Congress in 2009).

A. The Official Register

The Official Register (*Registro Oficial - ROE*) is Ecuador's equivalent of the U.S. Federal Register. As such, the country's laws, rules of application, executive decrees, and ministerial agreements, as well as national standards enter into effect on the day following their publication. The exception being if a specific date has otherwise been established. Ecuador's constitutional court publishes the [Official Register](#), informing the general public and stakeholders of new laws, decrees, agreements, and other legal dispositions.

B. The Ministry of Agriculture, Livestock, Aquaculture and Fisheries

Ecuador's MAGAP is responsible for ensuring sustainable agriculture and aquaculture development. It directs and evaluates all agricultural and livestock activities. [Laws and regulations](#) governing the MAGAP's activities include:

1. [Agricultural Development Law](#) (ROE 55, April 30, 1997)

The law guarantees entry access to agricultural inputs, improved seeds, plants and animals, machinery, equipment and technologies, except for those deemed harmful to the environment by the country of export.

2. [Plant Health Law](#) (ROE 475, January 18, 1974)

This law seeks to prevent and control the outbreak of plagues, illnesses and pests that could adversely affect agricultural crops. It establishes regulations, conditions and prohibitions for the export, import, and local trade and production of certain plant products.

3. [Animal Health Law](#) (ROE 409, March 31, 1981)

This law has been enacted to prevent, control and eradicate illnesses in the national livestock population. The Ministry of Public Health and MAGAP are assigned responsibility for controlling the quality of animal origin products in the human food chain. These ministries are responsible for issuing food recalls, as well as for prohibiting trade in products deemed harmful to consumers. The law requires MAGAP authorization and sanitary certification prior to the export or import of animals and their by-products.

4. [Seeds Law](#) (ROE 594, May 26, 1978)

This law regulates seed export-import requirements, as well as the trade in seeds and their by-products. Seed exporters-importers are required to register with the Ministry of Agriculture.

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

The law requires that importers, manufacturers, and distributors of pesticides and similar products used in agriculture to register with the Ministry of Agriculture. The law regulates the transport, storage, labeling, and advertisement of these products, as well as sets maximum residue levels for pesticides. This law is governed by the Andean Community of Nations (CAN), decision 436 (amended by CAN decision 684, May 21, 2008)

6. Food Sovereignty Law (ROE supplement 583, May 5, 2009)

The [Organic Law on Food Sovereignty](#) (LORSA) declares Ecuador to be free of transgenic crops and seeds.

Agencies of the Ministry of Agriculture, Livestock, Aquaculture and Fisheries:

1. Agricultural Quality Guarantee Agency (AGROCALIDAD)

AGROCALIDAD (formerly known as SESA) is responsible for ensuring livestock and crop sanitary/phyto-sanitary health. The agency is charged with preventing the introduction and spread of exotic (non-native) pests and diseases, as well as is responsible for eradicating existing animal and plant pest and diseases. AGROCALIDAD enforces domestic legal norms, as well as regional and international standards (e.g., CAN standards) regulating the export-import, manufacture, formulation, distribution, domestic trade, and end-use of agricultural products, pesticides, and veterinarian products. AGROCALIDAD issues sanitary and phyto-sanitary certificates for the import of animal and plant products and by-products (including plant breeding material). AGROCALIDAD is responsible for issuing harmlessness analysis, good agricultural practices, product quality, and production chain certifications.

2. Domestic and International Trade Office

The Domestic and International Trade Office reports to the MAGAP Under Secretary for Agricultural Commerce. As such, it is responsible for collecting and analyzing agricultural trade intelligence and production data; the office suggests both policy and legislative changes. This office is responsible for processing import authorization and license requests prior to remitting these to AGROCALIDAD for sanitary certification and the Under Secretary for final approval.

Note: *Prior import authorization and license requirements for food and agricultural products are contained in the [Foreign Trade and Investment Council's \(COMEXI\) Resolutions 585 and 590](#). These resolutions identify a positive list of agricultural products subject to prior MAGAP import authorization and or licensing. This ruling applies only for products originating outside the Andean Community of Nations. FAS Quito believes this to constitute a violation of WTO non-discrimination principles.*

C. The Ministry of Public Health

The Ministry of Public Health regulates the entry and consumption of (imported) processed food products, beverages, food additives, and pesticides by means of its National Control and Surveillance System (NCSS). Laws and regulations governing its activities include:

1. Health Law (ROE Supplement 423, December 22, 2006)

This law replaces the country's former Health Code. It requires importers to obtain a sanitary registration permit prior to the import, trade, production, storage or transportation of processed food, beverages, food additives, and pesticides for domestic, agricultural or industrial use. The law charges the MoPH and its dependent agencies with responsibility for the inspection and control of all processed foods, beverages, and food additives. The law prohibits the import, trade, utilization, or development of foodstuffs derived from GMOs without prior authorization. A documentary review of technical and scientific analysis documentation, acceptable to Ecuador's national sanitary authority, must be presented

for the MoPH agency's review. This law also specifies labeling instructions for GMO content food products. Food donations containing GMO content are subject to the same review and authorization process, as well as are subject to an interagency GMO review/control system. The GMO-related provisions of this law have yet to be enforced.

1. Sanitary Control and Registration Regulation (ROE 510, January 20, 2009)

This regulation regulates the sanitary registration process for imports and domestically produced food and beverage products. It stipulates that sanitary registration is required prior to the import and distribution of food products. This regulation however provides differing requirements for domestically produced and imported products.

3. Food Regulation

The regulation requires that all imported food products be authorized for free sale. The regulation specifies container, packaging, labeling requirements, as well as manufacturing processes. Transportation, distribution, and the trade in food is governed by this regulation.

4. Consumer Defense Law

The law guarantees consumers' rights to quality goods and services at fair prices. The law applies to all private (including professional services and business owners) and public entities that export-import, manufactures, and or distributes goods and services. The law requires that consumers be provided with sufficiently clear and complete enough information to make an informed (purchase) decision about a product or service. The consumer defense law establishes the product content information to be included on a label (including price, in the local currency), as well as weights expressed in Standard International Unites of Measurement. This law also requires that GMO content food be labeled as such; serving as consumer warning. The law's provisions, especially the GMO-related ones, have yet to be enforced.

Regulation for the Authorization and Control of Food Publicity and Promotions (February 18, 2011)

The regulation regulates the publicity and promotion of food products. This regulation will affect promotional events for established, new-to-market, and imported food products. Revisions expected for late December 2013 have yet to be published.

6. Labeling Regulation (November 15, 2013)

The regulation regulates processed food products' nutritional labeling, as well as transgenic content information. This regulation will become effective six (6) months from its publication date to allow manufacturers time to comply with new labeling requirements. This regulation requires that a new Ecuadorian Normalization Institute (INEN) norm be issued for its implementation.

D. Other Institutions Involved in Foreign Trade

The Ministry of Foreign Affairs (MoFA): As the lead foreign affairs agency, it collaborates with the Office of the President and coordinates with the MAGAP and Ministry of Foreign Commerce (MoFC) on international policies and enforcement of agreements and conventions. The ministry assists as well with (commercial) negotiations.

Ministry of Production, Employment and Competitiveness (MoPCT): This ministry is an inter-ministerial policy coordinating agency. To prevent the duplication of efforts, as well as align ministerial goals with overall government policies, the MoPCT serves as an umbrella entity for the MAGAP, MoFA, MoFC, and MIPRO.

Ministry of Industries and Productivity (MIPRO): This ministry is responsible for trade, investment, and industrialization policies. Its mission is to improve Ecuador's business environment by increasing the country's domestic and international competitiveness. This ministry is the lead agency for bi- and multi-lateral trade agreement negotiations.

Ecuadorian Normalization Institute: As a MIPRO agency, INEN prepares Ecuador's Technical Standards (NTE); these define the characteristics of raw materials, intermediate products, and finished products marketed in the country. Also, the INEN establishes methods of inspection, analysis, measurement, classification and denomination of such materials or products. It administers the local quality certification system, as well as implements and enforces the use of the International Measurement System. The INEN enforces compliance NTE standards, as well as serves as the Codex *Alimentarius* (CODEX) point-of-contact.

Ministry of Foreign Commerce: Created in 2013 to oversee foreign trade policy issues, the MoFC chairs Ecuador's Foreign Trade Council.

Foreign Trade Council (COMEX): Created as part of the Production, Commerce, and Investment Code (ROE 351, December 29, 2010), COMEX replaces the former Foreign Trade and Investment Council known as COMEXI. The council is responsible for approving commercial policies, as well as coordinating foreign trade.

Ecuadorian Customs Corporation (CAE): This agency is responsible for the surveillance and control of the entrance and departure of people and goods through the Ecuador's borders and ports. It is charged with collecting import duties and taxes. The [Organic Law for Customs](#) governs the CAE's activities.

Laws and regulations governing international trade include:

1. Foreign Trade Law (ROE 82, June 9, 1997)

The law prohibits any practice or administrative disposition that limits free competition or obstructs the development of domestic and international trade and production. The law nevertheless allows for corrective actions to be applied in cases contemplated under WTO regulations. 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 CAE and the National Health and Tropical Medicine Institute Leopoldo Izquieta Pérez (which shares responsibility for sanitary registration).

Section II. Labeling Requirements:

A. General Requirements

Ecuador's Health Law along with the sanitary registration regulation, the food regulation, and 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. 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, since the product must enter the country in its final presentation.
- The Solid Waste Management regulation determines that every label must promote recycling, recuperation or re-use of the package or container.
- Ecuadorian standards do not differ significantly from those established by the United States; they are based on CODEX and Food and Drug Administration (FDA) stipulations. 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 CODEX and 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 exempt.

New norms are expected in the near future due to a changes on the regulations issue by MoPH in November 2013, regarding nutritional information and transgenic content labeling

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” is available.
- The container should be made of the proper 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 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 on CODEX standards and the FDA Regulation Code. 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, 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 (MRL). 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 will temporarily detain agricultural products suspected of being contaminated with pesticides or similar products. If analysis and testing carried out by the MAGAP prove such affirmation, products will be destroyed and no compensation will be provided.

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 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 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 \$620 per item (applies to items originating outside of Ecuador). Before the registration takes place the product has to pass a certified lab analysis (costs run around \$400). 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 the National Sanitary Control and Regulation Agency (ARCSA). A revised procedure was established this year for accepting documents requested for filing applications. Filers will be advised of any observations within three (3) days from ARCSA’s receipt of the application through its electronic filing system.

The application must include the following documents:

- Request form (filed electronically) 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.
 - 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 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 \$620).

Note:

- 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 ARCSA offices in Quito rather than in Guayaquil, due to administrative and compliance problems encountered with the ARCSA-Guayaquil office.
- 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.

Note: Changes to sanitary registration procedures are expected as a new institution is being created that will take responsibility over the entire process. This new agency also will be in charge of creating new regulations regarding sanitary registration. A new regulation is expected in early 2014.

B. Sanitary and Phyto-sanitary Certification

Importers of animal and plant products are required to obtain a sanitary or a phyto-sanitary 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 (approvals), one from AGROCALIDAD and one from the Under Secretary of Strategic Management of the Ministry of Agriculture.

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 the import 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 Under Secretary of the Coastal Region in Guayaquil.

The Ecuadorian Agricultural Quality Guarantee Agency will check the documentation and will issue the corresponding sanitary or phyto-sanitary permit. If the documents are not in correct order, AGROCALIDAD will return the application to the Domestic and International Trade Directorate indicating that the import is not authorized.

In the sanitary and phyto-sanitary 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 sanitary or a phyto-sanitary certificate, the documents will remain pending the signature (i.e., final approval) by the Under Secretary of Agriculture for Policy, Trade and Investment. This authority will determine if the product can be imported or not, despite AGROCALIDAD’s positive technical examination results.

Other Requirements

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

- Animals must come from zones in which no infect-contagious illnesses were present, during a

specific period of time prior to shipment. Ecuador follows World Organization for Animal Health (OIE) standards in this regard.

- Animals must be immunized with all the vaccines as by AGROCALIDAD.
- Results of laboratory tests and exams carried out to investigate the presence of infectious and contagious illnesses should be negative.
- Animals should be treated against parasites, as well as should be in good physical condition without clinic symptoms of infectious or contagious illnesses.

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.
- AGROCALIDAD requires that product's to be accompanied by a Fumigation Certificate or Quarantine Treatment; signed by the competent authority of the country of origin.

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 with MAGAP's Under Secretariat for Agricultural Development. The validity of the registration is indefinite, but it can be canceled because of non-compliance with the dispositions stated in the Seed Law and in its accompanying regulation.

D. Control of Products at Retail/Wholesale Distribution

The Ministry of Public 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 lacks sanitary registration it can be confiscated and destroyed.

The Ministry of Public Health in coordination with the MAGAP controls products of animal origin destined to human consumption, prohibiting from trade those items deemed harmful to human health.

The Ministry of Agriculture, through AGROCALIDAD or other designated entities may inspect commercial or industrial facilities storing and selling seeds to verify the health status of the plant breeding material. If plant pests or infectious diseases are present, the staff will declare either an "Observation Zone" or "Quarantine Zone." If necessary infected material will be destroyed.

Section VII. Other Specific Standards:

A. Wine, Beer and Other Alcoholic Beverages

[Imports of alcoholic products, including beer](#), require prior authorization from the MoPH 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 must 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, 1994.

Note: Alcoholic products and imported beers sold in the national market which do not fulfill these requirements, will be considered contraband material.

B. Products Samples and Mail Order Shipments:

Export/ import regulations establish that samples are exempt from the payment of import duties, value-added tax (IVA) and special consumption tax (ICE), when the cost-insurance-freight (CIF) value does not exceed \$400 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 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.
- 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 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 their CIF value.

Similarly small packages, other packages, and postal cargo and samples without commercial value,

exempt or not of taxes, whose CIF values do not exceed \$160 will be dispatched by customs through a simplified declaration. Although samples can be permanently imported, the nationalization process is prone to complications.

Exports or imports 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 Intellectual Property Law, published in the Official Register on May 19, 1998, regulates and guarantees the intellectual property acquired according to the law. 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 foreign nationals residing in or not in Ecuador.

A. Trademarks

The trademark registration application should be filed with the National Institute of Intellectual Property (IEPI). The initial request to register a trademark made in WTO member country, the Andean Community, or through the Paris Agreement for the Protection of Industrial Property, will grant the applicant the priority right for a period of up to six (6) months in which to file the trademark application with Ecuador. The latter request should not refer to different or additional products than those contained in the initial request.

A trademark registration is valid for ten (10) years from the date of its concession and it can be renewed. The applicant must 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 surmount \$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. The right for exclusive use is created by the brand name's public and continuous use in trade for a period of no less than six (6) months. 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 an expiration date; it is indefinite, except for restricted goods. In

such cases, 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).
 3. Insurance Certificate (if needed).
 4. Import Verification Request (if needed): Only for goods which FOB value exceeds \$2,000. 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 \$2,000. 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 not equal, then the verification company will make sure that the difference is within the tolerance margin (maximum 10 percent 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 percent, it is considered illegal.
- The physical examination generally takes additional time. It is calculated that 70 percent 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 of verifying that what was declared matches what the accompanying documents of the DUI state. 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 CAE will demand a guarantee of 20 percent of the total amount to be paid within a maximum period of 60 days.
- For example, if only the commercial invoice is missing in the declaration and document delivery, the merchandise can be removed with a guarantee. The time period allowed for presenting a new invoice is 30 days. However, if the certificate of origin is missing, it is better to leave the merchandise with CAE 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

Inspection of agricultural products in the country of origin is a legal requirement. Verification companies hired for this purpose will carry out the 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

Seaports: 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, as well as will inspect the product itself to confirm the sanitary and/or phyto-sanitary condition.

Products in good condition will be granted a merchandise entry license.

Appendix I. Government Regulatory Agency Contacts:

MINISTRY OF FOREIGN RELATIONS

Address: Carrión E1-76 y Av. 10 de Agosto, Quito, Ecuador

Phone: (593 2) 299-3200 • www.cancilleria.gob.ec/

MINISTRY OF FOREIGN TRADE

Address: Av. Amazonas N21-147 y Ramón Roca, Quito, Ecuador

Phone: (593 2) 299-3200 • www.comercioexterior.gob.ec/

MINISTRY OF PUBLIC HEALTH

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

Phone: (593 2) 381-4400 • www.salud.gob.ec/

Under Secretary of Health Surveillance

Phone: (593 2) 381-4400

National Health Surveillance Control Department
Phone: (593 2) 381-4400

Food Safety Office
Phone: (593 2) 381-4400

MINISTRY OF AGRICULTURE, LIVESTOCK, AQUACULTURE AND FISHERIES

Address: Eloy Alfaro 30-350 y Amazonas, Quito, Ecuador
Phone: (593 2)-396-0100 and 396-0200 • www.agricultura.gob.ec/

Ecuadorian Agricultural Quality Guarantee Agency (AGROCALIDAD)
Phone: (593 2) 254-4476 • Fax: (593 2) 222-8448

Plant Health Directorate
Phone: (593 2) 254-8823 Ext. 131 • Fax: (593 2) 222-8448 Ext. 130

Animal Health
Phone: (593 2) 254-8823 Ext. 136 • Fax: (593 2) 222-8448 Ext. 133

Agricultural Products Food Safety Control and Register Division
Phone: (593 2) 254-3319 • Fax: (593 2) 222-8448

MINISTRY OF INDUSTRIES AND PRODUCTIVITY

Address: Yáñez Pinzón N26-12, entre Av. Colón y La Niña, Quito, Ecuador
Phone: (593 2) 394-8760 • www.industrias.gob.ec/

MINISTRY OF PRODUCTION, EMPLOYMENT AND COMPETITIVENESS

Address: Av. La Coruña N2558 y San Ignacio. Edificio Altana Plaza Piso 4, Quito, Ecuador
Phone: (593 2) 381-5600 • www.produccion.gob.ec/

CODEX COMMITTEE IN ECUADOR

Phone: (593 2) 256-5626 • Fax: (593 2) 256-7815 • www.codexalimentarius.net/

ECUADORIAN INSTITUTE OF NORMALIZATION (INEN)

Address: Baquerizo Moreno E8-29 y Diego de Almagro, Quito, Ecuador
Phone: (593 2) 252-8556 and 256-5626 • Fax: (593 2) 256-7815 • www.inen.gob.ec/

Normalization Directorate
Phone: (593 2) 250-1885

NATIONAL SANITARY CONTROL AND REGULATION AGENCY (ARCSA),

Address: 6 de Diciembre y Pasaja Batallas, Quito, Ecuador
Phone: (593-2) 290-2731 • www.arcsa.gob.ec/

Quito Office

Address: Iquique 2045 y Yaguachi - El Dorado

Phone: (593 2) 256-8041 and 255-2715 • Fax: (593 2) 256-8041

Guayaquil Office

Address: Julián Coronel 905 y Esmeraldas

Phone: (593 4) 228-2281 • Fax: (593 4) 229-3189

ECUADORIAN CUSTOMS CORPORATION (CAE)

District Manager Office – QUITO

Address: Nuevo Aeropuerto Internacional Mariscal Sucre - Parroquia de Tababela - Conector Alpachaca-Centro Logístico de Carga

Phone: (593 2) 394-5830 • www.aduana.gob.ec/

General Manager Office – GUAYAQUIL

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

Phone: (593 4) 248-0640

District Manager Office

Address: Seaport

Phone: (593 4) 248-1166 and 248-1879

Aero Cargo Deputy Manager Office

Address: Simón Bolívar Airport

Phone: (593 4) 228-7834 and 228-7827

Regional Deputy Manager Office

Address: Av. 10 de Agosto 1731 y San Gregorio - Edificio Epsilon

Phone: (593 4) 321-5019

NATIONAL INSTITUTE OF INTELLECTUAL PROPERTY

Address: Av. Republica 396 y Diego de Almagro - Edificio Forum 300, Quito-Ecuador

Phone: (593 2) 394-0000 • www.iepi.gob.ec/

Trademarks Department

Phone: (593 2) 250-8000 Ext. 235

Patents Department

Phone: (593 2) 255-4887 Ext. 220 • Fax: (593 2) 254-3894

Appendix II. Other Import Specialist Contacts:

CAMARA DE AGRICULTURA

Primera Zona

Address: Av. NN. UU. 1084 y Amazonas, Torre B-Edificio La Previsora, 8vo. Piso-Oficina 805, Quito-Ecuador

Phone: (593 2) 225-7618 and 227-4187 • Fax: (593 2) 225-7618 • www.agroecuador.com/

Segunda Zona

Address: Carchi 809 y 9 de Octubre, Guayaquil-Ecuador

Phone: (593 4) 239-4449 • Fax: (593 4) 239-4449

Tercera Zona

Address: Galápagos 237 entre Guayas y Remigio Tamariz, Cuenca-Ecuador

Phone: (593 7) 288-5930 • Fax: (593 7) 288-3870

U.S. EMBASSY QUITO, ECUADOR

USDA/ Foreign Agricultural Service/ Office of Agricultural Affairs

Address: Avigiras E12-170 y Av. Eloy Alfaro, Quito, Ecuador

Phone: (593 2) 398-5000 and 398-5247 • Fax: (593 2) 398-5031 • Email: Agquito@fas.usda.gov